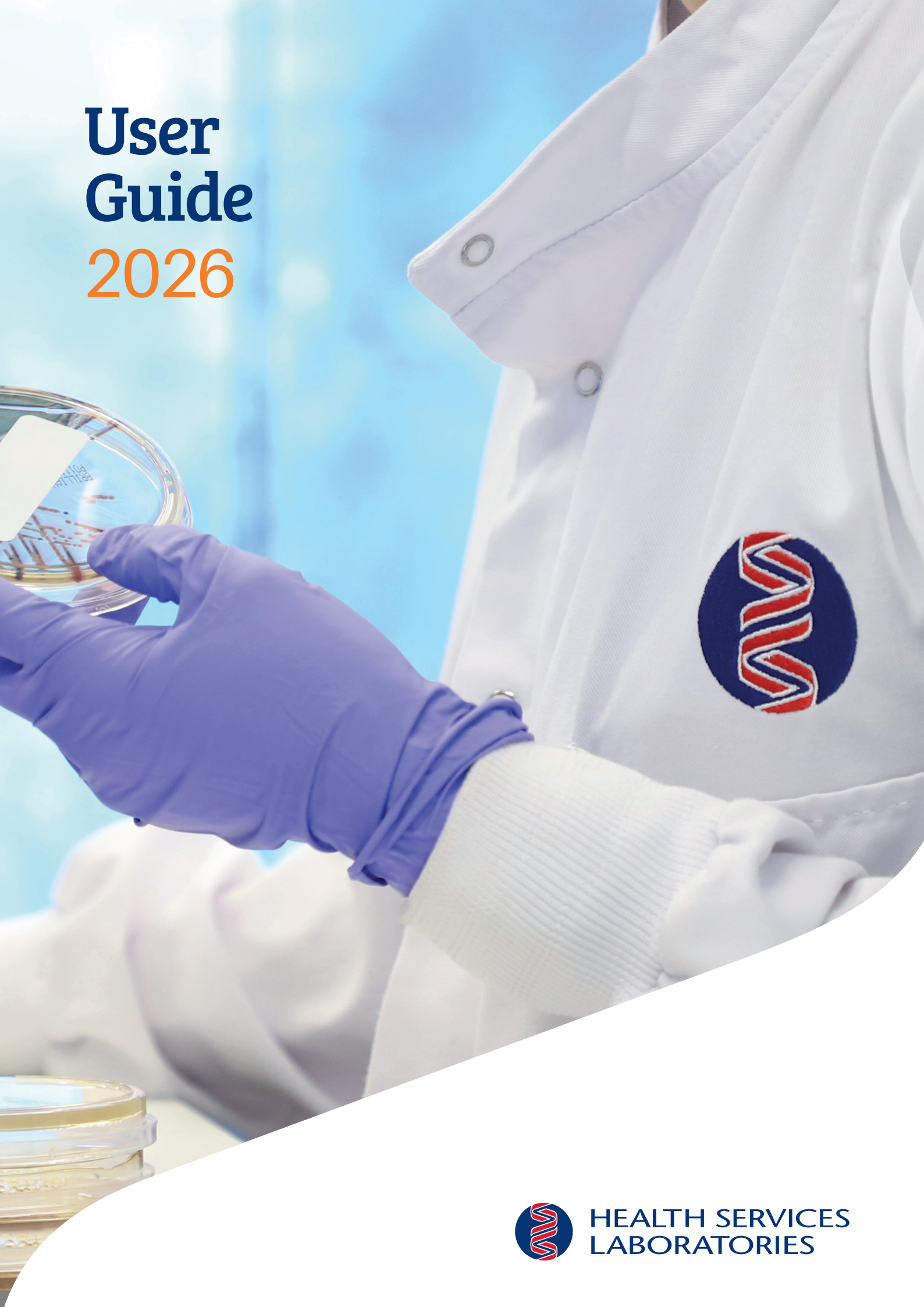


User Guide 2026



HEALTH SERVICES
LABORATORIES

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About Health Services Laboratories (HSL)

Health Services Laboratories (HSL) is a clinically-led provider of pathology and diagnostic services.

Our purpose is to deliver medically-led diagnostics, innovation, value and long-term investment to healthcare.

HSL is a progressive partnership between The Doctors Laboratory, the Royal Free London NHS Foundation Trust (the Royal Free London), and University College London Hospitals NHS Foundation Trust (UCLH).

We combine The Doctors Laboratory's specialist pathology expertise with the Royal Free London and UCLH's internationally recognised heritage of continual research, development and academic excellence. We maintain rigorously high standards of quality, while delivering efficiencies to healthcare through careful workforce planning, pioneering technology, and significant investment in infrastructure and IT.

OUR PROMISE

Our aim is to develop and deliver a sustainable business that delivers quality and value for everyone we work with.

We recognise that this must be achieved in a responsible manner and are committed to ensuring that our activities, carried out impartially, have a positive impact on both the communities in which we operate, and the wider healthcare sector and our services are delivered to patients free of discrimination.

To achieve this we will:

- play a key part in the development of healthcare in the UK. We will listen carefully to the requirements of NHS commissioners and the people they are commissioning for, and develop quality-based solutions that reflect their needs;
- engage with staff to ensure that they are treated fairly, enable them to realise their full potential, and have an active role in developing the UK's clinical pathology workforce;
- minimise any negative impact our business has on the environment. We have implemented a documented Environmental Management System based on the requirements of ISO 14001.

HSL Locations

HSL has a network of clinical laboratories across the country.

HALO

Spread over 11 floors with five split-level basements, the Halo facility is home to more than 1000 staff working within a connected suite of laboratories spanning more than 100,000 square feet. The Halo also has dedicated clinical and non-clinical cores for vertical connectivity.

1 Mabledon Place, London WC1H 9AX

Mortimer Market

Mortimer Market rapid response laboratory (RRL) provides urgent parasitology diagnostic work in association with the travel clinic and the Hospital for Tropical Diseases.

3rd Floor Mortimer Market Centre,
Mortimer Market, London WC1E 6JB

60 Whitfield Street

60 Whitfield Street has been transformed into a specialist centre for cellular pathology and a RRL for UCLH. The RRL serves all of UCLH's urgent work, including A&E, ITU and in-patient work.

Royal Free London and North Middlesex University NHS Trust

HSL has developed two RRLs at the Royal Free London and North Middlesex University NHS Trust, which launched in the summer of 2016. The services that are operated from the RRL include haematology, biochemistry, routine coagulation and blood transfusion.

Barnet and Chase Farm Hospitals

The pathology laboratories at Barnet and Chase Farm Hospitals joined HSL in October 2017. The RRL and SRA launched in the last quarter of 2018 at the Barnet site. The services that are operated from the RRL include haematology, biochemistry, routine coagulation and blood transfusion.

Quality assurance

HSL is committed to providing doctors with pathology of the highest quality.

The quality of results is of fundamental importance, and HSL operates to stringent UK regulatory and International standards. Internal quality assurance is achieved by strict adherence to standard operating procedures for all analytical processes.

Quality assurance is administered by HSL's Quality Management Group (QMG).

Quality management team

The QMG supports all HSL departments, to achieve and maintain the requirements of all relevant regulatory and accreditation standards. These include, but are not limited to international standards such as ISO 15189, and UK regulations such as Blood Safety and Quality Regulations, and the Health and Social Care Act 2012

The team is primarily responsible for the implementation and management of a quality management framework, including document control and auditing processes, along with more technical elements associated with change management processes and validation framework. Our objective is to deliver a framework, that supports our services, with, high quality, safe and patient focussed service provision at its core.

Led by the director of governance, the team also includes quality advisors, quality managers, a quality administration team, and quality officers.

Accreditation

HSL participates in accredited National External Quality Assessment Schemes. These schemes are subscribed to by NHS and private laboratories. Results are subjected to both internal and external quality control.

Details of the laboratories that HSL refers specialist testing to are available from HSL Referrals. These laboratories are UKAS accredited, or of equal accreditation status.

External Quality Assurance Schemes

ADVANCED DIAGNOSTICS

HSL-AD participates in EQA across various modules through UK NEQAS ICC & ISH, NordiQC, and GenQA. The laboratory repertoire includes a broad range of IHC markers, FISH probes, and molecular tests. For tests not covered by conventional EQA schemes within the previous 12 months, an alternative approach to EQA is implemented to ensure ongoing quality assessment.

UKNEQAS ICC & ISH for

ACTH
ALK Breakapart
ALK Lymphoma
ALK NSCLC IHC
BCL2
BER-EP4
C-MYC
Cam5.2

CD10
CD117
CD138
CD20
CD21
CD34
CD68
CDX2
CK20
CyclinD1
D240
DOG1
E-Cadherin
ER
FSH
GATA3
GFAP
HER2 Amplification
HER2 Breast
HER2 Gastric
HPV High Risk
Ki67

Melan A
MLH1
MOC31
MSH2
MSH6
MUM1
Neurofilament
NSE
p16 IHC
p40
p53
p63
PAX8
PGP9.5
PMS2
PR
PSA
ROS1 Breakapart
ROS1 NSCLC IHC
S100
SOX-11
Synaptophysin

Tdt
Thyroglobulin
TTF1

NordiQC for

AE1/AE3
ALK Lung
BAP1
BCL2
BCL6
BRAF
CD117
CD20
CD31
CD8
Chromogranin
CK20
CK7
GATA3
INSM1
Ki67
MSH6
p16
p53
PAX8
PD-L1 22C3
PD-L1 SP142
PMS2
PRAME
SMA
Synaptophysin

GENQA for

CDK4/CEP12 (Amplification)
DNA FFPE extraction
EGFR mutation (Lung Cancer)
MDM2/CEP12 (Amplification)
Prosigna: Breast Tumour Expression Profiling
TFE3 (Breakapart)
Tissue-i for tumour recognition for Molecular Testing

For other tests not covered in this accreditation list, please see the main HSL-AD chapter of this guide.

BLOOD SCIENCES

UKNEQAS, WEQAS, RIQAS, BIORAD, LABQuality, RCPAQAP for

ACE
ACTH (with PTH)
AFP/CEA & HCG
Antibiotics (Gentamicin, Vancomycin and Amikacin)
Anti-HBs Detection
Ammonia
Autoimmune (RF and TPO)
ASO
B2 Microglobulin
Borrelia IgM/IgG
Cardiac Markers
Clinical Chemistry
CMV IgG/IgM/Avidity
CRP & Ultra-Sensitive CRP
CSF
Cyclosporin and Tacrolimus
DEQAS
Diagnostic Serology
Diagnostic Serology Hepatitis
Drugs of Abuse
Ethanol
Free Beta HCG and PAPP-A
GFR
Glucose/Glucometer
Glycated Haemoglobins
Guildford Peptides
Haematinics
Healthcontrol Therapeutic Drugs Screen (TDM)
Hepatitis A (with B and C)
Hepatitis B Serology
Hepatitis C Serology
Hepatitis D serology
Hepatitis E Serology
HIV Serology
HSV 1 & 2 IgG & typing
Homocysteine
HTLV 1 & 2 serology
IGF-1
Immunity Screen

Lipase
Lipid Investigations
Measles and Mumps serology
NT-Pro BNP
Paediatric Bilirubins
Parasitology
Peptide Hormones
PSA
PTH, ACTH and hCT
Rubella IgG Serology
Salicylate and Paracetamol
SARS-CoV-2 (COVID-19) Antibodies
Specific Proteins
Steroid Hormones
Syphilis Serology
Thyroglobulin Surveys
Thyroid Hormones
Total IgE
Toxoplasma IgG/M Serology
Tumour Markers
Toxoplasma IgM Serology
Toxoplasma IgG Serology
Trace Elements
Urine Chemistry
Vitamin D (25 OH)

HAEMATOLOGY

UKNEQAS for

Automated Differential
Leucocyte Count
Blood Film Morphology
Coagulation (Including PoCT Coagulation)
ESR and NRBC (nucleated Rbc)
Flow Cytometry
Leukaemia immunophenotyping
Myeloperoxidase
Iron stain
Full Blood Count
Haematology
Haematology Analysis
Malaria
Parasite Films
Reticulocyte
Sickle Screening

Thrombophilia Screening
Factor assays:
Von Willebrand (vWD) screen
Lupus anticoagulant
ADAMTS-13 activity and antigen
Anti-Xa assay
Plasma viscosities

RCPA

PFA-100 analysis

GENETICS AND MOLECULAR VIROLOGY

GENQA, ISFG, EMQN, UKNEQAS, ECAT, LABQUALITY for

Acquired array (CLL/MDS)
Acute Leukaemia FISH pilot
Acute Lymphoblastic Leukaemia (ALL) – G banding and FISH
Chlamydia & Gonorrhoea detection by PCR
Constitutional Clinical Cytogenetics (Rounds for Amniocentesis, CVS, Solid Tissue, Blood, Array CGH)
Cystic Fibrosis
Duchenne/Becker Muscular Dystrophy
Hereditary Haemochromatosis (C282Y+H63D) genotyping + reporting
HLA Class I (HLA-A, HLA-B, HLA-C) Tissue Typing (low resolution)
HLA Class II (HLA-DRB1, HLA-DQB1) Tissue Typing (low resolution)
HLA-B27 Genotyping
HLA-B57*01 Genotyping
HLA+ Disease Typing Cytochrome P450 2D6/2C19 genotyping
Human Papillomavirus DNA
Mature B & T cell Neoplasms – FISH for CLL and Lymphoma
Mature B & T cell Lymphoma – G-banding
Myeloid (AML/MDS/CML) – G-banding and FISH
Myeloma – sample FISH set up and analysis plus online
NGS AML gene panel
NIPT for aneuploidies
NIPT for sexing

Paternity Testing
Prader-Willi and Angelman Syndromes
QF-PCR Aneuploidy Detection
SARS-CoV-2 (COVID-19) PCR/NAAT
Sexually Transmitted Diseases (CT/NG/MGEN/TV)
Spinal Muscular Atrophy
Thrombophilia (Factor II, V, MTHFR)
Y Microdeletion PCR Assay

QCMD, INSTAND

Atypical Mycobacterium
Adenovirus DNA Viral load
Bacterial 16S
B19 virus DNA Viral load
BK virus DNA Viral load
CMV DBS (dried blood spots)
CMV DNA Plasma Viral load
CMV DNA Whole Blood Viral load
CMV Resistance
EBV DNA Plasma Viral load
EBV DNA Whole Blood Viral load
Enterovirus RNA
Gastroenteritis Virus Panel
Hepatitis B Genotyping
Hepatitis B Drug Resistance Typing
Hepatitis B Viral Load
Hepatitis C genotyping
Hepatitis C Resistance genome detection (NS5a & b)
Hepatitis C Resistance Typing (NS3 & NS5a)
Hepatitis C Viral Load
Hepatitis D Virus Viral load and Qualitative PCR
Hepatitis E Virus Viral load and Qualitative PCR
HIV-1 Drug Resistance (Pol)
HIV-1 Drug Resistance (Integrase)
HIV-1 RNA Viral load
HIV-1 RNA Qualitative PCR
HIV-1 Tropism Genome Detection
HIV-2 Viral load and Qualitative PCR
HSV 1&2 DNA
HSV Drug Resistance
Human Herpes virus 6 DNA

Human Herpes virus 8 DNA
Influenza Haemagglutinin typing
JC virus DNA
Measles and Mumps PCR
MERS Coronavirus
Parechovirus RNA
Respiratory panel I
Respiratory panel II
SARS-CoV-2 (COVID-19) PCR/NAAT
Syphilis PCR
Transplantation Virus Panel
VZV DNA

MICROBIOLOGY

UKNEQAS, QCMD for

AAFB for Microscopy + Mycobacterium Culture
Antifungal Panel
Antifungal Susceptibility
Antimicrobial Susceptibility
Clostridium Difficile + MRSA Screening
Cryptococcal Antigen Detection (Pilot Scheme)
Faecal Parasitology
Faecal Haemoglobin EQA scheme
Faecal Markers for Inflammation (Calprotectin)
Fungal Biomarkers (Pilot Scheme)
General Bacteriology
Genital Pathogens
Molecular detection of Mycobacteria
Mycology
Urinary Antigen: Legionella
Urinary Antigens (Legionella and Pneumococcal antigen)
WEQAS Urinalysis scheme

IMMUNOLOGY

UKNEQAS – Immunology, Immunochemistry and Allergy for

ELISA
ANA/DNA
Autoimmune Serology
ANCA/GBM Antibodies
Allergen Component Testing

Bullous Dermatitis Antibodies
 C1IN & Functional Complement
 Coeliac Disease Antibodies
 Diabetic markers
 General Autoimmune serology
 Interferon Gamma Release Assay (IGRA)
 Myositis Antibodies
 Cardiolipin IgG & IgM Screen
 Specific Microbial Antibodies

UKNEQAS - Microbiology for

HIV Serology
 Syphilis Serology
 HepB surface Ag
 HepC Serology
 Lyme (Borelia) Serology
 HepE Serology

Labquality EQAS for

Anti Streptolysin O
 CMV IgG avidity
 HSV 1 and 2 (IgG)
 Helicobacter pylori IgG Serology

RCPAQAP (The Royal College of Pathologists of Australasia Quality Assurance Programs) for

Scleroderma Autoantibodies
 Brucella Serology
 Legionella Serology
 Chlamydia Serology
 Striated Muscle

INSTAND e.V. for

Adrenal Antibodies
 Hep E IgG & IgM Serology

CSCQ for

Lyme (Borelia) serology

IFQ - Lubeck for

Liver Autoantibodies

CERVICAL SCREENING

UKNEQAS for Microbiology for

Molecular Detection of HPV

NHSCSP EQA scheme for

Gynaecological Pathology
 The preparation and staining of cervical liquid based cytology samples

Hologic EQA Scheme for

ThinPrep Stain

ANDROLOGY

UKNEQAS for

Semen Analysis Scheme

Information security

Accredited by British Standards Institute ISO/IEC 27001:2013

Cyber Essentials

Cyber Essentials+

Links to the UKAS Schedules of Accreditation

HSL Blood Sciences (8169)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8169-Medical-Single.pdf

HSL Infection Sciences (8860)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8860-Medical-Single.pdf

HSL Molecular Pathology and Genetics (8059)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8059-Medical-Single.pdf

TDL Manchester (8812)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8812-Medical-Multiple.pdf

TDL Andrology (10199)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/10199-Medical-Single.pdf

HSL Cervical Screening (8511)

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8511-Medical-Single.pdf

Cellular Pathology (Histopathology, Diagnostic Cytology & HSL Advanced Diagnostics) (9007)

<https://www.ukas.com/download-schedule/9007/Medical/>

Data protection

It is the policy of Health Services Laboratories (HSL) supported by its board of directors, to take steps to ensure that your information is kept confidential and secure and to otherwise protect and respect your privacy. HSL will only ever collect and process the minimum amount of information required in order to provide our pathology services. As well as the steps set out in this policy, HSL is accredited to the international standard for Information Security Management Systems set out in ISO/IEC 27001, our certificate may be found at <https://www.hslpathology.com/media/2bfbc2e/is-655966-2024-2026.pdf>

This is a high level privacy notice describing the information that HSL processes, the purpose of that processing, and how we protect it. For more detailed information including the lawful basis for processing please read the 'Detailed Privacy Notice' at <https://www.hslpathology.com/media/hxjysui/health-services-laboratories-detailed-privacy-notice.pdf>

The data controller

HSL is a part of The Doctors Laboratory Group, the largest independent provider of clinical laboratory diagnostic services in the UK providing pathology services to the private and public sector, information about the companies that comprise our group can be found at the respective websites:

www.tdlpathology.com

www.hslpathology.com

This policy together with your terms and conditions sets out the basis on which any information HSL collects from you, or that you provide to HSL, will be processed. The following explains our views and practices regarding your information and how we treat it.

HSL as a data controller and/or processor

In providing products and services, HSL may be acting as a data processor on behalf of third parties (such as clinicians, hospitals and/or insurers) who will themselves be the data controllers, or as a data controller (if for example you are an employee). Where acting as a data controller, HSL will comply in full with this policy. Where acting as a data processor, HSL will be required to act on the instructions of the data controller.

Information HSL may collect from or about you

Typically, the information about data subjects that is processed by HSL comes from clinicians that you visit for healthcare purposes, but it may also be collected via email, over the phone or any other means of communication. They send us personal information in addition to pathology samples (body fluids or tissues) and request tests are carried out upon those samples.

The information provided to HSL may include:

- your name, date of birth, gender, address, email address and in some cases phone number and card payment details, and medical history;
- practice details of the requesting clinician such as address, specialities and secretary information;
- information that is necessary to process invoices including patient demographics, financial, bank and credit card information, medical and insurer specific information such as insurer name and policy/ identification details.

You may also give HSL information by accessing or filling in forms on its websites at: www.tdlpathology.com, www.hslpathology.com, <https://10to8.com/book/tdlandrology/>, or by corresponding with HSL via its products and services, by phone, email or otherwise. This includes information you provide when you register to use HSL's sites, place an order on HSL sites, when you report a problem with HSL sites, or participate in communications or discussions on other social media platforms.

Information regarding HSL's use of cookies can be found at www.hslpathology.com/cookie-policy/

Uses of the information you provide

HSL will use this information to carry out HSL's obligations arising from any contracts entered into between your clinician and HSL and to provide them with the information, products and services request from HSL such as:

- the provision of pathology services, and associated processing of bills for payment;
- providing test requesting and results delivery management tools
- to process invoices on behalf of various parties, such as clinicians, hospitals and insurers;
- for process management and improvement;
- to notify you or your clinician about changes to HSL's products and services and to otherwise manage HSL's communications with you; and/or;
- to ensure that content from HSL's sites are presented in the most effective manner for you and for your computer.

Disclosure of your information

HSL may share your information with selected third parties including:

- any member of The Doctors Laboratory Group, which means its subsidiaries, ultimate holding company and its subsidiaries, as defined in section 1159 of the UK Companies Act 2006;
- business partners, referral laboratories, suppliers, insurers, logistics companies, debt management agencies, and sub-contractors required for the performance of any contract HSL enter into with them, you or your clinician;
- for the purpose of investigating any potential legal claims against TDL, your information may be shared with our insurers in order to obtain insurance advice and services;
- National screening or public health monitoring schemes such as Public Health England;
- Information about your interactions with our websites may be shared with organisations that assist HSL in the improvement and optimisation of websites.

When HSL shares such information, it will ensure that it is only sharing as much information as is required to fulfil the purpose for which it is sharing it.

HSL may also disclose your information to third parties if HSL are under a duty to disclose or share your information in order to comply with any legal obligation, or in order to enforce or apply HSL terms and conditions and other agreements; or to protect the rights, property, or safety of HSL, its customers, employees, or others. This includes exchanging information with other companies and organisations for the purposes of fraud protection and credit risk reduction.

Where we store your information

Unless specific consent is sought and received, or another of the conditions for transferring data outside the EEA under GDPR satisfied (such as the inclusion of EU model contractual clauses in our contract with the supplier/ third party) we will not transfer your information outside of the EEA. The policy of your Data Controller, which could be your hospital, clinician, insurer etc... may be different to this so you should check carefully the relevant privacy policies in order to fully understand their implications.

Your rights

Under the General Data Protection Regulation, you are given certain rights to control aspects of the processing of your information. You can exercise these rights at any time by contacting HSL via the methods set out in the 'contact' section below.

Contact

Questions, comments and requests regarding this privacy policy are welcomed and should be made to:

HSL Data Protection
The Halo Building
1 Mabledon Place
London
WC1H 9AX

E dataprotection@hslpathology.com

Measurement Uncertainty

Medical laboratories are responsible for ensuring that test results are fit for clinical application by defining analytical performance goals and selecting appropriate measurement procedures. All types of measurement have some inaccuracy due to bias and imprecision; therefore measurement results can only be estimates of the values of the quantities being measured.

To properly use such results, medical laboratories and their clinical users need some knowledge of the accuracy of such estimates. The complete result of a measurement is a value, a unit and an estimate of uncertainty. This estimate of uncertainty is conventionally referred to as Measurement Uncertainty (MU) and incorporates the cumulative range of factors involved in the testing procedure itself in addition to consideration of the inter-individual and intra-individual biological variation which will potentially influence the overall test result.

Evaluating measurement uncertainty is an ISO 15189:2022 accreditation requirement.

In terms of Measurement Uncertainty determined by the HSL group of laboratories, it should be noted that all assays are performed in strict accordance with the manufacturers' instructions. Measurement Uncertainty, which has been estimated for each assay during the verification procedure, is reviewed at regular intervals to ensure that Measurement Uncertainty values do not exceed the pre-defined maximum allowable uncertainty for each assay. Overall assay performance is also regularly monitored through internal quality control (IQC) and external quality assessment (EQA) schemes and incorporated in test result interpretation. Measurement Uncertainty for individual assays is available upon request.

Service user feedback and Complaints policy

HSL is committed to service excellence and enthusiastic about continuous improvement. We welcome feedback on the service from our users, which can be forwarded to hsl@hslpathology.com. Patient feedback can be made to the test-requesting clinician or the Hospital Patient Advice and Liaison Service (PALS).

Where a doctor or patient needs to raise a complaint about service levels, they should contact Cyril Taylor, Laboratory Service Compliance Director, on hsl@hslpathology.com, giving details of the complaint and requesting that this be investigated.

The information forwarded will be treated as confidential and investigated by the above person. This process will link into the Quality Management Procedures for incident investigation and subsequent corrective and preventative actions will be introduced where needed.

The initial complaint will be acknowledged within 3 working days and the investigation, and any follow up actions will be completed within 30 days.

Internally, any complaints received will be shared and discussed at Executive Director level where appropriate, as it is the intention of HSL to provide unsurpassed excellence of service.

HSL referral laboratories

For certain specialist tests, HSL works with a selected network of TDL Group and Reference Laboratories. The specialist laboratory performing the testing can be identified on the final report. The quality of these laboratories is recognised by UKAS, or similar accrediting bodies for the laboratories outside the UK.

| | |
|---|--|
| ABS Laboratories Ltd | Great Ormond Street Hospital – Department of Histopathology |
| Addenbrooke’s Hospital – BGU and Immunology | Great Ormond Street Hospital – Enzyme Unit, Chemical Pathology |
| Affinity Biomarker Labs | Great Ormond Street Hospital – Immunology Department, Great Ormond Street Hospital – Neurometabolic Unit |
| Alder Hey Children’s NHS Foundation Trust – Biochemistry Department | Great Ormond Street – Virology Department |
| Alder Hey Liverpool | H & I Laboratory |
| Anthony Nolan Lab | Hammersmith Hospital – Molecular Endocrinology |
| Bart’s and Royal London Hospital | HCA |
| Biolab Medical Unit | Health Diagnostic Laboratory Inc |
| Biomnis | Health & Safety Laboratory |
| Bioscientia | Heartlands Hospital |
| Birmingham Children’s Hospital NHS Foundation Trust – Clinical Chemistry | HFL Sport Science |
| Brucella Special Diagnostics Unit Cambridge Life Sciences Cambridge Nutritional Science Ltd Cardiff & Vale Immunology | Homerton University Hospital – Department of Clinical Biochemistry |
| Brigham and Women’s Hospital – Department of Pathology | Igenomix UK |
| Cardiff Toxicology Laboratory | Imperial College London – Department of Investigative Medicine |
| Central Medical Laboratory | Independent Histopathology Services |
| Cerba | Institute of Neurology – Department of Neuroimmunology |
| Charing Cross Hospital – Chemical Pathology Department, Charing Cross Hospital – Infection and Immunity | Institute of Neurology – Neurogenetics Unit |
| Charing Cross Hospital – Medical Oncology | Institute of Neurology Pharmacology & Therapeutics Unit |
| Chelsea and Westminster Hospital | Instituto Bernabeu Biotech |
| Cheltenham General Hospital – Cellular Pathology Department | King’s College Hospital – HMDC Laboratory for Molecular Haemato-Oncology |
| Churchill Hospital – Immunology Department | King’s College Hospital – Liver Institute |
| City Hospital, Birmingham – Clinical Biochemistry Department, City Hospital, Birmingham – Toxicology Department | Lab21 Ltd |
| CNC forensic toxicology | Labor Augsberg MVZ GmbH |
| The European Laboratory of Nutrients | Laboratory of The Government Chemist (LGC) |
| Douglass Hanly Moir Pathology | Latis Scientific |
| Epsom and St Helier Hospital – Virology Department | Leeds General Infirmary |
| Genoid Kft | Liverpool Clinical Laboratories |
| Great Ormond Street Hospital – Department of Chemical Pathology | London School of Hygiene & Tropical Medicine – Diagnostic Parasitology Lab |
| | Manchester Royal Infirmary – Meningococcal Ref Unit Matrix Diagnostics |
| | Manchester Royal Infirmary – Vaccine Evaluation Unit |

HSL referral laboratories

| | |
|---|--|
| Mayo Medical Laboratories | Royal Victoria Infirmary |
| MDU Imperial College St Mary's Campus | SAS Leeds – Steroid Hormone Centre |
| Microbiological Solutions Ltd | SAS Metabolic Bone Laboratory |
| Micropathology Ltd | SAS Trace Elements Laboratory |
| Mycology Reference Centre – Department of Microbiology, Leeds | SCSA Diagnostics |
| National Genetics Institute (NGI) | Sheffield Children's NHS Trust – Clinical Chemistry |
| National Blood Service – Red Cell Immuno Haematology Department | Sheffield Northern General Hospital – Protein Ref Laboratory |
| National Mycobacterium Reference Lab | Sheffield Protein Unit – Protein Reference Unit & Immunology Department |
| NHSBT Birmingham | Singleton Hospital – Toxoplasma Reference Lab |
| NHSBT Tooting | Southmead Hospital – Antimicrobial Ref Lab |
| Norfolk and Norwich Hospital – Specialised Virology Centre | Southmead Hospital Bristol – Regional antimicrobial reference lab |
| Nutritional Analytical Service – University of Stirling Pathcare Reference Lab | St Barts – Antenatal Screening Service DEPM St George's Hospital – Cell Markers |
| Perinatal Centre | St George's Hospital Medical School – Forensic Toxicology Service Analytical Unit |
| PHE Brucella reference unit | St Helier – Biochemistry Department |
| PHE Centre for Infections – Bacterial Reference Laboratory | St Helier – Immunology Department |
| PHE Centre For Infections – Enteric And Respiratory Virus Lab | St Mary's Hospital – Department of Histopathology |
| PHE Centre for Infections – Legionella Reference Laboratory | St Mary's Hospital – Virology Department |
| PHE Centre For Infections – Virus Reference Division | St Thomas' Hospital – St John's Institute of Dermatopathology |
| PHE Mycology Reference Laboratory – Bristol | St Thomas' Hospital – Department of Histopathology |
| PHE Rare and imported pathogens laboratory – Porton Downs | Synergy Health Laboratory Services |
| Preston Microbiology Services Royal Preston Hospital | The Royal Marsden Hospital – Department of Haematology / Oncology |
| Queens University Hospital – Institute of Clinical Science | Trace Laboratories Ltd |
| Radboud University Nijmegen Medical Center | UCL Great Ormond Street Institute of Child Health University of Utah School of Medicine |
| Randox Health | University Hospital of Wales – Cardiff Medical Immunology Veterinary Labs Agency |
| Reflab | Veterinary Laboratories Agency |
| Reproductive Immunology Associates | Viapath – Guy's Biochemical Genetics Laboratory |
| Rosalind Franklin University | Viapath – Guy's Purine Research Laboratory |
| Royal Berkshire Hospital – Clinical Biochemistry | Viapath – King's College Clinical Biochemistry Viapath – St Thomas Hospital Haemophilia Centre Viapath – St Thomas Immunohistology |
| Royal Brompton Hospital – Department of Histopathology | West Yorkshire Analytical Services |
| Royal Group of Hospitals Trust, Belfast – Department of Pathology | |
| Royal National Orthopaedic Hospital – Department of Histopathology | |
| Royal Surrey County Hospital – SAS Peptide Hormone Section | |

HSL Genetics referral laboratories

Academic Medical Centre
Amplexa Genetics A/S
Asper Biotech
Bioscientia
Bristol Genetics Laboratory
Centogene AG
Connective Tissue Gene Tests
Diagenom GmbH
Douglass Hanly Moir Pathology
East Anglian Genetics Service
Fulgent Diagnostics
Great Ormond Street Hospital
Hammersmith Hospital
Health in Code
IBGRL Molecular Diagnostics
Institute of Neurology
John Radcliffe Hospital
King's College Hospital
Liverpool Women's Hospital
Medical Neurogenetics
Micropathology Ltd
Mitochondrial NGC Laboratory
Molecular Diagnostic Genetics
Molecular Vision Laboratory
Ninewells Hospital & Medical School
Northern Genetics Service
NW Thames Genetics Service
Oxford Genetics Laboratory
Polwarth Building Medical School
Prevention Genetics
Progenika
Protein Reference Unit & Immunology Department
Purine Research Laboratory
Reprogenetics
Royal Devon & Exeter NHS Trust
Royal Marsden Hospital
South East Scotland Molecular Genetics Service
Southern General Hospital
St Mary's Hospital
St. George's Hospital
SYNLAB Budapest Diag Center
The Anthony Nolan Trust
The Leeds Genetics Laboratory
UCLH Clinical Biochemistry
University Hospital of Wales
Viapath at Guy's Hospital
Wessex Genetics Laboratory
West Midlands Genetics Service

How to order a test

A completed request form (electronic or manual) must accompany each patient sample, with the details on the specimen label matching the details on the corresponding request form.

Note down the collection date and time on the request form.

Paper request forms should include the signature/initials of the person collecting the samples confirming:

- They have verified that the patient details on the label matches the patient details on the test requisition.
- The specimen has been drawn.

Electronic requesting can be made by:

- **EPR** is the Royal Free London NHS Foundation Trust's internal electronic ordering system and result viewer. Detailed information for EPR requesting is available on Freenet.
- **T Quest** is the electronic system (Indigo) for requesting and reporting tests in place for those GPs who have opted for this. A multipart single pathology request form is to be used when the electronic ordering system is unavailable.
- **EPIC** is the University College London Hospitals (UCLH) internal electronic ordering system and result viewer. Detailed information for EPIC is available from the UCLH EHRS team.
- **CELLMA** is the Mortimer Market electronic system for requesting and reporting in place for the STD service.
- **MEDWAY** is the North Middlesex NHS trust's internal electronic ordering system and result viewer. Detailed information for MEDWAY requesting is available from the trust.

Requests should be completed with all relevant information including:

- NHS number (or hospital number) when appropriate.
- Patient name (Last name and First name)
- Date of birth
- Ward or clinic (if a referral from a hospital)
- Requesting doctor with contact number the signature, bleep and/or contact number of the requesting doctor must also be completed.
- Clinical details
- Tests requested

- Date and time the sample was taken
- Consultant
- Date and time for crossmatched blood to be ready
- LMP (last menstrual period) – where appropriate
- Consent (where appropriate)

ROYAL FREE LONDON

Requests made on EPR

- Do not generate a request form except for Blood transfusion and both Cytopathology & Histopathology.
- Will generate a EPR label which needs to be attached to the patient sample at the bedside prior to despatch to the Central Pathology Reception except for Blood Transfusion samples – where it is a requirement that the label on samples must be hand written legibly and signed by the person who bled the patient.

Manual Requests - in case of EPR downtime

- In the event that electronic requesting is not available.
- Wards have a stock pile of paper request forms.
- Request forms can be accessed using the URL <http://freenet/freenetcms/Default.aspx?p=1795&m=2507&s=28#Downtime>.
- Please complete all requests (form) legibly and ensure full identity is entered on both the top and any under copies if applicable.
- Departmental request forms can be ordered via the trust ordering system, not direct from departments. Note: Molecular Cytogenetics tests are not available on EPR and forms are available on the TDL website: <https://www.tdlpathology.com/tests/request-forms/>

Virology resistance samples require paper request forms, which indicate current and past treatments and viral load. Request forms are kept in the Ian Charleson Day Centre.

UNIVERSITY COLLEGE LONDON HOSPITALS

Requests made on EPIC

- Will generate an Epic label which needs to be attached to the patient samples at the bedside/ clinic prior to dispatch to the RRL/Specimen reception (SRA) at 60 Whitfield Street.
- Any extra labels which have been printed but where a specimen is being shared, must be put into the sample bag with the specimen and sent to the specimen reception.

Manual Requests - in case of EPIC downtime

In the event that electronic requesting is not available:

- The wards will be given access to paper/ electronic version of request forms by the trust.
- Please complete all requests (form) legibly and ensure full identity is entered on both the top and any under copies if applicable.

MORTIMER MARKET

Requests made on CELLMA

- Will generate a CELLMA request form with barcode which needs to be placed in the specimen bag pouch to accompany the labelled patient sample, which is taken in the clinic. Specimen and request form then are sent to the SRA at 60 Whitfield Street.

NORTH MIDDLESEX

Requests made on MEDWAY

- Will generate a MEDWAY request form with barcode which needs to be placed in the specimen bag pouch to accompany the labelled patient sample, which is taken in the clinic. Specimen and request form then are sent to the SRA at the North Middlesex RRL.

Other Users

Any other user must ensure that specimens sent to the appropriate SRA, and all specimens are accompanied by a clearly and correctly filled out request form and clearly labelled specimen.

Urgent requests

Any urgent requests which have to be processed at the core laboratory must follow the urgent pathways which have been set up for each trust site.

- All requests for Virology and Microbiology must be cleared as urgent by an appropriate specialty pathology consultant. The laboratories will be contacted to indicate that there is an urgent sample coming to the core laboratory.
- Samples which are to be processed by the urgent pathway must be taken to the appropriate SRA and the need for this pathway indicated clearly.
- SRA will then arrange urgent courier and ensure that the correct procedure is followed to allow all laboratories to identify that this sample is urgent.
- Samples for MERS coronavirus must follow the urgent pathway and ensure that the samples are packaged in a Category B specimen box, and are not transported with other specimens.

Guidance on specimen collection

A properly collected specimen is critical to quality test results. Ensure that:

- The correct specimen type is collected.
- The correct amount is collected.
- The specimen is collected in the right container with any necessary additives.
- The specimens are collected following safe working practices.
- Ensure that there is no contamination from external sources when collecting microbiology and virology samples.
- Clean surgical instruments and surgical trays must be used when collecting Histopathology samples.
- The container is securely sealed and labelled.

Specimen packaging

- Place the labelled specimen container in a plastic specimen mini-grip bag which is available on the Wards, in the Clinics and from central stores and seal.
 - Each specimen bag must only contain samples from one patient (DO NOT mix patient samples).
 - For ease of sample processing in the laboratory it is advisable to place each discipline sample in a separate sample bag for the same patient.
- Place the matching requisition in the outside pouch of the bag.
- Always send the specimen promptly to the laboratory or the collection point.

Specimen labelling

Each specimen container:

- Must be labelled at the time of collection i.e. next to the patient when the sample is taken and not prior to, or remotely from the patient after collection.

Note: Never label the specimen bag.

Note: The Laboratory (apart from Cellular Pathology) will discard a specimen if it is received unlabelled.

- Must be labelled with the correct bar-code label (pre-printed label with accession numbers generated by an information system) except Blood Transfusion samples which must be labelled by hand.
- Must have a label whose information matches the information on the accompanying request form.

Note: Specimens will not be accepted if the information does not match. Cellular Pathology will liaise with the referring clinician to update details.

- Must have no more than one label placed on it.
- Must not have the request form wrapped around it as a specimen label. This is not acceptable.

A label that does not contain the required information or which has illegible information will be considered to be improperly identified and will result in delays or a decision not to process the specimen. In these instances, a repeat specimen will be requested. Cellular Pathology will liaise with the referring clinician to update details.

Note: Always label the specimen clearly with the name, hospital number, date of birth and collection date and time.

ROYAL FREE LONDON USERS: EPR

EPR labels can be placed on all specimens except for Blood Transfusion samples.

Blood Transfusion samples

- Collect and label samples from one patient at a time.
- Check the identity details on the patient wristband matches the identity details on the request form.
- The samples must be labelled by hand (refer to vein system being implemented on the 21st May).
- Do not label the samples with EPR generated barcode or addressograph labels.
- PDA printed labels can be attached to BT samples where this system is available.
- Label the sample at the patient's bedside using information from the patient's wristband. Write the patient's full name, date of birth, hospital number. Where the patient is able to communicate they should be asked their full name and date of birth to confirm details are correct.
- Write the date and time of collection, and signature of the person who took the blood.
- Phlebotomists covering wards need to ask a second person to check patient details written on the sample before the sample is sent to the laboratory.

Blood samples for all other disciplines

- Place the EPR label along the length of the tube, as straight and as far up as possible without touching the cap of the tube, so that the analysers can read the label.
- It is imperative that the label quality is checked prior to labelling the specimen bottles as poor quality barcodes cause delays and introduce risk of errors in the laboratory.
- Ensure the correct label goes on the corresponding tube. Requests for Clinical Biochemistry tests must be attached to the appropriate tube
- In addition write the date and time of collection on the label. If the date and time of collection is not recorded the sample may be rejected by the laboratory.

Cellular Pathology (Histopathology and Cytopathology) specimens, urine, stool, CSF, amniotic fluid specimens and respiratory specimens (Microbiology & Virology)

- Place the EPR barcode label along the length of the container. This is to enable bar code reading.
- It is imperative that the label quality is checked prior to labelling the specimen bottles as poor quality barcodes cause delays and introduce risk of errors in the laboratory. Please see section 3.4.2.3 below for correct attachment of labels to the specimen bottle

Note: EPR labels must NOT cover the barcodes on the blood culture bottles as these need to be read by the analyser

OTHER USERS

The minimum information required on the specimen label is three unique identifiers that **MUST** match the information on the request form. These should be:

- Patient name (Surname/family name and first name)
- Hospital number (or Private Patient number) and/or date of birth
- NHS number (if available)

In addition, specimens should be hand-labelled with the date, and time if appropriate, of collection. Please note it is a mandatory requirement to label the specimen with the date and time of collection.

Specimen transport

TO THE HALO

All samples are tracked and sent to the core laboratory at the Halo building using TDL couriers. There are a scheduled number of pickups throughout the day and night.

- Samples have to be booked on the department's Winpath LIMS system.
- They are then tracked into relevant static floor boxes at the SRA.
- Just before the courier pick up times, the samples in the static boxes are tracked and transferred into an appropriate Halo level transport box and the box set as dispatched.
- TDL couriers pick up all the full transport boxes and transport to the halo.
- Once they arrive at the Halo, the couriers drop off the full boxes at the ground-floor SRA reception area, where the boxes are marked as having arrived. The boxes are then put into labelled dumb waiter trays, and put in the dumb waiters to the correct floors.
- Once they have arrived at the correct floor, the transport boxes are receipted onto the floor, and the samples tracked out of the box into appropriate storage receptacles.

TO RRLS

All samples from within the hospital sites are either sent to the SRA within the RRLs by airchute or by porters.

Samples received from centres referring into HSL via the hospital routes arrive at the RRL SRA either by courier, post or Hays tracked specimen transport services.

TO 60 WHITFIELD ST

Samples are received into the sample receipting area on the ground floor of 60 Whitfield Street. For UCLH samples, they are delivered via the UCLH portering system and the pneumatic chute system. All other samples from users external to UCLH are delivered via the TDL courier system.

TO OTHER SITES

Samples referred to other sites are either sent by registered post or, if the receiving laboratory is within the HSL/TDL group, through the TDL couriers.

High-risk specimens for Porton Down must be packaged in Category A packaging and couriered with couriers insured to carry these pathogens (e.g City Sprint).

Transport of specimens out of normal working hours

Each trust has an urgent pathway set up for getting samples to the Halo out of hours. This includes contacting the relevant clinical consultants for sign off, and then using the urgent pathway set-up through the individual SRAs.

High-risk samples

Samples from certain patient groups or disease processes (some listed below), should have their 'high risk' status noted on the request form.

This is best done by giving full medical history in the clinical details section of the request. Please indicate this to the forefront of the clinical details.

The provision of sufficient information on Specimen Request forms to staff in Clinical Diagnostic Laboratories is essential to enable them to apply the correct safety measures to control the risk of infection.

High risk samples are defined as coming from the following groups:

- Those with known or suspected CJD
- Those with known or suspected typhoid fever
- Those with known or suspected Brucellosis
- Suspected meningococcal meningitis
- Faeces from patients with known/suspected typhoid, E coli 0157, dysentery
- Sputum or bronchial washing/lavage from suspected or known TB
- Pyrexia of unknown origin (PUO) – if patient has been abroad
- Suspected diphtheria

- Patients with suspected Histoplasma, Coccidioides or other dimorphic fungal infections.
- Patients with suspected viral haemorrhagic fever (VHF) infection.
- Patients with suspected avian influenza viruses or MERS-CoV or other newly isolated human pandemic viruses.

Please refer to the following HSE guidance for the full Approved List of Biological Agents: <http://www.hse.gov.uk/pubns/misc208.pdf>

Special considerations

Please note that for any patient suspected of being infected with a viral haemorrhagic fever (VHF) e.g. Ebola Virus Disease (EVD) or returning from travel to endemic areas with fever consultation should be sought from the Infectious Diseases (ID) team via switchboard on the patient assessment.

By definition, samples from these patients are considered to be extremely high risk (Hazard group 4 pathogens) and dictate a higher level of handling precautions.

Please refer to the Trust guidance for full instruction on the Management and Control of Viral Haemorrhagic Fevers http://freenet/guidelines/1035_Viral%20Haemorrhagic%20Fever%20VHF.pdf

The laboratories are unable to process CSF samples containing CJD or other prions without prior arrangement. The receiving laboratory must be informed in advance of any sample being sent to them. The sample must be clearly labelled. Each laboratory has its own protocol for dealing with specimens. It is unacceptable to send a specimen on such patient defined in Table 1 from the Infection Control Protocol – CJD and Other Transmissible Spongiform Encephalopathies without informing the laboratory in advance.

Sample rejection criteria

Sometimes tests cannot be performed in the laboratory if samples fall short of the quality, volume or other eligibility criteria such as clear sample labelling. In these cases, the potential risk to the patient management is that the laboratory may need to reject the samples, and not carry out processing.

Sometimes the laboratory can rectify a situation where a sample falls short of the sample acceptance criteria though in this case the risk to the patient management may be a breach of stated turnaround time and a delay to provision of the result. In order to reduce the risk of sample rejection or delay to provision of results, please ensure all sample taking criteria are met.

Summary list for sample rejection

- Incorrect sample types received:
 - Basic incorrect blood tube/other sample.
 - Samples without the appropriate preservative (e.g. acidified urine samples).
 - Samples that are received ambient, when a frozen sample is required.
 - Samples that are received unprotected from light, when they are required to be covered at the point of venepuncture.
 - Samples in incorrect containers (e.g. cervical cytology must be a ThinPrep vial; urine cytology must be in a uricite container).
- Insufficient sample received.
- No sample received.
- Labelling or form issues (mislabelled/unlabelled/no forms/no clinical information).
- Clotted/haemolysed/lipaemic/icteric samples.
- Sample is broken or has leaked in transit.
- Stability time has been exceeded. Stability time is test-dependent, and also refers to tests that can only be carried out on certain days of the week.
- Sample contamination (e.g. being in the same bag as a leaking sample):
- Samples that are received in expired tubes.

Samples deemed to be precious (e.g. CSF, fluid, tissue, bone marrow and paediatric samples) will not be discarded by the laboratory. Results will include a comment relating to the condition of the sample (e.g. sample unlabelled).

Department-specific list for sample rejection

Sample Reception will not accept samples packaged with needles of any kind.

Biochemistry cannot accept:

- previously frozen samples that have thawed in transit.
- samples that display antibody interference.
- samples that have had separation delays/un-centrifuged samples that have been stored in the fridge.
- paraprotein resulting in viscous samples.
- CSF protein that is blood-stained.

Cervical Cytology cannot accept:

- over- or under-filled samples for testing.
- samples received within three months of the previous test in order to allow epithelial cells to regenerate.

Coagulation cannot accept:

- over- or under-filled samples for testing.
- previously frozen samples that have thawed in transit.

Haematology cannot accept frozen whole blood for testing.

Microbiology cannot accept samples in non-sterile containers or in formalin.

Molecular Pathology cannot accept samples for haemophilia testing without informed consent.

Parasitology cannot accept TBQ kits that:

- Incorrect sample types: Plasma instead of serum or EDTA blood for most serology tests; blood samples other than citrate blood for Microfilarial microscopy; blood samples other than EDTA blood for malaria microscopy and PCR; peripheral blood for Leishmania microscopy and PCR.
- Samples that have been incorrectly stored/ treated: Refrigerated stool sample for stool culture; fixed sample for Leishmania culture (PCR will be performed); fixed sample for stool PCR (Microscopy will be performed).
- Insufficient sample volume (especially for Strongyloides culture, which requires around 20ml of stool)
- Samples whose delivery is delayed beyond viable processing time: 15 minutes for hot stool samples; 24 hours for Trypanosomal blood microscopy.

Referrals cannot accept:

- samples without three points of identification for DRP testing.
- samples that are not labelled by hand for blood group testing.

Urine cytology cannot accept delayed samples unless they have been refrigerated.

Virology cannot accept lithium heparin samples, or samples that are in non-sterile container or in formalin.

Sample requirements

| Vacutainer | Anticoagulant | Capacity | SAMPLE TYPES |
|------------|------------------|------------|--------------|
| Lavender | EDTA | 4ml/ 10ml* | A |
| Gold | SST/Gel | 5ml | B |
| Light Blue | Citrate | 4.5ml | C |
| Red | None | 6ml | F |
| Grey | Fluoride oxalate | 2ml, 4ml | G |
| Green | Lithium heparin | 6ml | H |
| Dark Blue | Sodium heparin | 7ml | K |

* 10ml EDTA tubes are used for specific PCR assays

| | |
|--|-------------|
| Streck Cyto-chex BCT Vacutainers for lymphocyte subsets (CD3/CD4/CD8) (stable for up to 7 days). They are not suitable for other CD markers. | Chex |
| Blood culture bottle: contact laboratory | BC |
| Contact laboratory for advice on sample taking | J |
| Test by appointment | X |
| Random Faeces | RF |
| Faecal Collection | LF |
| Random Urine | RU |
| First Catch Random Urine (for DL12/Chlamydia, etc.) | FCRU |
| 30ml aliquot from a 24 hour urine collection - state total volume | CU |
| 30ml aliquot from a 24 hour urine collection with 10ml of 0.1N Hydrochloric Acid added - state total volume | PU |
| Early Morning Urine (1st sample of the day) | EMU |
| 60ml container | SC |
| Cytec Thin Prep Vial | TPV |
| Orange/Blue swab for culture - swab in transport medium | STM |
| Black Charcoal swab | CS |
| Green Viral swab | VS |
| Liquid Amies swab for culture and/or PCR | LAS |
| PCR swab for Chlamydia/PCR Infection Screening | PCR |
| Tap/bottled water mouth wash - 20mls | MW |
| Ammotic fluid (5mls PCR - 10mls Karyotype) | AF |
| Chorionic Villus (medium provided by laboratory) | CVS |

Cervical Screening London

HSL provide a high-quality cervical screening service to the NHS in the London Region. Cervical Screening London (CSL) is the single provider for cervical screening in London.

The cervical screening service operates from the Halo Building in London and provides a single integrated service for molecular HPV testing and cytology.

Hologic ThinPrep vials are used for sample collection and primary high-risk Human Papillomavirus (HR-HPV) testing using the APTIMA mRNA assay. Reflex cytology is carried out on samples which are 'HR-HPV DETECTED'.

The department works closely with primary care, colposcopy units, and other hospital-based specialties to provide technical and clinical advice. The service is committed to the delivery of medical and scientific training as well as supporting research, development and clinical trial studies.

The department holds the IBMS pre- and post-registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. Cervical Screening London is a UKAS Accredited Medical Laboratory No. 8511.

London Cervical Sample Taker Database (LonCSTD)

CSL manages the London CSTD on behalf of NHSE (Public Health). All sample takers sending samples to CSL are required to register on the LonCSTD.

For further enquires please contact: hsl.csl.cstd@nhs.net

To access the database please visit:
<https://loncstd.england.nhs.uk>

Key contacts

GENERAL CONTACTS

| | | | |
|--|--------------------------------|--|--------------------|
| General Cervical Screening London Queries & Enquiries | | hsl.csl.queries@nhs.net | Tel: 020 7460 4851 |
| London MDTs Queries | | hsl.csl.londonmdt@nhs.net | Tel: 020 7460 4851 |
| Cancer Audit Review | | hsl.csl.canceraudit@nhs.net | Tel: 020 7460 4851 |
| Direct Referrals | | hsl.csl.directreferrals@nhs.net | Tel: 020 7460 4851 |
| Transport/Courier Queries (Sample Collection) | | couriers@tdlpathology.com cc: hsl.csl.queries@nhs.net | Tel: 020 7307 7373 |
| IT Department (T-Quest Queries) | | hsl.csl.queries@nhs.net | Tel: 020 7307 7365 |
| Medical Director / Cervical Screening Provider Lead | Dr Martin Young | martin.young@nhs.net | Tel: 020 7460 4851 |
| Cervical Screening London Consultant Speciality Lead | Dr Evangelia Mylona | evangelia.mylona@nhs.net | Tel: 020 7460 4851 |
| CSL Service Lead / Deputy Cervical Screening Provider Lead | Julie Smith | julie.smith@tdlpathology.com | Tel: 020 7460 4851 |
| Deputy Service Lead | Bernadette Shaw | Bernadette.Shaw@hslpathology.com | Tel: 020 7460 4851 |
| Programme Administration Manager | Rhoda Ankapong-Abankwah | Rhoda.Ankapong-Abankwah@tdlpathology.com | Tel: 020 7460 4851 |
| Failsafe Team | | hsl.csl.failsafeteam@nhs.net | Tel: 020 7460 4851 |
| London Cervical Sample Taker Database (LonCSTD) Enquires | | hsl.csl.cstd@nhs.net | Tel: 020 7460 4851 |

CERVICAL SCREENING ADMINISTRATIVE SERVICES - CSAS

| | | |
|-----------|--|---|
| Enquiries | CSAS.Enquiries@nhs.net | https://www.csas.nhs.uk/contact-us/ |
|-----------|--|---|

Cervical Screening London

Laboratory hours

The laboratory department is open between 8.00am and 6.00pm.

Out of hours service

There is no routine service for weekends and bank holidays. There is no on-call service for Consultant Pathologists.

Clinical advice

The clinical team is available to provide clinical advice as required by users.

HPV testing

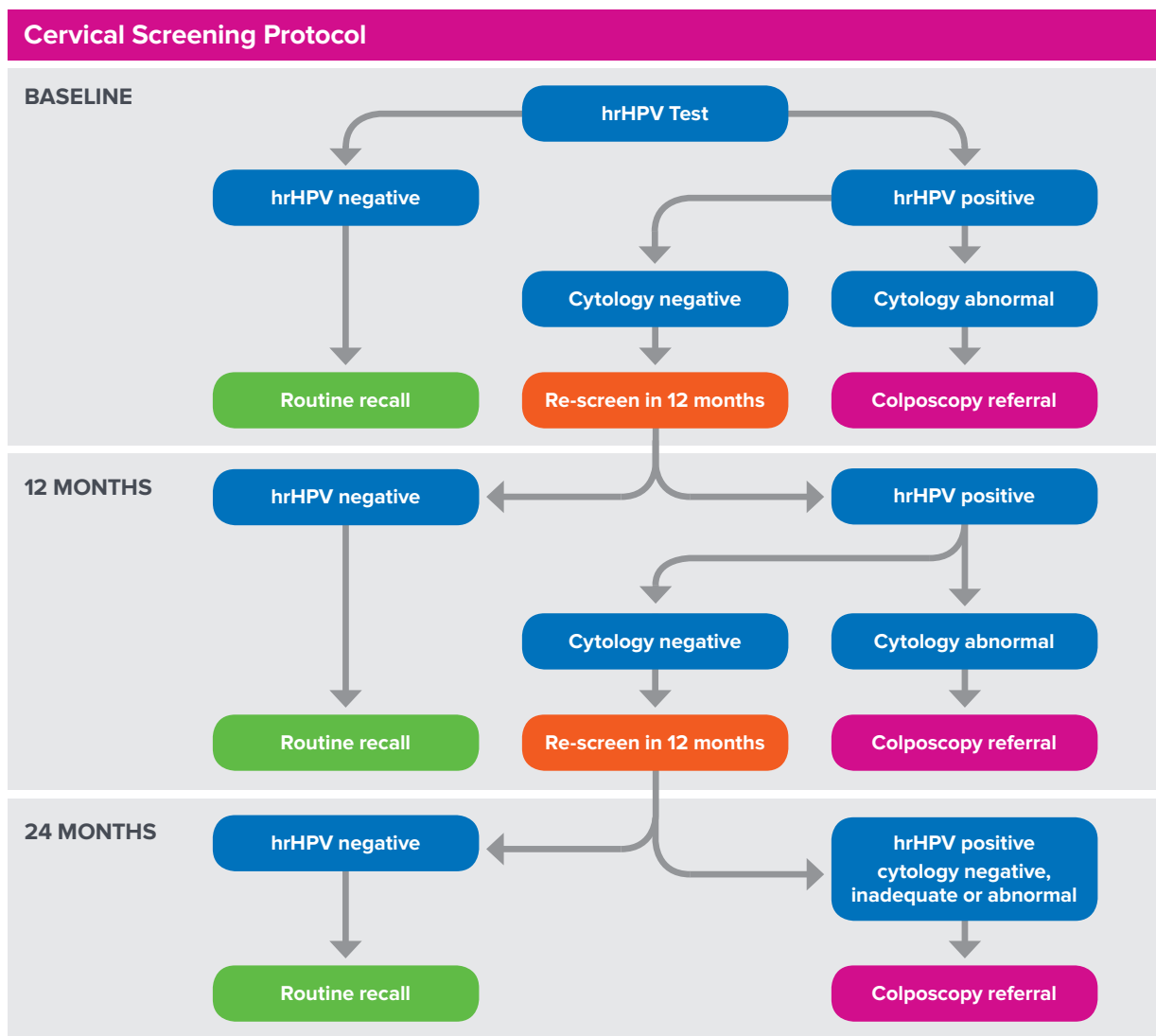
High-risk subtypes of human papillomavirus (HR-HPV) are linked to the development of abnormal cells and may cause cervical cancer. In 2017, the UKNSC recommended that high-risk Human papillomavirus (HR-HPV) testing should be the first (primary screening test).

Compared to cytology, HR-HPV testing has been shown to reduce the risk of developing cervical cancer through increased sensitivity for underlying disease.

In 2019, the UK moved to primary testing for HR-HPV, reserving cytology for women who test HR-HPV positive (also called reflex cytology).

Women will be managed according to the protocol below.

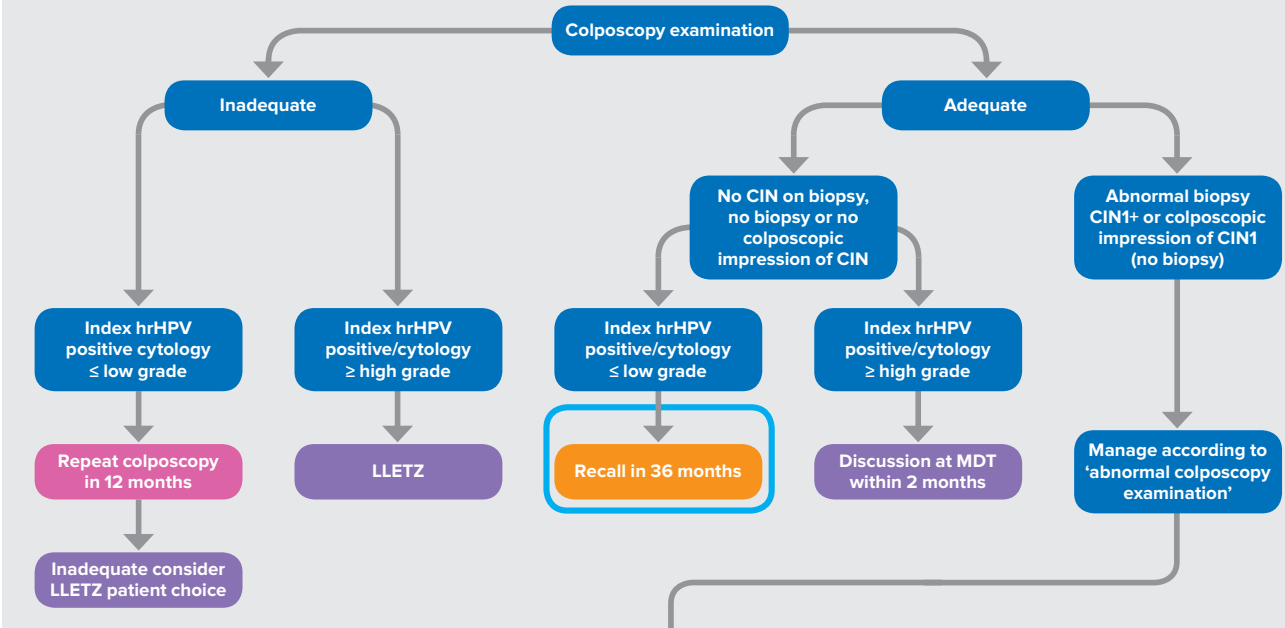
- **HR-HPV NOT DETECTED:** no further testing is required – Return to Routine Recall.
- **HR-HPV DETECTED:** reflex cytology will be processed from the same ThinPrep Vial. If the cytology result from this sample is **abnormal**, the recommendation is to refer to colposcopy regardless of the cytology grade.
- **HR-HPV DETECTED/CYTOLOGY NEGATIVE** – Repeat in 12 months
- **12M HR-HPV DETECTED/CYTOLOGY NEGATIVE** – Repeat in 12 months
- **24M HR-HPV DETECTED/CYTOLOGY NEGATIVE** – Refer to colposcopy



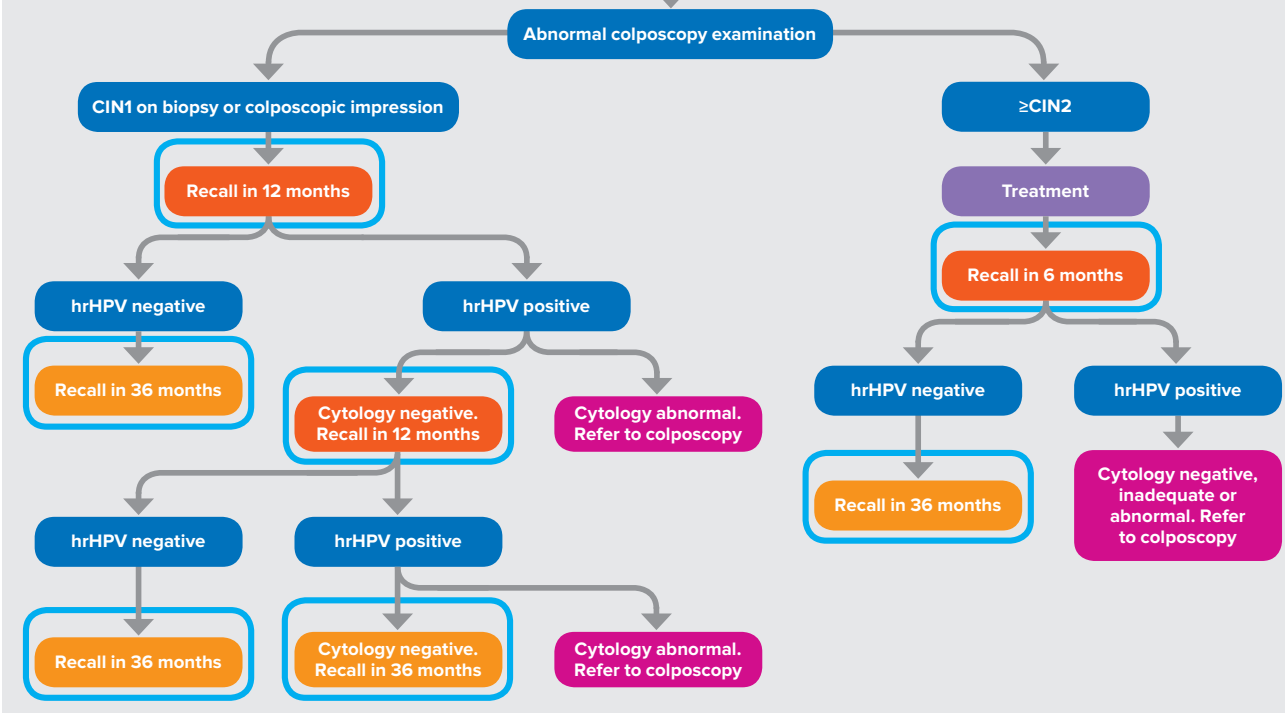
See also: Cervical screening care pathway – Gov.UK (www.gov.uk/government/publications/cervical-screening-care-pathway/cervical-screening-care-pathway)

Cervical screening colposcopy management recommendations

Indicates collection of hrHPV sample in primary care is appropriate.



Indicates collection of hrHPV sample in primary care is appropriate.



See also: Cervical screening care pathway – Gov.UK (www.gov.uk/government/publications/cervical-screening-care-pathway/cervical-screening-care-pathway)

Cervical screening requests

Sample takers using EMIS or SystmOne are strongly recommended to use tQuest to electronically request cervical screening tests.

For help and support with tQuest please contact our IT department at helpdesk@tdlpathology.com or 020 7307 7365

Where tQuest is not available all NHS samples must be accompanied by a HMR101 form.

A pdf version of the form is available at the back of this User Guide.

Alternatively, this may be accessed using the following link:

Cervical Screening Platform: Cervical Screening Management System (<https://cervicalscreening.nhs.uk>)

All request forms must include the following mandatory information, failure to include this information may delay the processing of the request.

- First name
- Last name
- Date of Birth
- NHS number
- Home address
- GP Details
- Sender details (if not the GP)

Cervical screening samples

Sample acceptance policy

CSL accepts samples based on the national acceptance policy. For further information regarding sample acceptance policy, including the minimum labelling criteria, please refer to:

www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories

- All vials must be labeled with a minimum of three identifiers.
- This must include the individual's last name in all circumstances.
- All cervical sample takers sending samples to CSL must have a LonCSTD PIN. Contact hsl.csl.cstd@nhs.net for further information.

Failure to comply with the sample acceptance policy will result in the rejection of samples.

For request form information please see Cervical Screening Requests.

Factors known to significantly affect the performance of the examination or the interpretation of results

- Only Hologic ThinPrep vials must be used
- The head of the cervical broom MUST NOT be left in the vial
- Lubricants should not be used as these will affect the quality of the sample

Ordering Supplies

Practices and clinics can order supplies (ThinPrep vials, brooms, supply bags and bar code labels) via our easy-to-use **online order page** at:

https://pathologyforms.formstack.com/workflows/hpv_surgery_supplies

Please do not try to order supplies via telephone or email.

Supplies will be delivered by ParcelForce; please allow 5 days for delivery.

For queries about sample taker supplies, please contact: ls.helpdesk@hslpathology.com or phone 020 7307 9440.

Cervical screening samples

Sample packaging

Check each sample is correctly labelled with full name, DOB, NHS/Hospital number and date of collection.

Ensure the matching request has all the necessary demographic, clinical and screening history information required for testing. Current cervical screening sample rejection criteria still apply. Unlabelled or partially labelled vials and samples with discrepancies identified between the information on the vial label and form will be rejected.

Place each vial and request form (if paper request being used) in an individual small clear sample bags. The vial goes in the sealable section, and the form in the pocket at the front. The individually packaged cervical screening samples should then be placed in the large purple CSL transport bags. Seal the bag using the self-adhesive strip.



Storage of ThinPrep Vials

ThinPrep vials contain a methanol-based buffered preservative solution used to support cells during

transport and slide preparation.

Vials should be kept tightly closed in dry conditions between 15-30°C and away from heat, sparks, and other sources of ignition.

Do not store in a fridge.

For further information, please refer to the manufacturer's safety data sheet.

Sample transport: Courier collection

TDL Collect is the name of the specialist pathology transport division servicing HSL, TDL and CSL referrers. Your cervical screening samples will be picked up by a **TDL Collect** courier and brought to our central London laboratory.

TDL Collect couriers can be contacted at:

couriers@tdlpathology.com cc: hsl.csl.queries@nhs.net

T: 020 7307 7373

Practices collecting high volumes of cervical screening samples will have daily pick-ups.

Lower volume surgeries will have a **TDL Collect** courier call every second workday – Monday, Wednesday, Friday one week, and Tuesday, Thursday the next week.



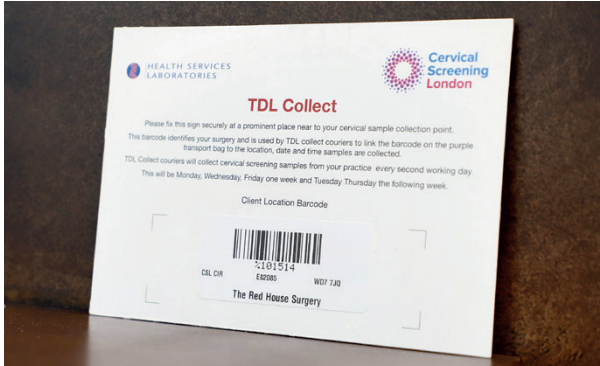
Please note:

- Cervical samples are collected directly from clinics/surgeries/practices across London.
- Sample takers and receptionists are reminded that a number of different pathology providers may collect samples from the same location.

- It is the responsibility of the sender to ensure the CSL purple bags are available at the designated collection point.
- CSL cannot accept responsibility for samples that enter the wrong sample pathway and may result in the individual requiring a repeat test and delayed management.
- Histopathological samples received in error will be repatriated to the correct location.
- All other samples should be repeated as delay caused by unnecessary transit to the CSL laboratory adversely impacts the sample stability.

Sample tracking

All practices and hospital clinics will have been provided with a card with a barcode identifying your location as shown below. This card should be firmly fixed to a bench or wall in the area where the purple sample transport bags will be placed for pick-up by the courier.



Always attach one of the barcode labels from the roll to the outside of each purple bag in the box marked 'Place Barcode Label Here'. Place the barcode-labelled purple bag near the practice identification barcode you have fixed to the bench or wall in the place designated for pick-up by the TDL Collect courier.

The courier will scan the practice identification barcode on the bench and then the barcode on the sample transport bag to log the pick-up of a cervical screening transport bag containing the samples from your location.

Important: never place other pathology samples in the CSL purple transport bags.

Cervical screening results

Turnaround times

In 2023, the average length of time to receive an authorised report was 8 days from the date the sample was taken.

Communication of results to the sample taker

All cervical screening results, which include both a result and a management recommendation, are sent to the sample requester. The majority of reports in primary care are sent electronically to the sample requester. A small number will continue to receive hard-copy reports. As part of the overall transition to primary HPV testing across London, the aim is to have all results sent electronically.

In secondary care, users receive reports by secure email to a dedicated mailbox.

Results to Cervical Screening Administration Service (CSAS)

Results are transmitted daily to the Cervical Screening Administration Service (CSAS), who are responsible for notifying individual women of their results in writing.

Direct referrals

All women who have a **HR-HPV DETECTED / CYTOLOGY ABNORMAL** test will be referred directly to colposcopy. The colposcopy administration team arranges appointments directly with the woman, unless a referral to another unit is requested by the woman. In this case the woman is referred back to her GP by colposcopy who will redirect the referral as per patient's choice.

Failsafe

CSL runs a failsafe system to ensure that women are not lost to follow up. The laboratory will send notifications to sample takers at specified time frames if the failsafe team have not been notified of attendance at colposcopy, or outcome of the referral.

Table 1: Laboratory failsafe notification time frame

| | Time from result being issued to failsafe letter being sent | | |
|------------------|---|------------|--------------------|
| | 1st letter | 2nd letter | 3rd (Final) letter |
| Routine failsafe | 16 weeks | 24 weeks | 32 weeks |
| Urgent failsafe | 4 weeks | 6 weeks | 8 weeks |

Multidisciplinary Team Meetings (MDT)

The clinical team provides support for MDTs across London. For any queries in relation to MDTs, please email hsl.csl.londonmdt@nhs.net.

Please send MDT lists to hsl.csl.londonmdt@nhs.net one week in advance of the meeting.

Cancer Audit Review

CSL participates in Cancer Audit Review. Legacy cases reported before 2 December 2019 remain the responsibility of Trusts. CSL works closely with Cervical Screening Provider Leads (CSPLs) and the London Screening Quality Assurance Service (SQAS) to ensure local and external reviews are carried out in line with national guidance.

For any queries or requests in relation to cancer audit, please email hsl.csl.canceraudit@nhs.net.

Cervical Sample Taker Training

All cervical sample takers taking samples with the NHS Cervical Screening Programme are required to comply with the training requirement specified in the National Guidance below.

<https://www.gov.uk/government/publications/cervical-screening-cervical-sample-taker-training>

It is highly recommended that all sample takers in primary and secondary care complete the e-learning for healthcare modules. To access e-learning for healthcare please follow the link below.

<https://www.e-lfh.org.uk/>

Cervical Sample Taker PIN Code

All sample takers, including those medically qualified, sending samples to CSL must be registered on the LonCSTD.

For further information on how to obtain your London PIN please contact hsl.csl.cstd@nhs.net.

Cervical Screening Professional Guidance

<https://www.gov.uk/government/collections/cervical-screening-professional-guidance>

Sample Taker Updates

Regular Sample Taker Updates (STU) are circulated to our users. Previous versions are available on the HSL website.

HSL Advanced Diagnostics

HSL Advanced Diagnostics (HSL-AD) is a specialist clinical and research referral laboratory for targeted cancer diagnostics. It has been providing expert services to UCLH Hospitals since the early 1980s and to other hospitals around the UK and overseas since 1990, and is wholly owned and managed by Health Services Laboratories (HSL).

HSL-AD provides immunohistochemistry (ICH), in situ hybridisation (ISH) and molecular tissue diagnostics services. For ICH and ISH tests on formalin-fixed paraffin embedded tissue sections, we have one of the largest collections of antibodies and in situ probes in the UK. Our molecular pathology services include HPV genotyping and breast cancer profiling. In 2023, we performed 350,000 immunohistochemistry and 8,500 fluorescent in situ hybridisation tests for a wide spectrum of diseases.

These services are available on a permanent or temporary basis to all laboratories, pathologists, and oncologists – whether they require a complete immunohistochemistry, in situ or molecular service, or just to complement their own local testing protocols with additional, specific biomarkers.

The laboratory's 39 scientific and administration staff are supported by a team of specialist Consultant Histopathologists.

HSL-AD is a UKAS Accredited Medical Laboratory (No. 9007).

Staff /Key personnel

CLINICAL STAFF

| | | |
|---|---|--------------------------|
| Professor Manuel Rodriguez-Justo | Consultant Specialty Lead, Histopathology | manuel.rodriguez@nhs.net |
|---|---|--------------------------|

LABORATORY STAFF

| | | | |
|--------------------|------------------------------------|------------------------------|---------------------|
| David Allen | Operational and Scientific Manager | david.allen@hslpathology.com | +44 (0)20 3912 0285 |
|--------------------|------------------------------------|------------------------------|---------------------|

| | | | |
|----------------------|--------------------------------------|--------------------------------|---------------------|
| Josep Linares | Deputy Head of Department / Lead BMS | josep.linares@hslpathology.com | +44 (0)20 3912 0286 |
|----------------------|--------------------------------------|--------------------------------|---------------------|

| | | | |
|------------------------|--|----------------------------------|---------------------|
| Sanuri Govender | FISH Service Lead / Deputy Quality Manager | sanuri.govender@hslpathology.com | +44 (0)20 3912 0285 |
|------------------------|--|----------------------------------|---------------------|

| | | | |
|--------------------------|-----------------|------------------------------------|---------------------|
| Sahar Zargarzadeh | Quality Manager | Sahar.zargarzadeh@hslpathology.com | +44 (0)20 3912 0280 |
|--------------------------|-----------------|------------------------------------|---------------------|

INVOICING & PRICING

| | | | |
|------------------------|--------------------------|-------------------------------|---------------------|
| Mr Simon Mackie | Finance & Office Manager | simon.mackie@hslpathology.com | +44 (0)20 3912 0287 |
|------------------------|--------------------------|-------------------------------|---------------------|

Laboratory hours

Specimen Reception Enquiries:
Monday–Friday: 09:30–18.00

Routine Opening Hours:
Monday–Friday: 07:30–19:00

General enquiries

HSL-Advanced Diagnostics
Ground Floor
60 Whitfield Street
London
W1T 4EU

Tel: +44 (0)203 912 0280
Email: AD@hslpathology.com

Clinical advice

Customers are encouraged to contact the laboratory with any queries about the testing service we provide. All requests should be either telephoned directly or emailed to AD@hslpathology.com. The laboratory will liaise with our consultant colleagues where their clinical input is required.

Out-of-hours service

No weekend work or on-call services are available.

Urgent samples

If a report is required urgently, please mark the request form 'Urgent' and contact the laboratory via telephone or email. Please note only urgent cases should be marked as 'Urgent'.

Specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

Slide requirements

All sections cut for immunohistochemistry (IHC) or fluorescent in situ hybridisation (FISH) testing require special precautions for optimal performance and quality of staining procedures. Sections should be cut onto the recommended slide type.

Immunohistochemistry (IHC) - stain and return only

For stain and return IHC requests, we require sections cut at 3-4µm placed on positively charged IHC slides. Please provide an appropriate number of unstained sections to cover the number of requests per case, plus an additional 2-4 sections for repeat staining that may be required.

Special stain (stain and return)

For special stains, most sections can be cut at 3µm onto positively charged IHC slides. Please provide an appropriate number of unstained sections to cover the number of requests per case.

IHC and FISH for interpretation

For all interpretative requests, we require an appropriate number of unstained sections plus an additional 2 unstained sections for repeat/reflex testing that may be required.

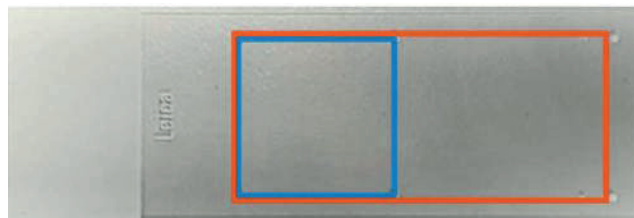
Tissue placement

Routine Stain and Return IHC, MMR

Section placement should not be excessively high. HSL-AD primarily uses the Leica Bond III platform for IHC staining and the staining area does not cover the entire surface area of the slide.

- Sections from biopsies and small pieces of tissue should be placed in the area within the bluebox.
- Sections from resections and larger / multiple pieces of tissue should be placed in the area covered by the red box.
- Placement of tissue in this way is applicable for all slide types.

- It is very important that the lesion of interest from mega blocks is placed on the test slides appropriately.



BRAF, Her-2, ER, ALK, ROS1, p16, pan-TRK, PD-L1 and FISH tests

These IHC tests are primarily performed on the Roche / Ventana and Agilent / Dako platforms.

- Section placement should be in the top third of the slide.
- Sections from resections and larger / multiple pieces of tissue should be placed as required, leaving some free space towards the bottom of the slide.



Virology / Bacteriology IHC Requests

- Cut a ribbon of 3 sections on each slide referred for these tests e.g. CMV, H. pylori, T. pallidum [Syphilis] and VZV.



Slide drying / baking

- Once cut, all sections for IHC and FISH should be left to dry naturally or in a slide rack above a gentle heat source in an upright position for 30 minutes to 1 hour.
- Ensure that there is no remaining water underneath the section before baking. The use of slides recommended in this user guide are selected to optimise the drying

Specimens

process, reduce the time required and significantly reduce the number of repeat tests we perform.

- All sections for IHC or FISH should be placed in a temperature controlled oven at 60°C for 1 hour or at 37°C overnight.
- Sections should not be hot-plated using direct heat on the slide, as this may cause poor tissue adherence and unreliable IHC / FISH staining quality.
- X-tra® Slides, from any manufacturer, are not suitable for FISH testing.
- If slide identification at the referring laboratory is done through printed labels, the maximum height of these labels must not exceed 22mm. If this is not possible, slides handwritten with pencil are preferable. **This is critical as HSL-AD primarily uses a range of staining platforms. IHC/CISH staining on these have been calibrated and validated for a specific slide surface area. Furthermore, labels extending down onto the slide staining area may exert a hydrophobic effect on the reagents applied.**
- Any deviations to these instructions may lead to compromised staining quality.

Packaging and sending of slides / blocks to HSL-AD

- All slides sent to us must be securely packaged in slide mailer boxes with lids taped down.
- Where possible, tape the slide boxes together to minimise movement inside the package.
- Blocks and slides must be thoroughly secured in protective material before sending i.e. blocks and slides should not be placed loose in any transport container (box) when accompanying other material.
- A new padded envelope should be used for all specimens. The reuse of envelopes is not advised as these may open during transport.
- Ensure all material (forms, slides and blocks) is in the package before sealing. (Confirm that three points of identification are present).
- Material receipt forms sent to HSL-AD must state the material sent i.e. block and slide numbers.
- Please ensure the correct address label is on the envelope.

Packaging and returning of slides / blocks to requestor

- We send all slides (slide mailer boxes) and blocks (secured in protective material) in securely padded envelopes via Royal Mail or courier.
- As standard, all cases are returned to referring laboratories using 1st class postage through the Royal Mail. Tissue blocks are tracked via the Royal Mail signed-for service.
- If you would like to arrange a courier, or want us to arrange one, please contact us directly.

Sample rejection criteria

Requesting laboratories will be notified where samples are unsuitable for testing. Changes to the request form or new tissue section may be requested and testing will commence once the issue has been corrected. Patient material and requests will be returned to sites for correction if no communication to resolve is received.

Request Forms

- Illegible request (all request forms are designed as editable PDF documents; we recommend that requesting laboratories complete forms electronically).
- Test(s) required not stated.
- Requesting laboratory not stated.
- Requesting laboratory/surgical slide/block number not stated.

Slides/blocks

- Number mismatch between slide/block and request form
- Slides/blocks without information.
- Insufficient material received or slides broken in transit.

Clinical Trials

- Inclusive of points above, all requests for work coming through the laboratory as part of an organised clinical trial must have all information points completed and correct. All identifiable patient information must be anonymised (unless such information forms part of the trial process, e.g. date of birth). Cases with incorrect or no information will be rejected. All corrections to request forms or data should be corrected with a single line through the incorrect information, be signed and dated. Where appropriate, an explanation of the nature of the correction should be stated.

Request procedures

See page 14 for general information on request procedures.

There are two request forms for all tests offered by the HSL-AD service, organized as 'Stain & Return tests' and 'Reported Tests'.

Our request forms are designed as editable PDF documents; we recommend that requesting laboratories complete forms electronically.

Copies of request forms can be downloaded from:

<https://www.hslpathology.com/services/hsl-advanced-diagnostics/request-procedures/>

Please complete the appropriate form fully. In particular, three points of patient identification are required. Ensure that the slide/block and request form information match.

Patient identification required:

- 1 Surname
- 2 Date of Birth
- 3 Referring hospital laboratory/surgical number

The referring hospital/laboratory accepts responsibility for errors caused due to insufficient patient identification provided for diagnostic tests.

For all interpretation requests, we use specific request forms. Please select the appropriate form and complete all details. These can be found by using the above link.

Terms and Conditions

Each individual test request is considered as an agreement between HSL-AD and the referring laboratory to perform all available tests requested.

Service level agreements are available for all referring laboratories/customers, please enquire for further information.

Results

Reports are returned by email to the requesting site only. A paper copy of the report is also sent out with stained slides. HSL is accredited to the NHS Digital standard DCB1596 for secure email and can send and receive email to and from NHS Mail addresses without the need for additional encryption systems. All other emails distributing patient results and information use encrypted email.

Turnaround times

HSL Advanced Diagnostics is always looking at ways to improve the turnaround times (TATs) without compromising diagnostic accuracy and patient safety. TATs are closely monitored by the laboratory management on a regular basis, and this information is available to service users upon request.

Please note that stated turnaround times are in working days and are dependent on:

- Day of receipt of tissue block or pre-cut slides.
- Test with or without interpretation.
- Arrival time in laboratory (all FISH requests must arrive in the laboratory by 12:00 for TAT calculation to begin on that day, otherwise it will begin from the following working day).
- Courier or standard post (please send by at least 1st Class Royal Mail or Special Delivery).

Stated TATs are based on receipt of sample in lab to sample/result leaving the HSL-AD.

Laboratory and do not include postal/courier delivery times to and from the lab. All requests involving interpretation are sent by encrypted email.

Downtime

There are times where instrument downtime may result in delay of slides being processed and returned. Such occurrences are very rare, and all major engineering tasks required for our IHC instruments and department are carried out during weekend periods. In the event of downtime, all customers will be contacted directly and will be informed of any situation with expected turnaround times.

HSL Advanced Diagnostics tests

HSL-AD participates in EQA across various modules through UK NEQAS ICC & ISH, NordiQC, and GenQA. The laboratory repertoire includes a broad range of IHC markers, FISH probes, and molecular tests. For tests not covered by conventional EQA schemes within the previous 12 months, an alternative approach to EQA is implemented to ensure ongoing quality assessment.

Immunohistochemistry (IHC)

Slide type: SuperFrost Plus, Leica Bond Plus recommended

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|---|-----------------------------|------------------------------|-----------------|
| Adrenocorticotrophic Hormone (ACTH) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| ALK-1 (Lung - D5F3) IHC | 3 USS | 3µm | N/A | 48 hours |
| ALK-1 (Lung - D5F3) IHC (Reported) | 3 USS | 3µm | N/A | 72 hours |
| ALK-1 (Lymphoma - 5A4) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Alpha-1-Anti Chymotrypsin IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Alpha-1-Antitrypsin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Alpha-1-Fetoprotein (AFP) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| AMACR (P504S, Racemase) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| AMACR/p63 Cocktail IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Androgen Receptor (AR) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Annexin IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Arginase IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| B-Cell Specific Octamer Binding Protein-1 (BOB-1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BAP1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BCL-2 (E17) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BCL-2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BCL-6 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BCL-10 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Ber-EP4 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Beta Catenin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BKV (Human polyomavirus 1) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BLIMP-1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| BRAF V600E (Reported) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 72 hours |
| BRAF V600E IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 72 hours |
| BSEP IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| C-MYC IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| C-Reactive Protein (CRP) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

[#] The antibody has been verified in HSL Advanced Diagnostics, to reflect clinical use. However, the expected staining characteristics have not been formally validated by the manufacturer. We are committed to using CE-IVD or FDA-approved methodologies whenever possible and update our antibody stock when these become available. New tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

HSL Advanced Diagnostics tests

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|------------------------------|-----------------|
| C4d IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Calcitonin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Calponin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Calretinin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cancer Antigen 125 (CA125) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Carbohydrate Antigen 19.9 (CA19.9) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Carbonic Anhydrase IX (CA-IX) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD1a IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD3 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD4 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD5 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD7 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD8 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD10 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD11c IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD13 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD14 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD15 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD16 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD19 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD20 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD21 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD22 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD23 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD25 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD27 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD28 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD30 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD31 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD33 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD34 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD35 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD38 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD43 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

[#] The antibody has been verified in HSL Advanced Diagnostics, to reflect clinical use. However, the expected staining characteristics have not been formally validated by the manufacturer. We are committed to using CE-IVD or FDA-approved methodologies whenever possible and update our antibody stock when these become available. New tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|---|-----------------------------|------------------------------|-----------------|
| CD44 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD45 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD45RO IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD52 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD54 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD56 (N-CAM) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD57 (HNK-1, LEU7) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD61 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD68 (KP1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD68 (PGM1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD71 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD79a IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD99 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD103 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD105 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD117 (c-KIT) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD123 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD138 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD163 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CD235a (Glycophorin A) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CDX2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CEA Monoclonal IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CEA Polyclonal IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Chromogranin A IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Chymotrypsin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CK5/p63 (Lung) Routine Double Stain IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CK5/p63/AMACR (PIN4 - Prostate) Routine Double Stain IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CK7/TTF1 (Lung) Routine Double Stain IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Claudin18.2 IHC [#] | 3 USS | 3µm | N/A | 24-48 hours |
| CMV Chromogenic in situ hybridization (CISH) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Collagen IV IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| CXCL-13 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cyclin A IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

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HSL Advanced Diagnostics tests

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|------------------------------|-----------------|
| Cyclin D1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 5 (CK5) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 5/p63 (CK5/p63) Cocktail IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 7 (CK7) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 8 (CK8) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 8/18 (CK18) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 14 (CK14) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 17 (CK17) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 19 (CK19) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin 20 (CK20) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin, High Molecular Weight (34βE12) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin, Low Molecular Weight (CAM 5.2) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin, Pan-cytokeratin (AE1/AE3) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin, Pan-cytokeratin (MNF116) (Red) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytokeratin, Pan-cytokeratin (MNF116) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Cytomegalovirus (CMV) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| DBA44 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Desmin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| DOG-1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| E-Cadherin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| E-Cadherin (Renal) IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| EBER Chromogenic in situ hybridization (CISH) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| EGFR (HER1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 48-72 hours |
| Epithelial Membrane Antigen (EMA) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Epstein-Barr Virus (LMP) IHC (test withdrawn - please request EBER ISH) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | |
| ERG IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Estrogen Receptor (ER - 6F11) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Estrogen Receptor (ER - EP1) IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Estrogen Receptor (ER - SP1) IHC (default test if not specified) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

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| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|------------------------------|-----------------|
| Factor VIII (vWF) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Factor XIIIa IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Fascin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Fibrinogen IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Folate Receptor Alpha (FLOR1) IHC (Reported)[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Follicle Stimulating Hormone (FSH) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| FoxP3 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Galectin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Gastrin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| GATA-3 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| GCDFP-15 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Germinal Center B-cell Expressed Transcript 1 (GCET-1) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Glial Fibrillary Acidic Protein (GFAP) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Glucagon IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Glut-1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Glutamine Synthetase IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Glypican 3 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Granzyme B IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Growth Hormone (GH) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| h-caldesmon IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| H. pylori IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| HMB45 (Red) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| HBME-1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Hepatitis B Virus Core Antigen (HBcAg) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Hepatitis B Virus Surface Antigen (HBsAg) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Hepatocyte Specific Antigen (HSA, HepPar1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Her-2 IHC (Reported) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 72 hours |
| Her-2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 48 hours |
| Herpes Simplex Virus 1 (HSV I) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Herpes Simplex Virus 2 (HSV II) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| HMB45 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

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HSL Advanced Diagnostics tests

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|---|-----------------------------|------------------------------|--|
| HPV RNAscope High & Low Risk (CISH) | 8 | 3µm | N/A | 72 hours Stain & Return, 5 days Interpretation |
| HPV RNAscope High Risk (CISH) | 8 | 3µm | N/A | 72 hours Stain & Return, 5 days Interpretation |
| HPV RNAscope Low Risk (CISH) | 8 | 3µm | N/A | 72 hours Stain & Return, 5 days Interpretation |
| Human Chorionic Gonadotropin (HCG) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Human Herpesvirus 8 (HHV8, KSHV) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Human Muscle Actin (HMA, HHF35) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Human Papillomavirus (HPV) IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| ICOS IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IgA IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IgD IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IgG IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IgG4 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IgM IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Inhibin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Insulinoma-associated protein 1 (INSM1) IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Insulin IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| IRTA-1 IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| J chain IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Kappa IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Kappa Chromogenic in situ hybridization (CISH) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Kappa (plasma cells) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Lambda IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Lambda Chromogenic in situ hybridization (CISH) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Lambda (plasma cells) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Laminin IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Langerin IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| LFABP IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Luteinising Hormone (LH) IHC [#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

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|--|---|-----------------------------|------------------------------|-----------------|
| Lymphoid enhancer binding factor 1 (LEF1)[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Lysozyme IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Mammaglobin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Maspin IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Mast Cell Tryptase (MCT) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Melan A IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Melan A (Red) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Mesothelin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MIB-1 (Ki67) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MIB-1 (Red) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MMR IHC (Reported) | 6 USS | 3µm | N/A | 7 days |
| MMR (MLH1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 7 days |
| MMR (MSH2) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 7 days |
| MMR (MSH6) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 7 days |
| MMR (PMS2) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 7 days |
| MOC31 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUC-1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUC-2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUC-4 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUC-5AC IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUC-6 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MUM-1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Myeloperoxidase IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| MYO D1 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Myogenin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Myoglobin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Myosin Heavy Chain (Smooth muscle), (SMM; S131) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Napsin A IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Nestin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Neurofilament Protein (NFP) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Neuron-Specific Enolase (NSE) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| NKX3.1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| OCT2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| OCT3/4 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| p16 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 48 hours |

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HSL Advanced Diagnostics tests

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|--|---|-----------------------------|------------------------------|-----------------|
| p16 IHC (Reported) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 72 hours |
| p27 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| p40 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| p53 (DO7) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| p57 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| p63 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Pan-TRK IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Pan-TRK IHC (Reported)[#] | 3 USS | 3µm | N/A | 72 hours |
| Pancreatic polypeptide (PPP) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Parathyroid Hormone (PTH) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Parvovirus B19 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Pax-2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Pax-5 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Pax-8 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| PD-L1 (22C3) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD-L1 (22C3) IHC (Reported) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD-L1 (28-8) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD-L1 (28-8) IHC (Reported) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD-L1 (SP142) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD-L1 (SP142) IHC (Reported) | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 5 days |
| PD1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Perforin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| PGP9.5 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| PLA2R (Renal) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| PLAP IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Podoplanin (D2-40) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Progesterone Receptor (16) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Progesterone Receptor (16) IHC (Reported) | 3 USS | 3µm | N/A | 72 hours |
| PRAME IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Prolactin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Prostate Specific Acid Phosphatase (PSAP) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Prostate Specific Antigen (PSA) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Prostate Specific Membrane Antigen (PSMA) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Prostein (P501S) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

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|---|---|-----------------------------|------------------------------|-----------------|
| PTEN IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Renal Cell Carcinoma (RCC) Antigen IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Ret 40f (Glycophorin C) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| ROS1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 48 hours |
| ROS1 IHC (Reported) | 3 USS | 3µm | N/A | 72 hours |
| S100 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SAA IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SALL4 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SATB2 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SDBH IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Serotonin (5HT) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SMAD4 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Smooth Muscle Actin (SMA; 1A4) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Somatostatin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SOX2 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SOX10 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| SOX11 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| STAT6 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Surfactant IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Synaptophysin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| TAL 1B5 (HLA-DR) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Tartrate-Resistant Acid Phosphatase (TRAP) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| TCR-Beta (Beta F1) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Tdt IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Thyroglobulin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Thyroid Stimulating Hormone (TSH) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Thyroid Transcription Factor (TTF-1 - 8G7G3/1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Thyroid Transcription Factor (TTF-1 - SPT24) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| TIA-1 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Treponema Pallidum (TP) IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Trypsin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| TTF1/CD31 IHC[#] | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Uroplakin-II IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

[#] The antibody has been verified in HSL Advanced Diagnostics, to reflect clinical use. However, the expected staining characteristics have not been formally validated by the manufacturer. We are committed to using CE-IVD or FDA-approved methodologies whenever possible and update our antibody stock when these become available. New tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

HSL Advanced Diagnostics tests

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|------------------------------|-----------------|
| Varicella Zoster Virus (VZV) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Villin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Vimentin IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| VS38c IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| Wilms Tumor-1 (WT-1) IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |
| ZAP70 IHC | No of tests + 1 USS per 4 IHC (max 4 USS) | 3µm | N/A | 24-48 hours |

The antibody has been verified in HSL Advanced Diagnostics, to reflect clinical use. However, the expected staining characteristics have not been formally validated by the manufacturer. We are committed to using CE-IVD or FDA-approved methodologies whenever possible and update our antibody stock when these become available. New tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

In situ hybridisation (ISH)

Slide type: SuperFrost Plus, Leica Bond Plus ESSENTIAL

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|-----------------------|-----------------------------|------------------------------|-----------------|
| ALK Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E, ALK IHC (if tested) | 10 days |
| BCL2 t(18q21) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| BCL2/IGH - Lymphoma FISH probe (Dual-Fusion, Dual-Colour) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| BCL6 t(3q27) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| CCND1 t(11q13) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| CDK4/CEP12 - Oncology FISH probe (Amplification) | No of tests + 2 USS | 3-4µm | H&E | 10 days |
| DDIT3 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| EGFR/CEP7 - Oncology FISH probe (Amplification)* | No of tests + 2 USS | 3-4µm | H&E | 10 days |
| ETV6/NTRK3 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| EWSR1 FISH probe | No of tests + 2 USS | 5µm | H&E | 10 days |
| FGFR1/CEP8 - Oncology FISH probe (Amplification) | No of tests + 2 USS | 3-4µm | H&E | 10 days |
| FGFR2 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| FGFR2/CEP10 - Oncology FISH probe (Amplification) | No of tests + 2 USS | 3-4µm | H&E | 10 days |

This probe is currently outside of our scope of UKAS/ISO 15189:2022 accreditation. The probe has been verified in HSL Advanced Diagnostics, to reflect clinical use. Where possible, new probes that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

| TEST | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|-----------------------------------|-----------------|
| HER2/CEP17 - Oncology FISH probe (Amplification) | 3 USS | 3-4µm | H&E, Her-2 IHC & any relevant IHC | 5 days |
| IGH t(14q32) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| IGK t(2p11) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| IGL t(22q11) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| IRF4,DUSP22 t(6p25) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| MALT1 t(18q21) - Lymphoma FISH probe (Breakapart) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| MAML2 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| MDM2/CEP12 - Oncology FISH probe (Amplification) | No of tests + 2 USS | 3-4µm | H&E | 10 days |
| Melanoma FISH (RREB1/CCND1/ MYB/CEP6) probes | No of tests + 1 USS per 4 IHC (max 4 USS) | 3-4µm | N/A | 10 days |
| MET/CEP7 - Oncology FISH probe (Amplification) | No of tests + 2 USS | 3-4µm | H&E | 10 days |
| MYB Breakapart - Oncology FISH probe (Translocation/Rearrangement) ISH | No of tests + 2 USS | 5µm | H&E | 10 days |
| MYC t(8q24) - Lymphoma FISH probe (Breakapart)* | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| MYC/BCL6 - Lymphoma FISH probe (Dual-Fusion, Dual-Colour)* | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| MYC/CEP8 - Oncology FISH probe (Amplification) | 3 USS | 3-4µm | N/A | 10 days |
| MYC/IGH/CEP8 - Lymphoma FISH probe (Dual-Fusion, Dual-Colour) | No of tests + 4 USS | 2-3µm | H&E & any relevant IHC | 10 days |
| NUTM1 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| PDGFB Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 3µm | H&E | 10 days |
| RET Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E | 10 days |
| ROS1 Breakapart - Oncology FISH probe (Translocation/Rearrangement) | No of tests + 2 USS | 5µm | H&E, ROS1 IHC (if tested) | 10 days |
| TFE3 Breakapart - Oncology FISH probe (Translocation/Rearrangement)* | No of tests + 2 USS | 5µm | H&E | 10 days |
| TFEB FISH | No of tests + 2 USS | 3-4µm | H&E | 10 days |

This probe is currently outside of our scope of UKAS/ISO 15189:2022 accreditation. The probe has been verified in HSL Advanced Diagnostics, to reflect clinical use. Where possible, new probes that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

HSL Advanced Diagnostics tests

Molecular Pathology

| | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|--------------------------------------|-----------------------------|--|-----------------|
| EGFR mutation[#] | Tissue block only | N/A | H&E | 72 hours |
| Prosigna Breast Cancer Assay | Tumour resection block only (Breast) | N/A | Patient should be ER Positive & HER2 Negative. Full pathology report, including original biopsy, sentinel node(s), resection and axillary clearance. | 7 days |
| Zytovision VisionArray HPV Genotyping Assay | Block only | N/A | TISSUE BLOCK ESSENTIAL (if not sent this will be stained as part of the patient workup and is mandatory for final reporting of this assay) | 7 days |

[#] This assay is currently outside of our scope of UKAS/ISO 15189:2022 accreditation. The assay has been verified in HSL Advanced Diagnostics, to reflect clinical use. New assays that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments.

Special Stains

| | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|---|---|-----------------------------|------------------------------|-----------------|
| Alcian Blue PAS (ABPAS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Alcian Blue PAS, Diastase (ABDPAS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Alcian Blue pH 2.5 (AB) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Congo Red - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Elastin H&E - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Fouchet - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Giemsa - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Gordon and Sweet (Retic) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Gram - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Grocott's Silver (GMS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Haematoxylin Van Gieson (HVG) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Martius Scarlet Blue (MSB) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Masson Fontana - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Masson Trichrome - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Miller's Elastic Van Gieson (EVG) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Orcein - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |

[#] This test is currently outside of our scope of UKAS/ISO 15189:2022 accreditation. The test has been verified in HSL Cellular Pathology, to reflect clinical use. Where possible, new tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments..

| | NO OF SLIDES REQUIRED | SECTION THICKNESS (MICRONS) | ADDITIONAL MATERIAL REQUIRED | TURNAROUND TIME |
|--|---|-----------------------------|------------------------------|-----------------|
| Periodic Acid Schiff (PAS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Periodic Acid Schiff, Diastase (DPAS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Periodic Acid-Methenamine Silver (PAMS) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Periodic Acid Schiff Fungi (PASF) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Perl's Prussian Blue - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Phosphotungstic Acid Haematoxylin - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Rhodanine - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Sirius Red - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Southgate's Mucicarmine - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Toluidine Blue - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Victoria Blue - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Von Kossa - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Wade Fite - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Warthin and Starry - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |
| Ziehl-Neelsen (ZN) - Special Stain | No of tests + 1 USS per 4 tests (max 4 USS) | 3µm | N/A | 48 hours |

This test is currently outside of our scope of UKAS/ISO 15189:2022 accreditation. The test has been verified in HSL Cellular Pathology, to reflect clinical use. Where possible, new tests that come on line will be assessed as part of the next assessment cycle and will form part of our updated UKAS accreditation scope following successful assessments..

HSL Biochemistry

HSL Biochemistry provides a high-quality, safe and effective service that facilitates the clinical care of patients. The service is set up across the HSL network of laboratories based on the hub-and-spoke model. The service includes routine, high-volume biochemistry testing provided through the rapid response laboratories (RRLs) located at each associated Trust site, combined with the specialist biochemistry service delivered from the hub laboratory (The Halo building). These services are supported by fully automated and tracked instruments, comprising general chemistry and immunoassay analysers on multiple platforms.

The purpose-built laboratory at the Halo is equipped with state-of-the-art instrumentation, and has an independent pre-analytics and tracking system traversing several floors and disciplines. The service is clinically-led and staffed by medical, scientific and support personnel providing a comprehensive analytical and advisory service. In addition to general guidance, expertise is available for steroid biochemistry and cardiovascular biomarkers through the established Supra-regional Assay Services (SAS). Furthermore, considerable clinical and technical expertise is provided through our senior scientists for the urology and proteins sections, the latter operating collaboratively with the National Amyloidosis Centre (NAC) located at the Royal Free Hospital site.

The department manages an extensive point-of-care testing (PoCT) service implemented by scientific teams located at partner hospitals.

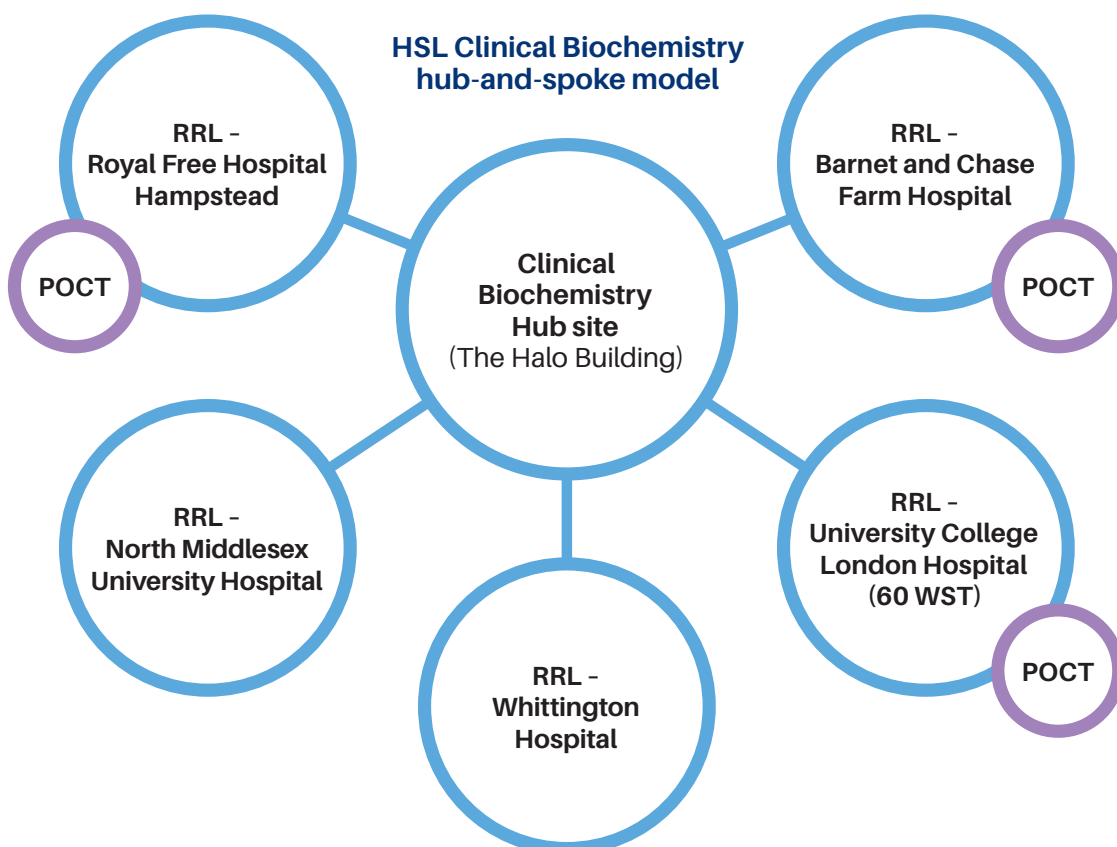
During core laboratory hours, a duty biochemist is available for clinical advice on test selection, interpretation and investigations. Additionally, on-call consultants can be contacted outside of core hours. Senior members of the department are always happy to discuss the needs of the users and to provide advice.

HSL Biochemistry is a UKAS Accredited Medical Laboratory No. 8169. Quality of the service is continuously monitored via a variety of quality assurance procedures. Clinical and laboratory audit programmes contribute to ongoing service review and improvement.

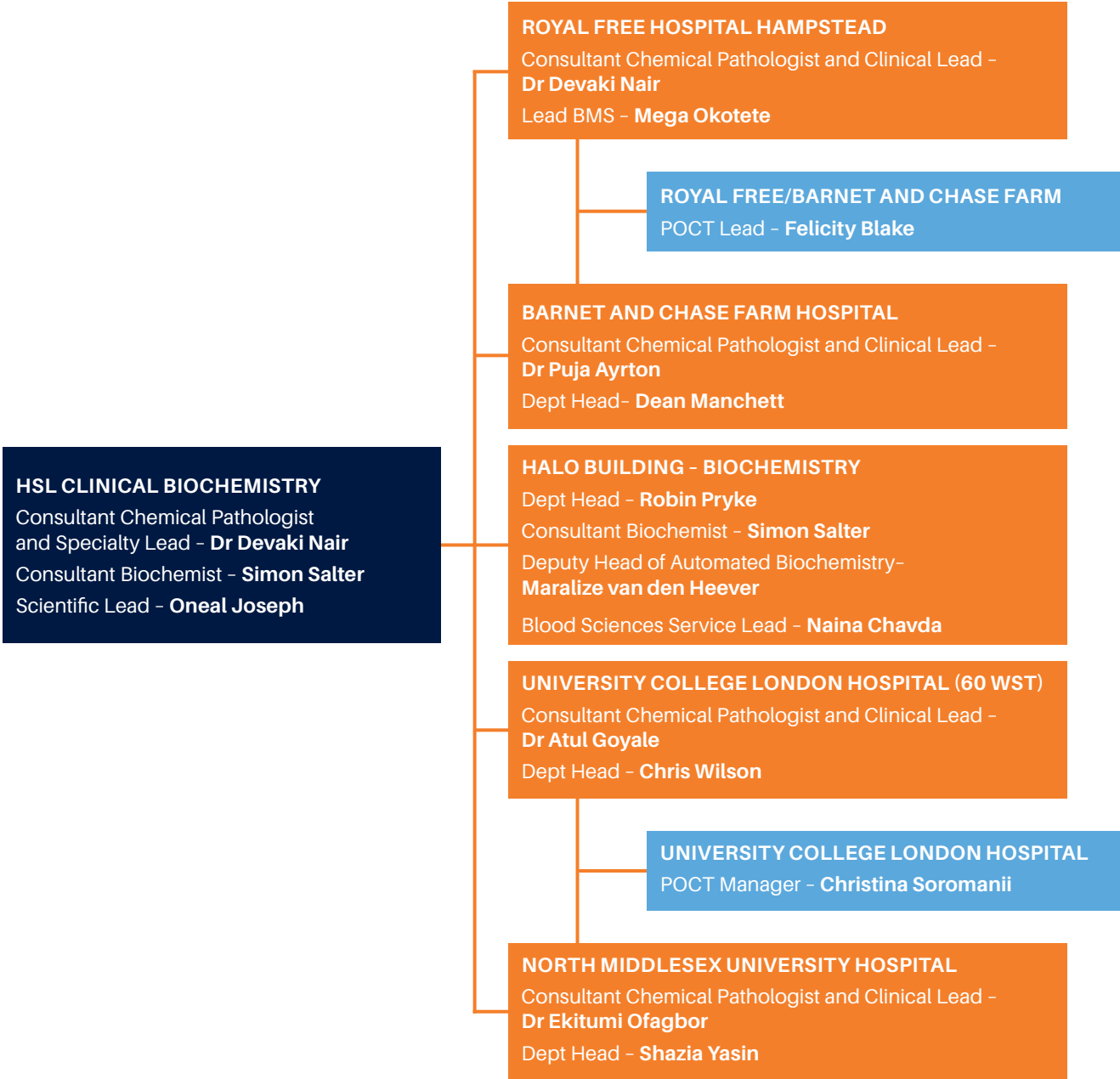
The department holds IBMS pre- and post-registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. It also has a Health Education England (HEE) recognised training programme for the laboratory aspects of Chemical Pathology and Metabolic Medicine.

Multi-professional training through a variety of HEE recognised courses is actively encouraged and promoted in order to develop a workforce required for the profession.

See page 4 for a full list of external accreditations.



Staff/Key personnel



| ALL SITES | | |
|---|--|--|
| Dr Devaki Nair | Consultant Chemical Pathologist and Specialty Lead | devaki.nair@nhs.net |
| Oneal Joseph | Scientific Lead | Oneal.joseph@hslpathology.com |
| BARNET & CHASE FARM | | |
| Dr Puja Ayrton | Consultant Chemical Pathologist and Clinical Lead | p.ayrton@nhs.net |
| Dean Manchett | Department Head | dean.manchett@hslpathology.com |
| THE HALO BUILDING | | |
| Simon Salter | Consultant Biochemist | simon.salter@hslpathology.com |
| Dr Daniel Hills | Consultant Biochemist | daniel.hills@hslpathology.com |
| Robin Pryke | Head of Biochemistry | robin.pryke@hslpathology.com |
| Maralize van den Heever | Deputy Head of Automated Biochemistry | Maralize.VanDenHeever@tdlpathology.com |
| Naina Chavda | Blood Sciences Service Lead | Naina.Chavda@hslpathology.com |
| NORTH MIDDLESEX HOSPITAL | | |
| Dr Ekitumi Ofagbor | Consultant Chemical Pathologist and Clinical Lead | |
| Shazia Yasin | Department Head | Shazia.yasin@hslpathology.com |
| ROYAL FREE HOSPITAL | | |
| Mega Okotete | Lead BMS | oghenemega.okotete@nhs.net |
| UCLH | | |
| Dr Atul Goyale | Consultant Chemical Pathologist and Clinical Lead | aul.goyale1@nhs.net |
| Chris Wilson | Department Head | Chris.wilson16@nhs.net |
| POCT: ROYAL FREE HOSPITAL AND BARNET/CHASE FARM | | |
| Felicity Blake | POCT Lead | Felicityblake@nhs.net |
| POCT: UCLH | | |
| Christina Soromani | POCT Manager | c.soromani@nhs.net |

Clinical Biochemistry enquiries

| ALL SITES | | |
|---------------------------|-----------------|--------------------------------------|
| Clinical Advice & support | Duty Biochemist | Duty.biochemist@hslpathology.com |
| BARNET & CHASE FARM | | |
| General enquiries | Helpdesk | BarnetRRL.Helpdesk@hslpathology.com |
| NORTH MIDDLESEX HOSPITAL | | |
| General enquiries | Helpdesk | nmuh.sra@hslpathology.com |
| ROYAL FREE HOSPITAL | | |
| General enquiries | Helpdesk | Rf.Haemchemaddon@nhs.net |
| UCLH | | |
| General enquiries | Helpdesk | uclh.enquiry.biochemhelpdesk@nhs.net |

Specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

All samples must be collected in the specified containers, as shown in the table on page 56.

Request procedures

See page 14 for general information on request procedures.

Add on tests (See pathway for the acute Trusts)

Samples are generally stored for up to 1 week after receipt. The decision to perform add-on tests will depend on analyte stability and sample availability.

Specialities

SAS steroid Biochemistry

The Biochemistry department is an established Supra-Regional Assay Service laboratory for urine steroid profiling, receiving samples from both national and international laboratories, and provides a full interpretative and advisory service. In addition, the specialist section provides serum steroid measurements and interpretative guidance. The service uses both gas and liquid chromatography coupled with mass spectrometry for the measurement of steroids.

Assays available:

- Urine steroid profiling
- 17-hydroxyprogesterone
- Androstenedione

Contact

Dr Daniel Hills
daniel.hills@hslpathology.com
020 3307 5417

SAS Centre for Cardiac Biomarkers

The network of SAS centers for cardiovascular biomarkers was set up in response to an increasing demand for tests, other than routine lipid profiles, to aid in the assessment of patients with inherited hyperlipidaemia and increased cardiovascular risk. The Department has a long-standing interest in the management of lipid disorders, with special interests in familial hypercholesterolaemia, anti-retroviral drug-induced hyperlipidaemia, and cardiovascular risk factors in South Asians. In collaboration with the Genetic Knowledge Park, the Centre participated in a project comparing DNA testing with traditional diagnostic methods for FH, funded by the Department of Health. The Centre is supported by a well-developed clinical infrastructure for lipid disorders, providing the interpretative and advisory service. There are several research and development activities including clinical trials with newer lipid lowering drugs, that the section is involved working with collaborators within the partner Trusts and external organisations, nationally and internationally.

Assays available:

- Apolipoprotein A1
- Apolipoprotein B
- Apolipoprotein E polymorphisms
- ApoE genotype
- Beta - Quantification (Ultracentrifugation)
- Floating beta test
- Lipid electrophoresis
- Homocysteine
- LDL (Calculated and Direct)
- Lipoprotein (a)

Research only

- HsCRP
- Small dense LDL
- Apolipoprotein CII
- Apolipoprotein CIII
- Adipokines
- Cytokines - Metabolic and Advanced

Contact

Dr Devaki Nair, Director of SAS
Devaki.nair@nhs.net
020 7472 6694

Proteins

The Proteins service covers a broad repertoire of investigations, including those for haematological (protein electrophoresis, immunofixation, serum free light chains, cryoglobulins and erythropoietin) and hepatic (enhanced liver fibrosis, alpha-1 antitrypsin phenotype) disorders, in addition to isoenzyme typing (alkaline phosphatase, creatine kinase). The service supports and has a close collaborative relationship with the National Amyloidosis Centre located at The Royal Free Hospital site.

Contact

Simon Salter
simon.salter@hslpathology.com
020 3908 1360

Jack Whitewood
Jack.Whitewood@hslpathology.com
020 3908 1363

Calculi and Urology

The calculi service provides an established investigative and interpretative service for the analysis of stones and associated metabolites (citrate, oxalate, cystine/homocystine screen), including the biochemical evaluation for primary hyperoxalurias (glycolate, glycerate, 2,4-dihydroxyglutarate). The specialist techniques used include Fourier transform infrared (FTIR) spectroscopy, and liquid chromatography–tandem mass spectrometry. Samples are received from both national and international sources.

Contact

Emma Woolman
Emma.Woolman@hslpathology.com
020 3908 1364

Dr Cassie Nash
cassandra.nash@hslpathology.com
020 3908 1365

Mass Spectrometry and Chromatography

The service provides a diverse repertoire of assays, including neuroendocrine tumour markers (plasma/urine metanephrines and urine 5HIAA) and metals (copper, zinc selenium, chromium and cobalt by ICPMS). A 7-day immunosuppressant TDM (ciclosporin A, tacrolimus, sirolimus) service is provided by the section for transplant services. In addition, the section provides analytical support for the other specialties such as steroids and urology.

Contact

Emma Woolman
emma.woolman@hslpathology.com
020 3908 1364

Biochemistry tests

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|-------------------------------------|--------------------|---------|--|
| 17-Hydroxyprogesterone (17-OHP) | Serum | 5 days | |
| Angiotensin converting enzyme (ACE) | Serum | 1 day | |
| Adrenocorticotrophic hormone (ACTH) | EDTA plasma | 5 days | Send sample to lab on ice and, if immediate analysis not possible, separate plasma and freeze. |
| Active B12 | Serum | 1 day | |
| Alpha Feto Protein (AFP) | Serum | 1 day | |
| Albumin | Serum | 1 day | |
| Alkaline Phosphatase (ALP) | Serum | 1 day | |
| Alkaline Phosphatase Isoenzymes | Serum | 10 days | |
| Alpha 1 Antitrypsin | Serum | 1 day | |
| Alpha-1 Antitrypsin Phenotyping | Serum | 15 days | |
| Alanine aminotransferase (ALT) | Serum | 1 day | |
| Amikacin | Serum | 1 day | |
| Ammonia | EDTA plasma | 1 day | Send sample to lab on ice and, if immediate analysis not possible, separate plasma and freeze. |
| Amylase | Serum | 1 day | |
| Androstenedione | Serum | 5 days | |
| Antimullerian Hormone (AMH) | Serum | 1 day | |
| Anti-Thyroglobulin Antibodies | Serum | 1 day | |
| Apolipoprotein A1 | Serum | 5 days | |
| Apolipoprotein B | Serum | 5 days | |
| Aspartate aminotransferase (AST) | Serum | 1 day | |
| B2-Microglobulin | Serum | 1 day | |
| Bicarbonate | Serum | 1 day | |
| Bile Acids | Serum | 1 day | |
| C-Reactive protein (CRP) | Serum | 1 day | |
| CA 125 | Serum | 1 day | |
| CA 15-3 | Serum | 1 day | |
| CA 19-9 | Serum | 1 day | |
| Calcitonin | Serum | 5 days | Freeze sample and send to lab frozen |
| Calcium | Serum | 1 day | |
| Calculus Analysis | Calculus (Stones) | 5 days | |
| Carbamazepine | Serum | 1 day | |
| CEA | Serum | 1 day | |

* Turnaround times are in working days

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|---|----------------------|---------|---|
| Caeruloplasmin | Serum | 1 day | |
| Chloride | Serum | 1 day | |
| Cholesterol | Serum | 1 day | |
| Chromium | EDTA or hip aspirate | 10 day | |
| Chromogranin A | Plasma | 10 day | Collect sample in trysolol, spin, separate immediately and freeze. Send sample to the lab frozen. |
| CK-MB | Serum | 1 day | |
| Cobalt | EDTA or hip aspirate | 10 day | |
| Complement C3 | Serum | 1 day | |
| Complement C4 | Serum | 1 day | |
| Conjugated Bilirubin (Direct Bilirubin) | Serum | 1 day | |
| Copper | Serum | 5 days | Collect sample in trace metal tube |
| Albumin-adjusted Calcium (calculated) | Serum | 1 day | |
| Cortisol | Serum | 1 day | |
| Creatine Kinase (Ck) | Serum | 1 day | |
| Creatine Kinase Isoenzymes | Serum | 30 days | |
| Creatinine | Serum | 1 day | |
| Creatinine clearance (Calculated) | Serum, urine | 1 day | |
| Cryoglobulins | Serum | 10 days | Collect serum into prewarmed serum tubes at 37°C and send to the lab at 37°C. Thermos flasks can be obtained from sample reception. Do not use gel tubes. |
| CSF Glucose | CSF | 1 day | Fluoride oxalate specimen required |
| CSF Lactate | CSF | 1 day | Fluoride oxalate specimen required |
| CSF Protein | CSF | 1 day | |
| CSF Xanthochromia | CSF | 1 day | Protect sample from light, wrap in foil or place in dark container and send to lab |
| Ciclosporin A | EDTA | 1 day | |
| Dehydroepiandrosterone sulphate (DHEAS) | Serum | 1 day | |
| Digoxin | Serum | 1 day | |
| Direct low-density lipoprotein (Direct LDL) | serum | 1 day | |
| Enhanced Liver Fibrosis (ELF) Testing | Serum | 5 days | |
| Erythropoietin (EPO) | Serum | 5 days | |
| Estimated GFR (eGFR) (calculated) | Serum | 1 day | |
| Ethanol | Plasma | 1 day | Fluoride oxalate specimen required |
| Faecal Calprotectin | Stool/faeces | 5 days | |

* Turnaround times are in working days

Biochemistry Tests

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|--|--------------------|---------|------------------------------------|
| Ferritin | Serum | 1 day | |
| Floating Beta | Serum | 10 days | |
| Folate | Serum | 1 day | |
| Free beta human chorionic gonadotropin (free bHCG) | Serum | 1 day | |
| Fructosamine | Serum | 1 day | |
| Follicle Stimulating Hormone (FSH) | Serum | 1 day | |
| Free triiodothyronine (FT3) | Serum | 1 day | |
| Free thyroxine (FT4) | Serum | 1 day | |
| Gentamicin | Serum | 1 day | |
| Gamma glutamyltransferase (GGT) | Serum | 1 day | |
| Glucose | Plasma | 1 day | Fluoride oxalate specimen required |
| Growth Hormone | Serum | 5 days | |
| Haemoglobin A1c | EDTA whole blood | 1 day | |
| Haptoglobin | Serum | 1 day | |
| HDL | Serum | 1 day | |
| High Sensitivity C-Reactive protein (hsCRP) | Serum | 1 day | |
| High Sensitivity Troponin I | Serum | 1 day | |
| High Sensitivity Troponin T | Serum | 1 day | |
| Homocysteine | Serum | 1 day | |
| Human chorionic gonadotropin (HCG) | Serum | 1 day | |
| Immunoglobulin A (IgA) | Serum | 1 day | |
| Immunoglobulin E (IgE) | Serum | 1 day | |
| Immunoglobulin G (IgG) | Serum | 1 day | |
| Immunoglobulin G Subclasses (IgG1-4) | Serum | 5 days | |
| Immunoglobulin M (IgM) | Serum | 1 day | |
| Insulin | Serum | 1 day | |
| Insulin-like growth factor 1 (IGF-1) | Serum | 1 day | |
| Iron | Serum | 1 day | |
| Lactate | Plasma | 1 day | Fluoride oxalate specimen required |
| Lactate dehydrogenase (LDH) | Serum | 1 day | |
| LDL-Cholesterol (Calculated) | Serum | 1 day | |
| Luteinising Hormone | Serum | 1 day | |
| Lipase | Serum | 1 day | |
| Lipoprotein electrophoresis | Serum | 10 days | |

* Turnaround times are in working days

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|--|--------------------|---------|---|
| Lipoprotein (a) | Serum | 1 day | |
| Lithium | Serum | 1 day | |
| Macroprolactin | serum | 3 days | |
| Magnesium | Serum | 1 day | |
| Metanephrines (normetanephrine, metanephrine, 3-methoxytyramine) | EDTA Plasma | 10 day | Send sample to lab on ice and, if immediate analysis not possible, separate plasma and freeze |
| Methotrexate | serum | 1 day | |
| Non-high density lipoprotein (non-HDL calculated) | Serum | 1 day | |
| n-Terminal pro b-type natriuretic peptide (NTproBNP) | Serum | 1 day | |
| Oestradiol | Serum | 1 day | |
| Osmolality | Serum/Urine | 1 day | |
| Oxalate | EDTA Plasma | 10 days | Freeze sample and send to lab frozen |
| Pregnancy associated plasma protein-A (PAPPA) | Serum | 1 day | |
| Primary Hyperoxaluria metabolites (glycolate, glycerate, dihydroxyglutarate) | Urine | 15 day | Acidified specimen required |
| Phenytoin | Serum | 1 day | |
| Phosphate | Serum | 1 day | |
| Potassium | Serum | 1 day | |
| Procalcitonin | serum | 1 day | |
| Progesterone | Serum | 1 day | |
| Prolactin | Serum | 1 day | |
| Prostate Specific Antigen (PSA) | Serum | 1 day | |
| Protein Electrophoresis | Serum | 5 days | |
| Paracetamol (Acetaminophen) | Serum | 1 day | |
| Parathyroid Hormone (PTH) | Serum | 1 day | |
| Salicylate | Serum | 1 day | |
| Selenium | Serum | 5 days | Collect sample in trace metal tube |
| Serum amyloid A (SAA) | Serum | 5 days | |
| Serum Free Light Chains | Serum | 5 days | |
| Serum Immunofixation | Serum | 5 days | |
| Sex Hormone Binding Globulin (SHBG) | Serum | 1 day | |
| Sirolimus | EDTA | 1 day | |
| Sodium | Serum | 1 day | |
| Tacrolimus | EDTA | 1 day | |

* Turnaround times are in working days

Biochemistry Tests

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|--|--------------------|--------|------------------------------|
| Testosterone | Serum | 1 day | |
| Theophylline | Serum | 1 day | |
| Thyroglobulin | Serum | 1 day | |
| Total Bilirubin | Serum | 1 day | |
| Total Glycated Haemoglobin (Boronate Affinity) | EDTA whole blood | 1 day | |
| Total Iron Binding Capacity (TIBC) (Calculated) | Serum | 1 day | |
| Total Protein | Serum | 1 day | |
| Transferrin | Serum | 1 day | |
| Transferrin Saturation (Calculated) | Serum | 1 day | |
| Triglyceride | Serum | 1 day | |
| Thyroid Stimulating Hormone (TSH) | Serum | 1 day | |
| Unsaturated iron binding capacity (UIBC) | Serum | 1 day | |
| Urate | Serum | 1 day | |
| Urea | Serum | 1 day | |
| Urine 5-hydroxyindoleacetic acid (5HIAA) | Urine | 10 day | Acidified specimen required |
| Urine Albumin:Creatinine Ratio (Calculated) | Urine | 1 day | |
| Urine Albumin | Urine | 1 day | |
| Urine Amphetamine Screen | Urine | 1 day | |
| Urine Amylase | Urine | 1 day | |
| Urine Barbiturate Screen | Urine | 1 day | |
| Urine Benzodiazepine Screen | Urine | 1 day | |
| Urine Bence Jones Protein (BJP) | Urine | 5 days | |
| Urine Calcium | Urine | 1 day | Acidified specimen required |
| Urine Cannabinoids Screen | Urine | 1 day | |
| Urine Citrate | Urine | 5 days | Acidified sample preferred |
| Urine Cocaine Screen | Urine | 1 day | |
| Urine Copper | Urine | 5 days | |
| Urine Cotinine | Urine | 1 day | |
| Urine Creatinine | Urine | 1 day | |
| Urine Cystine and homocystine screen | Urine | 1 day | |
| Urine Ethanol | Urine | 1 day | |
| Urine Glucose | Urine | 1 day | |
| Urine Magnesium | Urine | 1 day | |
| Urine metadrenaline (normetanephrine, metanephrine, 3-methoxytyramine) | Urine | 5 days | Acidified specimen preferred |

* Turnaround times are in working days

Biochemistry Tests

| TEST NAME | SAMPLE REQUIREMENT | TAT* | SPECIAL INSTRUCTIONS |
|---|--------------------|--------|--|
| Urine Methadone Screen | Urine | 1 day | |
| Urine Opiate Screen | Urine | 1 day | |
| Urine Oxalate | Urine | 5 days | Acidified specimen required |
| Urine Phosphate | Urine | 1 day | |
| Urine porphobilinogen screen (PBG) | Urine | 1 day | Protect sample from light, wrap in foil or place in dark container |
| Urine Potassium | Urine | 1 day | |
| Urine Protein | Urine | 1 day | |
| Urine Protein Electrophoresis | Urine | 5 days | |
| Urine Protein:creatinine Ratio (Calculated) | Urine | 1 day | |
| Urine Reducing Substances Screen | Urine | 1 day | |
| Urine Sodium | Urine | 1 day | |
| Urine Steroid Profile | Urine | 10 day | Please contact the lab for urgent samples, which can be prioritised with a shorter turnaround time |
| Urine Total Porphyrins | Urine | 1 day | Protect sample from light, wrap in foil or place in dark container |
| Urine Urate | Urine | 1 day | |
| Urine Urea | Urine | 1 day | |
| Urine Zinc | Urine | 5 days | |
| Valproate | Serum | 1 day | |
| Vancomycin | Serum | 1 day | |
| Vitamin B12 | Serum | 1 day | |
| 25-Hydroxyvitamin D | Serum | 1 day | |
| Zinc | Serum | 5 days | Collect sample in trace metal tube |

* Turnaround times are in working days

HSL Cellular Pathology

HSL's Cellular Pathology Department consists of Histopathology, Diagnostic Cytology and HSL-Advanced Diagnostics. Operating on a hub and spoke model, our laboratories provide diagnostic services for multiple hospitals and clinics across North Central London, aiming to provide clinicians with fast, safe and high quality laboratory testing.

Core Laboratories and opening hours

Histopathology Laboratory (60 Whitfield Street):
Monday–Friday, 07:30–19:00.

Diagnostic Cytology Laboratory (60 Whitfield Street):
Monday–Friday, 09:00–17:30.

HSL-Advanced Diagnostics (60 Whitfield Street):
Monday–Friday, 07:30–19:00.

Histopathology Laboratory (Royal Free Hospital):
Monday–Friday, 07:30–19:30.

Urgent requests

Please contact the relevant pathologist to discuss urgent processing prior to sending the sample.

Out-of-hours service

There is no routine consultant diagnostic service for weekends and bank holidays; for urgent results special arrangements must be made in advance.

Currently, only the RFH histopathology section of Cellular Pathology offers an out-of-hours service for RFH Patients. The on-call service is a consultant led out-of-hours telephone advisory service and is available every evening and at weekends; this includes a technical service for very urgent samples.

Where a sample requires out-of-hours processing the on-call consultant should be contacted first, via the switchboard.

There is no on-call or out of hours service for consultant histopathologists or cytopathologists for UCLH patients.

Clinical advice

During working hours (Monday–Friday, 09:00–17:30), please contact the relevant Consultant Pathologist.

Please note that Cervical Screening London is an independent department.

Diagnostic Histopathology and Diagnostic Cytology

Sites covered:

- University College London Hospitals (UCLH) – Hub Site
- Whittington Health (WH) – Spoke Site
- Royal Free Hospital (RFH) – Spoke Site with clinical histopathology services
- Barnet & Chase Farm Hospitals (B&CF) – Spoke Site
- North Middlesex University Hospital (NMUH) – Spoke Site

Histopathology

The services provided include:

- Routine histological diagnosis, using a wide variety of techniques including special stains, immunocytochemistry and molecular techniques.
- Rapid-response laboratory histological service, based at the Royal Free Hospital site.
- Mohs clinic technical support at Chase Farm and Royal Free Hospitals.
- Frozen section service on request, pre-booking is essential except for unforeseen intraoperative circumstances.

Specialities of the Cellular Pathology department include:

- Haematopathology
- Thoracic pathology
- Breast pathology
- Head and neck pathology
- Gynaecological pathology
- Gastro-intestinal pathology
- Skin pathology
- Urological pathology
- Endocrinology
- Hepatobiliary pathology
- Liver pathology
- Renal pathology

The department also provides a laboratory support-based service to the Mohs clinics at the Royal Free and Chase Farm Hospital's Dermatology departments.

Diagnostic Cytology

Diagnostic cytology is a specialist discipline that provides the examination of samples taken by non-invasive or minimally invasive procedures. This is done by examining cells from fluids, brushings or fine needle aspirates (FNAs) to give a diagnosis of disease.

Opening hours

9:00am to 5:30pm, Monday to Friday (except bank holidays and excluding weekends).

All samples should reach the laboratory as soon as possible and preferably early in the working day to avoid deterioration of cells. Samples should be received in the department by 4:00pm.

If a delay in transportation is anticipated, or samples have been taken out of hours, then they should be kept refrigerated at 4°C until they can be sent. There is no out of hours Diagnostic Cytology service.

All specimen processing is performed at the 60 Whitfield Street hub laboratory. Cases received and booked in at Royal Free, NNUH and B&CF are transported to 60WS for processing and testing before being returned to Royal Free Hospital for reporting.

Department Laboratory Accreditation

HSL Cellular Pathology is a UKAS Accredited Medical Laboratory No. 9007 (UKAS schedule of accreditation).

The department is IBMS-approved for HCPC registration portfolios, specialist portfolios, advanced practice portfolios, and the RCPATH diagnostic histopathology reporting post graduate diploma and actively promotes the training and continual development of its staff to ensure we retain the highest levels of professional and academic excellence.

Combining UCLH and RFH Consultant histopathologist groups, they are tertiary referral centres for hospitals throughout the UK, Republic of Ireland and over 200 overseas hospitals. UCLH and RFH are part of the North London Cancer Network, which co-ordinates cancer services in specialist pathology for the North Thames Central Sector of London.

Staff have the opportunity to experience and specialise in all the areas of the laboratory.

Staff /Key personnel

GENERAL ENQUIRIES

| | | |
|---|----------------------------------|---------------|
| HSL Cellular Pathology Office - UCLH and Whittington Please check EPIC/ICE for results before contacting | uclh.cellpath@nhs.net | 020 3456 8402 |
| HSL Cellular Pathology Office - RFH, B&CF and NNUH Please check Cerner for results before contacting | rfh-tr.rfh-cellpathadmin@nhs.net | 020 7830 2227 |

HSL SPECIALITY LEADS

| | | | |
|--|---|------------------------------|-----------------------------|
| HSL Speciality Lead for Histopathology | Professor Manuel Rodriguez-Justo | manuel.rodriguez@nhs.net | 020 3456 8424 |
| HSL Speciality Lead for Cytopathology | Dr Miguel Perez-Machado | miguel.perez-machado@nhs.net | 020 7794 0500 Ext: 33615 |

TRUST CLINICAL STAFF

| | | | |
|---|-----------------------|--|-----------------------------|
| UCLH Clinical Director of Pathology | Dr Mary Falzon | mfalzon@nhs.net | 020 3456 8416 |
| UCLH Cellular Pathology Consultant Pathologists | | uclh.enquiry.pathology.queries@nhs.net | 020 3456 8402 |
| RFL Clinical Director of Pathology | Dr Dhili Arul | dhili.arul@nhs.net | 020 7794 0500 Ext: 37218 |
| RFL Cellular Pathology Consultant Pathologists | | rf-tr.pathologyadminsUPPORT@nhs.net | 020 7794 0500 Ext: 35309 |

HSL Cellular Pathology

HSL LABORATORY AND ADMINISTRATIVE STAFF

| | | | |
|--|--------------------------------|--------------------------------------|---|
| HSL Cellular Pathology Operations Manager | Mr Neal Byron | neal.byron@hslpathology.com | 07507 151277 |
| Cellular Pathology Manager - 60WS | Mr David Allen | david.allen@hslpathology.com | 020 3912 0285 |
| Cellular Pathology Manager - RFH | Mrs Reshmi Patel | reshmi.patel@hslpathology.com | 020 3307 5432 |
| Cellular Pathology Office Manager - 60WS & RFH | Ms Camelia Bouzid | camelia.bouzid@hslpathology.com | 020 3456 8402 (60WS) 020 3307 5430 (RFH) |
| Histology Services Manager/ Lead Biomedical Scientist | Mrs Barinder Kaur-Desai | barinder.kaur-desai@hslpathology.com | 020 3912 0361 |
| Diagnostic Cytology Services Manager/Lead Biomedical Scientist | Mrs Cherlehan Etman | cherlehan.etman@hslpathology.com | 020 3912 0354 |
| Frozen Section Bookings - UCLH Patients | | | 020 3912 0349 (Internal Ext 4844) |
| Frozen Section and Renal Bookings - RFH Patients | | | 020 3307 5434 |

All Diagnostic Cytology laboratory tests are carried out at 60 Whitfield Street. Please contact the following for any guidance.

Diagnostic Cytopathology
Department of Cellular Pathology 2nd Floor (South)
60 Whitfield Street
London W1T 4EU

Email: Diagnostic.Cytology@hslpathology.com

Cellular Pathology samples

Types of samples

Histology samples

| TYPE OF SAMPLE | SAMPLE REQUIREMENT |
|---|--|
| Histopathology - Routine Diagnosis | Tissue in 10% Neutral Buffered Formalin, at least 10x the volume of the specimens. |
| Histopathology - Frozen sections (on request) | Fresh tissue (i.e. no fixative) - delivered immediately to the laboratory. |

Diagnostic cytology samples

| SAMPLE TYPE | SAMPLE VOLUME | LAB REQUIREMENT |
|---|---|--|
| Anal brushings | Brush in Hologic ThinPrep vial. | Brush tip must not be placed in vial. Ensure ThinPrep vial is in date and stored between 15-30°C. |
| Broncho-Alveolar Lavage (BAL) | Place in a plain sterile container. | Cells deteriorate rapidly so the specimen should be brought to the lab immediately. Where a Cell Differential Count is required sample must be submitted within a couple of hours of sample being taken. |
| Cerebrospinal Fluids (CSF) | 2ml sample ideal (less OK). | Cells deteriorate rapidly so the specimen should be brought to the lab immediately. Inform lab staff that a CSF sample is being sent. Samples should be received in the lab before 4.00pm (Monday to Friday except bank holidays) to ensure they are processed that day. Ensure a separate sample has been submitted to clinical chemistry and Microbiology as well, if appropriate CSF suspected of containing Creutzfeldt-Jakob disease (CJD) must not be sent to the lab. |
| Cyst Fluid | 25ml (max) of fluid. Place in a plain sterile container. | |
| Endoscopic Brushings (eg. Bronchial) | Placed in 15ml CytoLyt solution. | Please call lab for universal containers containing CytoLyt solution. |
| Endoscopic Washings (eg. Bronchial) | Place in a plain sterile container. | Cells deteriorate rapidly so the specimen should be brought to the lab immediately. |
| FNA Slides & Needle Rinses | Fixed slides must be fixed in 95% IMS or spray fixed. Needle rinses must be placed in a plain sterile container, and can also be sent in Roswell Park Memorial Institute Medium (RPMI) or CytoLyt solution. Ask laboratory if unsure. | Ensure method of fixation is clearly stated on submitted slides. Number of slides submitted must be written on request form. Slides must be allowed to fully dry before placing them into a slide mailer. |
| Genital/Perigenital Lesions (For Diagnosis of Donovanosis) | Samples must be submitted as unfixed air-dried slides. Ensuring the sample is smeared evenly onto the slide. | Number of slides submitted must be written on request form. Slides must be transported in a labelled slide mailer. |
| Nipple Discharge | A direct smear is made by placing a small drop of sample onto a labelled glass slide. A second slide is used to create a smear preparation. Slides can be submitted as air dried or fixed. Fixed slides must be fixed in 95% IMS or spray fixed. | Ensure method of fixation is clearly written on submitted slides. Number of slides submitted must be written on request form. Slides must be allowed to fully dry before placing them into a slide mailer. |

Cellular Pathology samples

| SAMPLE TYPE | SAMPLE VOLUME | LAB REQUIREMENT |
|---|---|--|
| Serous Fluid (e.g. Pleural, Ascitic, Abdominal, Peritoneal, Pericardial) | 60ml (min) of fluid recommended. Place in a plain sterile container. | If patients have been supine for any length of time, please get the patient to sit up and move a little, so that any cells that have settled are resuspended. |
| Sputum | Place in a plain sterile container. | Should only be taken where patients are unfit for Bronchoscopy. For best results obtain sputum following chest physiotherapy, with an early morning sample before the patient has eaten or brushed their teeth. Multiple samples (x3) may be needed, but they should be taken on 3 separate days. The whole of the expectorated sample should be submitted. |
| Synovial Fluid | 5ml (min) of fluid. Place in a plain sterile container. | |
| Urine | 20ml (min) of fluid in a plain sterile container. Second void of the day to be collected. RED TOPPED Borate Universals are NOT Suitable for Cytology. The lab will not accept these samples. | Send to lab ASAP, if delay anticipated refrigerate and store at 4°C or in a preservative, such as Hologic PreservCyt solution. This may be added to the sample in a 2:1 ratio (2 parts urine to 1 part fixative) and this must be recorded on the request form. |

Preparation of Specimens

Histopathology

All specimens must be sent in fixative, except in special circumstances where other arrangements have been made (e.g. for frozen section requests). The recommended fixative is 10% Neutral Buffered Formalin (NBF), which is a hazardous reagent and instructions for dealing with it should be followed carefully.

Please use a container large enough to accommodate the specimen without forcing it in, and sufficient volume of fixative (at least 10x the volume of the specimen).

Please note, all histology tests have been verified using 10% NBF. Due to the nature of histological samples (most samples cannot be repeated) the department will not currently reject samples received in 10% formal saline. These samples will be transferred to 10% NBF at the earliest opportunity. For samples requiring direct immunofluorescence, please contact St John's Institute of Dermatology (020 7188 6364).

Frozen Sections - UCLH cases

Requests for a frozen section must be made on 020 3912 0349 (Internal Ext 4844). If you know in advance that you will require a frozen section, please book as promptly as possible, giving the date, time, patient's name, specimen type, infection status, consultant's name, your bleep number and the theatre number for telephoning the result.

For health and safety reasons, it is departmental policy not to carry out a frozen section on known positive patients for TB, HIV, Hep C and mPOX cases if the patient is still compromised or not under treatment. If you are in any doubt about this, please speak to the Consultant Histopathologist on duty, who can be contacted via 020 3456 8402. In such cases it is usually possible to arrange an urgent paraffin section which can be reported later the same day.

Specimens must be taken immediately to the Ground Floor Specimen Reception Area, 60 Whitfield Street, London W1T 4EU; in a suitable rigid container which prevents patient identifiable data from being seen by members of the public and is compliant with UN3373 regulations. These can be found on the wards and theatres. A courier service is used at Westmoreland Street.

Full instructions are posted in each theatre; if this is not the case please inform the Histology Services Manager / Lead Biomedical Scientist (020 3912 0361).

Frozen Sections - RFH cases

Requests for a frozen section must be made on Ext 35180. If you know in advance that you will require a frozen section, please book as promptly as possible, giving the date, time, patient's name, specimen type, infection status, consultant's name, your bleep number and the theatre number for telephoning the result.

For health and safety reasons, it is departmental policy not to carry out a frozen section on known positive patients for TB, HIV, Hep C or mPOX cases if the patient is still compromised or not under treatment. If you are in any doubt about this, please speak to the Consultant Histopathologist on duty. In such cases it is usually possible to arrange an urgent formalin fixed paraffin embedded section which can be reported later the same day.

Specimens must be taken immediately to the Histology Laboratory, Specimen Reception, 2nd Floor, adjacent to room 2/429, in a suitable rigid container which prevents patient identifiable data from being seen by members of the public and is compliant with UN3373 regulations.

Diagnostic Cytology

All samples should reach the laboratory as soon as possible and preferably early in the working day to avoid deterioration of cells. Samples should be received in the department by 4.00pm.

If a delay in transportation is anticipated or samples have been taken out of hours then they should be kept refrigerated at 4°C.

There is no out of hours Cytology service.

Full instructions are posted in each theatre; if this is not the case please inform the Diagnostic Cytology Services Manager on 020 3912 0354.

Cellular Pathology

Fine Needle Aspiration Cytology -UCLH

There are a number of FNA clinics held weekly within the Trust for a variety of specialties including breast, thyroid, head and neck and lymph nodes. Samples must be delivered directly to the department for same day reporting.

Cytology samples that do not reach the laboratory within working hours or have missed the last collection must be stored in the refrigerator at 4–8°C.

Specimen labelling

A minimum acceptance criteria for all Cellular Pathology samples of three patient identifiers must be provided for all samples.

Sample site must be provided in both request form and sample pot, if multiple pots are sent all must be clearly labelled (e.g. A, B, C).

All Cytology request forms, sample containers, glass slides and slide boxes must be labelled and completed as per the following:

Acceptance criteria

Cytology Request forms, sample containers/slides/ slide mailer boxes must have a minimum of 3 key Patient identifiers, and these Patient identifiers must include:

- Full name (first name & surname)
- A unique patient identification number, Hospital number or NHS number
- Date of birth

Rejection criteria

Samples will be rejected if:

- The request form has less than 3 of the key patient identifiers
- The sample container/slide/slide mailer box has less than 2 key patient identifiers
- The patient data on the form and sample container do not match.

Cytology request forms and samples containers/slides/ slide boxes that do not meet these standards will need verifying by a senior clinician. In such cases the requesting clinician will be asked to visit the Diagnostic Cytology department to verify the request form and specimen or complete a Specimen Deficiency Form accepting responsibility for any clinical decisions that are made based on the results of the sample submitted.

Please ensure the correct sample containers are used.

Transport to the laboratory

Instructions for the transportation of Histopathology samples

Small biopsy pots (universals, 60ml) should be placed into a small, clear plastic bag with absorbent sheet, usually attached with the request form and sealed.

If the form does not have a bag attached, please use the clear bags provided at the clinic. The request form should never be placed inside the bag with the specimens in case of leakage. The form must be attached to the sample using tape, please do not use pins or staples as this is hazardous.

Cellular Pathology samples

Larger specimens should be placed into the snap-top white plastic bucket supplied by theatres, clinics or our department. The bucket should then be placed inside a plastic bag and request form attached using tape. Never use yellow clinical waste bags as these can be mistaken for waste.

Instructions for the transportation of Diagnostic Cytology samples

Sample pot lids and slide boxes must be secured properly and checked to ensure no leakage or that slides cannot fall out.

The sample container(s)/slide boxes must be placed in a clear plastic transport bag, and sealed properly, with the accompanying request placed in the side pocket. Forms should not be stapled to the bag or placed with the samples.

Collection and deliveries

The Trust portering service is instructed not to collect pots which are damaged or leaking. The Trust portering service will place all samples into a rigid container which prevents any patient identifiable data from being seen by members of the public and is compliant with UN3373 regulations.

There are collection points for specimens in theatres, wards and clinics. It is important that specimens are left in these designated areas. Please place specimens at collection points as soon as possible, to avoid batching and delay in reaching the laboratory.

If a specimen is received at the laboratory but is not clearly identifiable, (e.g. the pot is not labelled, or its label does not correspond to the accompanying request form), it will not be processed. Laboratory staff will contact the requesting clinician to identify the specimen and correct the detail.

Diagnostic Cytology samples that do not reach the laboratory within working hours or have missed the last collection must be stored in the refrigerator at 4-8°C.

Cellular Pathology samples must not be put in the Pneumatic Tube System (PTS) under any circumstances. For further information please refer to Trust Guidance.

If a specimen is received at the laboratory but is not clearly identifiable, (e.g. the pot is not labelled, or its label does not correspond to the accompanying request form), it will not be processed. Laboratory staff will contact the requesting clinician to identify the specimen and correct the detail.

Cytology samples that do not reach the laboratory within working hours or have missed the last collection must be stored in the refrigerator at 4-8°C.

At the Eastman Dental Hospital, specimens should be taken to the reception desk where they will be collected by courier.

Factors that affect performance and interpretation

Histology

Ensure all samples are placed immediately into 10% Neutral Buffered Formalin (NBF). A delay may lead to a loss of morphology through autolysis and putrefaction, affecting interpretation, reporting and further testing.

All samples must be placed in containers that have at least 10 times the volume of 10% NBF, when compared with the size of tissue. Placing tissue into a container that is not large enough will lead to the tissue distortion and poor fixation.

Please note, all histology tests have been verified using 10% NBF. Due to the nature of histological samples (most samples cannot be repeated) the department will not currently reject samples received in 10% formal saline. These samples will be transferred to 10% NBF at the earliest opportunity.

Diagnostic Cytology

Diagnostic Cytology samples not being delivered and received by the lab ASAP

- Diagnostic Cytology specimens (unless they have been placed in preservative as outlined above) do not contain any preservatives/fixatives that prevent the cells from deteriorating or prevents microbes from growing. The longer a specimen takes to reach the lab there is an increased chance that the cells will deteriorate and that the sample may become unsuitable for diagnosis.
- The cells in some samples (e.g. Respiratory and CSF samples) deteriorate rapidly, so a delay may mean that a diagnosis may not be possible.

Delayed samples not being refrigerated (4°C)

- These specimens (unless they have been placed in preservative) do not contain any preservatives/fixatives that prevent the cells from deteriorating or prevents microbes from growing. Placing them in a fridge will help to slow down cell deterioration and microbial growth,

especially important with urine samples.

Patient not being prepared properly and therefore not obtaining the best sample possible

- If serous fluid is being sampled and the patient has been supine for a long time it is important to get them to sit up and move a little to re-suspend the cells that have settled.
- Sputum samples should be taken first thing in the morning before patient has eaten or brushed their teeth.
- Sputum samples need a very deep cough and it is recommended that this is obtained by a physiotherapist. If this is not done the sample may just be saliva.
- Early morning urine should be avoided because the cells will appear degenerate and interpretation will be difficult.

FNA technique inadequate

- Sample does not contain the cells needed to make a diagnosis and may be heavily blood stained.

FNA smears inadequate

- If sample is too thick the viewing of cells down the microscope is difficult, only a small drop of sample needed.
- If sample is all over the slide, cells at the sides of the slide may be lost or uninterpretable.
- Cells squashed/smashed when slide pressure applied was too great.

FNA smear incorrectly fixed

- Slow drying causes air drying artefact where the cells appear bigger and lack definition.
- If the slide is incorrectly labelled wet or dry, the wrong stain may be applied in the lab making interpretation difficult.

FNA smear on back of slide

- If the smear is placed on the back of the slide and not the front, cells or even the whole sample might be removed when being handled by lab staff.

Request procedures

See page 14 for general information on request procedures.

Handwritten request forms are no longer in use. All Histopathology and Diagnostic Cytology requests should only be made on the electronic health record system (EHRS). It is essential that you ensure a printed request form with an electronic request number is sent with the specimen to Cellular Pathology.

The following details must be provided as a minimum acceptance criteria:

- Patient first and surname (clearly printed labels must be present on all copies)
- Date of birth

- Patient gender
- Hospital number/ NHS number
- Site of specimen
- Clinical details
- Date and time of sample collection (this information is paramount to ensure timely processing of your request)

The destination of the report, the name of the requesting clinician and a contact number for the responsible clinician must be provided.

This enables the laboratory to contact the clinician regarding unsuitable samples and for communication urgent results.

Please provide information on what you are looking for from the sample.

Request procedures

HILIS forms (HMDS Integrated Laboratory Information System) can be downloaded directly from HILIS and must be completed in full. All forms should be marked 'HIGH RISK' if known.

Urgent Samples

Any case that is required urgently (in working hours) must be discussed with the duty consultant prior to its receipt.

To ensure the case is dealt with at the earliest opportunity, the sample should be brought to the department by a member of the ward staff or specially-arranged porter. In this situation, the sample should be transported in a suitable receptacle, which prevents members of the public seeing patient identifiable details and within UN3373 regulations. Such containers should be available on each ward.

High-Risk Samples

Please note that it is the responsibility of the referring clinician to ensure that high-risk samples are clearly identified to reduce the risk of infection to staff and others.

Turnaround Times

Histology

The time taken to process and report a specimen depends on its size, and the complexity of the case. An urgent, same-day diagnosis can be arranged by telephoning the specialty lead consultant histopathologist.

Depending on the complexity of the case and additional specialist techniques required for diagnosis, the average turnaround time to diagnostic report after receipt in the laboratory is:

- Aim to report 80% in 7 days
- Aim to report 98% in 10 days

A typed report will not be available before this time, but an interim report may be issued by the Consultant Histopathologist. Consultants are always available to discuss cases upon request.

Diagnostic Cytology

We aim to report on Diagnostic Cytology specimens within 48 hours of receipt into the laboratory.

Urgent samples

In some circumstances a report may be required urgently. In these cases the request form must be marked 'URGENT' and with a contact name and telephone/bleep number. In exceptional circumstances, for some cases, it is possible to obtain results on the same day as sampling. Such requests must be discussed beforehand with one of the Consultant Histopathologists.

Results

Summary reports of histology and diagnostic cytology requests are available electronically via EPIC (UCLH), ICE (WH) or Cerner (RFH, B&CF and NMUH). Results are available as soon as the report has been authorised electronically by the reporting pathologist, and therefore provides prompt information. It is essential to check results on your institutions patient management system before contacting the medical administration team.

Molecular results are directly uploaded and available on your institutions patient management system. Regular users of the molecular service may be able to get direct access to results via the Marsden Order and View system.

Clinicians are welcome at all times to visit the laboratories to discuss their cases and view slides.

Manual Haematology (Immunophenotyping and Immune Monitoring)

HSL's Immunophenotyping and Immune Monitoring laboratory is equipped with a suite of state-of-the art 10-colour 3-laser flow cytometers. We use a sophisticated automated lysing process that allows 40 markers of differentiation to be interrogated, diagnosing malignancies with a rapid turnaround time.

The Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) coordinates, manages and guides laboratory scientists and clinicians towards a fully comprehensive, streamlined and rapid diagnostic and monitoring service to the patient. Our repertoire includes HIV Immune (CD4:CD8) and CD19 monitoring.

The SIHMDS diagnostic algorithm, drafted and updated by haematology oncology consultants, includes the disciplines of immunophenotyping, cytogenetics, histology and molecular testing of acute leukaemia (myeloid, T-cell, B-cell), chronic leukaemia (T-CLL, B-CLL, B-PLL) and lymphoma (MCL, FL, HCL and other) on bodily fluids.

At the dedicated SIHMDS reception, staff carry out pre-analytical work such as data entry, processing slides, lymphocyte subsets and calibrating analysers.

Morphological screenings, where level of work-up is discussed, are attended by scientists and medical staff. Samples are then dispatched to the correct disciplines, and data are entered onto an integrated reporting system.

Customised panels are used, pre-prepared by the manufacturer with full QC and titre information. Panel contents are selected by scientists and clinical consultants from WHO's 'Classification: Tumours of Haematopoietic and Lymphoid Tissues'. All laboratory staff process malignancy samples, and fully trained BMSs interpret and report onto LIS; authorisation includes consultants and laboratory staff. An integrated report for all disciplines with a joint conclusion is made and reported by consultant staff.

We hold the IBMS pre- and post- registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. HSL Manual Haematology (Immunophenotyping and Immune Monitoring) is a UKAS Accredited Medical Laboratory No. 8169.

Staff/Key personnel

CLINICAL STAFF

| | | |
|----------------------------------|---|-------------------------------|
| Dr Rajeev Gupta | Clinical Specialty Lead for Haematology | rajeev.gupta@ucl.ac.uk |
| Dr Andrew Wilson | | andrew.wilson19@nhs.net |
| Dr Jenny O'Nions | | jenny.o'nions@nhs.net |
| Dr Kate Xu | | ke.xu@nhs.net |
| Dr Suranjith Senevirathne | HSL Clinical Lead for Immunology | suranjith.seneviratne@nhs.net |

LABORATORY STAFF

| | | | |
|-----------------------|--------------------------------|---------------------------------|---------------|
| Karen Orfinada | Haematology Laboratory Manager | Karen.Orfinada@hslpathology.com | 020 3908 1344 |
|-----------------------|--------------------------------|---------------------------------|---------------|

Manual Haematology (Immunophenotyping and Immune Monitoring)

General enquiries

- 020 3908 1339
- 020 3908 1340
- Flow.cytometry@hslpathology.com

Out of hours service

Acute Leukaemia Screen + MRD

An out-of-hours service in place covering Saturday and Sunday and all Bank Holidays, 9.00am–3.00pm. This is for undiagnosed new acute leukaemias which have to be treated BEFORE next working day. All call-out have to be authorised by one of the consultants named above.

Bone Marrow Aspirate (BMA)

There is no out of hours service for BM aspirate reporting unless it is part of an undiagnosed new acute leukaemia screen where a consultant has authorised on-call work to be carried out.

Manual Haematology (Immunophenotyping and Immune Monitoring) specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

- All citrate samples sent by post or with an overnight delay must be double spun and sent frozen.
- Samples must be labelled correctly with three points of ID.
- Samples must be left in correct courier pick-up point.

Please send samples to:

Health Services Laboratories
Manual Haematology
(Immunophenotyping and Immune Monitoring)
Halo Level 2
The Halo Building
1 Mabledon Place
London WC1H 9AX

Request procedures

See page 14 for general information on request procedures.

Manual Haematology (Immunophenotyping and Immune Monitoring) tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|---|---|
| Bone Marrow Aspirate (BMA) | 8 Bone Marrow slide smears (all slides to be labelled with hospital number, surname and date sample was taken). | 2 days 8 hours for undiagnosed new acute leukaemia | All new acute leukaemia for flow cytometry must have BMA requested and slide sent. Date of sample MUST be on slides BM smears must be dried thoroughly before being placed in plastic holder (red cells lyse). Slides must be correctly spread. Minimum 2 slides. Samples must be < 24 old on delivery to lab. Heavily clotted samples will affect results. Haemodilute samples will affect results. |
| Cerebral Spinal Fluid Morphology (CSF), Pleural Fluid morphology and Ascites Fluid morphology | CSF in sterilin pot. No minimum volume. | 2 days | Samples must be <48 hours old. Samples must be taken in correct pot. Heavily blood-contaminated samples will affect results. |
| Acute Leukaemia Screen + MRD | BM liquid in EDTA CSF, Pleural Fluid or Ascites Fluid in sterilin pots No minimum volume In cases where BM is not possible PB can be used but only if there is morphological evidence of disease. | 2 days 8 hours for undiagnosed new acute leukaemia | All flow cytometry requests for new acute leukaemia must have BMA. Samples must be <24 hours old. EDTA sent without BM smears is a problem. No EDTA sent will result in incomplete processing. |
| Chronic Leukaemia Screen + MRD | PB in EDTA No minimum volume Where possible, recent FBC result must also be sent. | 2 days | Samples must be < 24 hours old. EDTA sent without BM smears is a problem. No EDTA sent will result in incomplete processing. |
| Myeloperoxidase Stain | BM smears x 2 or PB in EDTA | 2 days | This is not a UKAS accredited test. Samples must be < 24 hours old. Sample must be in EDTA. If BM is sent, there must be slides sent. No EDTA sent will result in incomplete results. |
| Esterase Stain | BM smears x 2 or PB in EDTA | 2 days | This is not a UKAS accredited test. Samples must be < 24 hours old. If BM is sent, there must be slides sent. No EDTA sent will result in incomplete results. |
| Iron Stain (BMA) | BM smears x 2 | 2 days | Must receive minimum 2 BM smears. |
| Haemosiderin | Urine in Sterilin pot | 2 days | |
| Myeloma Flow[#] | BM in EDTA | 7 days | Sample must be < 12 hours old. Samples must not be sent on Fridays. |
| PNH[#] | PB in EDTA | 3 days | Sample must be <12 hours old. Samples must not be sent on Fridays. |
| CD20/CD21 | PB in EDTA | 2 days | This test has been set up specifically for one client and is not routinely offered. We can set up a contract for other clients if required. Clotted samples will not be processed. Sample must be >48 hours old. |

Manual Haematology (Immunophenotyping and Immune Monitoring) tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--------------------|--------|---|
| CD57 | PB in EDTA | 2 days | This test has been set up specifically for one client and is not routinely offered. We can set up a contract for other clients if required. Clotted samples will not be processed. Sample must be > 48 hours old. |
| NBT* | PB in EDTA | 2 days | Sample must be <12 hours old. Sample should not be sent on Friday. |
| Common Variable Immunodeficiency (CVID) (B-Cells) | PB in EDTA | 2 days | Samples must be <24 hours old. Clotted samples will not be processed. |
| T-Cell Immunodeficiency (TCID) (T-Cells) | PB in EDTA | 2 days | Samples must be <24 hours old. Clotted samples will not be processed. |
| T Cell Proliferation* | Lithium Heparin | 2 days | Sample must not be requested on Friday. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

HSL Genetics

HSL's Genetics division has expertise in the testing, diagnosis and counselling of inherited disorders and of genetic variation that can influence susceptibility to disease or therapeutic response to drugs.

Using molecular genetic and cytogenetic methods, we analyse patients' DNA for variants and study whole chromosomes to assess for a range of inherited disorders, genetic associations and disease risk. Our oncogenomics tests use various cytogenetic analysis methods to look for acquired chromosome rearrangements.

Our pharmacogenetics tests identify variations in genes involved in drug metabolism, and can help improve drug safety and efficacy. They can provide vital data when selecting volunteers for trials.

Genetic tests are available for:

- Prenatal diagnosis and rapid trisomy screening
- Carrier screening
- Newborn chromosome analysis
- Confirmation of symptomatic individuals and pre-symptomatic testing
- Genetic variation that influences risk of disease
- Identity studies (paternity, zygosity, tissue typing)
- Fertility studies
- Studies of products of conception

Genetic tests vary in their ability to detect variants or to detect all patients who have, or will develop, a particular disease. Some tests are diagnostic for a condition, others are indicative or are associated with an altered risk for a condition. Where testing will predict the inheritance of a disease in a healthy person, counselling and consent are mandatory. For these tests, please complete the Genetic Request form (including informed consent). Our service provides result interpretation and risk assessment to patients and their family members. Genetic counselling can be arranged by TDL's Consultant Clinical Geneticist.

To meet the increasing range and complexity of genetic testing we have developed an excellent collaboration with other specialist laboratories (see page 11). Tests marked with a hash (#) in the test table are sent to these laboratories within our network (these tests are not on TDL/HSL scopes of accreditation).

HSL Genetics is a UKAS Accredited Medical Laboratory No. 8059.

Staff/Key personnel

| GENETICS | | | |
|---|---------------------------------|---------------------------------------|---------------|
| Consultant Clinical Geneticist | Professor Michael Patton | michael.patton@tdlpathology.com | 020 7307 7409 |
| Director of Genetic Services | Dr Lisa Levett | lisa.levett@tdlpathology.com | 020 7307 7409 |
| Genetics & Molecular Pathology Operations Manager | Oliver George | oliver.george@tdlpathology.com | 020 3908 1282 |
| Consultant Clinical Scientist/ NHS FASP Screening Lead for NIPT | Elaine Holgado | elaine.holgado@tdlpathology.com | 020 7307 7409 |
| Head of Genetics & Molecular Pathology | Dr Stuart Liddle | stuart.liddle@tdlpathology.com | 020 7307 7409 |
| Head of Cytogenetics | Rebecca Watts | rebecca.watts@hslpathology.com | 020 7460 4787 |
| Cytogenetics Operations Manager | Emma Wilcock | emma.wilcock@tdlpathology.com | 020 7307 7409 |
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| Molecular Cytogenetics Manager | Alessandra Callegari | Alessandra.callegari@tdlpathology.com | 020 7307 7409 |
| Senior Cytogeneticist | Kath Masters | kath.masters@tdlpathology.com | 020 7307 7409 |
| MOLECULAR HAEMATOLOGY | | | |
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| Head of Oncogenomics | Dr Elisabeth Nacheva | elisabeth.nacheva@hslpathology.com | 020 3908 0130 |
| Consultant Haematologist | Dr Derralynn Hughes | derralynnhughes@nhs.net | |
| Molecular Haematology Operations Manager | Robert Baker | Robert.Baker@hslpathology.com | 020 3908 1292 |

Specimen Receipt at the Halo is 24 hours a day, 7 days a week.

HSL Genetics results service is available Monday to Friday 08:30 – 17:30.

The Cytogenetics Laboratory is also open for processing of samples on Saturdays from 09.00 – 13.00.

The OncoGenomics (Molecular Cytogenetics) Laboratory is open Monday to Saturday 09:00 – 18:00.

If you do not find the test you require in this directory or need more information and advice please telephone the head of department on the contact number shown.

Genetic specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

All samples must be collected in the specified containers, as shown in the table.

Samples should be fresh and in good condition (e.g. not clotted or haemolysed if EDTA or heparinised whole blood is required); otherwise testing may be adversely affected and another sample may be required.

Specimens must not be allowed to come in contact with request forms, but should be kept separate by using dual - pocketed plastic bags. Specimens for inland postage must be packed in a rigid crush-proof container according to current Post Office guidelines. IATA guidelines should be followed for international transport (Advice is available from the laboratory).

Always provide Clinical Details and Family History with requests for Genetic Tests.

All specimens should be kept at room temperature and dispatched to the laboratory as soon as possible, by TDL/international courier, first class post, guaranteed next day delivery or a reliable alternative.

If a delay in sending the sample is unavoidable, please refrigerate overnight - do not freeze. NIPT samples should be kept at room temperature only and never stored in the fridge or freezer.

High-risk samples

Please note that it is the responsibility of the referring clinician to ensure that high-risk samples are clearly identified to reduce the risk of infection to staff and others.

Unlabelled samples

Unlabelled samples will only be processed if the individual who took the sample can confirm the sample is from the patient in question. In the absence of this assurance, the sample will be discarded and a repeat required.

DNA storage

Small DNA samples are stored routinely for one year; DNA samples can be stored for longer by special arrangement. Haemoglobinopathy DNA samples are stored for at least 30 years as they may be needed for family studies.

Request procedures

See page 14 for general information on request procedures.

To order a test, please complete a Genetics Request form and, when appropriate, a Consent Form. Both forms are available at the end of this guide and on the TDL website.

NIPT requests need to be accompanied by their own Harmony request form supplied with the sample-taking pack.

Haemoglobinopathy genetics: For UCLH requests, it is mandatory to include informed consent for DNA testing and storage, otherwise a request cannot be made. Referrers outside UCLH use the Haemoglobinopathy request forms: Prenatal Diagnosis request form or Haemoglobinopathy Genotype request form.

Haemophilia and thrombophilia genetics: Requests for Haemophilia and Thrombosis Molecular Genetics must be accompanied by a request form. For users on the Royal Free network, the form is available on Freenet (<http://freenet/freenetcms/Default.aspx?&s=38&p=860&m=1778>). For other users, please contact the the laboratory for a form. Genetic testing for inherited bleeding disorders requires patient consent. Please use the following consent form and information – <http://www.ukhcd.org/docs/Genetic%20testing%20consent%20form.doc>

HLA B*57:01 and HLA B*27: For RFH requests, please order on EPR. The SRA then fill out a Genetics Request form to send with the sample to the Halo.

In order to avoid unnecessary time spent in obtaining details please provide the following information:

Information for request forms:

- Surname, forename (not initials) and date of birth.
- Full name (not initials) and location of referring clinician.
- Full address of clinician to whom the result should be sent.
- Legible clinical summary, including details of any relevant family history.
- Address for billing – doctor, patient or other.
- Gestation and number of fetuses on prenatal samples.
- Hospital or reference number.
- Test required.

Essential information on sample container label:

- Patient's surname and forename (not initials).
- Date of birth.
- Hospital number or reference number.

Consent forms

Consent forms are available for genetic testing. As genetic testing may have implications for other family members and is regarded as personal data, it is recommended that written consent is obtained wherever possible. In cases with predictive testing for severe disorders, as indicated in the laboratory guide, it is essential that patients should also be offered formal genetic counselling.

It is the responsibility of the referring clinician to obtain appropriate consent from the patient.

Clinical Details

Clinical details are very important when providing genetic analysis. The more clinical information that is available (e.g. details of ultrasound information, phenotypic features or family history) the better the service we can provide. Failure to provide this information for genetic studies may result in an inaccurate analysis or interpretation.

Specialities

Cytogenetics (Constitutional cytogenetics)

Cytogenetic analysis is performed according to the Professional Guidelines for the Association of Clinical Genetic Science, and the recommendations provided are dependent on the clinical indications given for each case.

Clinical details inform the investigation at all stages:

- Prior to analysis, clinical details may indicate, for example, that procedures such as chromosome breakage or leukaemic studies are required, which must be referred to a specialist centre.
- During analysis, they may indicate that extra cells should be screened to investigate the possibility of mosaicism (in a diagnosis of suspected Turner syndrome, for example) or that particular chromosomes must be targeted for high-resolution study, (chromosome 4 in suspected Wolf-Hirschhorn syndrome, for example).
- When the analysis has been completed, they may help to provide an accurate interpretation of the findings and, in some instances, prompt further investigations, such as FISH or molecular genetic studies.

When clinical details are not available, a routine analysis will be performed and a conditional report issued.

Samples

Cytogenetic studies require living cells, so please ensure that samples reach the laboratory as soon as possible.

If a delay before dispatch is unavoidable, samples may be stored in a refrigerator (4°C) but must not be frozen.

Samples sent more than 48 hours after sampling, or kept at temperatures below 4°C or greater than 38°C, may have inhibited growth.

Requesting additional tests

Any further tests that not requested at the time of sample receipt must be requested within:

- 1 week for tests requiring prenatal culture or cultured cells
- 2 weeks for DNA testing
- 2 weeks for cell culture testing
- 3 months for FISH testing

Samples can be stored for longer periods if specifically requested at the time of sample receipt.

Haemato-oncology

The molecular haemato-oncology service provides a molecular diagnostic, prognostic and treatment monitoring service for malignant haematological disorders. The laboratory works closely with the UCLH SIHMDS and other specialist units within the hospitals we provide a service to.

The laboratory offers:

- A comprehensive molecular work up for new acute leukaemia diagnoses.
- A comprehensive molecular work-up for chronic myeloproliferative disorders.
- Assessment of B and T cell clonality as well as MYD88 status for lymphomas.
- Monitoring of treatment efficacy in CML and Philadelphia positive ALL (qBCR-ABL).
- Assessment of IgVH mutation status in CLL.

We are always looking to expand our test repertoire in response to clinical demand

Samples

- EDTA blood samples, which should be transported to the laboratory at ambient temperature.
- EDTA bone marrow samples, which should be transported to the laboratory at ambient temperature.
- FFPE tissue samples – please provide a minimum of five curls with a thickness of 5–10 microns each.
- Extracted DNA.
- Cerebrospinal fluid, pleural fluid, ascitic fluid and other aspirated body fluids.

Factors that significantly affect the performance of the examination or interpretation of results:

- Clotted samples
- Aged Samples (>48 hours)
- Haemolysed samples

Note that samples for qBCR-ABL must arrive at the laboratory within 72 hours of having been taken. Samples received that are more than 72 hours old cannot be processed.

Specialities

Reporting times

FLT3 and urgent Q30 leukaemia multiplex results will be reported within 48 hours of arriving in the laboratory. All other tests will be reported within 14 calendar days with the exception of IgVH mutation analysis which will be reported within 28 calendar days.

Requesting additional tests

Additional tests can be requested at any time via UCLH/SIHMDS HiLIS or by emailing the lab directly via molecular.haemonc@hslpathology.com.

Haemophilia Laboratory

The Haemophilia Laboratory provides a comprehensive diagnostic service for inherited and acquired bleeding and thrombotic disorders. The service covers phenotyping for the diagnosis of congenital bleeding and thrombotic disorders, treatment monitoring and inhibitor detection and monitoring, and molecular genetics analysis. The Laboratory also acts as a reference service for other Haemophilia treatment units.

Requests

Requests must be accompanied by a request form and, where appropriate, by an informed consent form – see page 78.

Samples for platelet aggregometry testing can only be accepted on Mondays–Wednesdays. Please discuss in advance with a haemostasis consultant.

Samples

Samples for Platelet studies (aggregometry, Lumiaggregometry, and platelet nucleotides) and whole blood assays (IMPACT R, PFA-100 and ROTEM) must be hand-delivered to the RFH Special Coagulation laboratory as soon as possible after collection (within two hours of venepuncture).

Pre-examination sample suitability and integrity is important to the final test result that is reported by the laboratory and/or to the safety of laboratory staff. As a result, the laboratory will reject the specimen and not proceed with analysis of samples if it meets one or more of these criteria:

- Samples or request forms are received without the minimum essential identification criteria listed in the above table and as a result the details on the sample label cannot be matched with the details on the request form
- If the sample is unlabelled or mislabelled
- Blood samples for coagulation testing are filled above the Maximum or below the Minimum fill line etched in the sample tube. A minimum of 90% and maximum of 110% fill is required to have an appropriate ratio of blood to anticoagulant/plasma otherwise the samples are subject to unpredictable dilution and anticoagulation effects which would invalidate the test results.
- Samples are haemolysed
- Samples are clotted
- Sample tubes are used past their expiry date
- Samples are received leaking and the container is found to be damaged
- The wrong sample has been received for a given investigation or the sample has been collected in the wrong sample bottles
- Samples received after 4 hours of collection for clotting screens, APTT, FV and FVIII and after 6 hours of collection for PT/INR
- Samples received for Specialist Coagulation testing (Bleeding state work ups – Factors II, V, VII, VIII, IX, XI, XII, VWF:Ag, VWF:RCo, VWF:CB, Platelet Aggregation studies, PFA-100, Pro-thrombotic (Thrombophilia testing) – protein C (PC), protein S (PS), Antithrombin (AT), APC-R ratio, other tests plasminogen, antiplasmin, PAI-1, tPA, ROTEM, Thrombin generation, Lupus Anticoagulant, DOAC (Rivaroxaban, Apixaban, Dabigatran, Argatroban levels, LMWH, UFH, Fondaparinux, and Danaparoid levels), which fulfil the above criteria and are received more than 4 hours after collection.
- Frozen plasma aliquots that have thawed in transit due to incorrect transport conditions (delay in transit, lack of dry ice etc.)
- Samples for Platelet Studies (Platelet aggregation studies) and ROTEM testing which have been sent via the pneumatic tube. Samples for these tests should be delivered by hand or via the dumb waiter from the Haemophilia and Thrombosis centre
- Whole citrated blood samples for PAI-1 antigen analysis which are not delivered on crushed ice
- Samples for genetic testing received without indication that informed consent has been given. In such cases, the laboratory will contact the Requestor informing them that the sample will not be tested unless informed consent is given.

Factors that significantly affect the performance of the examination or interpretation of results

- Underfilled or Overfilled Citrate tubes so that the ratio of anticoagulant to blood is less or greater than 1:9
- Clotted samples
- Haemolysed samples as a result of mixing tubes too vigorously, using the wrong size tube, using the wrong size needle or when the blood is drawn too slowly
- Heparin contaminated samples (unless for monitoring heparin levels)
- Out of date citrate tubes
- Samples for coagulation tests greater than four hours old
- Samples for INR greater than six hours old
- Lipaemic samples may interfere with some of the tests carried out.
- Patients samples with low platelet counts (<80-100 x10⁹/dL) for platelet function investigations

Requesting additional tests

Please call the department routine hours for additional tests. Please note that additional tests are dependent during upon sample integrity and suitability for the test:

- D-dimers within same day
- INR less than 6 hours
- All other coagulation tests less than 4 hours

Molecular Genetics

Clinical details can be extremely important for clinical interpretation of a molecular genetic test.

For example, the clinical comments accompanying a cystic fibrosis screening report will vary depending on whether the patient is a potential gamete donor or a person exhibiting a cystic fibrosis phenotype.

It may also be crucial, where a variant has already been shown to be segregating in a family, to be provided with information concerning the variant and a family pedigree to ensure the correct analysis is performed and reliable risk figures calculated.

Samples

- Whole blood collected in EDTA should be sent to the laboratory at ambient temperature within 48 hours, and kept between 4-28°C.
- Long term storage should be at 2-8°C.
- Extracted DNA samples should be sent to the laboratory between 4-28°C.
- Samples for NIPT should be kept at room temperature and never placed in the fridge or freezer.

Non-invasive prenatal testing

Non-invasive prenatal testing (NIPT) analyses cell-free DNA circulating in a pregnant mother's blood. It is used as a screen for trisomy 21, 18 and 13. Options are also available to screen for X and Y chromosome conditions, and for fetal sex.

Samples

Samples - two 10ml tubes of maternal blood - must be taken in special tubes provided by the laboratory. These samples must not be refrigerated, but stored at ambient temperature protected by the gel packs provided. The lab must receive the samples within 7 days to allow testing to proceed.

There needs to be enough cell-free fetal DNA in the maternal blood to be able to provide a result. If there is insufficient fetal DNA in the sample (which occurs in 3% of cases), another blood sample from the mother may be required. This will be processed in the laboratory at no extra charge.

Specialities

OncoGenomics (Molecular Cytogenetics)

The OncoGenomics (Molecular Cytogenetics) Laboratory provides a diagnostic service for malignant haematological disorders and carries out research in cancer genomics. The laboratory works closely with the internationally respected bone marrow transplant unit and other specialist units in the hospital.

Tests offered:

- Karyotyping by G-banding
- FISH screening (single test or disease target panels)
- Microarray CGH (chromosome microarray analysis/ molecular karyotyping)
- Next Generation Sequencing (Myeloid malignancies target panel)
- Genetic screening of CD138+ cells isolates

A record of the sample details should accompany all samples submitted for cytogenetic analysis. See attached Cytogenomics request form.

Samples

For optimal results, samples for conventional cytogenetic tests and FISH analysis should be collected in preservative-free heparin or in sterile containers provided by the laboratory. Call on +44(0)20 7307 9400 ext 3711 (office) / 3612 (lab) to obtain 'Cytogenetic collection containers'.

Samples for DNA-based molecular karyotyping and/or next generation sequencing (NGS) analysis should consist of fresh or frozen cells (bone marrow aspirate, lymph node biopsy, trephine, needle biopsy, pleural effusion or ascites) or 5–8µg total genomic DNA.

Cytogenetic analysis requires living cells. Please ensure the sample reaches the Laboratory within 24 hours of donation. Multiple myeloma samples should arrive by 3.00pm on the day of sampling whenever possible. Samples should not be frozen, i.e.; below 1°C or exposed to excess heat, i.e. above 38°C. If there is a delay in transit please store the sample at 4°C (in a refrigerator).

Factors that significantly affect the performance of the examination or interpretation of results:

- Clotted samples
- Aged Samples (>48 hours)
- Haemolysed samples
- Under-filled or over-filled transport medium tubes.

Reporting times

Urgent FISH results such as PML-RARA may be available within 4 hours of receipt of sample. Prior agreement with the lab is required for all urgent tests. Tests for query acute leukaemia (e.g. AML, ALL, PCL, CML at presentation, transforming CML and acute phase of NHL) can be urgently processed with results available within 10 calendar days. The reporting time for the remaining samples is normally within 21 calendar days. Molecular karyotyping and NGS analyses are carried out according to current requirements of 21 calendar days.

Requesting additional tests

Additional tests can be requested at anytime via UCLH/SIHMDs HiLIS or by emailing the lab directly via oncogenomics@hslpathology.com.

Postnatal Diagnosis (Blood Culture)

Chromosome studies are requested where problems that may have a cytogenetic basis are suspected – such as in cases of babies with birth defects; children with developmental delay and physical handicaps, or adults with fertility problems. Additionally, prospective gamete donors are screened to detect carriers of balanced chromosome rearrangements.

Samples

Lithium heparin whole blood specimens are required – gently mixed to prevent clotting and must not be frozen. See sample stability section for cytogenetic samples. Sample volumes may be reduced for children (2–4ml) and neonates (1–2ml).

Turnaround time

The usual turnaround time is 2-3 weeks however the laboratory will endeavour to respond to urgent requests. Where a major trisomy is suspected, a rapid PCR screen may be performed to provide an urgent provisional result.

Notes

- Rarely, blood samples fail to culture (in less than 1% of cases);
- The culture may yield chromosomes of insufficient quality. This will be indicated on the report and a repeat study suggested;

- The laboratory should be informed if the patient has recently received a blood transfusion.
- The laboratory should be informed if the patient has EVER had a bone marrow transplant.

Prenatal testing

Chromosome studies are requested where pregnancies are identified as being at risk of a cytogenetic abnormality. Risks may include:

- advanced maternal age;
- positive maternal serum screening;
- fetal abnormalities found on ultrasound;
- where a parent is a known carrier of a chromosome anomaly,
- where a high risk trisomy has been found by NIPT.

As false positive NIPT results may arise from placental mosaicism, amniocentesis is the suggested sample type for confirmation of NIPT results.

Samples

Amniotic fluid – 10ml+ in a plain sterile, leak-proof container. Suitable containers can be provided by the laboratory. The specimen must not be frozen. See sample stability section for cytogenetic samples.

Chorionic villus – 5mg+ in sterile transport medium. Suitable containers containing medium can be provided by the laboratory. The specimen must not be frozen. See sample stability section for cytogenetic samples.

Fetal blood – 1–2ml lithium heparin whole blood, gently mixed to prevent clotting. The specimen must not be frozen. For QF-PCR or array CGH, please provide EDTA whole blood.

See sample stability section for cytogenetic samples.

Turnaround time

This is dependent on the rate of cell growth; however, the usual turnaround time is approximately 2 weeks. As invasive prenatal diagnosis becomes less common, a number of circumstances now occur more frequently that may result in delayed reporting time. These include:

- A delay in transportation in order to collect a batch of samples to reduce courier costs. Even when couriered promptly, sample growth may be slower than that seen in samples sent immediately.

- Sampling at early or late gestations, for example to confirm non-invasive tests or follow up anomaly scans.
- A tendency to take smaller quantities of sample or to take insufficient sample for multiple techniques.
- The request for karyotyping as an add-on after an initial PCR test.

Fetal blood results will usually be reported by 10 calendar days. For all other prenatal tests, please contact the laboratory prior to taking samples.

Notes

- Maternal contamination, and mosaicism may complicate the analysis and may lead to the suggestion that a second invasive test is performed.
- Rarely, cultures fail to grow (overall <1%)
- Very small chromosome abnormalities may not be detected (this is why the phrase 'No trisomies or major chromosome abnormalities detected...' is used in our reports).
- For Twin to Twin Transfusion samples or heavily bloodstained amniocentesis samples, please provide a maternal EDTA blood sample for comparison studies.

Solid Tissue

Fibroblast cultures may be used in addition to blood cultures, such as when tissue-specific mosaicism is suspected, or where blood samples cannot be obtained. Products of conception samples may be requested for early spontaneous miscarriages, stillbirths, or to confirm a prenatal diagnosis.

Samples

All specimens should be placed in a sterile container, preferably containing transport medium. This can be supplied by the laboratory. Sterile normal saline can be used if transport medium is not available. Samples must not be placed in formaldehyde or other preservative and must not be frozen. See sample stability section for cytogenetic samples.

Turnaround time

This is dependent on the rate of cell growth; however, the usual turnaround time is approximately 4 weeks.

Specialities

Notes

- Material from miscarriages has a relatively high culture failure rate (around 20%). Where failure occurs, alternative molecular methods may be attempted, usually a KaryoLite Bacs-on-Beads assay that can detect whole monosomy or trisomy of any chromosome, if possible.
- If no villus or fetal parts are identified in supposedly products of conception material, and a normal female chromosome result is found, this may indicate that maternal tissue has been cultured (this will be noted on our report).
- Material from miscarriages can be returned for sensitive disposal if requested at the time of receipt. If no special request is made, fetal material will be sent for incineration separate from general clinical waste. Placental and other products of conception material will be disposed of in general clinical waste for incineration.

Fluorescence *in situ* hybridisation (FISH)

Where FISH studies for specific microdeletion syndromes are required this must be indicated on the request form.

Notes

- FISH studies for a rapid pre- or postnatal aneuploidy screen have now been superseded in our laboratory by multiplex-PCR technology.
- Subtelomeric screens are now performed by array CGH as part of developmental delay investigations.
- Common microdeletion syndrome testing is now performed by CGH analysis.
























Cell-line karyology

The cytogenetics laboratory can perform cell line karyology on live cultures or fixed cells suspensions (recommended) on a research basis. Please note: a laboratory processing charge of £100 + VAT is applicable to those cases wherein a successful analysis cannot be obtained. Please contact the laboratory for further details.

Statement regarding measurement uncertainty (MU)

See page 10.

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|---|------------|--|
| 1p36 Deletion Syndrome – karyotype + FISH | CVS/AF/  | 12-17 days | Clinical history must be provided. |
| 21-Hydroxylase Deficiency (Congenital Adrenal Hyperplasia) [#] | Requires patient informed consent  ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| 22q11 & 10p14 deletion (Di George Syndrome) – CGH | CVS/AF/   ⁹ | 10 days | Clinical history must be provided. |
| Achromatopsia NGS Panel – full gene sequencing [#] | Requires patient informed consent   ⁹ | 5 weeks | Clinical history must be provided. |
| Aicardi-Goutières Syndrome NGS Panel – full gene sequencing [#] | Requires patient informed consent   ⁹ | 5 weeks | Clinical history must be provided. |
| Alagille Syndrome NGS Panel – full sequencing JAG1 + NOTCH2 genes [#] | Requires patient informed consent   ⁹ | 8 weeks | Clinical history must be provided. |
| Alpha Fetoprotein on Amniotic fluid | AF ⁹ | 5-10 days | Clinical history must be provided. |
| Alpha Thalassaemia – multiplex PCR for common large deletions [#] | Requires patient informed consent  ⁹ | 4 weeks | Clinical history must be provided. |
| Alpha-1 Antitrypsin Genotype – PI*M, PI*S, PI*Z [#] | Requires patient informed consent  ⁹ | 5 weeks | Clinical history must be provided. |
| Alport Syndrome NGS Panel – full sequencing with deletions and duplications [#] | Requires patient informed consent   ⁹ | 5 weeks | Clinical history must be provided. |
| AML/ALL Molecular MRD – NPM1, PML-RARA, CBFB-MYH11, RUNX1-RUNX1T1, ETV6-RUNX1 | Requires patient informed consent Bone Marrow /  | 5 weeks | Contact lab for further information. |
| Amniocentesis culture (karyotype) only | AF ⁹ | 10-15 days | Clinical history must be provided. |
| Amniocentesis – rapid PCR diagnosis for common aneuploidies (2 days) + culture (10-15 days) | AF ⁹ | 2-15 days | Clinical history must be provided. |
| AmnioPCR only – rapid common aneuploidy diagnosis by QF-PCR | AF ⁹ | 2 days | Clinical history must be provided. |
| Amyotrophic Lateral Sclerosis (Motor Neurone Disease) NGS Panel – full gene sequencing [#] | Requires patient informed consent   ⁹ | 5 weeks | Clinical history must be provided. |
| Androgen Insensitivity – AR gene sequencing [#] | Requires patient informed consent  ⁹ | 4 weeks | Clinical history must be provided. |
| Aneurysm/Connective Tissue Disorders/ Ehlers-Danlos Syndrome NGS Panel – full gene sequencing [#] | Requires patient informed consent   ⁹ | 7 weeks | Clinical history must be provided. |
| Angelman Syndrome (Primary Screen) – methylation PCR |  ⁹ | 10 days | Clinical history must be provided. |
| Angelman/Rett Syndromes NGS Panel – full gene sequencing [#] | Requires patient informed consent   ⁹ | 5 weeks | Clinical history must be provided. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|------------|--|
| Aniridia, Isolated - PAX6 gene sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Anophthalmia/Microphthalmia/Coloboma NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Antithrombin Deficiency - SERPINC1 Gene Variant Analysis (Known Genotype) | Requires patient informed consent A A (Whole Blood) ⁴⁰ | 6 weeks | Informed Consent is required for these tests. |
| Antithrombin Deficiency - SERPINC1 Gene Variant Analysis (Unknown Genotype) | Requires patient informed consent A A (Whole Blood) ⁴⁰ | 12 weeks | Informed Consent is required for these tests. |
| Aortopathy/Marfan Syndrome and Thoracic Aortic and Dissection NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Apert Syndrome - common FGFR2 variants [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Apolipoprotein E genotype - E2, E3, E4 | A ⁹ | 14 days | Clinical history must be provided. |
| Array CGH (Comparative Genomic Hybridisation) | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Ashkenazi Breast Cancer Screen - common variants [#] | Requires patient informed consent A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Ashkenazi Jewish Carrier Screen | A ⁹ | 4 weeks | Clinical history must be provided. |
| Ataxia NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Autoinflammation/Periodic Fever NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Azoospermia - karyotype + cystic fibrosis screen + polyT(5T) + Y deletions | A H ⁹ | 10-15 days | Clinical history must be provided. |
| B cell clonality assay (IgH and IgK) | A or FFPE | 2 weeks | |
| Bardet-Biedl Syndrome NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Batten Disease (Neuronal Ceroid Lipofuscinosis) NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| BCR-ABL diagnostic assay | A | 2 weeks | |
| BCR/ABL Quantitative - fusion gene sizes p190 + p210 - MUST arrive in the laboratory within 48 hours, before 12pm on Fridays | A A ⁹ | 10 days | Clinical history must be provided. |
| Becker/Duchenne Muscular Dystrophy - deletions/duplications | A ⁹ | 10 days | Clinical history must be provided. |
| Beckwith-Wiedemann Syndrome - methylation studies on 11p15 imprinting domains KvDMR + H19 [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |

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| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|---------|--|
| Behcet's Disease - HLA Tissue Typing B*51 | A ⁹ | 10 days | Clinical history must be provided. |
| Beta Thalassaemia - beta-globin gene sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Blood PCR for Chromosome 13, 18, 21 and sex chromosomes | A | 5 days | |
| Breast Cancer Ashkenazi Screen - common variants [#] | Requires patient informed consent A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Breast Cancer - BRCA1 + BRCA2 only gene sequencing + deletions/duplications | Requires patient informed consent A | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Breast Cancer NGS Panel - full gene sequencing | Requires patient informed consent A A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Brugada Syndrome /Long-QT NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 4 weeks | Clinical history must be provided. |
| C-KIT D816V variant by PCR for Mastocytosis | Requires patient informed consent Bone Marrow /A | 14 days | |
| CADASIL - NOTCH3 gene sequencing [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| CAKUT (Congenital Anomalies of Kidney & Urinary Tract) NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Calreticulin - CALR exon 9 variant screen | A ⁹ | 2 weeks | Clinical history must be provided. |
| Cancer, Comprehensive NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Cardio-Facio-Cutaneous/Noonan/LEOPARD/Costello Syndromes NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Cardiomyopathy, Dilated NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Cardiomyopathy, Hypertrophic NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Cardiovascular, Comprehensive NGS Panel - full gene sequencing + deletions/duplications | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Carrier Screen (Ashkenazi Jewish) | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|------------|--|
| Carrier Screen (Ashkenazi Jewish) - Partnered Report - Please contact the lab for special requirements before sending [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Carrier Screen (Pan-Ethnic)[#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Carrier Screen (Pan-Ethnic) - Partnered Report - Please contact the lab for special requirements before sending [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Charcot-Marie-Tooth Syndrome NGS Panel - full gene sequencing - Contact lab prior to sending. Referral from clinical neurologist or clinical geneticist required with genetic consent form. [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Charcot-Marie-Tooth Type 1A - PMP22 duplications - Contact lab prior to sending. Referral from clinical neurologist or clinical geneticist required with genetic consent form. [#] | Requires patient informed consent A ⁹ | 7 weeks | Clinical history must be provided. |
| CHARGE Syndrome - CHD7 gene sequencing[#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Chediak-Higashi Syndrome - LYST gene sequencing [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Cholestasis, Intrahepatic NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Chromosome Analysis (Amniocentesis) - culture only | AF ⁹ | 10-15 days | Clinical history must be provided. |
| Chromosome Analysis (Amniocentesis) - rapid PCR diagnosis for common aneuploidies (2 days) + culture (10-15 days) | AF ⁹ | 2-15 days | Clinical history must be provided. |
| Chromosome Analysis (Blood) | H ⁹ | 5-15 days | Clinical history must be provided. |
| Chromosome Analysis (Chorionic Villus) - rapid PCR diagnosis for common aneuploidies (2 days) + culture (10-15 days) | CVS ^{1,9} | 2-3 weeks | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Chromosome Analysis (Chorionic Villus) - culture only | CVS ^{1,9} | 10-15 days | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Chromosome Analysis (Products of Conception) | Placental Sample ^{1,9} | 20-25 days | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Chromosome Analysis (Solid Tissue) | Fetal tissue ^{1,9} | 4-5 weeks | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Chromosome Analysis (Stem Cells) - CGH | Culture/Fixed cells | 5 days | Contact laboratory to discuss requirement |
| Chromosome Y Deletion - AZFa, AZFb, AZFc + SRY | A ⁹ | 5 days | Clinical history must be provided. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|------------|--|
| Coeliac Disease - HLA DQ2/DQ8 genotyping | A ⁹ | 10 days | Clinical history must be provided. |
| Colorectal Cancer NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Comparative Genomic Hybridisation (Array CGH) | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Comprehensive Neuropathy NGS Panel - full gene sequencing. | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Congenital Absence of Vas Deferens - karyotype + cystic fibrosis screen + polyT(5T) + Y deletions | A H ⁹ | 10-15 days | Clinical history must be provided. |
| Connective Tissue Disorders/Ehlers-Danlos Syndrome/Aneurysm NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Cornelia de Lange Syndrome NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| Costello/Noonan/LEOPARD/Cardio-Facio-Cutaneous Syndromes NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Craniosynostosis NGS Panel [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Cri du Chat Syndrome - CGH | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| CVS PCR for common aneuploidies (2 days) + culture (10-15 days) | CVS ^{1,9} | 2-15 days | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Cystic Fibrosis (139 common variants) - reflex to Poly T when CFS required | A ⁹ | 5-7 days | Clinical history must be provided. |
| Deafness NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Diabetes - Obesity NGS Panel [#] | A ⁹ | 6 weeks | Clinical history must be provided. |
| DiGeorge Syndrome (22q11 & 10p14 deletion) - CGH | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Dihydropyrimidine Dehydrogenase deficiency screening (Fluoropyrimidine Toxicity) [#] | A ⁹ | 1-2 weeks | Clinical history must be provided. |
| Dilated Cardiomyopathy NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| DNA Extraction & Storage - 3 years (longer upon request) | A ⁹ | 20 days | Clinical history must be provided. |
| DNA Identity Profile - 15 STR markers | A ⁹ | 10 days | Clinical history must be provided. |
| Duchenne Muscular Dystrophy - deletions/duplications only | A ⁹ | 10 days | Clinical history must be provided. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|--|
| Duchenne Muscular Dystrophy - full sequencing DMD1 gene [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| DVT/Pre-travel Screen | A A B ⁹ | 5 days | Clinical history must be provided. |
| Ehlers-Danlos Syndrome/Aneurysm/ Connective Tissue Disorders NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Endometrial Cancer NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Epidermolysis Bullosa NGS Panel - full sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Epilepsy, Adolescent / Adult Onset Panel - sequencing + deletions/duplications [#] | Requires patient informed consent A | 6 weeks | |
| Epilepsy, Comprehensive NGS Panel - full sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Fabry Disease, X-linked - GLA gene sequencing | A ⁹ | 4 weeks | Clinical history must be provided. |
| Facioscapulohumeral Muscular Dystrophy (FSHD) - D4Z4 repeat deletion - Contact lab prior to sending - Evidence of neurology counselling and genetic consent form is required. [#] | Requires patient informed consent A A A ⁹ | 9 weeks | Clinical history must be provided. |
| Factor II Prothrombin - G20210A variant | A ⁹ | 5 days | Clinical history must be provided. |
| Factor V Leiden - G1691A variant | A ⁹ | 5 days | Clinical history must be provided. |
| Familial Adenomatous Polyposis (FAP) - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Familial Exudative Vitreoretinopathy (FEVR) NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 8 weeks | Clinical history must be provided. |
| Familial Hypercholesterolaemia NGS Panel [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Familial Hypocalcaemic Hypercalcaemia (FHH) Panel - full sequencing CASR + AP2S1 + GNA11 genes [#] | Requires patient informed consent A A ⁹ | 9 weeks | Clinical history must be provided. |
| Familial Medullary Thyroid Carcinoma - hotspot sequencing RET gene [#] | Requires patient informed consent A ^{9,11} | 8 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Fatty Acid Oxidation Disorders NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| FLT3-ITD and FLT3-TKD screening assay | A | 24 hours | |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|------------|--|
| Fragile X Syndrome screen – FMR1 repeat analysis PCR [#] | Requires patient informed consent A A A ⁹ | 3-8 weeks | Clinical history must be provided. |
| Friedreich Ataxia – frataxin gene repeat analysis [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Gaucher disease full gene sequencing | A ⁴⁰ | 4 weeks | Informed Consent is required for these tests. |
| Genetic Reproductive Profile (Male) | A H ⁹ | 10-15 days | Clinical history must be provided. |
| Gilbert Syndrome – common UGT1A1 repeat variation [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency – full G6PD gene sequencing [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Glycogen storage disease type 2 (Pompe) mutation analysis | A | 4 weeks | |
| Haemochromatosis – HFE common variants C282Y + H63D | A ⁹ | 3 days | Clinical history must be provided. |
| Haemophilia A (Factor VIII deficiency) – CVS | CVS ⁴⁰ | 3 days | [40] Informed Consent is required for these tests. |
| Haemophilia B (Factor IX deficiency) – CVS | CVS ⁴⁰ | 3 days | [40] Informed Consent is required for these tests. |
| Hearing Loss NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| Hereditary Cancer NGS Panel, Comprehensive – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Hereditary Neuropathy with Liability to Pressure Palsy – PMP22 deletion analysis. Contact lab prior to sending. Referrals only from consultant neurologist or clinical geneticist. Genetic consent form required. [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Hereditary Colon Cancer (Lynch Syndrome) NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Hereditary Spastic Paraplegia NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| HFE gene (Haemochromatosis) – common variants C282Y + H63D | A ⁹ | 3 days | Clinical history must be provided. |
| Hirschprung Disease NGS Panel – full gene sequencing with deletions and duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| HLA Tissue Typing A/B/C/DRB1/3/4/5/DQB1 (Class I & II) | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing A/B/DRB1/3/4/5/DQB1 | A ⁹ | 10 days | Clinical history must be provided. |

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Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|---|
| HLA Tissue Typing A/B/DRB1/3/4/5 | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing A+B+C (Class I) | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing A+B | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing A | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing B*27 only | A ⁹ | 3 days | Clinical history must be provided. |
| HLA Tissue Typing B*51 (Behcet's Disease) | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing B*57:01 high resolution | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing B | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing C | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing Coeliac Disease - DQ2/DQ8 | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing DRB1/3/4/5/DQB1 (Class II) | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing DRB1/3/4/5 | A ⁹ | 10 days | Clinical history must be provided. |
| HLA Tissue Typing Narcolepsy - DQB1*06:02 [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Huntington Disease - HD gene repeat analysis PCR - Contact lab prior to sending. Referrals only from consultant neurologist or clinical geneticist. Genetic consent form required. [#] | Requires patient informed consent A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Hyperinsulinism NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Hyperparathyroidism - CASR sequencing [#] | Requires patient informed consent A ⁹ | 8 weeks | Clinical history must be provided. |
| IDH1/2 screening assay [#] | Requires patient informed consent A | 48 hours | |
| Identity Profile (DNA) - 15 STR markers | A ^{9,11} | 10 days | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| IgVH variant analysis for CLL | A | 4 weeks | |
| Inherited bleeding and platelet disorders (R90) | Requires patient informed consent A A | 12 weeks | Clinical synopsis, levels of relevant proteins, thrombosis history, family history and informed consent required. Please contact the laboratory if further guidance is needed on what to include on the request form. |
| Intellectual Disability NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Iron Overload Profile | B ⁹ | 3 days | Clinical history must be provided. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|--|
| JAK2 – exon 12 sequencing (rare variants) – MUST arrive in the laboratory within 48 hours, before 12pm on Fridays [#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| JAK2 V617F genotyping assay | A | 2 weeks | |
| Joubert/Meckel-Gruber Syndrome NGS Panel – full gene sequencing [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Kallmann Syndrome NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Kennedy Disease (Spinal Bulbar Muscular Atrophy) – AR repeat expansion [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Kidney/Urinary Tract Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Krabbe Disease – GALC sequencing + 502T/del common deletion [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| KRAS/NRAS screening assay [#] | Requires patient informed consent A | 48 hours | |
| Lactose Intolerance Gene | A | 2 weeks | |
| Langer-Giedion Syndrome – CGH | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Leber's Congenital Amaurosis NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Leber's Hereditary Optic Neuropathy – m.3460G>A + m.11778G>A + m.14484T>C common variants [#] | Requires patient informed consent A ⁹ | 8 weeks | Clinical history must be provided. |
| Leigh and Leigh Like Syndrome NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| LEOPARD/Noonan/Cardio-Facio-Cutaneous/Costello Syndromes NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Leukaemia (Rapid Acute) DNA and RNA NGS Panel | Requires patient informed consent A | 3 days | |
| Leukaemia/Lymphoma RNA Sequencing (Fusion Gene and SNV/Indel) Panel | A | 2 weeks | |
| Leukaemia Fusion Gene Screening Assay (Q30) | A | 24 hours | |
| Li-Fraumeni Syndrome (p53-related cancer predisposition) – TP53 sequencing + MLPA [#] | A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Limb-Girdle Muscular Dystrophy (LGMD) NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|---|------------|--|
| Lissencephaly NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Loeys-Dietz Syndrome/Marfan Syndrome/Aortic Aneurysm and Dissection NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Long-QT Syndrome/Brugada Syndrome - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 4 weeks | Clinical history must be provided. |
| Low (Oculocerebrorenal) Syndrome - OCRL sequencing [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided |
| Lung Disorders NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Lynch Syndrome (HNPCC) NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent AA ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Lysosomal Storage Disorders NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 4-6 weeks | Clinical history must be provided. |
| Male Genetic Reproductive Profile | AH ⁹ | 10-15 days | Clinical history must be provided. |
| Marfan Syndrome and Thoracic Aortic Aneurysm and Dissection NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Marfan Syndrome - FBN1 sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Maturity-Onset Diabetes of the Young (MODY) NGS Panel - full gene sequencing [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Meckel-Gruber/Joubert Syndrome NGS Panel - full sequencing across 38 genes [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Medium-Chain Acyl-CoA Dehydrogenase Deficiency - ACADM sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Melanoma Comprehensive Cancer NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent AA ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Microdeletion (common) Syndromes - CGH | CVS/AF/AH ⁹ | 10 days | Clinical history must be provided. |
| Microphthalmia/Anophthalmia/Coloboma NGS Panel - full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Miller-Dieker Syndrome - CGH | CVS/AF/AH ⁹ | 10 days | Clinical history must be provided. |
| Mitochondrial genome sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Mitochondrial genome - full mitochondrial DNA sequencing + deletions [#] | A ⁹ | 6 weeks | Clinical history must be provided. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|---------|--|
| Motor Neurone Disease (Amyotrophic Lateral Sclerosis) NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| MPL exon 10 analysis | A | 2 weeks | |
| MTHFR – common C677T + A1298C variants | A ⁹ | 5 days | Clinical history must be provided. |
| Mucopolysaccharidosis NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Multiple Endocrine Neoplasia Type 1 – full MEN1 sequencing [#] | Requires patient informed consent A ^{9,11} | 9 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Multiple Endocrine Neoplasia Type 2 – RET gene hotspot sequencing [#] | Requires patient informed consent A ^{9,11} | 8 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Myeloid Gene Panel – This is a 75 gene targeted NGS panel for acute myeloid leukaemia, myeloproliferative neoplasms, myelodysplastic syndromes, and also contains a number of targets which are useful for lymphoid malignancies (ALL and lymphoma). It uses Anchored Multiplex PCR (AMPTM) chemistry which enables deep strand-specific amplification of molecular barcoded DNA fragments for sequencing. | Requires patient informed consent A | 2 weeks | |
| Myeloproliferative Neoplasm NGS Screening Panel – This NGS assay allows for rapid generation of comprehensive profile of variants (both DNA and RNA) from a single NGS run. This assay can profile both DNA and RNA targets including DNA mutations and translocations detected from RNA targets and allows for simultaneous interrogation of 45 DNA target genes and 30 RNA fusion driver genes. The broad fusion panel enables sequencing of over 700 unique fusion transcripts. The panel covers relevant targets for acute myeloid leukaemia, myelodysplastic syndromes and myeloproliferative neoplasms, including CML, CMML and JMML. | Requires patient informed consent A | 1 week | |
| Myotonic Dystrophy Type 1 – DMPK repeat PCR [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Myotonic Dystrophy Type 2 (PROMM) – ZNF9 repeat PCR [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Narcolepsy (HLA DQB1*06:02)[#] | Requires patient informed consent A ⁹ | 4 weeks | Clinical history must be provided. |
| Nephrotic Syndrome, Steroid-Resistant NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Nervous System/Brain Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|----------|--|
| Neurofibromatosis Type 1 – NF1 + SPRED1 sequencing + deletions/duplications. Contact lab prior to sending [#] | Requires patient informed consent AA ^{9,11} | 8 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Neurofibromatosis Type 2 (Bilateral Acoustic) – NF2 sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 8 weeks | Clinical history must be provided. |
| Neuronal Ceroid Lipofuscinosis (Batten Disease) NGS Panel – full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Non-Invasive Prenatal Testing – common aneuploidy screening from maternal blood | J/Special tubes ¹ | 3-5 days | Contact the laboratory for special sample tubes/containers/instructions. |
| Noonan Syndrome Prenatal Screening – PTPN11 exons 3 & 8 only [#] | Requires patient informed consent CVS/AF | 2 weeks | |
| Noonan/LEOPARD/Cardio-Facio-Cutaneous/Costello Syndromes NGS Panel – full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| NPM1 mutascreen assay | A | 24 hours | |
| Nystagmus, X-linked Infantile – FRMD7 gene sequencing [#] | Requires patient informed consent A ⁹ | 7 weeks | Clinical history must be provided. |
| Oculopharyngeal Muscular Dystrophy – PABPN1 repeat analysis [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Optic Atrophy NGS Panel – full sequencing OPA1 + OPA3 genes [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Osteogenesis Imperfecta NGS Panel – full gene sequencing [#] | Requires patient informed consent AA ⁹ | 6 weeks | Clinical history must be provided. |
| Ovarian Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent AA ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| p53-related cancer predisposition (Li-Fraumeni Syndrome) – TP53 sequencing + MLPA [#] | Requires patient informed consent A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Pancreatic Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent AA ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Paranglioma/Pheochromocytoma NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent AA ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|------------|---|
| Paternity Testing (postnatal and prenatal) - sample required from each person being tested (3 people) | A / AF / CVS ^{9,11,12} Contact lab | 5 days | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. Please provide one sample for each person being tested. |
| Pelizaeus-Merzbacher Disease - PLP1 sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Pendred Syndrome - SLC26A4 gene sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Periodic Fever/Autoinflammation NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Peutz-Jegher Syndrome - STK11 sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Phelan-McDermid Syndrome - karyotype + FISH | CVS / AF / H ⁹ | 12-17 days | Clinical history must be provided. |
| Pheochromocytoma/Paraganglioma NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Pigmentation/Oculocutaneous Albinism/Hermansky-Pudlak Syndrome NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| POLG-Related Disorders - full POLG sequencing + copy number variant [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Polycystic Kidney/NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Pontocerebellar Hypoplasia NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Postnatal array CGH | A H ⁹ | 10 days | Clinical history must be provided. |
| Prader-Willi Syndrome (Primary Screen) - methylation PCR | A ⁹ | 10 days | Clinical history must be provided. |
| Prenatal array CGH | Amniotic fluid or CVS ⁹ | 10 days | Clinical history must be provided. |
| Prenatal Test (Non-Invasive Prenatal Testing) - common aneuploidy screening from maternal blood | J / Special tubes ¹ | 3-5 days | Contact the laboratory for special sample tubes/containers/instructions. |
| Pre-travel Screen (DVT) | A A B ⁹ | 5 days | Clinical history must be provided. |
| Primary Ciliary Dyskinesia (PCD) NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Primary Hyperoxaluria Panel - full gene sequencing + CNV [#] | Requires patient informed consent A | 6 weeks | |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|------------|--|
| Products of Conception (Culture) | Placental Sample or Solid Tissue ^{1,9} | 20-25 days | Contact the laboratory for special sample tubes/containers/instructions. Clinical history must be provided. |
| Prostate Cancer NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Protein C Deficiency - PROC Gene Variant Analysis (Known Genotype) | A A (Whole Blood 10ml) ⁴⁰ | 6 weeks | [40] Informed Consent is required for these tests. |
| Protein C Deficiency - PROC Gene Variant Analysis (Unknown Genotype) | A A (Whole Blood 10ml) ⁴⁰ | 12 weeks | [40] Informed Consent is required for these tests. |
| PTEN-related disorders (including Bannayan-Riley-Ruvalcaba, Cowden & Proteus Syndromes) - sequencing + deletions/duplications [#] | A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| QF-PCR rapid common aneuploidy screen | AF/A ⁹ | 2 days | Clinical history must be provided. |
| Recurrent Miscarriage Profile (female) | Requires patient informed consent A A B C C C H ^{9,18} | 10-15 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking, if a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Renal Cysts and Diabetes (RCAD) - HNF-1β sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 6 weeks | Clinical history must be provided. |
| Renal/Urinary Tract Cancer NGS Panel - full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Retinal Disorders NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Retinoblastoma - RB1 sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 6 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Rett Syndrome (MECP2 gene only) - full sequencing + deletions/duplications [#] | Requires patient informed consent A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Rett/Angelman Syndromes NGS Panel - full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Short Stature - SHOX variant screening + deletions/duplications [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Short-Chain Acyl-CoA Dehydrogenase Deficiency - ACADS sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |

This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|---|
| Silver-Russell Syndrome – methylation studies on 11p15 imprinting domains KvDMR + H19 [#] | Requires patient informed consent A ⁹ | 7 weeks | Clinical history must be provided. |
| Skeletal Dysplasia NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Smith-Lemli-Opitz Syndrome – DHCR7 sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Smith-Magenis Syndrome – CGH | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Sotos Syndrome (Cerebral Gigantism) – NSD1 sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Spastic Paraplegia NGS Panel – full gene sequencing + deletions/duplications + mitochondrial DNA [#] | A A ⁹ | 6 weeks | Clinical history must be provided. |
| Spinal Bulbar Muscular Atrophy (Kennedy Disease) – AR repeat analysis [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Spinal Muscular Atrophy – SMN1 deletions/duplications | A ⁹ | 10 days | Clinical history must be provided. |
| Spinocerebellar Ataxia – multiplex SCA1+2+3+6+7+17 common repeat expansions [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Spinocerebellar Ataxia NGS Panel – full gene sequencing | A A ⁹ | 6 weeks | Clinical history must be provided. |
| SRY (Sex-determining Region Y) | A ⁹ | 2 days | Clinical history must be provided. |
| Systemic mastocytosis – C-Kit common variants (KIT D816V) [#] | Requires patient informed consent A ⁹ | 14 days | Clinical history must be provided. |
| T cell clonality assay (TCR beta and TCR gamma) | A or FFPE | 2 weeks | |
| Tay Sachs Screen – common variants [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Thrombophilia with a likely monogenic cause (R97) | Requires patient informed consent A A | 12 weeks | Clinical synopsis, levels of relevant proteins, thrombosis history, family history and informed consent required. Please contact the laboratory if further guidance is needed on what to include on the request form. |
| Thrombotic Risk Profile | A A B C C C ¹⁸ | 5 days | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking, if a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Thyroid Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 4 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|---------|--|
| Torsion Dystonia (DYT1) – TOR1A common variant c.904-906delGAG [#] | Requires patient informed consent A ⁹ | 7 weeks | Clinical history must be provided. |
| Treacher-Collins Syndrome NGS Panel – full sequencing POLR1C + POLR1D + TCOF1 [#] | Requires patient informed consent A A ⁹ | 8 weeks | Clinical history must be provided. |
| Tuberous Sclerosis – full TSC1 + TSC2 gene sequencing [#] | Requires patient informed consent A A ⁹ | 5 weeks | Clinical history must be provided. |
| Urinary Tract/Renal Cancer NGS Panel – full gene sequencing + deletions/duplications [#] | Requires patient informed consent A A ^{9,11} | 5 weeks | Clinical history must be provided. Patient consent required. Consent Form can be found at the back of this guide. |
| Usher Syndrome NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 7 weeks | Clinical history must be provided. |
| Very Long-Chain Acyl-CoA Dehydrogenase Deficiency – ACADVL sequencing [#] | Requires patient informed consent A ⁹ | 5 weeks | Clinical history must be provided. |
| Von Hippel-Lindau Syndrome – VHL sequencing + deletions/duplications [#] | Requires patient informed consent A ⁹ | 9 weeks | Clinical history must be provided. |
| Wolf-Hirschhorn Syndrome – CGH | CVS/AF/A H ⁹ | 10 days | Clinical history must be provided. |
| Y chromosome microdeletions – AZFa + AZFb + AZFc + SRY | A ⁹ | 5 days | Clinical history must be provided. |
| Zellweger Syndrome/Peroxisomal Disorders NGS Panel – full gene sequencing [#] | Requires patient informed consent A A ⁹ | 6 weeks | Clinical history must be provided. |
| Ziwig Endotest [®] | Endotest saliva collection kit | 25 days | For information about this test and to order kits please contact endotest@tdlpathology.com. The quality of the saliva sample collection is important. Samples should be collected under supervision. |
| Zygoty testing – comparative DNA profile | A (From each twin and both parents) ⁹ | 5 days | Clinical history must be provided. |

[#] This test is referred to a specialist laboratory within our network of collaborators (test not on TDL/HSL scopes of accreditation).

Haemoglobinopathies

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---------------------------------------|--|---|
| Alpha Thalassaemia - multiplex PCR and HBA MLPA for large deletions. Alpha globin gene sequencing for small deletions and point mutations | A ⁹ | 3-20 working days depending on urgency | Clinical history must be provided. Complete the request form: Genotyping of Haemoglobin Disorders |
| Beta Thalassaemia - beta-globin gene sequencing, ARMS PCT, RE-PCR, Gap-PCR, HBB MLPA | A ⁹ | 3-20 working days depending on urgency | Clinical history must be provided. Complete the request form: Genotyping of Haemoglobin Disorders |
| HPFH and δβthalassaemia - Gap PCR, HBB MLPA, beta and gamma globin gene sequencing | A ⁹ | 3-20 working days depending on urgency | Clinical history must be provided. Complete the request form: Genotyping of Haemoglobin Disorders |
| Haemoglobin variants (alpha and beta globin gene variants) including sickle cell - ARMS PCR, RE-PCR, alpha and beta gene sequencing | A ⁹ | 3-20 working days depending on urgency | Clinical history must be provided. Complete the request form: Genotyping of Haemoglobin Disorders |
| Xmn and gamma gene - gamma globin gene sequencing, RE PCR | A ⁹ | 3-20 working days depending on urgency | Clinical history must be provided. Complete the request form: Genotyping of Haemoglobin Disorders |
| Prenatal diagnosis for haemoglobinopathies | CVS/ Amniocentesis/ Fetal Blood | 3 days | Parental EDTA blood samples should also be provided. Complete Request form: Prenatal Diagnosis of Haemoglobin Disorders |

Oncogenomics (haematological cytogenetics) tests

Performed are per requirements of the WHO Classification of Tumours of haematopoietic and Lymphoid Tissues and European recommendations, No2 (Swerdlow et al., 2017), Quality assurance for cytogenomic analysis of haematological neoplasms (Rack et al., Leukemia 2019) and following the UCLH/SIHMS diagnostic algorithm (see <https://www.uclh.nhs.uk>) as described below:

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|-------------------------------|------------------|-----------------------------------|
| AML Genome profile <i>Chromosome, target FISH and gene variant screening</i> | Bone marrow, peripheral blood | 10 calendar days | Min of 10x10 ⁶ cells |
| ALL Genome profile <i>Chromosome, target FISH and gene variant screening</i> | Bone marrow, peripheral blood | 10 calendar days | Min of 5-10x10 ⁶ cells |
| MDS Genome profile <i>Whole genome scan complemented with target FISH gene rearrangements testing</i> | Bone marrow | 21 calendar days | Min of 5x10 ⁶ cells |
| MPD Genome profile <i>Chromosome and gene variant screening by CMA, FISH and NGS</i> | Bone marrow | 21 calendar days | Min of 5x10 ⁶ cells |
| CLL Prognostification FISH screen <i>FISH screen for del13q, trisomy 12, ATM and TP53 gene loss</i> | Bone marrow, peripheral blood | 21 calendar days | Min of 5x10 ⁶ cells |
| CLL Genome profile <i>Whole genome and FISH screen</i> | Bone marrow, peripheral blood | 21 calendar days | Min of 5x10 ⁶ cells |

Genetic tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|-------------------------------|------------------|--------------------------------|
| Myeloma FISH high risk markers screen <i>Target screening of CD138(+) enriched BM isolates for the high risk genetic markers</i> | Bone marrow | 21 calendar days | Min of 5x10 ⁶ cells |
| Myeloma Genome profile <i>Whole genome and target fusion gene assesment by FISH of CD138(+) enriched BM isolates</i> | Bone marrow | 21 calendar days | Min of 5x10 ⁶ cells |
| Chromosome banding karyotype | Bone marrow | 21 calendar days | Min of 5x10 ⁶ cells |
| Single FISH test as per request | Bone marrow, peripheral blood | 10 calendar days | Min of 5x10 ⁶ cells |
| Molecular Karyotyping <i>Array CGH aka Chromosome Microarray Analysis</i> | Bone marrow, peripheral blood | 21 calendar days | Min of 5x10 ⁶ cells |
| Next-generation sequencing <i>Target Myeloid panel (Illumina)</i> | Bone marrow, peripheral blood | 21 calendar days | Min of 10µg cells |

External accreditation

- See page 2.

HSL Haematology

HSL's routine haematology laboratories form part of the blood sciences and local rapid response laboratories. Fully automated and some manual testing of both routine and some more specialised haematological parameters are provided.

The departments use the Sysmex XN9000 system to analyse FBC and routine coagulation parameters – the XN9000 can provide both routine and more specialised parameters for FBC enumeration. The XN9000 also incorporates a digital morphology module with automated slide makers to speed up and allow electronic back up of data for blood film analysis. Automated analysis of HBA1c can also be available on this track, enabling sample workflow to be improved.

The routine coagulation section uses the Sysmex CS5100, which is both reliable and fast, and enables a high sample throughput to be managed efficiently. The CS5100 can automatically detect haemolysis and lipaemic samples, assisting the lab staff to make informed decisions about sample rejection criteria.

The Haemostasis department uses a range of highly specialized equipment to cater for platelet function testing, bleeding disorders, thrombotic disorders, monitoring anticoagulation therapy, and the diagnosis and monitoring of microangiopathy disorders.

The laboratory is also able to offer some manual testing such as sickle cell screening, glandular fever and malaria testing.

We hold the IBMS pre- and post- registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. HSL Haematology is a UKAS Accredited Medical Laboratory No. 8169.

Staff /Key personnel

CLINICAL STAFF

| | | |
|------------------------|---|------------------------|
| Dr Rajeev Gupta | Clinical Specialty Lead for Haematology | Rajeev.gupta@ucl.ac.uk |
|------------------------|---|------------------------|

LABORATORY STAFF

| | | | |
|-----------------------|---------------------------------|---------------------------------|---------------|
| Billy Janda | Scientific Lead for Haematology | Billy.janda@tdlpathology.com | 020 3447 8961 |
| Deepak Singh | Dept Lead for Haemostasis | Deepak.singh@tdlpathology.com | 020 3447 9829 |
| Karen Orfinada | Haematology Laboratory Manager | | |
| Richard Munden | Deputy Manager for Haematology | Richard.munden@tdlpathology.com | |

General enquiries

- 020 7460 4865
- Haematology.User@tdlpathology.com

Out of hours service

Routine haematology tests are performed 24/7.

Haematology specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

All citrate samples sent by post or with an overnight delay must be double spun and sent frozen.

Samples should be sent to:

Health Services Laboratories
The Halo Building
1 Mabledon Place
London WC1H 9AX

Request procedures

See page 14 for general information on request procedures.

Please note that sample stability times will affect the feasibility of running add-on tests - please phone the lab to discuss.

Haematology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------|---------|---|
| Anaemia Profile | A A B | 2 days | |
| Antenatal Profile | A A B B B G | 3 days | Sample must be labelled by hand with first name, family name, gender and date of birth detailed on sample and form. Do not use labels other than the tube label. |
| APTT/KCCT | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Atypical Antibody Screen (handwritten tube label) | A | 2 days | Sample must be fresh. Sample must be labelled by hand with first name, family name, gender and date of birth detailed on sample and form. Do not use labels other than the tube label. |
| Blood Film Examination | A | 1 day | |
| Blood Group† | A | 2 days | Sample must be fresh. The tube's own label must be completed by hand. This must correspond with same name and date of birth details as given on the request form. Do not affix additional computerised or hand written labels. |
| Carboxyhaemoglobin | A | 1 week | |
| Coagulation Profile 1 | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Coagulation Profile 2 | A C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| D-Dimers (Fibrinogen Degradation Products) | C | 4 hours | Send to the laboratory without delay. |
| DVT/Pre-travel Screen | A A B | 5 days | Clinical history must be provided. |
| ESR | A | 4 hours | |
| Fibrinogen | C | 4 hours | Send to the laboratory without delay. Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Full Blood Count | A | 4 hours | |
| Haematology Profile | A | 4 hours | |
| Haemoglobin | A | 4 hours | |
| Immune Function Evaluation (Total) | A or Chex + B | 7 days | Do not send sample to the laboratory between Friday noon and Monday morning. Contact the laboratory for special stability tubes for lymphocyte subsets - or take an EDTA sample and ensure same day delivery to the laboratory, Monday to Friday noon (do not send sample between Friday noon and Monday morning). |
| INR | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as |
| Lymphocyte Subsets (CD3/CD4/CD8) | A / Chex | 1 day | Contact the laboratory for special stability tubes for lymphocyte subsets - or take an EDTA sample and ensure same day delivery to the laboratory, Monday to Friday noon (do not send sample between Friday noon and Monday morning). |
| Malarial Parasites | A | STAT | Send to the laboratory without delay. Clinical history must be provided. Provide details of travel history. Provide full contact details of the requestor for communication of positive cases. |

Haematology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---------------------------|--------------------|---------|---|
| Mean Cell Volume (MCV) | A | 4 hours | |
| Microfilaria Blood Film | | STAT | |
| Natural Killer Profile 2 | A | 2 days | |
| PAI1 4G/5G Polymorphism | A | 10 days | |
| Paul Bunnell (Monospot) | A or B | 8 hours | |
| Pre-Travel Screen (DVT) | A A B | 5 days | Clinical history must be provided. |
| Prothrombin Time | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Prothrombin Time + Dose | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Reticulocyte Count | A | 4 hours | |
| Thrombin Time | C | 4 hours | Citrate Samples: Samples should be double spun and separated and frozen within 4-8 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Vitamin K (With PIVKA II) | B | 10 days | Protect from light. |

Special haemostasis

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--------------------------------|--------------------|--------|---|
| Activated Protein C Resistance | C | 3 days | Send to the laboratory without delay. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| ADAMTS - 13 Activity Assay | C | 3 days | Send to the laboratory without delay. Clinical history must be provided Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Antithrombin III | C | 3 days | Send to the laboratory without delay. Clinical history must be provided Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor II Assay | C | 5 days | Send to the laboratory without delay. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor II Prothrombin Gene FX2 | A | 5 days | Clinical history must be provided. |
| Factor V Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor V Leiden | A | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--------------------|---------|--|
| Factor VII Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor VIII Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor VIII Inhibiting Antibody | C C | 2 weeks | Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor IX Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor IX Inhibiting Antibody | C C | 2 weeks | Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor X Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Anticoagulation monitoring • Anti-Xa LWMH • Anti-Xa Apixaban • Anti-Xa Rivaroxaban • Anti-Xa Arixtra • Anti Xa UFH (Heparin) • Dabigatran | C | 5 days | Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. Select test based on what drug patient is on. Name of Anticoagulation drug, dose amount, and time of dose must be provided. |
| Factor XI Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor XII Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Factor XIII Assay | C | 5 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Hughes Syndrome | C | 2 days | Clinical history must be provided. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Lupus Anticoagulant and Anticardiolipin Abs | B C | 2 days | Send to the laboratory without delay. Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen. Note: The Lupus Anticoagulation test is not appropriate when a patient is on anticoagulation therapy. Suggest testing when the patient is cleared of anticoagulation or, selecting the Taipan Snake Venom test for lupus anticoagulant assessment if the patient is on oral anticoagulation. |

Haematology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|--|
| Lupus Anticoagulant only | C | 2 days | <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> <p>Note: The Lupus Anticoagulation test is not appropriate when a patient is on anticoagulation therapy. Suggest testing when the patient is cleared of anticoagulation or, selecting the Taipan Snake Venom test for lupus anticoagulant assessment if the patient is on oral anticoagulation.</p> |
| Miscarriage/Thrombotic Risk Profile | A A B C C C | 5 days | <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Plasma Viscosity | A | 3 days | Send to the laboratory without delay. |
| Platelet Aggregation Studies | Contact laboratory for advice on sample taking | 3 days | <p>Do not send sample to the laboratory between Friday noon and Monday morning.</p> <p>Contact the Haemostasis Department before taking and sending sample to the laboratory.</p> <p>Send samples without delay. Test has only 4 hours stability post-collection.</p> <p>Send sample directly to: Haemostasis Department, 60 Whitfield Street, London W1T 4EU</p> |
| Platelet function assay (PFA-100 assay) | C (Whole blood) | 1 day | <p>Do not send sample to the laboratory between Friday noon and Monday morning.</p> <p>Contact the Haemostasis Department before taking and sending sample to the laboratory.</p> <p>Send samples without delay. Test has only 4 hours stability post-collection.</p> <p>Send sample directly to: Haemostasis Department, 60 Whitfield Street, London W1T 4EU</p> |
| Protein C | C | 3 days | <p>Send to the laboratory without delay.</p> <p>Clinical history must be provided.</p> <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Protein S Free Ag | C | 3 days | <p>Send to the laboratory without delay.</p> <p>Clinical history must be provided.</p> <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Taipan Snake Venom Time | C | 1 week | <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Thrombotic Risk Profile | A A B C C C | 5 days | <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Total Glycated Haemoglobin (Boronate Affinity) | A (Min 0.5mL) | 3 days | |
| Von Willebrand Profile | C C C | 5 days | <p>Send to the laboratory without delay.</p> <p>Clinical history must be provided.</p> <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |
| Von Willebrands Multimers | C C C | 3 months | <p>Citrate Samples: Samples should be double spun and separated and frozen within 6 hours of sample taking. If a delay is expected with transportation to the laboratory, samples must be transported as frozen.</p> |

*Referral test.

HSL Manual Haematology (Red Cells)

This laboratory mainly specialises in haemoglobinopathy investigations for diagnosis and monitoring. The service covers a range of haemolytic anaemias, including enzyme deficiencies (G6PD), pyruvate kinase (PK) and hereditary spherocytosis (HS).

Common Haemoglobinopathies are diagnosed using Capillary Electrophoresis (CE), High Performance Liquid Chromatography (HPLC) and Sickle solubility Testing. Unidentified haemoglobin variants and thalassaemias may be further characterised where required by the Haemoglobinopathy Genetics Laboratory using DNA analysis.

Other tests available include:

- The measurement of haemoglobin A1C in the presence of a haemoglobin variant by boronate affinity methodology;
- A quantitative assay for red cell enzymes by spectrometry;
- A flow cytometric method for the diagnosis of hereditary spherocytosis; and
- Erythropoietin measurement, which is useful for differentiating primary and secondary polycythaemia and assessing response to anaemia.

The laboratory provides a service to large populations of patients with major haemoglobinopathies, offering rapid results for monitoring purposes, particularly pre and post-red cell exchanges. The workload also includes screening for a large antenatal population and complies with the national sickle cell and thalassaemia screening programme guidelines.

Teaching and training are an integral part of the laboratory culture. We hold IBMS pre- and post-registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas.

HSL Manual Haematology (Red Cells) is a UKAS Accredited Medical Laboratory No. 8169.

Staff/Key personnel

CLINICAL STAFF

| | | |
|------------------------|---|------------------------|
| Dr Rajeev Gupta | Clinical Specialty Lead for Haematology | Rajeev.gupta@ucl.ac.uk |
|------------------------|---|------------------------|

LABORATORY STAFF

| | | | |
|-----------------------|--------------------------------|---------------------------------|---------------|
| Karen Orfinada | Haematology Laboratory Manager | Karen.Orfinada@hslpathology.com | 020 3908 1344 |
| Gareth Ellis | Head Biomedical Scientist | gareth.ellis@hslpathology.com | 020 3908 1351 |

General enquiries

- 020 3908 1351
- Special.haematology@hslpathology.com

Out of hours service

No urgent out-of-hours service is available.

Haemoglobinopathy monitoring for urgent Sickle and HbF monitoring for North Middlesex University Hospital and Whittington patients

This is carried out at with a turnaround time of 4 hours:

North Middlesex University Hospital
Pathology
Haematology
Sterling Way, London 18 1QX

Manual Haematology (Red Cells) specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

Please send samples to:

Health Services Laboratories
Manual Haematology (Red Cells)
Halo Level 2
The Halo Building
1 Mabledon Place
London WC1H 9AX

Request procedures

See page 14 for general information on request procedures.

For requests that are for DNA analysis only, see the Genetics section of this user guide.

Manual Haematology (Red Cells) tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--------------------|--------|--|
| Coombs (Direct Antiglobulin Test) | A | 2 days | |
| Eosin-5-Maleimide Dye Binding Assay for Hereditary Spherocytosis (EMA) | A (min 0.5ML) | 2 days | Recent transfusion will affect interpretation of result. This test is performed Monday - Thursday and samples must be received by Manual Haematology (Red Cells) within 48 hours of being taken. It is advised that a 'traveling control' should accompany sample if being sent by post. |
| Erythropoietin | B | 4 days | |
| G6PD Assay | A (min 0.5ML) | 3 days | Recent transfusion will affect interpretation of result. Reticulocytosis may falsely elevate result above steady state. Reticulocyte and FBC should be undertaken when requesting G6PD. |
| Haemoglobinopathy Screen | A | 3 days | Recent transfusion will affect interpretation of result. |
| Pyruvate Kinase | A | 3 days | Recent transfusion will affect interpretation of result. |
| Sickle Solubility (Urgent testing only) | A | 3 days | |
| Thalassaemia Screen (Haemoglobinopathy Screen) | A | 3 days | |

HSL Immunology

HSL's Immunology department provides a comprehensive testing service to users in the public and private sector. It receives requests from primary and secondary care, as well as specialist test requests from across the UK and overseas.

HSL Immunology is a UKAS Accredited Medical Laboratory No. 8169. It participates in the External Quality Assessment Schemes (EQA) such as the UK National External Quality Assurance Schemes (UK NEQAS) for all analytes where schemes are available.

A full repertoire of allergy and allergen components testing is available in house – more than 200 common allergens can be tested.

The latest available ELISA platforms, immunofluorescent digital microscopy, ISAC and blot techniques are used to investigate immunological and allergic conditions.

Staff/Key personnel

CLINICAL STAFF

| | | |
|--|--|-------------------------------|
| Professor Suranjith Seneviratne | HSL Clinical Specialty Lead for Immunology | suranjith.seneviratne@nhs.net |
| Dr Scott Pereira | Consultant Immunologist | scott.pereira@doctors.org.uk |

LABORATORY STAFF

| | | | |
|---------------------------|---------------------------------|----------------------------------|------------------------|
| Dr Kushen Ramessur | Scientific Lead/HOD, Immunology | Kushen.ramessur@tdlpathology.com | 020 7307 7373 ext 3215 |
| Emily Apsley | Clinical Scientist/ Deputy HOD | Emily.apsley@tdlpathology.com | 020 7307 7373 ext 3221 |
| Lisa Wallace | Quality manager | Lisa.wallace@hslpathology.com | 020 7307 7373 ext 3221 |

Working hours

The department is open between 8am and 7pm on weekdays for receipt of specimens and telephone inquiries.

We also offer a limited service between 9am to 5:30pm on Saturdays.

Specimens

See section 2 for general information on ordering tests, and on specimen collection, packaging and transport.

All TB Quantiferon samples must reach the laboratory within 16 hours of collection.

Request procedures

See section 2.

Urgent requests

There is a provision for urgent investigations received within normal working hours. Urgent Myeloperoxidase (MPO) IgG, Proteinase 3 (PR3) IgG, Glomerular Basement Membrane (GBM) IgG and Acetyl Choline Receptor (ACRA) antibody requests must be discussed with an appropriate member of staff before sending the sample to the laboratory.

Specialities

The Immunology service is part of the Blood Sciences department at HSL, and offers both autoimmune serology and allergy testing.

Autoimmune serology

The autoimmune laboratory offers a diagnostic and monitoring service for organ specific autoimmune disease, renal and connective tissue disease and primary immunodeficiency.

Allergy

The department also offers a full repertoire of allergy and allergen components testing. We currently test over 200 common allergens, including customised allergy panels to ensure a client tailored service. Our component resolved diagnostics service uses the latest ISAC microarray and ImmunoCap sIgE technology.

Immunology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|-------------------------|----------|--|
| Acetylcholine Receptor Antibodies | B | Referral | |
| AChR Cluster | B | Referral | |
| Actin Antibodies | B | 5 days | |
| ADA (Adenosine deaminase) (Nucleotide Metabolism) | A | Referral | |
| Adrenal Cortex Antibodies | B | 2 days | |
| Adulimimab Antibodies | B | Referral | |
| Alpha 3 Ganglionic Antibodies | B | Referral | |
| Anti-mitochondrial Antibodies (M2) (see Myositis Immunoblot) | B | 3 days | |
| AMPA 1 and 2 Antibodies | B | Referral | |
| ANCA (Anti-Neutrophil Cytoplasmic Antibodies) | B | 2 days | Urgent samples must be arranged with the laboratory in advance. |
| Anti-Nuclear Antibodies | B | 2 days | |
| AP50 (Alternative Pathway) | B (Frozen) ⁴ | 4 weeks | Send to the laboratory within 2 hours of collection. |
| Apoptosis Assay | H + Control | Referral | |
| Aquaporin 4 Antibodies (Neuromyelitis Optica) | B | 2 weeks | |
| Aspergillus Fumigatus Precipitins | B | Referral | |
| Autoantibody Profile I | B | 2 days | Refer to TDL Lab Guide test information section www.tdlpathology.com |
| Autoantibody Profile II | B | 2 days | Refer to TDL Lab Guide test information section www.tdlpathology.com |
| Avian Precipitins (11 Species) | B | 5 days | |
| B2 Microglobulin | B | 2 days | |
| Basal Ganglia Antibodies | B | 3 weeks | |
| Beta 2 Glycoprotein 1 Antibodies | B | 5 days | |
| BPO (M2-3E) Antibodies (see Liver Immunoblot) | B | 7 days | |
| BRAF-V600E | A | Referral | |
| Bruton's Tyrosine Kinase (BTK) | A + Control | Referral | |
| Bruton's Tyrosine Kinase (BTK) Gene | A | Referral | 2 x 5ml A required. |
| C1 Esterase Inhibitor (Functional) | B (Frozen) | Referral | Sample needs to be delivered to the laboratory immediately for separation and storage at -20°C. |
| C1 Esterase gene | A | Referral | |
| C1 Esterase Inhibitor (Antigenic) | B | 5 days | |
| C1 Inhibitor Antibodies | B | Referral | |
| C1q Binding Immune Complex | B | 5 days | |
| C2 | B | Referral | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|-------------------|---|
| C2 Gene | A | Referral | |
| C3 Complement | B | 4 hours | |
| C3 Nephritic Factor | B | Referral | |
| C3/C4 Complement | B | 4 hours | |
| C3d | A (Frozen) | Referral | Sample needs to be delivered to the laboratory immediately for separation and storage at -20°C (Monday - Friday up to 5pm). |
| C4 Complement | B | 4 hours | |
| C7 Gene | A | Referral | |
| C8 Gene | A | Referral | |
| Candida Stimulation | H + Control | Referral | |
| Cardiolipin Antibodies (IgG+IgM) | B | 2 days | |
| Cartilage Antibodies | B | 5 days | |
| CASPR2 Antibodies | B | Referral | |
| CCP Antibodies ([RF]) | B | 2 days | |
| CD40 | A + Control | Referral | |
| CD40 Ligand (CD154) | A + Control, H + Control | Referral | |
| CD40L Gene Mutation Analysis | A + Control | | |
| CENP A Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| CENP B Antibodies (see Extractable Nuclear Antibodies/ Scleroderma Immunoblot) | B | 2 days/ 7 days | TAT - 2 days if ENA but 7 days if scleroderma immunoblot method used |
| Centromere Autoantibodies (see Anti Nuclear Antibodies) | B | 2 days | |
| CGD Proteins p22, gp47, 67, gp91 | A + Control | Referral | |
| CH100 (Classical pathway) | B (Frozen) ⁴ | 4 weeks | Send to the laboratory within 2 hours of collection. |
| Chlamydia Species Specific Antibodies Screen | B | 2 days | |
| Coeliac/Gluten Profile 2 | A B | 10 days | Refer to TDL Lab Guide test information section www.tdlpathology.com |
| Coeliac/Gluten Sensitivity Profile | B | 2 days | Refer to TDL Lab Guide test information section www.tdlpathology.com |
| Colloid Antigen-2 Antibodies | B | 2 weeks | |
| Common Gamma Chain | A + Control | Referral | |
| Crithidia Antibodies (dsDNA Abs) | B | 2 days | |
| Cytokine Defect Investigations | B + Control, A + Control, H + Control | Referral | To reach referral laboratory within 24 hours, Monday - Thursday only. |
| DC Phenotype | B + Control, A + Control | Referral | To reach referral lab within 24 hours. |

Immunology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------------|----------|---|
| Dihydrohodamine-123-Respiratory-Burst Assay (DHR) | H + Control | Referral | To reach the laboratory within 24 hours and by 2:30pm on a Friday (not processed over weekends). Store at room temperature. |
| DNA (Double Stranded) Antibodies | B | 2 days | |
| DNA (Single Stranded) Antibodies | B | Referral | |
| Dock 8 Mutation Analysis | A + Control | Referral | |
| Dock 8 Protein | A + Control | Referral | |
| DVT/Pre-travel Screen | A A B ⁹ | 5 days | Clinical history must be provided. |
| EJ Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Endomysial Antibodies (IgA) | B | 2 days | |
| Extractable Nuclear Antibodies (nRNP, Sm, Ro, La, Jo-1, Scl-70, CENP-B) | B | 2 days | |
| Factor B Level | B | Referral | |
| Factor H Antibodies | B | Referral | |
| Factor H Level | B | Referral | |
| Factor I Antibody | B | Referral | |
| Factor I Level | B | Referral | |
| Factor XII Gene | A | Referral | |
| Farmers Lung Precipitins | B | 5 days | |
| FH3L | B + Control, A + Control | Referral | To reach referral lab within 24 hours. |
| Fibrillarlin Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| FLT3 Ligand | B + Control, A + Control | Referral | To reach referral lab within 24 hours. |
| Functional C1 Esterase Inhibitor | B | | Sample needs to be delivered to the laboratory immediately for separation and storage at -20°C. |
| GABAR Antibodies | B | Referral | |
| Ganglionic Alpha 3 Acetylcholine Receptor Antibodies | B | 1 month | |
| Ganglioside GM1, GD1B, GQ1B Antibodies | B | 5 days | |
| Gastric Parietal Cell Autoantibodies (see Tissue Battery) | B | 2 days | |
| GATA2 Sequencing | B + Control, A + Control | Referral | |
| Gliadin Antibodies (IgG) (deamidated) | B | 2 days | |
| Glomerular Basement Membrane Antibodies | B | 2 days | Urgent samples must be arranged with the laboratory in advance. |
| Glutamic Acid Decarboxylase Antibodies (GAD 65) | B | 5 days | |
| Gluten Allergy Profile | A B B | 10 days | Refer to TDL Lab Guide test information section www.tdlpathology.com |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|------------|--|
| Gluten Sensitivity Evaluation | B | 2 days | |
| Gluten/Coeliac Profile 2 | A B | 10 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Glycine Receptor Antibodies | B | Referral | |
| GMCSF Antibodies | B (no control) + (H) + control for function if required) | Referral | 24 hours, sample to arrive no later than Thursday. |
| gp210 Antibodies (see Liver Immunoblot) | B | 7 days | |
| Granule Release Assay | A + Control | Referral | |
| Granulocyte Antibodies | B | Referral | |
| Granulocyte Immunology | A A | 2 weeks | |
| H. Pylori Antibodies (IgG) | B | 2 days | |
| Haemophilus Influenzae Antibodies (HIB) | B | 5 days | |
| Histamine | A (Frozen plasma) | 5 days | |
| Histamine (Urine) | RU | 5 days | |
| Histamine Releasing Urticaria Test | B | 10-14 days | |
| Histone Antibodies | B | 5 days | |
| HMG CoA Reductase Autoantibodies | B | Referral | |
| Human Anti-Mouse Antibodies | B (Frozen) | 6 weeks | |
| IA2 Antibodies | B | Referral | |
| IFN Gamma Antibodies | B (no control) + (H) + control for function if required) | Referral | 24 hours, sample to arrive no later than Thursday. |
| IgA Antibodies | B | Referral | |
| IgG Subclasses (IgG1, IgG2, IgG3, IgG4) | B | 2 days | |
| IL17 (Th17) | H + Control | Referral | |
| IL2R Gene Mutation Analysis | A | Referral | |
| IL6/Interleukin 6 | B or CSF | Referral | |
| IL7R alpha and JAK3 gene Mutation Analysis | A | Referral | |
| Immune Function Evaluation (Total) | A or Chex+ B ^{5,10} | 7 days | Do not send sample to the laboratory between Friday noon and Monday morning. Contact the laboratory for special stability tubes for lymphocyte subsets - or take an A sample and ensure same day delivery to the laboratory, Monday to Friday noon (do not send sample between Friday noon and Monday morning). |
| Immune-Complexes | B | 5 days | |
| Immuno Solid Phase Allergen Chip (ISAC) | B | 3 days | |
| Immunoglobulin E - Total | B | 1 day | |
| Immunoglobulins (IgG, IgM, IgA) | B | 4 hours | |

Immunology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|-------------------------------|-----------|--|
| Infliximab antibodies | B | Referral | |
| Infliximab levels | B | Referral | |
| Inner Ear Antigen (Ottoblot) | B | 3 weeks | |
| Insulin Antibodies IgG | B | 5 days | |
| Interferon - Alpha | B (Frozen) ⁹ | 3 weeks | Clinical history must be provided. |
| Interferon - Gamma | A (Frozen) | 3 weeks | |
| Interleukin 1 Beta | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay. Sample should be separated and frozen if sending overnight. |
| Interleukin 10 | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay. Sample should be separated and frozen if sending overnight. |
| Interleukin 2 | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay Sample should be separated and frozen if sending overnight. |
| Interleukin 4 | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay. Sample should be separated and frozen if sending overnight. |
| Interleukin 6 | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay. Sample should be separated and frozen if sending overnight. |
| Interleukin 8 | B (Frozen) ^{4,7} | 1-2 weeks | Send to the laboratory without delay. Sample should be separated and frozen if sending overnight. |
| Intrinsic Factor Antibodies | B | 2 days | |
| Islet Cell Antibodies | B | 2 days | |
| ITK mutation analysis | A | Referral | |
| JAK 3 | A | Referral | |
| Jo-1 Antibodies (see Extractable Nuclear Antibodies/ Myositis Immunoblot) | B | 3 days | |
| Ku Antibodies (see Scleroderma/Myositis Immunoblot) | B | 3-7 days | |
| La Antibodies (see Extractable Nuclear Antibodies) | B | 2 days | |
| LC-1 Antibodies (see Liver Immunoblot) | B | 7 days | |
| Legionella Antibodies | B | 2 days | |
| Leukotriene E4 | CU (Frozen) | 3 weeks | |
| LGI 1 Antibodies | B (plasma and CSF acceptable) | Referral | |
| Liver Cytosol Antibodies | B | 5 days | |
| Liver Kidney Microsomal (IIF) (see Tissue Battery) | B | 2 days | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---------------------|-----------|---|
| LKM-1 (immunoblot) (see Tissue Battery/Liver Immunoblot) | B | 7 days | |
| Lupus Anticoagulant and Anticardiolipin Antibodies | B C ^{4,18} | 2 days | Send to the laboratory without delay. Citrate Samples. Samples should be double spun and separated and frozen within 4-8 hours of sample taking, if a delay is expected with transportation to the laboratory, samples must be transported as frozen. |
| Lymphocyte Antibodies | B | Referral | |
| M2-3E (BPO) Antibodies (see Liver Immunoblot) | B | 7 days | |
| Mast Cell Tryptase | B | 2 days | 1 sample at onset of reaction, 1 sample 3 hours post reaction, 1 sample 24 hours post reaction. Clearly mark this in Clinical details for each sample. Specimens may be kept at room temperature for shipping purposes for 2 days, store at 2-8°C if assayed within 5 days after collection. For longer periods, store samples at -20°C and -70°C. |
| MBL (Mannose Binding Lectin) | B (Frozen) | 31 days | Sample needs to be delivered to the laboratory immediately for separation and storage at -20°C. |
| MDA5 Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Meningococcal Antibodies (A, C, W, Y) | B | 2-4 weeks | |
| Meningococcal Serum Bactericidal Titre | B | Referral | |
| MHC Class 1 | A + Control | Referral | |
| Mi-2α Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Mi-2β Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Mitochondrial Antibodies (see Tissue Battery) | B | 2 days | |
| Mitochondrial Antibodies M2 | B | 5 days | |
| Mitochondrial mutation M.1555 analysis | A | Referral | |
| MOG [Myelin Oligodendrocyte Glycoprotein] Antibodies | B | 3 weeks | |
| MUSK Antibodies | B | 2 weeks | |
| Musk Cluster Antibodies | B | Referral | |
| Myasthenia Gravis Evaluation | B | 5 days | |
| Myelin Associated Glycoprotein Antibodies (MAG) | B | 5 days | |
| Myelin Basic Protein Antibodies | B | 2 weeks | |
| Myeloperoxidase (MPO) Antibodies | B | 2 days | |
| Myocardial Antibodies | B | 1 week | |
| Myositis Immunoblot (Mi-2α, Mi-2β, TIF1γ, MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52) | B | 3 days | |

Immunology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|-----------------------|----------|---|
| NBT Test (Nitro Blue Tetrazolium) | A + Control | Referral | To be analysed within 24 hours. To reach specimen reception on day of collection before 15.30 (Monday to Thursday) and before 13:00 on Fridays. Not processed over the weekends. Store at room temperature. |
| Neuronal Antibodies (Hu, Ri, Yo, Cv2, Ma2) | B | 10 days | |
| Neutrophil Antibodies | B | Referral | |
| Neutrophil Phenotypic Analysis (CD11a and CD18) | A + Control | Referral | |
| NK Killing | A + Control | Referral | To reach referral laboratory on the same day (Monday to Friday only). |
| NMDA Receptor Antibodies | B | 3 weeks | |
| NOR90 Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| nRNP Antibodies (see Extractable Nuclear Antibodies) | B | 2 days | |
| Nucleotide Metabolism (ADA and PNP) | A | Referral | |
| NXP2 Antibodies (see Myositis Immunoblot) | B | 3 days | |
| OJ Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Ovarian Autoantibodies | B | 2 days | |
| Pancreatic Islet Cell Antibodies | B | 2 days | |
| Parathyroid Antibodies | B | 1 week | |
| PDGRF Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| Pemphigus/Pemphigoid Autoantibodies | B | 2 days | |
| Perforin | A + Control | Referral | |
| Phagocytosis Assay | H + Control | Referral | |
| Phosphatidylserine Antibodies | B | 5 days | |
| Phospholipase A2 Receptor | B | 3 weeks | |
| Pituitary Antibodies | B ⁴ | 1 month | Send to the laboratory without delay. |
| PL-12 Antibodies (see Myositis Immunoblot) | B | 3 days | |
| PL-7 Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Platelet Antibodies | B | Referral | Requires NHSBT Bristol request form. |
| PML Antibodies (see Liver Immunoblot) | B | 7 days | |
| PM-Scl100 Antibodies (see Scleroderma Immunoblot) | B | 3-7 days | |
| PM-Scl75 Antibodies (see Scleroderma Immunoblot) | B | 3-7 days | |
| Pneumococcal Antibodies - Serotype Specific | B | 5 weeks | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--|----------|--|
| Pneumococcal Antibody (PCP) | B | 2 days | |
| PNP (Nucleotide Metabolism) | A + Control | Referral | |
| PRF1 (perforin) gene and MUNC 13-4 mutation analysis | A | Referral | |
| Proliferation Assay | H + Control | Referral | Store at room temperature. To reach specimen reception by 13:00 on Fridays (not processed over weekends). |
| Proteinase 3 Antibodies | B | 2 days | |
| Purkinje Cell Antibodies (Hu and Yo) | B | 5 days | |
| Quantiferon Gold (see TBQ) | Special tubes or H ¹ 4 QuantiFERON tubes: QuantiFERON Nil tube (grey cap, white ring); QuantiFERON TB1 tube (Green cap, white ring); QuantiFERON TB2 tube (yellow cap, white ring); QuantiFERON Mitogen tube (purple cap, white ring) | 3 days | Fill samples to 1 ml black mark on side of tube. Overfilled/underfilled tubes not accepted. To reach laboratory within 12 hours of venepuncture. |
| Retinal Antibodies | B | Referral | |
| Rheumatoid Factor | B | 1 day | |
| Rheumatology Profile 1 (Screen) | A B | 2 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 2 (Connective Tissue) | A A B B | 3 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 3 (Rheumatoid/Basic) | A B | 2 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 4 (Systemic Lupus) | A B B | 2 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 5 (Mono Arthritis) | A A B B | 3 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 6 (Rheumatoid Plus) | B | 2 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| Rheumatology Profile 7 (Sjogren's Syndrome) | B | 2 days | Refer to TDL lab Guide test information section www.tdlpathology.com |
| RNA Polymerase Antibodies | B | 2 days | |
| Ro Antibodies (see Extractable Nuclear Antibodies) | B | 2 days | |
| Ro-52 Antibodies (see Scleroderma/Myositis/ Liver Immunoblots) | B | 3-7 days | |
| RP11 Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| RP155 Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| SAE1 Antibodies (see Myositis Immunoblot) | B | 3 days | |

Immunology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---------------------------------|-----------------------------|--|
| Salivary Gland Antibodies | B | 15 days (now referral test) | |
| SAP | A + Control | Referral | |
| Scl-70 Antibodies (see Extractable Nuclear Antibodies/Scleroderma Immunoblot) | B | 2-7 days | |
| Scleroderma Immunoblot (Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR, Ro-52) | B | 5 days | |
| Serotype Specific Pneumococcal Antibodies | B | Referral | |
| Signal Recognition Particle (SRP) Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Signal Transducer and Activator of Transcription 3 Gene (STAT3) | A | Referral | |
| Skin (Pemphigus/Pemphigoid) Autoantibodies | B | 2 days | |
| SLA (Soluble Liver Antigen) Antibodies | B | 10 days | |
| SLA/LP Antibodies (see Liver Immunoblot) | B | 7 days | |
| Sm Antibodies (see Extractable Nuclear Antibodies) | B | 2 days | |
| Smooth Muscle Antibodies (see Tissue Battery) | B | 2 days | |
| Soluble IL2 receptor (CD25) | B | Referral | |
| Sp100 Antibodies (see Liver Immunoblot) | B | 7 days | |
| Specific IgE to Allergen | B | 2 days | |
| Sperm Antibodies (Serum) | B | 5 days | |
| Staphylolysin Titre Antibodies (SGOT) | B | 2 days | |
| STAT4 Tyrosine Phosphorylation | A + Control | Referral | |
| STAT5 Tyrosine Phosphorylation | A + Control | Referral | |
| Steroid Cell Antibodies | B | 2 days | |
| Streptolysin Titre Antibodies/ASOT | B | 2 days | |
| Striated/Skeletal Muscle Antibodies | B | 2 days | |
| Sulfatide Antibodies | B | 5 weeks | |
| Synthetase Antibodies (PL7, PL12, EJ, OJ) (see Myositis Antibodies) | B | 3 days | |
| T Cell Receptor Excision Circlet Analysis (TRECS) | A | Referral | |
| T Cell Spectratyping | A | Referral | |
| TB Quantiferon®-TB Gold* | Special tubes or H ¹ | 3 days | Contact the laboratory for special sample tubes/containers/instructions. |
| Testicular Autoantibodies (see Steroid Cell Antibodies) | B | 2 days | |
| Tetanus Toxoid Antibody | B | 2 days | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------------------|------------|--|
| TGN (TGN Antibodies) | A + Control | Referral | |
| Th/To Antibodies (see Scleroderma Immunoblot) | B | 7 days | |
| Thyroglobulin Antibodies | B | Referral | |
| Thyroid Antibodies (incl. Thyroglobulin + Thyroid Peroxidase Antibodies) | B | 1 day | |
| Thyroid Peroxidase Antibodies/Anti TPO | B | 1 day | |
| TIF1γ Antibodies (see Myositis Immunoblot) | B | 3 days | |
| Tissue Battery (AMA Anti mitochondrial antibody, SMA smooth muscle antibody, LKM1 liver kidney microsomal 1, GPCA Gastric parietal cell antibody) | B | 2 days | |
| Tissue Transglutaminase IgA (Coeliac) | B | 2 days | |
| Tissue Transglutaminase IgG | B | 5 days | |
| TNFRSF6 (FAS) gene mutation analysis | A | Referral | |
| Total IgE | B | 1 day | |
| Total Immune Function Evaluation | A or Chex + B ^{5, 10} | 7 days | Do not send sample to the laboratory between Friday noon and Monday morning. Contact the laboratory for special stability tubes for lymphocyte subsets - or take an A sample and ensure same day delivery to the laboratory, Monday to Friday noon (do not send sample between Friday noon and Monday morning). |
| Total Immunoglobulin E | B | 1 day | |
| Transmembrane Activator and CAML interactor (TACI) | A | Referral | |
| TSH-Receptor Antibodies | B | 4 days | |
| U3-RNP Antibodies (Fibrillarin) (see Scleroderma Immunoblot) | B | 7 days | |
| Urticaria Test (Histamine Releasing) | B | 10-14 days | |
| V Beta Repertoire | A + Control | Referral | |
| Vascular Endothelial Growth Factor | B | 2 months | |
| VDRL (RPR) | B | 2 days | |
| Voltage Gated Calcium Channel Antibodies | B | 3 weeks | |
| Voltage Gated Potassium Channel Antibodies | B | 3 weeks | |
| WAS Protein | A + Control | Referral | To reach referral laboratory within 24 hours. |
| XIAP | A + Control | Referral | To reach referral laboratory within 2 days (and before 2pm on Fridays). (Not processed over weekends). |
| Zinc Transporter 8 | B | Referral | |

HSL Microbiology

The HSL Microbiology service (located within the Infection Sciences department) is a broad-ranging pathology service. In addition to routine microbiology diagnostics, the laboratory includes reference and developmental clinical services, with expertise in all areas of conventional and molecular microbiology. As a clinically-led department, we offer a comprehensive 24/7 service in a state-of-the-art pathology complex divided across two levels of the Halo building. HSL Microbiology is a UKAS Accredited Medical Laboratory No. 8860.

The services provided reflect the needs of our users. Specialist areas include: solid organ and stem cell transplantation, renal dialysis, hepatology, neurosurgery, ENT, ophthalmology, bone and joint infection and blood culture diagnostics. In addition, the laboratory hosts a UK regional Clinical Mycology Network facility and the UK PHE Parasitology reference service.

HSL Microbiology is also responsible for running and developing the laboratory at the high-level isolation pathology unit based within the Royal Free Hospital, where we offer a clinically-led 24/7 multidisciplinary service for patients with the diagnosis of viral hemorrhagic fever (hazard group 4 pathogens).

The department holds the IBMS pre- and post-registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. The laboratory also holds accreditation for STP clinical scientist training. In addition, the department is a leader in training of Microbiology specialist registrars and medical undergraduates, as well as regularly hosting visiting PHE doctors and ESCMID observers. The department has an extensive research portfolio, working closely with UCL Centre for Clinical Microbiology and other collaborators on translational research projects.

Staff/Key personnel/Contacts

INFECTION SCIENCES

| | | |
|---|------------------------------|---------------------------------------|
| Consultant Specialty Lead, Microbiology | Dr Robin Smith | Robinsmith1@nhs.net |
| Head of Department, Microbiology | Alan Spratt | Alan.Spratt@hslpathology.com |
| Quality manager | Andrew Clarke | andrew.clarke@hslpathology.com |
| Training Manager | Ashleigh Dadson- Butt | Ashleigh.Dadson-Butt@tdlpathology.com |

INFECTION SCIENCES DEPARTMENT ENQUIRIES

| | | |
|----------------------------------|---|---------------|
| General enquiries - all sections | Microbiology.Enquiries@hslpathology.com | 0203 908 1390 |
| Training - all sections | Microbiology.Training@hslpathology.com | |

INFECTION SCIENCES DEPARTMENT OUT OF HOURS (8pm-8am and weekends, bank holidays)

| | | |
|-------------------------------------|--|---------------|
| All enquiries - all sections | | 0203 908 1390 |
|-------------------------------------|--|---------------|

Level 3 Infection Sciences

| SECTION | SPECIMEN | EMAIL |
|---|---------------------------------|---------------------------------|
| Blood cultures | Blood culture | Blood.Cultures@hslpathology.com |
| Tissues/Fluids/CSF/ Moorfields | Tissues/Fluids/ Intra-ocular | Tissues.Fluids@hslpathology.com |
| CL3 ^sTB/Respiratory | Respiratory/TB | Mycobacteria@hslpathology.com |
| Gynaecological/*GUM | Swabs, Semen | Gynae.GUM@hslpathology.com |
| Wounds | Swabs | Wounds@hslpathology.com |

*Genitourinary medicine. ^sMycobacteria tuberculosis (incl. non-tuberculosis mycobacteria).

Level 4 Infection Sciences

| SECTION | SPECIMEN | EMAIL |
|-----------------|---|---|
| Enteric | Stool | HaloLevel4.EntericMicrobiology@tdlpathology.com |
| Mycology | Skin/Hair/Nail Fungal culture Serology | Mycology@hslpathology.com |
| Urines | Urine and associated specimens | Urines@hslpathology.com |
| *HCAI | MRSA/VRE/CPE and resistance screening swabs | MRSA.HAI@hslpathology.com |

*Health Care Associated Infection

Microbiology specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

Labelling

The specimen must be labelled with the patient details as on the request form. Please ensure that electronically created barcodes are placed down the length of the specimen container and do not obscure any pre-existing barcodes.

Unlabelled samples or samples with insufficient unique identifiers cannot be processed and will be discarded.

Clinical details

Clinical details are essential for to ensure that specimens are processed appropriately. For example:

- Include travel history if submitting an enteric specimen to ensure that specific agar plates necessary for detecting travel-related organisms such as *Vibrio* sp. are set up.
- Specify whether prosthetic material is present when submitting joint specimens to ensure that cultures have the prolonged incubation and enrichment conditions required to identify PJI-related organisms such as *Cutibacterium acnes*.

Containers

All samples must be collected in the specified sterile containers, as shown below.

Factors that significantly affect the performance of the examination or interpretation of results

General factors

- Specimens must be sent in sterile containers.
- Always use aseptic technique for collection of specimens.
- Specimens can easily be contaminated with surface and mucosal flora, so the specimen should be collected using methods to minimise contamination. For example, take mid-stream clean catch urine samples to minimize contamination from urethral flora.
- False-negative results may occur in patients taking antibiotics.

- The time that a specimen is collected can impact on the diagnostic yield e.g. early morning urine (EMU) sample for TB investigation.
- Delays in transport and/or incorrectly stored samples may lead to loss of viability of some organisms and/or overgrowth of other flora.
- Always send separate samples if requesting multiple tests from different departments. Failure to adhere to this may result in the testing being missed or delayed.
- Storage conditions of the samples prior to testing are important.

Blood cultures

- Hospital procedures for optimal blood culture technique should be followed to minimise contamination with skin flora.
- Incorrectly collected blood cultures (under/overfilled) may affect organism growth and recovery.
- Never refrigerate blood culture samples.
- Blood cultures should be delivered to the laboratory promptly to ensure rapid incubation for maximal diagnostic yield.
- The time and date of blood culture collection should be clearly stated on the blood culture bottle labels.

Urine specimens

- The optimal non-invasive urine specimen is a mid-stream clean catch urine.
- Urine for culture should be sent in a container with boric acid preservative to preserve specimen quality and minimise overgrowth of contaminating flora.
- Urine culture specimens should be stored in a fridge prior to transportation to reduce the rate of multiplication of microorganisms.

Therapeutic drug monitoring (TDM)

- Clinical details should include the name of the antimicrobial given, dose, date and time of dose, and date and time of sample.
- Avoid the use of gel tubes for TDM as they may impact analysis.

Serology testing

- Haemolysed, lipaemic and icteric blood samples are not suitable for serological investigations.

Molecular testing

- Swabs with additives (such as charcoal or gel) cannot be used for PCR tests. A specific NAAT swab or dry swab should be used.

Dermatology specimens

- Do not refrigerate Dermapak specimens (nail, skin, hair) as this will lead to loss in viability of Dermatophytes.

Sterile fluid microscopy analysis

- Sterile fluid is prone to clotting which makes accurate cell count impossible. If sending sterile fluid for the investigation of infection please send an additional aliquot of fluid in an EDTA vial for an accurate cell count.

Swabs

- Where possible, services should use liquid Amies swabs (code: LAS) for culture and/or PCR for bacterial and fungal pathogens, as they provide higher-quality results than gel Amies swabs. Gel Amies swabs will still be accepted but are sub-optimal sample types.

Swabs for *Neisseria gonorrhoeae* culture

- As this organism dies rapidly, these should be transported to the laboratory as soon as possible after collection to ensure maximal yield.

Pre-inoculated culture plates

- Where possible pre-inoculated plates for *Neisseria gonorrhoeae* culture should be pre-incubated for a minimum of 18 hours in appropriate CO₂ gas packs prior to referral to the laboratory.
- All other pre-inoculated plates should be transported to the laboratory urgently to prevent plate dehydration, which will reduce recovery of organisms.

Request procedures

UCLH (EPIC)

All routine specimens from the main hospital sites and Mortimer Market should be sent to the Rapid Response Laboratory (RRL) specimen reception area (SRA) located in 60 Whitfield Street.

ROYAL FREE LONDON

All routine specimens should be sent to the Central Pathology Reception Area 2 (SRA2) on the 1st floor of the main Royal Free Hospital Building or to the Barnet site Rapid Response laboratory. Where possible please order test request(s) using EPR. If unable to use the system, send a blue microbiology request form with the test request(s) and clinical details.

NMUH

All routine specimens from the main hospital sites should be sent to the Rapid Response Laboratory (RRL) specimen reception area located on the North Middlesex Site.

ALL OTHER USERS

All other users of services must ensure that samples are sent to the hospital site with which you have pre-agreed prices and/or a service level agreement in place. Samples must be received with clear requests with clinical details, and clearly labelled specimens.

Requesting additional tests (add on requests)

After sample receipt: this is dependent on the retention time of the sample in the laboratory. The retention time varies for different types of clinical specimens; this information is available from microbiology on request. Please discuss the additional requests with the microbiology doctors or the laboratory.

Specimen acceptance/rejection criteria

Pre-examination sample suitability and integrity will influence the final test result that is reported by the laboratory and can also impact on the safety of laboratory staff. As a result the laboratory will reject the specimen and not proceed with analysis of samples if it meets one or more of the following criteria:

- Specimens or request forms are received without the minimum essential identification criteria (see Section 2).
- Grossly leaking or broken specimen containers.
- Inappropriate specimens for the test requested (see table above for guidance on specimens).
- Tissue specimens received in formalin, formal saline or any other fixative is not suitable for investigation by microbiological culture.

Creutzfeldt-Jacob Disease

All samples received for Creutzfeldt-Jacob Disease (CJD) testing are sent to the National Creutzfeldt-Jacob Disease surveillance unit (CJDSU) in Edinburgh. The clinical team considering sending the test must discuss the case with CJDSU (Dr Alison Green or Dr Mary Andrews on 0131 537 3075) in advance. If testing is agreed, the CJDSU will organize a courier to pick up the specimen from the laboratory and they will liaise with the laboratory in advance to arrange a suitable time for collection. The sample is stored at -20°C in the CL3 laboratory until collection.

Laboratory opening hours and urgent processing

The department operates a 24/7 shift system. There are always Microbiology staff available on site at the Halo Building, including at nights, weekends and public holidays. There is a reduced number of staff working after 8pm on weekdays, and at weekends and bank holidays.

Microbiology sample reception on all sites is also open 24/7 on all days for receipt of specimens and to arrange transport of urgent specimens. Each site has regular set transport times to transport specimens to the Halo building. In addition, the SRAs will arrange urgent courier collection to expedite transfer for urgent specimens to the Halo for urgent processing.

Urgent samples

A 24-hour service is provided for urgent requests. Requests submitted for urgent analysis must be agreed with the laboratory in advance and may require discussion with the microbiology clinical doctors if the urgent request is not part of laboratory urgent repertoire.

Urgent specimens should be marked clearly and, ideally, should be hand delivered to the SRA and handed directly to a member of SRA or RRL staff. If hand-delivery is not possible, the SRA staff should be telephoned to alert them that a specimen requiring urgent attention is on its way. If the SRA is not alerted to an urgent specimen, it is unlikely to be detected among the routine work arriving at the SRA.

The SRA will arrange an urgent courier to transport the specimen to the Halo building for urgent processing. The Laboratory will endeavour to report out all urgent tests within the published turnaround times.

Pre-inoculated agar plates for corneal scrapings must be transported immediately to the laboratory for incubation.

For the diagnosis of amoebic dysentery, fresh (still warm) 'hot stool' or rectal scrape is required. Any aspirated pus from abscesses for parasite investigations must also be submitted fresh and warm and treated as urgent. The specimen needs to be examined without delay; the sample collected must therefore be transported and rushed to the laboratory immediately. Please contact the laboratory or RRL in advance, to inform them that the sample is on its way.

Out of hours (8pm-8am)

A limited number of Microbiology tests are available out of hours in order to prioritize tests where a rapid result can influence the treatment of a patient:

- Cerebrospinal (CSF), peritoneal, ascitic or other sterile fluid for microscopy and culture set up
- Corneal scrapings pre-inoculated plates and slides for microscopy and incubation
- Urgent auramine stain for TB (AAFB microscopy)
- Paediatric urine microscopy
- Stool samples for *Clostridium difficile* testing in consultation with the on-call medical microbiologist
- Other specimens in consultation with the on-call medical microbiologist
- Processing within High Level Isolation Unit in the event of patient admission (via specific on-call rota)

Specialities

The Microbiology service is sub-divided into eight key areas throughout the Infection Sciences department across levels 3 and 4 of the Halo building with the aim of developing highly skilled, specialist teams that process specimens according to their pathology.

Level 3

Blood cultures

Blood cultures focuses on the investigation of bacterial and fungal blood infection. Blood cultures bottles are incubated on continuous monitoring culture systems (BacTec FX) based either on site at the local SRA or at the Halo building. Bottles which 'flag' positive are removed and processed 24/7 to minimise time to identification and susceptibility results for patient management.

Positive cultures are gram-stained and cultured. In addition, rapid identification of bacterial pathogens direct from the positive blood bottle using MALDI-TOF, within 4 hours of blood culture positivity is performed during daytime shift and positive bottles processed at night have 8-hour rapid culture MALDI-TOF identification the following morning. All positive blood cultures are communicated to the Microbiology doctors for management. Interim negative blood culture results are reported at 36-hours for paediatric patients, 48-hours for adult patients and final negative results are reported after 5-days incubation.

Mycobacterial and respiratory investigation

Housed in our state of the art containment level 3 laboratories, the CL3 service offers a comprehensive Mycobacterial diagnostics service.

Our service includes auramine smear microscopy, with a 24-hour turnaround from the time the sample arrives at the Halo, and rapid PCR testing to detect *M. tuberculosis* complex and Rifampicin resistance.

The mainstay of detection is mycobacterial culture, from specimens including blood, tissue, early morning urine (EMU; minimum 60ml) and respiratory samples. Mycobacteria isolates are first examined with MPT64 rapid antigen testing for the preliminary identification of MTB; Isolates are then referred to the Mycobacterial Reference Laboratory (MRL) for full identification and susceptibility testing.

The routine culture of specimens for Mycobacterium species is primarily carried out through MGIT liquid broth automated culture. After careful clinical review, the laboratory service has discontinued Löwenstein-Jensen (LJ) agar slope culture on all specimens.

The following lists detail the specimens which will have a LJ agar slope culture carried out in addition to the routine MGIT liquid broth automated culture:

- Supplementary LJ slope culture at 30°C, incubated for 8 weeks:
 - All skin biopsies
 - Any specimen where clinical details indicate possible *M. marinum* infection
- Supplementary LJ slope culture at 37°C, incubated for 8 weeks:
 - Any specimen which is positive on *Mycobacterium tuberculosis* PCR direct from specimen
 - Any specimen which is positive on auramine stain direct from specimen
 - All lung and pleural biopsies
 - On clinical request via laboratory communication or through clinical details provided with the specimen. For LJ slopes to be set up, the request needs to specify the clinical reasons why extended Mycobacterial culture is required.

Negative mycobacterial cultures are reported after 6-weeks incubation. Routine respiratory culture is performed for the detection of respiratory pathogens, and PCR for the investigation of atypical Pathogens (*Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*) is available.

If you wish to contact the laboratory to request supplementary LJ slope culture at 37°C please see details on page 121.

Swabs

Automated culture of swab specimens using twin Kiestra total laboratory systems. The automated microbiology section offers a comprehensive bacteriology service processing ENT, wound, genital, orthopaedic/staphylococcal screen swabs and other clinical swab specimens.

The molecular service also performs PCR for the detection of the Panton Valentine Leukocidin toxin gene from *Staphylococcus aureus* isolates on clinical request.

Please note: culture for *Trichomonas vaginalis* from genital swabs has been discontinued due to unavailability of reagents. Analysis is performed by direct microscopy and is limited to swabs from non-GUM settings with appropriate clinical details including: pregnancy, STI screen or *Trichomonas vaginalis* infection.

In view of the low sensitivity of direct microscopy compared with culture or PCR a negative microscopy result should be interpreted with caution. Please consider TV PCR testing if clinically indicated, please see page 188 for TV PCR requirements.

Tissue, fluids and specialist microbiology

Investigation of sterile specimens including: tissue, bone, CSF fluids and prosthetic material. The specialist service offers semi-quantitative and quantitative microscopy, synovial fluid crystal analysis and enrichment culture for all sterile fluids using BacTec broth continuous monitoring culture. Prosthetic joint specimens will undergo prolonged enrichment culture for 14 days, but only if the clinical details alert the laboratory to the presence of prosthetic material. If these details are not provided, routine 5-day enrichment culture will be applied.

Level 4

Enterics

The service provides investigation of non-travel related diarrhoeal infections using the EntericBio multiplex PCR for Salmonella, Shigella, Campylobacter, STEC, Giardia and Cryptosporidium, with culture follow-up of positive Salmonella, Shigella and STEC specimens. Travel-related diarrhoeal pathogens are tested using culture techniques for bacteria and microscopy for ova, cysts and parasites, *Clostridium difficile* using PCR screening assay followed by toxin EIA detection on all positive PCR samples. The enterics service also includes the detection of *Helicobacter pylori* antigen.

Mycology

Our UK Clinical Mycology Network regional laboratory provides culture, serological and molecular diagnostics. The service offers PCR, microscopy and culture for the investigation of superficial fungal infection, identification and susceptibility testing of clinically significant yeasts, routine (7-day) and extended (21-day) fungal culture from clinical specimens. The serology service provides TDM for triazoles, Galactomannan antigen detection, 1-3- β -d-glucan detection, Cryptococcal antigen by LFD and the detection of Histoplasma antigen from urine. The molecular mycology service offers *Pneumocystis jirovecii* PCR, Candida PCR by T2MR and Aspergillus PCR.

Healthcare-associated infection

Processing of routine screening specimens for MRSA, carbapenemase-producing organisms (CPO) and vancomycin-resistant enterococci (VRE) as well as bespoke screening for outbreak management. The service offers rapid molecular MRSA detection for high-risk in-patients, culture screening for multi-drug resistant bacteria including: MRSA, CPO and VRE. A rapid response service is available for potential outbreak of infections via liaison with the laboratory.

Urine investigation

Routine and complex urinary pathology investigation. The service offers automated and manual microscopy, culture, identification and susceptibility testing. Urine antigen test for legionella and pneumococcal antigen is available. A specialist urine service includes the analysis of sequential urine samples and prostatic secretions in the diagnosis of prostatitis and other complex genitourinary samples including VBU specimens, and invasive urine samples such as suprapubic aspirates and ureteric urine.

Microbiology tests

Healthcare associated infections

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------|--|---|
| Carbapenemase-producing organism (CPO) screen | LAS (rectal) | 4-5 days*** | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. *** Presumptive positive isolates will be sent to the PHE reference laboratory for confirmation. |
| Extended beta lactamase (ESBL) screening | LAS (rectal) | Negative result 48 hours; Positive result 96 hours | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| MRSA rapid PCR (one swab per site) | PCR swab | 24 hours | Expedite delivery to laboratory. |
| MRSA Culture (one dual swab - nose and groin) | LAS (dual swab) | 3 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| VRE screen (one swab per site) | LAS | 3 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| Acinetobacter screen (one swab per site) | LAS | 3 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |

Enteric microbiology

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|----------|---|
| <i>Clostridium difficile</i> Toxin by PCR/EIA (positive) | RF | 2 days | |
| Stool for OCP travel associated (microscopy) | RF | 3 days | |
| Stool for endemic community pathogens by PCR | RF | 2 day | |
| Stool for travel-related diarrhoea by culture | RF | 3 days | Travel history is essential to ensure appropriate detection agar plates are set-up. |
| <i>Helicobacter pylori</i> antigen | RF | | |
| Sellotape Test | Send Sample** | 1 day | ** Use clear Sellotape only and attach to microscope slide. |
| Schistosoma (Urine) | Mid-morning terminal urine following exercise | 1-2 days | Must send terminal urine. |

Tissues, fluids, CSF

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--------------------------------|---|----------|---|
| CSF for Microscopy and Culture | UC | 1-3 days | |
| CSF PCR | UC (200 µl) | 24 hours | This test must be requested clinically by contacting the tissues and fluids laboratory. |
| Ascitic fluid | EDTA sample for microscopy plus sample inoculated into BacTec bottles for culture | 4 days | EDTA is optimal sample for microscopy. |
| CAPD fluid | Follow local protocol | 4 days | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|---|--|--|
| Sterile Fluid Culture | UC | 7 days | |
| QIAstat Bacterial Meningitis PCR | CSF Minimum sample volume: 200 µl | 4 hours from clinical request | This test is restricted and is only performed on clinical request by microbiology clinical staff. To request this test please contact your local microbiology clinical team. |
| Synovial fluid | EDTA and 20ml universal | 7 (up to 16 days for prosthetic joint specimens) | EDTA is optimal sample for microscopy sample prone to clotting). State whether prosthetic material is present to ensure prolonged enrichment culture. |
| Synovial Fluid (For Crystals) | UC | 1 day | |
| Tissue for culture | Tissue sample in SC or 20mL universal | 7 (up to 16 days for prosthetic joint specimens) | If sending tissue from prosthetic joint, state presence of prosthetic material in clinical details to ensure prolonged enrichment culture. |
| 'Hardware' or device | Send device in SC | Up to 14 days | |
| Corneal scrapings | Pre-inoculated culture plates and slides | Up to 7 days | Collect plates and slides from the SRA. Return inoculated plates and slide to SRA immediately and request urgent transport to the laboratory. |
| H. pylori Culture | Send biopsy in sterile saline | 3 weeks | Laboratory will transfer to protagerm medium prior to transfer to reference laboratory. |

Mycobacterial/Respiratory

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------------------|---------------|--|
| Bordetella PCR | Pernasal dry PCR swab | 48 hours | Must be sent as a PCR dry swab for in-house testing. *Alternative specimens of Nasopharyngeal aspirate for PCR in 20mL universal, VTM or UTM can be sent however, this testing will be referred to an external laboratory for testing and the TAT will be extended to 7 days. |
| Sputum for TB microscopy (AFB) and culture | UC3 | up to 6 weeks | |
| TB Culture | UC | up to 6 weeks | |
| TB Culture (Urine) | 3 x Early Morning Urine | up to 6 weeks | |
| Sputum for Routine Culture | UC | 4 days | |
| TB PCR | UC | 2 days | |
| Atypical mycobacterial culture (tissues) | UC | | |
| Atypical PCR | UC | 5 days | |

Blood cultures

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|---|--|--|
| Inoculated blood culture bottles | Set of aerobic and anaerobic bottles (adults) Paediatric bottle (children) | 5 days (negatives) 7-10 days (positive) | Follow local protocol to minimise contamination and maximise diagnostic yield. |

Microbiology tests

Urine analysis

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|----------------------------------|--|--------------|---|
| Urine (Microscopy Only) | RU | 1 day | |
| Urine for Microscopy and Culture | Mid-stream clean catch urine in boric acid container | 2-4 days | Send in boric acid container to preserve quality and minimise contaminant overgrowth. |
| Urine for Extended Culture | MSU | up to 7 days | |
| Pneumococcal Urinary Antigen | RU | 1 day | |
| Prostatitis Screening Panel | VB1U+VB2U+EPS or EPSW + VB3U | 4-5 days | |
| Legionella Urinary Antigen | RU | 1 day | |
| Semen Culture | Semen in UC | 4 days | |
| Specialist urine culture | VB1, VB2, VB3, ureteric in UC | 4 days | |

Genitourinary/ENT/Wounds/Swabs

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|------------------------------|---|
| HVS | LAS | 4 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| IUCD for Culture | Send device in sterile container | 11-12 days | |
| Swab (Ear) | LAS | 4 days (Culture) | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. See Mycology for fungal TAT. |
| Group B Streptococcus screening | LAS | 4 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. Send a combined LVS and rectal swab to maximise yield (national guideline). |
| Swab for Bordetella pertussis culture investigation | Throat or pernasal charcoal swab | 7 days | PCR is gold-standard test and should be sent in preference to culture swab. |
| Nose screen for <i>Staphylococcus aureus</i> carriage | LAS | 4 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| GC culture | LAS | 5 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. Swabs should be sent immediately to the laboratory for culture to maximize the chance of recovery of GC. |
| PVL toxin gene PCR | <i>S. aureus</i> isolates from culture | 7 days from positive culture | Please contact the laboratory to request PVL PCR on <i>S. aureus</i> isolates if required |

Mycology

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|--------------------|----------|----------------------|
| 1-3-Beta D Glucan | F | 72 hours | (4ml minimum volume) |
| Galactomanan (Aspergillus Antigen) | F | 72 hours | (4ml minimum volume) |
| Fungal investigations (superficial/ dermatophyte PCR test) | Skin, Hair, Nails | 3-7 days | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---------------------------------------|--------------------|----------|--|
| Antifungal TDM | F | 72 hours | (4ml minimum volume) |
| Cryptococcal antigen | F or CSF | 48 hours | (4ml minimum volume) |
| Histoplasma antigen (Urine) | UC | 72 hours | Sample stability is reliant on freezing to preserve the antigen therefore please inform the laboratory when sending requests |
| Fungal culture swabs (Ear, other) | LAS | 8 days | Pink liquid Amies swabs (LAS) are preferred as they provide higher-quality results than gel Amies swabs. |
| Extended fungal culture | UC | 22 days | |
| Dimorphic fungal culture | UC | 42 days | |
| Dermatophyte investigation (PCR) | Dermapak | 8 days* | *If the specimen is insufficient for PCR cultures will be extended to 15 days to optimize fungal recovery |
| <i>P. jirovecii</i> PCR (BAL, Sputum) | UC | 72 hours | |
| T2MR Candida PCR | A | 72 hours | (4ml minimum volume) |
| Antifungal susceptibility testing | | 72 hours | |
| Aspergillus PCR (Sputum/BAL) | UC | 7 days | |

Referral serology tests (sent to UK reference laboratories for processing)

| TEST NAME | SAMPLE REQUIREMENT | TAT | REFERENCE UNIT |
|--|--------------------|----------|------------------------------|
| <i>Borrelia burgdorferi</i> antibodies | F | 14 days | RIPL Porton down |
| Teicoplanin level | F | 14 days | Southmead Bristol |
| TB: Isoniazid level | A (minimum 2mL) | 14 days | Cardiff Toxicology |
| TB: Rifampicin level | F | 14 days | Southmead Bristol |
| Other antibiotic assays | F | 14 days | Determined by antimicrobial |
| Bordetella antibodies | F | 14 days | RVPBRU Colindale |
| Coxiella antibodies | F | 14 days | RIPL Porton Down |
| <i>Mycoplasma pneumoniae</i> PCR | F | 14 days | Colindale PHE |
| Histoplasma antibodies | F | 14 days | Bristol PHE Mycology |
| Meningococcal PCR | A or CSF | 24 hours | Meningococcus reference unit |
| Rickettsial antibodies | F | 14 days | RIPL Porton Down |
| Leptospira antibodies | F | 14 days | RIPL Porton Down |
| Toxoplasma B1 PCR | F | 14 days | Swansea ref lab |
| Coccidioides antibodies | F | 14 days | Bristol Mycology PHE |
| <i>Tropheryma whippellii</i> PCR | F | 14 days | GOSH |
| Campylobacter serology | F | 14 days | LSHTM |
| Yersinia antibodies | F | 14 days | GBRU Colindale PHE |
| Leptospira DNA detection | F or Urine | 14 days | RIPL Porton down |
| <i>H. pylori</i> culture (biopsy) | UC (in saline) | 21 days | |

Other referrals are available on request.

HSL Parasitology

HSL's Department of Clinical Parasitology serves as a National Parasitology Reference Laboratory. It services requests from general practitioners, the UK Health Security Agency (UKHSA) and medical laboratories in the NHS and private sector. The department has an international reputation, and provides a parasitology service to clinicians and laboratories worldwide.

We offer a wide range of investigations including diagnosis and identification of parasites in clinical material, diagnosis of human parasitic disease by immunological methods in addition to culture of parasitic organisms and detection of parasitic genomic material from clinical samples. The Department processes over 36,000 requests per annum.

A 24-hour service for microscopic diagnosis of malaria, trypanosomiasis and gastrointestinal amoebiasis (via hot stools) is available.

We also offer guidance regarding the appropriateness and timing of tests as well as a clinical advice service covering result interpretation and patient management.

The department is situated in two purpose built laboratories. Sample reception and urgent blood films for malaria and African trypanosomiasis diagnosis, as well as hot stool examination for intestinal amoebiasis are performed in the Mortimer Market Building. All other diagnostic services are carried out in the Halo Building at 1 Mabledon Place.

Routine access to the laboratories is restricted to the laboratory staff, with controlled entry for visitors.

HSL Parasitology is a UKAS Accredited Medical Laboratory No. 9702.

Our remit is:

- To provide a comprehensive diagnostic, identification and advisory service for clinical and laboratory staff on human parasites and the diseases they cause.
- To develop, evaluate and advise on new parasite diagnostic techniques.
- To produce epidemiological data for UKHSA.
- To liaise with other diagnostic and research parasitology laboratories in the UK and overseas, so that best practice is shared globally.

Our services:

- **Diagnosis and identification of parasites in clinical material.** Examples of this service include:
 - Identification or confirmation of identity of ova, cysts, larvae and worms in faeces, tissues, urine and other samples. The department aims to provide a 24 hour turnaround time within the working week for such specimens. If histology is required the sample will be dealt with in conjunction with a histopathologist.
 - Identification of malaria parasites in thick and thin blood films. The department aims to provide a 2 hour turnaround time within the working week, for these specimens. Communication with the laboratory before the specimen is dispatched is recommended for urgent samples.
- **Diagnosis of human parasitic diseases by immunological methods:** Immunological diagnosis of the following infectious diseases is available upon request: amoebiasis, babesiosis, cysticercosis, fascioliasis, filariasis, echinococcosis (hydatid disease), leishmaniasis (visceral only), malaria, schistosomiasis, strongyloidiasis, toxoplasmosis, trichinosis, trypanosomiasis (South American and African).
- **Culture of *Leishmania* from clinical material by prior arrangement:** Culture of *Leishmania* from clinical material can take up to 3 weeks. Prior arrangement is advised to obtain the most efficient service.
- **PCR assays:** PCR assays for *Leishmania*, Babesia, Microsporidia, the triple assay for *Entamoeba histolytica*, *Giardia* and *Cryptosporidium*, free-living amoebae and detection of subpatent (repeatedly slide negative) malarial infections are available on request.
- **Advisory service:** We provide an advisory service on the investigation of patients for parasitic disease, the appropriateness of tests, their timing and interpretation together with advice on treatment (see above). Information regarding this service can normally be provided by telephone, fax or email.

Staff /Key personnel

CLINICAL STAFF

| | | |
|-------------------------|--|--|
| Dr Laura Nabarro | Consultant Parasitologist and Clinical Lead for Parasitology | laura.nabarro@nhs.net |
| Dr Gauri Godbole | Consultant Microbiologist and Parasitologist | |
| | Specialist Registrar (on rotation) in Parasitology | |

LABORATORY STAFF

| | | |
|-----------------------------|--|--|
| Dr Spencer Polley | Scientific Lead for Parasitology | Spencer.Polley@hslpathology.com |
| Ms P Lowe | Serology Section Head (BMS 8a) | |
| Mrs Rashmita Bodhani | Microscopy & PCR Section Head (BMS 8a) | |

Laboratory hours

Information and advice is available from staff in the Department of Clinical Parasitology within normal working hours (0900–1700 Monday to Friday).

General enquiries

Phone +44 (0)20 7307 9400 (switchboard) and, when connected, ask for one of:

- Parasitology microscopy
- Parasitology serology
- Dr Spencer Polley (Scientific Lead)
- Parasitology medical staff

For healthcare professionals seeking advice regarding services offered by the Department of Clinical Parasitology or the suitability and transport of specimens, as well as test results please contact the Scientific Lead or appropriate laboratory section.

For clinical enquiries including appropriate test section, interpretation of results, or patient management please contact the Consultant Parasitologist or Parasitology Registrar (your call will be transferred to the laboratory team if they are unavailable).

Regrettably, the Department of Clinical Parasitology is unable to offer clinical advice directly to members of the public. Patients are advised to contact their GP in the first instance or follow the advice available on the Hospital for Tropical Diseases website if unwell following travel.

<http://www.thehtd.org/emergencies.aspx>

Please note: the Department will only release test results to recognised health care providers. It is unable to release results to members of the general public, patients or their friends and family.

We are always happy to receive feedback on the quality or scope of service offered. Please send to spencer.polley@hslpathology.com.

Urgent requests during normal hours

If a result is likely to have a direct and immediate impact on patient care, we will endeavour to process the test as quickly as possible. Please contact the laboratory to advise them of any such urgent sample using the following number:

Phone 020 7307 9400 (switchboard)

When connected, ask for one of:

- Parasitology microscopy
- Parasitology serology

HSL Parasitology

A responsible person (and deputy) capable of accepting and transmitting the result(s) in the submitting organisation must be identified at this time, along with a suitable contact number. The results of urgent tests will be telephoned by a senior member of staff to the identified person (or deputy) in the submitting organisation as soon as the result is verified.

Out of hours service

For out-of-hours urgent malaria/hot stool/African trypanosomiasis diagnosis only, please call +44 (0)845 155 5000 or +44 (0)20 3456 7890 and ask for the on-call Parasitologist.

For urgent out-of-hours advice on clinical matters, please phone switchboard (020 3456 7890) and ask to be transferred to the duty tropical medicine SPR.

Emergency On-call Service

A 24-hour, 7-day service is provided for urgent diagnosis of malaria, trypanosomiasis and intestinal amoebiasis (via hot stools). See above.

Parasitology specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

Types of specimens

Diagnosis of parasitic infection may be made by direct examination of a clinical specimen to identify the presence of a parasite. Indirect methods for parasite detection (such as serology) are also available for many parasitic infections.

Faeces, blood and sera constitute the majority of samples received for analysis. Other samples include adhesive tape smears, urine, semen, skin snips, tissue biopsies, liver aspirates, CSF, vitreous humour and corneal scrapes. Additionally, organisms suspected of causing parasitic infection, such as whole worms or arthropods can be examined.

Please send separated serum rather than whole blood for routine serology requests (to prevent lysis of sample if delayed in post). Plasma may be processed in a limited number of assays if not other sample type is available (please contact the Department of Clinical Parasitology for further information).

If you are uncertain of the type(s) of specimen(s) you should submit for analysis, telephone prior to sending the sample, in order that you can discuss the appropriateness of the specimen with a senior member of staff from the Department of Clinical Parasitology.

Labelling and packaging

Label all samples clearly with hospital number, name, and date of collection.

Location, consultant code/name, doctor's name, bleep/extension and test(s) required in addition to the patient details above should be put on the request form.

Specimens MUST be packaged according to Packing Instructions P650 and UN3373 requirements. Refer to the most up to date information on the HSE website (<http://www.hse.gov.uk>).

The outside must be marked conspicuously with:

'BIOLOGICAL SUBSTANCE, CATEGORY B' or **'BIOLOGICAL SUBSTANCE, CATEGORY A'** as appropriate.

It is essential that such substances are properly packed and labelled and appropriate instruction and protection provided to the carrier(s).

The sender is responsible for ensuring the health and safety of any employee or taxi driver that is used to transport samples to the Parasitology laboratory.

Safety

Current local and national guidelines must be followed to avoid needle stick injuries or accidental exposure to blood and blood-contaminated body fluids of those persons taking, transporting and processing the samples.

Any accident should be reported at once to your immediate superior as urgent action may be required; please refer to your local Safety Policy/Infection Control guidelines.

Ensure that the sample is correctly packed and that neither the request form nor the outside of the container should be contaminated with the sample (see below).

Ensure that the container is correctly sealed. All specimens from human sources must be regarded as potentially infectious.

High risk samples should be appropriately labelled (see below).

Hazardous specimens

Any specimens from known or suspected cases of hepatitis, tuberculosis, Viral Hemorrhagic Fever (VHF – see below) or HIV must be clearly identified as a 'RISK OF INFECTION'. Refer to the most up to date information on the HSE website for guidance (<http://www.hse.gov.uk>) for list of ACDP categorised pathogens.

Spillage of body fluids/leaking containers may necessitate the rejection of the specimen. If this occurs, a member of the Department of Clinical Parasitology staff will inform a responsible person in the submitting organisation by telephone and advise that a request for a repeat sample be made.

The sample will be booked, cancelled and then reported to provide evidence of this activity.

Parasitology specimens

Transport to the Laboratory

Specimens are received (by a number of routes, including: Royal Mail post, DX, hospital van, taxi, or by courier) at the Mortimer Market laboratory. A regular van delivery and pickup of specimens between local centres is maintained by the TDL and UCLH Transport departments.

If specimens are to be brought to the Mortimer Market laboratory personally by medical or nursing staff, they must be carried in an approved container for transport.

The Department of Clinical Parasitology is unable to receive samples sent by members of the public that are not accompanied by a request form from an approved laboratory, medical practitioner or health care provider.

See also Request Procedures below.

Postal address

Send your specimens, together with an official request form or signed letter containing as much clinical information as is deemed necessary and requesting the service(s) required to:

The Department of Clinical Parasitology
The Hospital for Tropical Diseases
3rd Floor Mortimer Market Centre
Mortimer Market
London WC1E 6JB

Dx Number: DX 6640701
Exchange: TOTTENHAM CT RD 91 WC

We would ask that your request form has an address, a contact phone number, sample time and date added to the patient identifiable information and travel history.

Bespoke request forms can be obtained from spencer.polley@hslpathology.com, these will ensure the correct booking of your request and resulting in a timely manner. See below

Please note: specimens sent for diagnosis or further investigation to a clinical laboratory must comply with the conditions set down in the Post Office Regulations governing the transport of pathological specimens. For insurance purposes, the value of a routine specimen is not likely to exceed £1 sterling.

Specimens which are known or suspected to contain Hazard Group 4 pathogens should not be sent by post (see www.hse.gov.uk/pubns/misc208.pdf for a list of group 4 pathogens)

Sample rejection criteria

Sample rejection criteria would include the following (although testing of specific samples may be done upon consultation with the Clinical Lead):

- Wrong sample type
 - Plasma instead of serum or EDTA blood for most serology tests (unless discussed beforehand with the Parasitology Clinical Lead).
 - Blood samples other than Citrate blood for Microfilarial microscopy
 - Blood samples other than EDTA blood for malaria microscopy and PCR
 - Peripheral blood for Leishmania microscopy and PCR (except where specifically agreed with the Clinical Lead)
- Sample incorrectly stored/treated
 - Refrigerated stool sample for stool culture
 - Fixed sample for Leishmania culture (PCR will be performed)
 - Fixed sample for stool PCR (Microscopy will be performed)
- Contaminated or broken container/slide
 - Container contaminated due to leaking sample.
 - Container/slide poses safety risk due to breakage.
- Insufficient sample volume (especially for Strongyloides Culture which requires around 20ml of stool)
- Heavily lipemic or hemolyzed serum sample.
- Sample delivery delayed beyond viable processing time.
 - 15 minutes for Hot Stool sample
 - 24 hours for Trypanosomal blood microscopy
- Sample unaccompanied by request form or accompanied by an incorrect or incorrectly filled out request form. Such errors would include lack of specific tests requested. Please ensure that suitable travel history is completed as specified by individual tests (such as African and South American Trypanosomiasis).

Retention of Samples

Please note that we do not keep all samples once tested, so if extra tests are required please phone the laboratory at the earliest opportunity to request the additions. Please see below for approximate sample retention times:

Standard retention times for samples

Serum and CSF supernatant for serology tests:

2 months unless specifically requested to be saved (or found to be positive), although CSFs are normally kept as long as space allows.

Citrated blood for filarial microscopy:

Discarded after filtration.

EDTA Blood for microscopy: 7 days.

Body fluids inc semen, Aspirates, Duodenal and jejunal aspirates, Cyst fluids, Stool:

Excess sample stored 14 days after final report produced by Parasitology Laboratory.

Bronchoalveolar Lavage, Sputum, Urine, Perianal swab: Processed sample stored 14 days after final report produced by Parasitology Laboratory (although sample may be altered by processing).

Skin scrapes, Skin snips, Swabs, Rectal scrapes, Rectal snips, Sellotape slide: Discarded after processing and testing.

Biopsies, Bone marrow, Slit skin smears: 6 months (unless all sample used in testing).

Ectoparasites, Adult worms: 1 year.

Tapeworm Segments: 48 hours after final report produced by Parasitology Laboratory.

Send away sample (including Ticks): Not kept (sent to ref lab for further ID).

Transplant Donor Samples: If clearly labelled, these are stored for 10 years.

Pre-transplant Recipient Samples: If clearly labelled, these are stored for 30 years.

Request procedures

See page 14 for general information on request procedures.

Where possible, use a Parasitology request form personalised to your location. A personalised request form will have the code assigned to your laboratory or practice; this ensures expeditious processing of the specimen and ensures the report is returned to the requesting address.

If a laboratory would like a copy of the new Parasitology request form please email the Scientific Lead providing the laboratory address, responsible person to whom results are to be sent (where appropriate), telephone and fax number using the following email address:

spencer.polley@hslpathology.com

Request forms can be dispatched to you by prior arrangement. Use a separate form for each specimen type. Personalised request forms will ensure your tests are booked in correctly and you receive the results in a timely manner. Complete all sections of the form using a ball-point pen or ink. Mark clearly the name of the responsible person (and deputy where appropriate) to whom results are to be sent.

Please give complete patient identification and relevant clinical details, including risk category and travel history. This information is needed to help determine which special precautions are required and which tests are to be performed. If you use your own form, please include your address and a contact telephone number that we can use in case of a clinically urgent result.

The test requestor must be an authorised person, not a member of the public.

The recipient of the results must be a recognised laboratory, medical practitioner or health care provider.

Processing times for different specimens vary according to clinical priority, as does the frequency of individual tests.

Clinically urgent requests will be given priority and the results telephoned to you by a senior member of staff at the earliest opportunity.

Reporting times

The reporting time is defined as the period from the receipt and booking in of a specimen to the time the report is issued to the individual requesting the test.

Clinically important requests will be given priority and the results telephoned to you at the earliest opportunity.

A table listing the range of tests for parasitic diseases that are undertaken in the Department of Clinical Parasitology is available as a separate turnaround times document.

Microscopy turnaround times

Within the working week, we aim to provide a 24-hour turnaround time for the majority of microscopy tests, although some tests have an official turn-around-time which is longer than this period. The majority of microscopy tests can be performed and reported by telephone within 24 hours of receiving an urgent specimen if prior notice is given.

PCR turnaround times

It is most economical to carry out molecular tests in batches and, in general, molecular tests are not necessarily performed as soon as a specimen is received (except for the diagnosis of Free Living Amoebae). Most tests are batched weekly, thus when tests are carried out at the Department of Clinical Parasitology, written reports may not be available for eight to 21 days after the specimen has reached the laboratory depending upon the assay type. The extended period is to allow for required reflex testing such as species identification where this would be of clinical importance.

Serology turnaround times

It is most economical to carry out serological tests in batches and, in general, serological tests are not necessarily performed as soon as a specimen is received. Most tests are batched weekly, thus when tests are carried out at the Department of Clinical Parasitology, written reports may not be available for 8 days after the specimen has reached the laboratory. The exception to this is Amoebiasis, which is tested for on a daily basis.

When several tests are to be carried out on the same specimen, urgent tests such as Amoebiasis will be booked on a separate number to facilitate rapid reporting.

If urgent results are required or if you want to know when a particular result will be available, please contact the relevant department via Switchboard.

Samples sent to external reference laboratories

The following tests may be referred to external laboratories for primary or confirmatory testing:

- Angiostrongylus, Anisaksis, Paragonimus, Gnathostoma serology
- Insects (for further identification) and malaria PCR
- Ancathamoeba kerrititis samples.

We would hope for a 28-day turnaround from sending of a sample to another reference laboratory to receiving a result and reporting it on our computer system.

Results

Normal reporting practice

Reports are currently issued in either paper format (via postal system) or Encrypted PDF reports via email and GP link for local GPs.

Where possible the Department would prefer to issue reports as encrypted PDFs via email system to ensure the speed and security of data delivery (including compliance with GDPR).

Encrypted PDFs are sent as soon as the results are ready, and ensure the fastest routine reporting system available.

If you would like to set up email reporting you will need an email address that is regularly monitored. Please email Spencer.Polley@hslpathology.com

Telephoned results

Results are telephoned under the following circumstances:

- If it is thought that a result might lead to an immediate change in patient management (including positive Malaria films, Positive Leishmania results, Positive African Trypanosomiasis results (HAT), Positive Neuroschistosomiasis).
- If further information is required to decide whether the submitted sample should be processed further.
- If a telephoned result has been requested.
- All on-call results.
- Results will usually be telephoned by the Specialist Registrar or by the individual who has performed the test, but if clinical advice is likely to be needed the call may be made by the Consultant Parasitologist or Deputy. If a telephone number, telephone extension or bleep number has been indicated on the report, the call will be made to that number.

Although written and email reports are issued as soon as they are available, the laboratory is happy to make results available by telephone when these would be of clinical assistance. Users are asked to use this service only when necessary as it does delay the routine work of the laboratory.

The use of encrypted PDF reports via email offers a significant improvement in the speed of returning results to our users and has been found to largely negate the requirement for telephoning the department.

Storage of results

All records are currently maintained in the department for a minimum period of ten years.

Information Governance Policy

Please note we are unable to fax results.

Advisory service

If advice is needed on the clinical interpretation of results by Clinical or Laboratory staff, the Consultant Parasitologist or the Specialist Registrar can be reached via the switchboard (see above). If the advice relates to a particular result, it is helpful if the clinical details and laboratory reference number are available.

For urgent out of hours advice on clinical matters please phone switchboard (020 3456 7890) and ask to be transferred to the duty tropical medicine specialist registrar.

Laboratory staff will not give out clinical advice.

Patients looking to book a clinical appointment or requiring clinical advice are advised to contact their GP initially or if acutely unwell following recent travel, please refer to the Hospital for Tropical Diseases Website: <http://www.thehtd.org/emergencies.aspx>

For further advice on the types of samples and containers appropriate for different tests please contact the relevant section – see above.

If you are unsure which of the above numbers is appropriate, please telephone either section and the Department of Clinical Parasitology staff will put you in touch with the appropriate section/ people.

Please note: Laboratory staff can only give out results to a recognised laboratory or medical practitioner and not members of the general public.

Tests for parasitic diseases and specimen requirements

Amoebiasis (*Entamoeba histolytica*)

Amoebiasis is caused by infection with *Entamoeba histolytica* which is transmitted primarily through the faecal-oral route. Symptoms may include: abdominal cramps, bloody diarrhoea or diarrhoea with mucus, nausea and vomiting, loss of weight and intermittent fever. Extra-intestinal amoebiasis can occur if the amoebae spreads to other organs, most commonly the liver where it causes amoebic liver abscess. Amoebic liver abscess often present with fever and right upper quadrant abdominal pain.

In patients with a travel or exposure history compatible with intestinal amoebiasis, it is advised that the following investigations are performed prior to starting immunosuppression or surgery for suspected inflammatory bowel disease: hot stool examination for trophozoites, PCR of stool for *E. histolytica*, amoebic serology and rectal scrapings/biopsies. Positive results should be discussed with a member of the Parasitology clinical team.

Detection of *Entamoeba histolytica*/*Entamoeba dispar* cysts and trophozoites by microscopy

- Sample type: **Standard stool sample** – cysts may be identified in stool samples, but *Entamoeba histolytica* and *Entamoeba dispar* cysts are indistinguishable by microscopy.
- Sample type: **Hot stool sample** – Examination for trophozoites requires that the stool is examined within 15 to 20 minutes of voiding. Stool samples for examination can be sent by conventional means so long as they arrive within this time frame. Please phone the laboratory to inform them of expected sample arrival in advance of submission.
- Sample type: **Rectal scrapings** – Microscopy for these samples must be arranged with the laboratory in advance.

Detection of *Entamoeba histolytica*, *Cryptosporidium* species and *Giardia intestinalis* by PCR

- Sample type: **Standard stool sample** must **NOT** be in any fixative as this may cause false negatives
- Sample type: **Liver aspirates** for the molecular test must **NOT** be in any fixative as this may cause false negatives (please note this test has not been validated for this sample type but will still be performed upon request).
- Sample type: **Duodenal biopsy or fluid** for the molecular test must **NOT** be in any fixative as this may cause false negatives (please note this test has not been validated for this sample type but will still be performed upon request).

This test offers several advantages over standard microscopy based diagnostics. The assay is significantly more sensitive (greater than ten fold improvement in the limit of detection for some species) than light microscopy. In addition, the assay is semi-quantitative and can therefore reveal detailed information on the response of a patient's parasite load to subsequent drug therapy.

For *Entamoeba histolytica*, the assay also has the advantage of being specific for this pathogen, and does not pick up morphologically related but non pathogenic cysts such as those of *Entamoeba dispar*.

Finally, the assay can be run on a much wider range of samples, such as biopsies and liver aspirates, as it does not rely on the presence of morphologically intact parasites, although the assay is not currently validated for anything other than stool samples.

Detection of antibodies to *E. histolytica* by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required (can be transported at room temperature).

The *Entamoeba histolytica* ELISA is an essential test in cases of suspected amoebic liver abscess (ALA). The reported sensitivity of this ELISA is 100% in patients suffering from an amoebic abscess. The specificity of this test is reported as: 96% in uninfected Swiss blood donors; 89% in patients suspected to have amoebiasis where the disease has been ruled out; and 80% in patients with other parasitic infections. Cross-reactivity mainly occurs in patients with leishmaniasis, malaria, filariasis and strongyloidiasis.

Amoebic serology may be negative in amoebic dysentery, especially in the early stage. If clinical suspicion remains, please send a further serum sample 2 weeks after the first sample. In addition, for all suspected cases of intestinal amoebiasis, faecal microscopy and PCR for *Entamoeba histolytica* should be performed.

Diagnosis of amoebic liver abscess is based on imaging plus serology. Amoebic serology can take up to 2 weeks to become positive in amoebic liver abscess. Therefore, a further serum sample should be sent if the first one is negative, if clinical suspicion remains. In the interim, empirical treatment with metronidazole or tinidazole should be considered. In cases of diagnostic uncertainty where liver abscess aspiration has been performed, please send an aliquot of the aspirate for *Entamoeba histolytica* PCR. Light microscopy alone is not adequate to confirm or exclude the presence of amoebae in liver abscess pus.

Babesiosis

Babesiosis is a tick borne parasitic infection caused by *Babesia microti* (commonly North America) and *Babesia divergens* (commonly Europe).

Many people who are infected with *Babesia microti* are asymptomatic. Patients may experience nonspecific flu-like symptoms such as fever, chills, sweats, headache, body aches, loss of appetite, nausea and/or fatigue. In severe cases it may result in hemolytic anemia, blood clots, organ failure, unstable blood pressure, and in very rare cases death may occur.

Detection of *Babesia* spp. by microscopy

- Sample type: Please send a **minimum** of 2ml of **EDTA anti-coagulated blood**. Diagnosis is via microscopic examination of thick and thin blood films.

Detection of *Babesia* spp. by PCR

- Sample type: Please send a **minimum** of 0.5ml of **EDTA anti-coagulated blood**. PCR may be performed on the same sample that is sent for microscopic examination of thick and thin blood films if required

Detection of antibodies to *Babesia microti* by serology

Please note that detection of antibodies to *Babesia microti* is no longer available.

Cryptosporidium spp

Cryptosporidiosis is an intestinal infection resulting from ingestion of oocysts of the coccidian parasite *Cryptosporidium* spp. (including *Cryptosporidium parvum*, *canis*, *hominis* and *felis*). It is the second most commonly diagnosed intestinal parasite in the UK and its oocysts are resistant to chlorine. It may be associated with swimming or drinking infected water as well as contact with infected lambs and calves when visiting farms. Symptoms commonly include severe watery diarrhea. It is most common in children between one and five years of age, and in people who are immunocompromised, where symptoms may be more severe.

Detection of *Cryptosporidium* spp. oocysts by microscopy

- Sample type: **Standard stool sample** – Oocysts may be identified in stool samples, by modified Zn staining

Detection of *Cryptosporidium* spp. by PCR

- See section on Detection of *Entamoeba histolytica*, *Cryptosporidium* species and *Giardia intestinalis* by PCR above.

Detection of *Cryptosporidium* spp. by serology

- Serology is not available for the detection of this parasite.

Cyclosporiasis

Cyclosporiasis is an intestinal illness resulting on average 7 days after the ingestion of sporulated (requiring temperatures between 22 to 32 degrees) *Cyclospora cayetanensis* oocysts via contaminated food or water. Direct fecal-oral transmission can not occur. Symptoms generally involve watery diarrhea, and sometimes non-specific systemic symptoms (such as headache, low-grade fever, malaise). Malabsorption is a relatively common finding in patients with *Cyclospora cayetanensis*.

Tests for parasitic diseases and specimen requirements

Detection of *Cyclospora cayetanensis* oocysts by microscopy:

- Sample type: **Standard stool sample** – Oocysts may be identified in stool samples, by modified Zn staining. Up to three samples may be necessary due to the intermittent excretion of this parasite.

Detection of *Cyclospora cayetanensis* oocysts by PCR:

- Sample type: **Standard stool sample** – The STAT-DX system may be used to determine the presence of *Cyclospora cayetanensis* DNA in fecal samples where appropriate. Please contact the Department of Clinical Parasitology for further information if you feel this is required. Please do NOT send samples in fixative for this assay.

Detection of *Cyclospora cayetanensis* oocysts by serology:

- Serology is not available for the detection of this parasite.

Cystoisosporiasis

Cystoisosporiasis is an intestinal infection caused by the coccidian parasite *Cystoisospora belli* (formerly *Isospora*). Infection is transmitted faeco-orally and symptoms are typically of profuse watery diarrhoea with or without systemic upset. Acalculous cholecystitis is also associated with infection.

Detection of *Cystoisospora belli* oocysts by microscopy:

- Sample type: **Standard stool sample** – Oocysts may be identified in stool samples, by modified Zn staining. Up to three samples may be necessary due to the intermittent excretion of this parasite.

Detection of *Cystoisospora belli* oocysts by PCR:

- PCR is not available for the detection of this parasite.

Detection of *Cystoisospora belli* oocysts by serology:

- Serology is not available for the detection of this parasite.

Cysticercosis (larval *Taenia solium* infection) and Taeniasis (Adult *Taenia* Spp. Infection)

Cysticercosis is a disease caused by the larval stage of the pork tapeworm (*Taenia solium*). Infection is contracted when humans accidentally consume food contaminated with embryonated eggs of *Taenia solium*. Ingested larvae then disseminate throughout the body and form cysts within tissue (mostly commonly subcutaneous tissue, the central nervous system and ocular tissue). Disease is a result of the presence of these cysts and the associated inflammation in tissue. Neurocysticercosis is the most severe form of the disease and may present with unexplained seizures, confusion or focal neurological deficit.

Taeniasis, caused by the presence of the adult stage of either the beef tapeworm (*Taenia saginata*) or the pork tapeworm (*Taenia solium*) within the human gastrointestinal tract. Disease is contracted via ingestion of meat (beef or pork respectively) containing cysticerci. These larvae then mature in the human gut. Infection is often asymptomatic, but patients may experience non-specific gastrointestinal upset and may also visualise segments (proglottids) of the adult worm in their stool.

Detection of *Taenia* spp. ova and segments by microscopy

- Sample type: **Standard stool sample/tapeworm segment(s)** must NOT be in any fixative. If sending segments for identification (see also HUMAN HELMINTHIASIS for identification of worms) **HIGH RISK** stickers must be used if *Taenia solium* is suspected.

Microscopy of stools for ova is recommended in these cases but cannot differentiate to species level.

Detection of antibodies to *Taenia solium* by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required, CSF testing is also available (please inform laboratory before hand and provide as much CSF as you are able to spare). Samples can be transported at room temperature.

A serological service (EITB Immunoblotting) is provided.

Intestinal infections with *Taenia solium* or *saginata* (taeniasis) do not usually result in positive *Taenia* serology.

Detection of *Taenia solium* antigen

- Sample type: A **minimum** of 0.5ml of **serum** is required, CSF testing is also available, please provide as much CSF as you are able to spare (minimum volume for the test is 0.2ml).

For individuals with a high suspicion/confirmed infection with *Taenia solium*, detection of circulating cysticercal antigens is also available. This test detects the presence of antigens secreted by live cysticerci within the patient.

Ectoparasites

Ectoparasites are those parasites which remain external to, or in the surface layers of skin of the human body. They may cause pathology due to reaction against the parasite by the host immune system, destruction of tissue, or the introduction of another pathogenic agent by their feeding.

Ectoparasites include: insects such as *Pediculus humanus capitis* (head lice) and insect larvae such as *Dermatobia hominis* (human botfly); arachnids such as mites including *Sarcoptes scabiei* (causative agent of scabies) and ticks such as those from the family *Ixodidae*. Please note this is not an exhaustive list.

Diagnosis of Ectoparasites by microscopy

Sample types may include:

- The putative parasite itself in a small sealed container. This may be embedded in host tissue where the parasite has been surgically removed, such as occurs with *Tunga penetrans* (Jigger flea)
- Eggs attached to hair (eg. head lice) in a small sealed container
- Scrapings of skin from the location of a putative parasitic infection (eg. scabies). For skin scraping, ideally the sample should be scraped onto a black dermapak before transport

Samples may be referred on to the London School of Hygiene and Tropical Medicine for further analysis.

Enterobiasis

Enterobiasis is caused by intestinal infection with the helminth *Enterobius vermicularis*, also known as threadworm or pinworm. Infection occurs following the ingestion of eggs. The females will migrate to perianal area to lay eggs and may cause perianal pruritus (itching) such that auto-innoculation can occur following scratching of the perianal area. Vulvovaginitis may also occur in females. Enterobiasis is a common infection particularly in children under 10 years of age and may be asymptomatic.

Detection of *Enterobius vermicularis* by microscopy

- Sample type: **Adhesive tape smear** (Sellotape, Scotch tape (i.e. clear transparent adhesive tape)) taken first thing in the morning from the perianal skin and attached sticky side down to a microscope slide, is the appropriate specimen for detecting *Enterobius vermicularis* ova.
- Sample type: **Standard stool sample** – adult worms and/or ova may be present in stool samples, a negative stool result for worms and ova does not exclude the diagnosis because the ova are laid on the perianal skin.

Detection of *Enterobius vermicularis* by PCR

- PCR is not available for the detection of this parasite within the department.

Detection of *Enterobius vermicularis* by serology

- Serology is not available for the detection of this parasite.

Fascioliasis

Fascioliasis is caused by *Fasciola hepatica* and *Fasciola gigantica*. Ruminants are the natural hosts of these liver flukes. Human infection occurs following consumption of freshwater plants contaminated with the encysted metacercariae (commonly watercress and khat). Disease is typified by fever and abdominal pain with a marked eosinophilia during the acute phase. Occasional sporadic outbreaks of *Fasciola hepatica* have occurred in the UK, although the majority of cases are imported.

Fasciolopsiasis is a similar disease caused by the fluke *Fasciolopsis buski*.

Detection of *Fasciola hepatica*, *Fasciola gigantica* and *Fasciolopsis buski* by microscopy

- Sample type: **Standard stool sample** – ova may be present in stool sample but are often scanty and may not be found in up to 30% of cases.
- Sample type: **Whole worm** – Please send fresh and do **NOT** add any fixative.

Tests for parasitic diseases and specimen requirements

Detection of *Fasciola hepatica* by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required (can be transported at room temperature).

Serology can be helpful and an IFAT test for antibody is available. The IFAT (screening titre 1/32) has given reliable results. It is species specific. In proven *Fasciola hepatica* infections the titre is in the order of 1/128. Serology is the best method of diagnosis in the early stage of the infection.

Patients with upper abdominal pain, thought to be hepatic, eosinophilia and fever, should be investigated.

Filariasis

Lymphatic filariasis, onchocerciasis and loiasis are the three common forms of filariasis in humans.

The majority of lymphatic filariasis is caused by two species of filarial nematode (roundworm), *Wuchereria bancrofti* and *Brugia malayi*. Infection is transmitted via the bite of an infected mosquito (*Culex* spp). Adult worms settle in the lymphatics where they cause mechanical obstruction and scarring. Chronic infection results in the characteristic lymphoedema with lichenification of the overlying skin. The microfilarae (juvenile form) are detectable in the peripheral blood at night time.

Onchocerciasis is an infection caused by the filarial nematode *Onchocerca volvulus*. The worm is transmitted via the bite of *Simulium* spp (blackflies) which are found near fast flowing bodies of freshwater. Adult worms settle in subcutaneous tissue causing nodular swellings as well as other skin rashes. Microfilarae migrate around the body, including to the eye where they cause inflammation, which can lead to blindness. Onchocerciasis is the second most common infectious cause of blindness worldwide and is also termed River Blindness. Microfilarae are not detectable in peripheral blood but can be visualised in skin snips.

Loiasis is an infection caused by the filarial nematode *Loa loa*. The worm is transmitted via the bite of an infected deer fly (*Chrysops* spp). Often infection is asymptomatic, however loiasis may manifest with soft tissue swellings (Calabar swellings) and occasionally with the presence of a visible adult worm migrating across the subconjunctiva. Microfilarae are detectable in peripheral blood during the middle of the day.

The syndromes produced by the various species of filarial worms are usually associated with eosinophilia. A patient with an eosinophilia who has lived in, or visited, a filaria-endemic area might reasonably be tested for filariasis.

Detection of Filariasis (except *Onchocerca volvulus*) by microscopy:

- Sample type: 20 millilitres of **anti-coagulated blood (citrate tube)** are required so that the microfilariae can be detected by filtration. Day blood (for *Loa loa*) should be taken between 12pm (noon) and 2pm local time and night blood (for *Wuchereria bancrofti* or *Brugia malayi*) at 12am (midnight). Samples should be kept at room temperature until processed.

Correct blood collection times for diagnosis of human filariasis

| | Periodicity | Collection Time (Hr/Local) |
|-----------------------------|---------------------------------------|----------------------------|
| <i>Wuchereria bancrofti</i> | Nocturnal (except in Pacific Islands) | 2400-0200 |
| <i>Brugia malayi</i> | Nocturnal | 2400-0200 |
| <i>Loa loa</i> | Diurnal | 1200-1400 |
| <i>Mansonella perstans</i> | No periodicity | Anytime |
| <i>Mansonella ozzardi</i> | No periodicity | Anytime |

With the exception of *Onchocerca volvulus*, a definitive diagnosis of filariasis is usually made by the demonstration of microfilariae in the peripheral blood.

Detection of *Onchocerca volvulus* by microscopy

- Sample type: *Onchocerca volvulus* is diagnosed by demonstration of microfilariae in **skin snips**. Please contact the department before sample is taken for information about sample transport and to let the laboratory know the sample when the sample will be arriving.

Detection of filariasis by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required (can be transported at room temperature).

A filaria ELISA, using *Brugia pahangi* as antigen is used as a 'generic' screening test. A negative result does not exclude the diagnosis and this is especially so with onchocerciasis.

The filaria ELISA is a non-specific screening test that is positive in many types of filariasis and cross reacts in cases of strongyloidiasis. It is most useful in the diagnosis of TPE (Tropical Pulmonary Eosinophilia) where high antifilarial antibody levels are required to make the diagnosis. Positive results are reported at Levels 1 to 9. Levels 1 and 2 are regarded as weak positives; Levels 5 and over are strong positives.

Reactive symptomatic cases with moderate eosinophilia tend to give high level positives. Non-reactive cases, which may be asymptomatic though microfilariae are present, give low levels of positivity and may be negative. Known causes of false positive results are *Strongyloides*, Hookworm (about 50% of cases) and occasionally *Ascaris* infection. We are unable to determine the species of Filaria infections using our ELISA test. This may be done if microfilariae are seen in a blood film, or by staining the microfilariae obtained by filtration.

Free-living Amoebae

This section on free living amoebae refers to human infection with any of the following amoebae: *Naegleria fowleri*, *Acanthamoeba* spp. and *Balamuthia mandrillaris*.

Naegleria fowleri is a free living amoeba found in warm, fresh water. Infection is contracted via inhalation of infected water, often during recreational activities. It causes primary amoebic meningoencephalitis which is a rapidly progressive, haemorrhagic meningoencephalitis. Symptoms resemble bacterial meningoencephalitis with fever, headache, altered mental state, seizure and coma. The disease follows a fulminant course with an exceptionally high associated mortality. Trophozoites can be visualised in the CSF.

Acanthamoeba spp and *Balamuthia mandrillaris* cause granulomatous amoebic encephalitis. Infection is more common in immunocompromised hosts and acquisition of the amoeba is via inhalation of the cysts from the environment. The syndrome follows a sub-acute course with a headache, low grade fever, focal neurological deficit and behavioural change, typically evolving over a period of weeks and months. Examination of CSF or brain tissue is usually required for diagnosis.

If infection with free living amoebae is suspected, please discuss the case with the Parasitology consultant or registrar.

Diagnosis of primary amoebic meningoencephalitis or granulomatous amoebic encephalitis by Microscopy

- Sample type: **CSF** – please send a fresh sample (as much as you are able to spare) without fixative for microscopy. CSF microscopy may detect *Naegleria fowleri*, but is much less sensitive for the detection of *Acanthamoeba* or *Balamuthia mandrillaris*.

Diagnosis of primary amoebic meningoencephalitis or granulomatous amoebic encephalitis by Culture

- Sample type: **CSF** or **brain tissue** without fixative and received in the laboratory as soon as possible.

Culture is available for *Naegleria fowleri* and *Balamuthia mandrillaris* on discussion with the Consultant Parasitologist or Parasitology registrar.

Diagnosis of primary amoebic meningoencephalitis or granulomatous amoebic encephalitis by PCR

- Sample type: **CSF** or **brain tissue** without fixative and received in the laboratory as soon as possible.

A PCR is available upon discussion with the Consultant Parasitologist or registrar for the diagnosis of *Naegleria fowleri*, *Balamuthia mandrillaris* and *Acanthamoeba* spp.

Molecular detection of free living amoebae is not currently validated as a clinical test or covered under our accreditation by UKAS. Please phone the Consultant Parasitologist or registrar to discuss its relevance to patient management.

Diagnosis of amoebic keratitis by culture and PCR for *Acanthamoeba* spp.

Samples should be referred directly to:

Diagnostic Parasitology Laboratory
The London School of Hygiene and Tropical Medicine,
Keppel Street, London WC1E 7HT

DX address: HPA Malaria Reference Lab
DX 6641200
Tottenham Crt RD92WC

Tel: +44 (0)207 927 2427
Fax: +44(0)207 637 0248

This is best diagnosed by sending **corneal scrapings** suspended in a small volume (0.2ml) sterile saline or sterile distilled water.

Tests for parasitic diseases and specimen requirements

They can also perform culture from **contact lenses or fluids**; isolation from these specimens, whilst suggestive, does not necessarily implicate the amoeba as causing the patient's symptoms.

Request forms can be found at:
<http://www.parasite-referencelab.co.uk/>

Giardiasis (See also intestinal protozoa)

Giardiasis is caused by the single celled parasite *Giardia intestinalis*. Infection occurs following the ingestion of cysts in contaminated water, food or via direct person to person contact. Infection may be asymptomatic or present with abdominal pain, bloating, nausea, flatulence, diarrhea and steatorrhoea. Giardiasis may also lead to temporary lactose intolerance. It is the most commonly diagnosed intestinal parasite in the UK.

Drug-resistant *Giardia intestinalis* is increasingly recognised as a cause of treatment refractory disease. If treatment failure due to drug resistance is suspected, please discuss investigation and management with the Parasitology consultant or registrar.

Detection of *Giardia* by microscopy

- Sample type: **Standard stool sample** (for cyst examination) – this does not need to be fresh as cysts are robust. *Giardia* trophozoites are only detectable when stools are examined within **4 hours of voiding**. *Giardia* cysts are frequently excreted intermittently so that a minimum of **six stools** may be required for microscopic exclusion.
- Sample type: **Duodenal or jejunal aspirate** – *Giardia* trophozoites may be demonstrated in aspirated duodenal or jejunal fluid if examined within 4 hours (cysts will last longer but may not be present).

Detection of *Giardia* by PCR

- Sample type: **Standard stool sample** – molecular diagnosis via the multiplex stool parasite PCR (including *Cryptosporidium* species, *Giardia intestinalis* and *Entamoeba histolytica*) offers several advantages over standard microscopy based diagnostics. The assay is significantly more sensitive (greater than ten fold improvement in the limit of detection for some species) than light microscopy.

Stool samples for the molecular test must **NOT** be in any fixative as this may cause false negatives.

- Sample type: **Biopsies, duodenal or jejunal aspirate fluid and other sample types (following discussion with staff)** – divergent sample types may be analysed for the presence of *Giardia* DNA where microscopy would be inappropriate. Please contact Clinical Parasitology staff for further information. Please note that we have not validated this test for sample types other than stool.

These samples must **NOT** be in any fixative as this may cause false negatives.

Detection of *Giardia* by serology

- *Giardia* serology is no longer available, please send an unfixated stool sample for microscopy and PCR.

Hydatid disease (Echinococcosis)

Hydatid disease or echinococcosis is caused by infection with the cestodes (tapeworms) *Echinococcus granulosus* (cystic echinococcosis) and less commonly *Echinococcus multilocularis* (alveolar echinococcosis). Humans are infected via ingestion of embryonated eggs passed by the definitive host (dog or related carnivores). Oncospheres (invasive form) hatch in the gastrointestinal tract and migrate to tissue where large cysts form (most commonly affected organs are the liver or lungs). Infection is often asymptomatic and may be unrecognised for many years. Symptoms relate to direct mechanical pressure from the cysts or if the cyst leaks or ruptures, causing an anaphylactic reaction.

Echinococcosis should be considered in patients with a compatible exposure history and evidence of one or more cystic lesions with an organ (particularly the liver). Suspected cases should be discussed with the Parasitology consultant or registrar. Diagnosis requires a combination of serology, radiology and sampling of lesions.

Detection of hydatid disease by microscopy (*Echinococcus granulosus*)

- Sample type: **Aspirated cyst fluid, whole liver section, excised cyst or other fluids following putative cyst rupture (eg pleural fluid)**.

Aspiration of a cyst should be considered only after taking expert advice and, if felt to be indicated, should be conducted in a centre experienced in the management of hydatid disease. If viability testing is required the aspirate should be kept at room temperature and reach us with 24 hours.

Echinococcus multilocularis usually presents as suspected malignancy is diagnosed by a combination of imaging, serology and biopsy.

Detection of hydatid disease by serology (*Echinococcus granulosus* and *multilocularis*)

- Sample type: A **minimum** of 0.5ml of **serum** is required (CSF testing is available, please provide as much CSF as possible, along with a paired serum sample).

Serology is performed in two steps. An initial ELISA for *Echinococcus* spp. is performed. Serological cross-reactions, giving rise to false positives, can occur with sera from patients with other parasitic infections, notably larval cestodes and filarial worms, and with some neoplasms. False negatives may occur and are more common in the case of non-hepatic hydatid cysts.

A Western blot may also be performed to confirm the ELISA and to differentiate cystic from alveolar hydatid (if not possible based on radiological findings).

For watchful waiting of confirmed cases of *Echinococcus granulosus* or to determine patient response to surgical intervention and/or drug treatment an IgG2 subclass ELISA is available. Please contact medical staff for advice on this service.

Human Helminthiasis (worm identification)

Human heminthiasis includes infections with **Nematodes** (e.g. *Ascaris lumbricoides*, *Gnathostoma* spp., Hookworm, *Angiostrongylus cantonensis*, *Anisakis* spp., *Enterobius vermicularis*, *Trichinella* spp., microfilaria and *Toxocara* spp.), **Trematodes** (e.g. *Paragonimus* spp., *Fasciola hepatica*, *Clonorchis sinensis*) and **cestodes** (e.g. *Taenia* spp., *Dipylidium caninum*, *Diphyllobothrium latum* and Hydatid disease) – please note this is NOT an exhaustive list.

For specific information on individual helminth infections please refer to the relevant section(s) of this manual where relevant.

Detection/identification of human helminths of medical importance by microscopy

- Sample type: **Tapeworm segments for identification** (see also section on Cysticercosis) – please send in saline. **DO NOT** send in formalin or other fixative agent as this prevents identification beyond genus level.

HIGH RISK stickers must be used if *Taenia solium* is suspected.

- Sample type: **Other worms, part or whole** – please send as they are or in saline, **DO NOT** send in formalin or other fixative agent.
- Sample type: **Standard Stool samples** – please forwarded with minimum delay. (A minimum of two separate samples should be examined before a diagnosis is excluded.)

Detection/identification of human helminths of medical importance by Serology

- Serology in-house is available for Cysticercosis, Fascioliasis, Filariasis, Schistosomiasis, Strongyloidiasis, Toxocariasis, Trichinosis and Hydatid. Paragonimiasis, Angiostrongyliasis, Anasikiasis and Gnathostomiasis are referral tests and not conducted at the HTD. Please see individual sections of this user manual for information on these.

We are unable to provide serological diagnosis for other helminth infections.

Intestinal Protozoa (See also Amoebiasis, Cryptosporidiasis, cyclosporiasis, Giardiasis and Microsporidia)

For the major parasitic causes of human gastroenteritis, please see individual sections on Amoebiasis, Cryptosporidiasis, Cyclosporiasis Giardiasis and Microsporidia. In addition, non-pathogenic protozoa such as: *Entamoeba coli*, *Entamoeba hartmani*, *Entamoeba dispar* (indistinguishable from *Entamoeba histolytica* as cysts by morphology), *Iodamoeba buetschlii*, *Endolimax nana*, *Chilomastix mesnili* and *Blastocystis hominis* will also be reported if viewed by microscopy.

Diagnosis of intestinal protozoa by microscopy

- Sample type: **Stool samples** for the demonstration of trophozoites, cysts and oocysts should be forwarded with the minimum of delay (other sample types may also be analysed).

For further information on the diagnosis of intestinal protozoa by microscopy please refer to the relevant section(s) of this manual.

Tests for parasitic diseases and specimen requirements

Diagnosis of intestinal protozoa by PCR

- Sample type: **Stool samples** for the demonstration of trophozoites, cysts and oocysts should be forwarded **without fixatives** (other sample types may also be analysed).

PCR is currently available only for Giardiasis, Cryptosporidiasis, Amoebiasis and Cyclosporiasis. For further information on the diagnosis of these protozoa by PCR please refer to the relevant section(s) of this manual.

Diagnosis of intestinal protozoa by serology

For *Entamoeba histolytica* infection, serology gives very good results in cases of amoeboma. In amoebic colitis the test is positive, often at low titre, in about 75% of cases. In cyst passers it is often negative and in other cases it may be positive because of past infection. The test is therefore not suitable for the investigation of vague abdominal symptoms or as a routine check. For further information on the diagnosis of amoebiasis please refer to the relevant section of this manual.

For Giardiasis and other intestinal protozoal pathogens we are unable to offer serological investigation. Please send a stool sample for PCR and Microscopy – please refer to the relevant section(s) of this manual.

Leishmaniasis

Leishmaniasis is an obligate intracellular protozoal infection. Human leishmaniasis can be caused by multiple species of *Leishmania*, classically divided into Old World (Eastern Hemisphere) and New World (Western Hemisphere). It is transmitted by the bite of a sandfly and may be classified as Cutaneous, Mucosal (previously known as Mucocutaneous) and Visceral according to travel history and clinical presentation.

Cutaneous leishmaniasis is the most common form, resulting in skin nodules and often subsequent ulceration. Visceral leishmaniasis usually affects the spleen, liver, and bone marrow, and can be fatal if left untreated. Patients usually present with fever, weight loss, splenomegaly, hepatomegaly and pancytopenia. Mucosal leishmaniasis can be a sequela of cutaneous leishmaniasis acquired in Latin America (most commonly, but not restricted to, the sub-genus *L. Viannia*).

The different species are morphologically indistinguishable, but can be differentiated by other diagnostic techniques detailed below.

Please do not send unfixed samples over the weekend (it is better to store samples in the fridge over the weekend before sending to reduce bacterial/ fungal growth).

Please send a travel history with all specimens (this is essential for species determination).

Diagnosis of Cutaneous and Mucosal Leishmaniasis by microscopy

- Sample type: **Punch Biopsy** – Take from the edge of the lesion. Ideally placed in a small volume of sterile saline in a suitable sterile container (DO NOT FREEZE AND WHERE POSSIBLE AVOID FIXING SINCE THIS WILL AFFECT CULTURE AND PCR – see below).

If histology is required, please take a second biopsy, or cut original biopsy in half vertically through the epidermis and tissue. Put half in sterile saline for Parasitology and half in formal saline for histology.

- Sample type: **Slit skin smears**; Take from the edge of the lesion, onto a slide. Air dry and then fix with methanol.

Diagnosis of Visceral Leishmaniasis by microscopy

- Sample type: **Bone marrow or Splenic aspirate** – please provide two methanol fixed slides and a **small** amount (less than 1ml) of sample in a sterile EDTA tube (e.g. Vacutainer purple top).
- Sample type: e.g. **Biopsies** – Microscopy based diagnosis of Leishmaniasis may be performed on sample types other than bone marrow or splenic aspirate under consultation with the Department of Clinical Parasitology. Please phone for advice if considering such an investigation.

In cases of suspected visceral Leishmaniasis, an attempt should always be made to find *Leishmania* from aspirated/ trephine material (bone marrow or spleen) – contact laboratory for advice.

- Sample type: **Histology Sections** – if histology is required, please contact the Department of Clinical Parasitology so this may be actioned as a referral test.

Diagnosis of Cutaneous, Mucosal and Visceral Leishmaniasis by PCR

PCR can be used to detect (with very high sensitivity) and identify the species of *Leishmania* when an accurate travel history is provided. Contact microscopy section of laboratory for advice.

- Sample type: **Unfixed tissue** – see above for information on **Biopsies, Bone marrow or Splenic aspirate and Slit skin smears**. In addition *Leishmania* PCR may also be performed on additional unfixed samples such as **Vitreous fluid** and **BAL** under consultation with the Department of Clinical Parasitology. Please phone for advice if considering such an investigation.
- Sample type: **Fixed tissue** – please send at least 6 normal thickness sections in a small screw capped or Eppendorf (snap lip) tube.

The Fixation of tissue containing DNA is known to significantly decrease the sensitivity of PCR based diagnostics and therefore we request unfixed tissue where possible.

Diagnosis of Visceral and Mucosal Leishmaniasis by serology

- Sample type: a **minimum** of 0.5ml of **serum** is required.

Note: negative serology does NOT exclude the diagnosis of visceral leishmaniasis in heavily immunosuppressed patients.

Serology is **NOT** helpful in the diagnosis of cutaneous infections.

Serology is usually positive in mucosal leishmaniasis, except in early cases.

A Direct Agglutination Test (DAT) for Leishmaniasis using formalinised promastigotes of *Leishmania donovani* stained with Coomassie blue is the standard serology test and a rapid test (rK39) antibody detection assay is also provided. The DAT is considered positive when the titre exceeds 1600 and in visceral leishmaniasis titres may rise to 51,000 or above. The rK39 antibody test is reported as positive or negative, with no titre available.

Microsporidiosis

Microsporidiosis is an opportunistic disease typically affecting immunocompromised patients. Microsporidia have now been re-classified as fungi and consist of several species. *Enterocytozoon bienersi* and *Encephalitozoon intestinalis* are most commonly found in the small intestine, whereas *Encephalitozoon cuniculi* may be systemic in location. *Encephalitozoon hellem* may present as cause of ocular lesions or keratitis. Although rare, *Trachipleistophora hominis* may be detected in muscle biopsies by PCR and microscopy, and *Vittaforma corneae* in ocular samples (including corneal scrapes) for investigation of keratitis.

Diagnosis of Microsporidiosis by microscopy

Microscopy is rarely used in the diagnosis of microsporidiosis due to molecular techniques showing significantly improved sensitivity and the ability to identify the infecting species. Microscopy may be attempted on individual high value, small volume samples such as corneal scrapes, where the entire sample may be analysed for a small number of spores, although PCR is preferable.

Sample type: please consult the Department of Clinical Parasitology for advice if considering such an investigation.

Diagnosis of Microsporidiosis by PCR

- Sample type: **Unfixed stool, tissue and urine samples**.

Stool samples for the molecular test must NOT be in any fixative as this may cause false negatives.

Please note: requests for microsporidiosis should be clearly marked.

The molecular test for microsporidial species offers several advantages over standard microscopy. The assay is significantly more sensitive (greater than one hundred fold improvement in the limit of detection) than light microscopy. In addition, the assay is semiquantitative and can therefore reveal detailed information on the response of a patient's parasitic load to subsequent drug therapy. Finally, the assay can differentiate between morphologically identical microsporidia, a feat only possible previously with electron microscopy.

Please note this test has not been validated on tissues and urines but will still be performed upon request.

Diagnosis of Microsporidiosis by serology

Serology is NOT available for these parasites.

Tests for parasitic diseases and specimen requirements

Malaria

Malaria remains endemic in many countries and can be fatal if left undiagnosed. There should not be a delay in testing if the clinical history and epidemiology suggests a possible diagnosis of malaria.

Diagnosis of Malaria by Microscopy (essential for a suspected medical emergency)

All suspected acute malarial infections MUST be urgently diagnosed by slide microscopy.

- Sample type: A **minimum of 2ml of EDTA anti-coagulated blood** sent without delay.

Diagnosis will be made by thick and thin film microscopy, ideally using fresh blood. Delay in receipt of an EDTA specimen can adversely affect the integrity of the sample and consequently make accurate diagnosis difficult.

For users other than University College London Hospitals NHS Trust, please make 2 thin and 2 thick films for examination and send together with any original slides from the blood sample in addition to the original blood sample.

Samples are also screened with a Rapid Diagnostic Malaria Antigen Test (RDT). This utilises lactate dehydrogenase (LDH) for pan-malarial species detection and Histidine-rich protein (HRP-2) for *Plasmodium falciparum* specific identification. Please note, due to rare gene deletions in *Plasmodium falciparum* species, this test can result in false negatives and we recommend its use in conjunction with microscopy.

Malaria serology is **NOT** suitable for diagnosing acute infection.

Diagnosis of Malaria by PCR

This is useful for suspected slide negative, sub patent, on going malaria infections and species identification where morphology is inconclusive.

- Sample type: A **minimum of 0.5ml of EDTA anti-coagulated blood**.

For suspected malaria infections that are repeatedly negative by slide microscopy, highly sensitive diagnosis may be made by the use of species specific PCR. Alternatively, where the morphology is inconclusive, species identification may be performed on old microscopy positive bloods to identify *P. falciparum*, *P. vivax*, *P. ovale*, *P. malariae* and *P. knowlesi*.

Diagnosis of Malaria by Serology

This is useful for suspected past infection and blood, tissue and organ donor screening.

- Sample type: A **minimum** of 0.5ml of **serum** or EDTA **plasma** is required.

Serology for malaria may be requested for the following reasons:

- If for some reason it is important to attempt a retrospective diagnosis.
- For the investigation of splenomegaly or nephrotic syndrome in a patient who might have been exposed to malaria.
- For donor screening where the donor has potentially been exposed to malarial infection.

It is NOT recommended for the investigation of acute fever, as urgent blood film examination is the method of choice. An ELISA assay is performed using *Plasmodium falciparum* and *vivax* antigens. Positive results will be reported as an optical density and a cut-off point will be stated.

Sera/plasma from suspected Tropical Splenomegaly Syndrome patients will be tested by IFAT if the ELISA is positive.

The malaria ELISA used cannot be used to identify the species in malaria infections.

Schistosomiasis

Schistosomiasis is a helminth infection contracted when infective cercariae penetrate the skin of the human host during exposure to infected water (e.g. swimming and bathing). Fertilised females lay eggs which are shed via the lumen of the intestine (*S. mansoni* and *S. japonicum*) and of the bladder and ureters (*S. haematobium*), to spread via faeces or urine. Symptoms may include fever, cough, abdominal pain, hepatosplenomegaly, eosinophilia and bloody diarrhoea for *S. mansoni* and *S. japonicum* or hematuria for *S. haematobium*.

Diagnosis of Schistosomiasis by microscopy

- Sample type: **terminal urine, stool samples and unfixed biopsy.**

Definitive diagnosis is by demonstration of the characteristic ova in clinical material. Deposition of ova commences at about six weeks after exposure to the infection but their first appearance (e.g. in urine) may be delayed for several (typically three) months. Confirmation of *Schistosomiasis* by finding ova should be sought where possible.

For *S. haematobium*, a **terminal urine sample (the last 10 to 20ml of urine passed)** is required.

For *S. mansoni* (and *S. japonicum*) **standard stool samples** are the ideal specimens.

Given that *S. mansoni* and *S. haematobium* overlap in geographical distribution and can affect both genitourinary and alimentary systems both terminal urine and stool samples should be sent from all patients being investigated for schistosomiasis when serology is positive.

Biopsy material (unfixed) from rectum, sigmoid or bladder is valuable for the detection of ova by crush preparation and permits assessment of their viability. If biopsies are taken, fixed material should also be sent for histology. Rectal/sigmoid scrapings are also useful samples for the diagnosis of schistosomiasis. Such samples must be sent to the laboratory by prior arrangement only.

Diagnosis of Schistosomiasis by PCR

- PCR is NOT available for these parasites within the Department of Clinical Parasitology.

Diagnosis of Schistosomiasis by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required.

The test should be requested on patients known to have been exposed to fresh water in endemic areas. It starts to become positive approximately six weeks after exposure. In asymptomatic individuals though to have acquired schistosomiasis, serological testing should be delayed until three months post exposure.

The ELISA is reported to detect about 96% of *Schistosoma mansoni* and 92% of *Schistosoma haematobium* infections. The test does not distinguish active from treated infections. The actual time taken to become seronegative post treatment varies, but in some patients the test may remain positive for over two years after treatment.

Positive results are reported at Levels 1 to 9. Levels 1 and 2 are regarded as weak positives; Levels 5 and over are strong positives.

It is known that patients may become seropositive through contact with cercaria from animal species of schistosome and probably when harbouring unisexual infection with human species.

The schistosomal egg antigen used in the ELISA may cross-react with the sera of trichinosis cases or with those of hepatitis cases in some instances.

Currently it is not possible to identify the infecting species using our Schistosomal ELISA test.

It is not recommended to retest patients post treatment for at least 18 months after the completion of treatment.

Strongyloidiasis

Strongyloidiasis is a disease caused by a soil-transmitted nematode. It is the result of free living filariform larvae penetrating the human host skin to initiate infection and migrating to the small intestine where they lay their eggs. Larvae are passed in the stool and can cause autoinfection, contributing to lifelong carriage. It is commonly acquired in tropical and subtropical areas, but cases also occur in temperate areas.

It is often asymptomatic but can be associated with mild abdominal symptoms including bloating, pain, diarrhoea and constipation. In mild disease, it can also cause a dry cough and skin rashes. Strongyloidiasis is an occasional cause of Loeffler's syndrome and, in fulminating cases, may cause secondary bacterial septicaemia or meningitis. Rarely, hyperinfection syndrome can occur, which is life-threatening. Patients on immunosuppressive agents, transplant recipients, or those co-infected with HTLV-1 are at greater risk of this.

Testing for Strongyloides is indicated for the investigation of eosinophilia or if there is a good clinical history to suggest strongyloidiasis.

Tests for parasitic diseases and specimen requirements

Diagnosis of *Strongyloides* by microscopy

- Sample type: **Standard stool sample.**

Faecal specimens should NOT be refrigerated before sending if *Strongyloides* culture is required.

Direct observation of *Strongyloides* larvae is achieved by faecal microscopy and stool culture. The larvae may not be present in every specimen.

- Sample type: **duodenal/jejunal aspirates, BAL (bronchoalveolar lavage) and Sputum**

Strongyloides larvae (and adults) can also be demonstrated in the above samples. Sputum may be useful in cases of hyperinfestation. None of these samples will be analysed by culture.

Diagnosis of *Strongyloides* by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required.

There is known to be cross reaction between filaria and strongyloides antibody in ELISA tests.

Strongyloides serology may be negative in cases of strongyloides hyperinfestation.

After treatment, we do not recommend follow up serology until at least a year after treatment.

Toxocariasis

Toxocariasis occurs following the ingestion of embryonated eggs in infected dog (*Toxocara canis*) or cat (*Toxocara cati*) faeces. Occasionally infection may occur from ingestion of encysted larvae in paratenic hosts. Infections are often asymptomatic except for eosinophilia but occasionally result in Visceral Larva Migrants with concurrent symptoms (fever, anorexia, weight loss, cough, wheezing, rashes, hepatosplenomegaly) and Ocular Larva Migrants to produce various ophthalmologic lesions.

Diagnosis of Toxocariasis by microscopy

- Sample type: **Standard stool samples.**

Stool samples may be examined for putative intestinal infections.

Diagnosis of Toxocariasis by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required.

Serology is the method of choice for the diagnosis of toxocariasis. The ELISA is usually performed on serum, but can be undertaken on aqueous humour, vitreous humour or CSF under the guidance of the Consultant Parasitologist. Please contact the serology section if you intend to send any non-serum samples.

The Toxocara IgG antibody ELISA test against larval excretory/secretory antigen is the most appropriate method for diagnosis. Sensitivity is 91% and specificity is 86% (with cross reactivity possible with strongyloidiasis, trichinosis, amoebiasis and fascioliasis). Results are expressed as an optical density value.

Positive ELISA tests will be confirmed using a Western blot. Sera that are high negative by ELISA will also have a Western blot performed. All CSFs requiring analysis for Toxocara antibody will have a Western blot performed, as the ELISA is not validated for this sample type.

Negative Toxocara serology on serum does **NOT** exclude ocular toxocariasis. Vitreous sampling may be necessary to confirm or exclude ocular toxocariasis. Please contact the Consultant Parasitologist for queries about ocular toxocariasis.

Toxoplasmosis

Toxoplasmosis diagnosis is NOT routinely performed by the Department of Clinical Parasitology.

Please refer samples and enquires about this infection to the Toxoplasma Reference Laboratory (TRL) at Singleton Hospital, Swansea (General enquiries: 01792 285058).

The use of microscopy to detect the presence of Toxoplasmosis in samples may be undertaken in specific cases following consultation with the Department of Clinical Parasitology.

Trichinosis

Trichinosis (also known as Trichinellosis) is caused by the ingestion of encysted larvae of *Trichinella* spp. within undercooked meat. Larvae are released, mature and mate in the small intestine to produce more larvae which migrate and encyst, most commonly in striated muscle. Initial symptoms are predominantly abdominal including nausea and vomiting, abdominal discomfort, diarrhoea and can include fever and fatigue. As the larvae encyst, they can result in further fevers, facial swelling, muscle pains, pruritus and diarrhoea/constipation.

Diagnosis of Trichinosis by microscopy

- Sample type: **muscle biopsy**.

Crush/digested preparations of muscle biopsy specimens may reveal larvae.

Biopsies should also be fixed and sent for histology.

Diagnosis of Trichinosis by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required.

Serology is the mainstay for diagnosing this condition.

Except in the rare event of an outbreak in the UK, serology is usually requested for symptoms suggestive of the stage of muscle encystment: myalgia, eosinophilia, and, in the early stages, fever. The IFAT (screening titre 1/32) has proved reliable and specific with positive titres of about 1/128.

Trypanosomiasis (Overview)

(Human) African trypanosomiasis (HAT) is caused by *Trypanosoma brucei rhodesiense* or *gambiense* following the bite of an infected Tsetse fly. This disease is restricted to Africa. The Department of Clinical Parasitology should be IMMEDIATELY notified about any suspected cases of African trypanosomiasis sent for diagnosis to ensure that the samples arrive correctly and are rapidly progressed as disease progression to Stage 2 (CNS involvement) can be rapid.

American trypanosomiasis (Chagas disease) is caused by *Trypanosoma cruzi*. Once confined entirely to the Americas, it has now spread to other continents. Testing is most generally performed following suitable travel or clinical history or to screen potential organ donations.

Please include relevant travel and clinical history with all requests for Trypanosomiasis so that the correct testing may be performed.

African Trypanosomiasis

Diagnosis of (Human) African Trypanosomiasis by microscopy

- Sample type: A **minimum** of 2ml of **EDTA anti-coagulated blood** and/or as much CSF as you can spare.

Trypanosomes quickly disintegrate upon removal from the body, therefore, it is vital that specimens for microscopy are examined rapidly. EDTA whole blood must be examined within 24 hours and CSF within 20 minutes of taking the sample.

If there is the possibility of a delay in the receipt of EDTA whole blood for microscopy, films should be made locally for examination.

Diagnosis is made by examining stained blood films or CSF in cases with neurological involvement.

Diagnosis of (Human) African Trypanosomiasis by serology

- Sample type: A **minimum** of 0.5ml of **serum** or as much CSF as you are able to spare where neurological involvement is suspected.

Sera are screened by IFAT for *Trypanosoma brucei*.

Please give the relevant travel history so that the appropriate species can be tested for *Trypanosoma brucei rhodesiense* and *gambiense*, which have different geographical locations in Africa and are tested by different IFAT slides.

American Trypanosomiasis (Chagas disease)

Diagnosis of Chagas disease by microscopy

- Sample type: A **minimum** of 2ml of **EDTA anti-coagulated blood**

Microscopy on blood films can be performed for diagnosis of *T. cruzi* following consultation with the Clinical Parasitologist. Bloods should be taken for examination within two months of the acute phase of infection or reactivation in cases of immunosuppression.

Tests for parasitic diseases and specimen requirements

Diagnosis of Chagas disease by PCR

- Sample type: Two tubes of 5ml of EDTA anti-coagulated blood

This test is referred to the London School of Hygiene and Tropical Medicine. Please contact the Clinical Lead for Parasitology before requesting this test.

Diagnosis of Chagas disease by serology

- Sample type: A **minimum** of 0.5ml of **serum** is required for serological analysis.

Screening and serodiagnosis of *T. cruzi* is performed by ELISA plus IFAT.

Visceral Larva Migrans

Visceral larva migrans (VLM) is a condition in humans caused by the migratory larvae of certain nematode species. Serology offers almost the only prospect of specific diagnosis. Please contact the Department of Clinical Parasitology where further information is required regarding testing for filariasis, strongyloidiasis, toxocariasis and other helminths where appropriate. Please see specific sections for the diagnosis of helminth infections in this manual.

HSL Rapid Response Laboratories

The HSL Pathology Service comprises core laboratories, which are the centralised services based in the Halo Building, Central London, and nine Rapid Response Laboratories based locally. These serve University College London Hospitals, Royal Free London Hospital, Barnet and Chase Farm Hospitals, North Middlesex University Hospital, Whittington Hospital, Watford General Hospital, Hemel Hempstead Hospital, Princess Alexandra Hospital, and Lister Hospital.

UCLH Rapid Response Laboratory (RRL)

60 Whitfield Street, London W1T 4EU

HSL UCLH RRL is a UKAS Accredited Medical Laboratory No. 10204.

Tests performed at the HSL UCLH RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/10204/Medical/>

Royal Free London Rapid Response Laboratory (RRL)

Pond Street, London NW3 2QG

HSL RFH RRL is a UKAS Accredited Medical Laboratory No. 8793.

Tests performed at the HSL Royal Free London RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/8793/Medical/>

North Middlesex University Hospital Rapid Response Laboratory (RRL)

Level T0, Main Building, North Middlesex Hospital Sterling Way, Edmonton, London, N18 1QX

HSL NMUH RRL is a UKAS Accredited Medical Laboratory No. 9354.

Tests performed at the HSL North Middlesex RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/9354/Medical/>

Barnet General Hospital Rapid Response Laboratory (RRL)

(also serves Chase Farm Hospital)
Level 3, Wellhouse Lane, Barnet
Hertfordshire EN5 3DJ

HSL BCF RRL is a UKAS Accredited Medical Laboratory No. 8359.

Tests performed at the HSL BCF RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/8359/Medical/>

Whittington Hospital Essential Services Laboratory (ESL)

5th Floor, K Block, Whittington Hospital, Magdala Avenue, London, N19 5NF

HSL Whittington Hospital ESL is a UKAS Accredited Medical Laboratory No. 8200.

Tests performed at the HSL Whittington Hospital RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/8200/Medical/>

Watford General Hospital Essential Services Laboratory (ESL)

Vicarage Rd, Watford, WD18 0HB

HSL Watford General Hospital ESL is a UKAS Accredited Medical Laboratory Nos. 9095, 9037, 9106 and 9039.

Tests performed at the HSL Watford Hospital ESL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/9095/Medical/>

<https://www.ukas.com/download-schedule/9037/Medical/>

<https://www.ukas.com/download-schedule/9106/Medical/>

<https://www.ukas.com/download-schedule/9039/Medical/>

Hemel Hempstead Hospital Essential Services Laboratory (ESL)

Hillfield Road, Hemel Hempstead, Hertfordshire, HP2 4AD

HSL Hemel Hempstead RRL is a UKAS Accredited Medical Laboratory Nos. 9037, 9106 and 9039.

Tests performed at the HSL Hemel Hempstead Hospital ESL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/9037/Medical/>

<https://www.ukas.com/download-schedule/9106/Medical/>

<https://www.ukas.com/download-schedule/9039/Medical/>

HSL Rapid Response Laboratories

Princess Alexandra Hospital Essential Services Laboratory (ESL)

Hamstel Rd, Harlow CM20 1QX

HSL Princess Alexandra Hospital RRL is a UKAS Accredited Medical Laboratory No. 8820, 8821 and 9306.

Tests performed at the HSL Princess Alexandra Hospital RRL (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/8820/Medical>

<https://www.ukas.com/download-schedule/8821/Medical/>

<https://www.ukas.com/download-schedule/9306/Medical/>

Lister Hospital Essential Services Laboratory (ESL)

Lister Hospital, Coreys Mill Ln, Stevenage SG1 4AB

HSL Lister Hospital RRL is a UKAS Accredited Medical Laboratory No. 8846.

Tests performed at the Lister Hospital (UKAS schedule of accreditation):

<https://www.ukas.com/download-schedule/8846/Medical/>

Clinical services

Blood Transfusion

Clinical services offered are:

- Blood grouping
- Antibody screening and Identification
- Estimation of foetal maternal haemorrhage
- Red cell phenotyping
- DAT
- Issue of blood components

HSL blood transfusion laboratories adhere to a strict zero-tolerance policy for sample labelling and acceptance criteria, in line with national guidance.

Routine Haematology

Clinical services offered are:

- Full blood counts
- Reticulocytes
- ESR
- Blood and Bone Marrow Morphology
- Malarial Parasite
- Infectious mononucleosis diagnosis
- Routine coagulation tests

Clinical Biochemistry

The RRLs carry out routine biochemistry testing. Other tests are analysed at the Halo Building, including:

- Tumour markers
- Specialised Proteins
- Drugs of abuse

Immunology

Immunology tests are analysed at the Halo Building.

Point of Care Testing at UCLH RRL

Services provided near patients (satellite laboratories)

- 1st Trimester combined screening service (UCLH)
- HbA1c monitoring – Adult Diabetes Outpatient clinic (UCLH)
- Intra-operative parathyroid hormone measurements (Parathyroidectomies at UCLH, RF, BCF)
- Support with POCT devices used in the Trusts

Haemostasis (Specialist Coagulation) Services

Diagnosis, treatment and monitoring of inherited and acquired coagulopathy disorders including:

- Thrombotic disorders.
- Haemophilia and acquired bleeding disorders.
- Thrombotic Thrombocytopenia Purpura (TTP), Atypical Haemolytic Uraemic Syndrome (aHUS) and Thrombotic Microangiopathies (TMAs).
- Molecular Genetics services in inherited bleeding disorders and thrombophilia

Staff/Key personnel

Royal Free Hampstead – Main Switchboard: 020 7794 0500

GENERAL

HSL Helpdesk **Monday-Friday 09:00-17:00** Call 020 3758 2070, internal number 38858

CLINICAL STAFF

Consultant Haematologist responsible for Blood Transfusion **Dr Mallika Sekhar** mallika.sekhar@nhs.net Ext 34936 or Bleep 71-2639
 Department Clinical Lead/
 Laboratory Lead

Consultant Haematologist **Dr Momin Ahmed** momin.ahmed@nhs.net 020 7794 0500 Ext 35173

Consultant Chemical Pathologist and Clinical Lead **Dr M. Ewang** mfon.ewang@nhs.net Ext 33489 Direct Line: 020 7472 6694

Consultant Haematologist and Co-Centre Director and Clinical lead for Coagulation for Royal Free and HSL **Professor Pratima Chowdary** pratima.chowdary@nhs.net Ext 35921

Haematology SpR. Rotational SpR cover for blood transfusion Bleep 71-1811

Transfusion Practitioner, RFH Hampstead site **Anna Li** Anna.li@nhs.net Ext 35875 Bleep 71-2033

Specialist Registrars Clinical Biochemistry Ext 5195

Consultant on call, Clinical Biochemistry through air call (24h) Available via switchboard

LABORATORY STAFF

RRL Manager **Saida Solkar** saida.solkar@nhs.net Ext 33266 020 7820 2082

Lead BMS Blood Transfusion, HSL Scientific Lead for Blood Transfusion **Rita Atugonza** rita.atugonza@nhs.net Ext 33392 020 7830 2150

Lead BMS Routine Haematology **Yan Kit Man** yankit.man@nhs.net Ext 33662 020 7794 0500

Lead BMS Clinical Biochemistry **Oghenemega Okotete** oghenemega.okotete@nhs.net Ext 38857 Bleep 2797

Specimen Reception Manager **Jill Price** jill.price2@nhs.net Ext 32943

Blood Sciences Quality Manager **Paulo Leite** paulo.leite@hslpathology.com Ext 36567

Biochemistry Quality Manager **Stan Hoeck** stan.hoeck@hslpathology.com 07971 474928

Duty Biochemist Scientist, Clinical Biochemistry duty.biochemist@hslpathology.com 020 3908 1362

Point of Care Testing Area Manager (RFL and BCF) **Felicity Blake** felicity.blake@hslpathology.com Ext 38464/38742 Bleep 2459

HSL Rapid Response Laboratories

Barnet General Hospital – Main Switchboard: 020 8216 4600 (also serving Chase Farm Hospital)

GENERAL

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|--------------|----------------------------------|----------------------------------|-----------|
| HSL Helpdesk | Monday-Friday 09:00-18:00 | rf-tr.barnetlab.helpdesk@nhs.net | Ext 64885 |
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CLINICAL STAFF

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|--|---------------------------|----------------------------------|---------------------------|
| Consultant Chemical Pathologist and Clinical Lead | Dr Puja Ayrton | p.ayrton@nhs.net | Ext 64930 |
| Consultant Haematologist responsible for Blood Transfusion | Dr Nishil Patel | nishil.patel@nhs.net | 020 8216 4383 |
| Consultant Haematologist | Dr Maxine Lissack | m.lissack@nhs.net | |
| Consultant Haematologist | Dr Poornima Kumar | poornimakumar@nhs.net | |
| Consultant Haematologist | Dr Andreas Virchis | avirchis@nhs.net | |
| Haematology SpR Rotational SpR cover for blood transfusion | | | Bleep 71-1811 |
| Transfusion Practitioner | Sneha Patole | sneha.patole@nhs.net | 020 8216 4547 |
| Clinical Queries/Duty Biochemist (routine hours) Clinical Biochemistry | | duty.biochemist@hslpathology.com | 020 3908 1362 |
| Consultant on-call (outside of routine hours) Clinical Biochemistry | | | Available via switchboard |

LABORATORY STAFF

| | | | |
|---------------------------------------|-----------------------|-----------------------------------|--|
| RRL Manager | Angus Wyatt | angus.wyatt@hslpathology.com | Ext 64635 |
| Lead BMS Blood Transfusion | Ishmael Carboo | ishmael.carboo@hslpathology.com | Ext 64391 |
| Lead BMS Haematology | Jayesh Mankani | jayesh.mankani@hslpathology.com | Ext 64413 |
| Clinical Biochemistry Department Head | Dean Manchett | dean.manchett@hslpathology.com | 020 8216 4394 (Ext. 64394) |
| Specimen Reception Manager | Tina Marechera | tina.marechera@hslpathology.com | Ext 64737 |
| Deputy Specimen Reception Manager | Amy Scott | amy.scott@hslpathology.com | 020 8216 4394 |
| Quality Manager | Abigail Galea | abigail.galea@hslpathology.com | 020 8216 4391 |
| Point of Care Testing (POCT) Team | | RF-TR.Pointof-caretesting@nhs.net | Barnet Ext: 64049/64934 Chase Farm Ext: 51534/51013 |
| Andrology Clinic | | Barnet.Andrology@hslpathology.com | 020 3912 0366 |

University College London Hospitals – Main Hospital Switchboard: 020 3456 7890

GENERAL

| | |
|------------------|---------------|
| HSL Lab Helpdesk | 020 3447 9405 |
|------------------|---------------|

CLINICAL STAFF

| | | | |
|--|------------------------|-----------------------|---------------------------------|
| Consultant Blood Transfusion and HSL Clinical Lead for Blood Transfusion | Dr Sam Aliman | s.alimam@nhs.net | Via switchboard – 020 3456 7890 |
| Consultant Haematologist Department Clinical Lead and HSL Clinical Lead for Haematology | Dr Rajeev Gupta | rajeev.gupta1@nhs.net | Via switchboard – 020 3456 7890 |
| Haemostasis SpR Rotational SpR cover for coagulation | | | Bleep 7044 |
| Haematology SpR Rotational SpR cover for blood transfusion | | | Bleep 7050 |
| Transfusion Practitioner | Zeynab Jeewa | zeynab.jeewa@nhs.net | 020 3447 5457 |
| Consultant Chemical Pathologist and Clinical Lead | Dr Atul Goyale | Atul.goyale1@nhs.net | Via switchboard – 020 3456 7890 |

LABORATORY STAFF

| | | | |
|--|-----------------------|---------------------------------|--|
| RRL Manager | Julie Dilling | julie.dilling@hslpathology.com | 07703 609 034 |
| HOD Blood Transfusion | Reshma Patel | reshma.patel@hslpathology.com | 020 3447 8521 07970 230651 |
| HOD Haematology and HSL Scientific Lead Haematology | Billy Janda | billy.janda@tdlpathology.com | 020 3447 8961 |
| HOD Clinical Biochemistry | Chris Wilson | chris.wilson16@nhs.net | 020 3447 9405 |
| Specimen Reception Manager | Ujiro Ojeanelo | ujiro.ojeanelo@hslpathology.com | 020 3912 0297 |
| Blood Sciences Quality Manager | Ragini Khurana | Ragini.Khurana@tdlpathology.com | 07890 513 027 |
| Blood Transfusion Quality Manager | Sofhia Akhtar | Sofhia.Akhtar@hslpathology.com | 020 3447 8521 |
| Point of Care Testing (POCT) Team | | uclh.poct@nhs.net | Helpline: 020 344 72950 (x72950) |
| HOD Haemostasis | Deepak Singh | Deepak.Singh@tdlpathology.com | 020 3912 0298 |

North Middlesex University Hospital - Main Switchboard : 020 8887 2000

GENERAL

| | | | |
|--------------------------------|------------------------------------|--------------------------------|--|
| Specimen Reception Area | Hours of Operation: 24/7 | nmuh.sra@hslpathology.com | 020 8887 2263 |
| Results/Enquiries | Hours of Operation: 09:00–18:00 | | 020 8887 2484 |
| Andrology | Hours of Operation: 08:30–16:00 | Nmuhandrology@hslpathology.com | 020 8887 2925 Same number to make appointments for semen analysis |

HSL Rapid Response Laboratories

| GENERAL | | | |
|----------------------------|--|-----------------------------------|--|
| Biochemistry | | nmuhrrl@hslpathology.com | 0208 8887 2670 Bleep 147 for emergencies |
| Haematology | | Haematology.nmuh@hslpathology.com | 0208 887 2436 or bleep 124 for out of hours |
| Blood Transfusion | | | 020 8887 2276 020 8887 2679 Bleep 124 for major haemorrhages and out-of-hours |
| Medirest | GP sample pick up queries | | 020 8887 2220 |
| CLINICAL STAFF | | | |
| Clinical Lead Biochemistry | Dr Devaki Nair Dr Nair (or deputy) is based at the Royal Free Hospital | devaki.nair@nhs.net | Mon to Friday: 09:00 – 17:00 Royal Free switchboard 020 7794 0500 ext. 35083 or 35082 Out of hours (OOH) 07976 111253 or air call via Royal Free switchboard |
| LABORATORY STAFF | | | |
| RRL Manager | Shazia Yasin | Shazia.Yasin@hslpathology.com | 020 8887 2633 |
| Lead BMS Andrology | Swapna Pothuguntla | | 020 8887 2925 |
| Head of Biochemistry | Girish Ravindra | Girish.Ravindra@hslpathology.com | 020 8887 2670 |
| Duty Biochemist | Mon to Friday: 09:00-17:00 | duty.biochemist@hslpathology.com | 020 3908 1362 |
| Head of Haematology | Carlos Zamora | Carlos.Zamora@hslpathology.com | 020 8887 2436 |
| Lead BMS Blood Transfusion | Aarondeep Gill | Aarondeep.Gill@hslpathology.com | 020 8887 2263 |

Opening times

All RRLs operate a 24/7 service for Specimen Reception, Chemistry, Haematology and Blood Transfusion.

Normal working hours are considered to be 09:00 – 20:00 Monday – Friday.

Out of hours are considered to be 20:00 – 09:00 Monday – Friday and weekends/public holidays. During these periods, a reduced staff complement is present in all sections. Priority is given to urgent and emergency cases.

Contacting the laboratories out of hours:

Royal Free

020 7794 0500 bleep 71-1595

Barnet Chase Farm

020 8216 4600 extension 65037

North Middlesex

020 8887 2263/2670

University College London Hospitals

020 3447 9405

Specimens

Specimen reception

Royal Free Hospital

The Pathology Specimen Reception is located on the First floor on the south side of the main RFH building.

Specimen Reception Manager

Jill Price

Jill.price2@nhs.net

University College London Hospital

The RRL and Cellular Pathology joint Specimen Receipt is located on the Ground Floor at 60 Whitfield Street, London.

The RRL Specimen Reception is on Floor 1; the Cellular Pathology Specimen Reception is on Floor 2.

Specimen Reception Manager:

Ujiro Ojeanelo

Ujiro.ojeanelo@hslpathology.com

North Middlesex University Hospital

The Pathology Specimen Reception is located on level T0 of the Main Building.

Specimen Reception Manager

Ryhan Anwar

020 8887 2263

Ryhan.anwar@hslpathology.com

Barnet General Hospital

The Specimen Reception is located on Level 3 of the Main Hospital.

Specimen Reception Manager

Tina Marechera

020 8216 4394

Tina.marechera@hslpathology.com

There is a small Specimen Reception room on Lower Ground Floor of Chase Farm Hospital; this is a satellite of the Barnet Specimen Reception.

Factors that significantly affect the performance of the examination or interpretation of results

- Haemolysis, Icterus and Lipaemia significantly affect the results to varying degrees depending on the tests that have been requested
- For serum samples, contamination from EDTA, Fluoride Oxalate and Sodium Citrate as well as samples taken from a drip arm will affect the results to varying degrees and some or all results will not be reported.
- Routine Coagulation samples **must not be underfilled** as this affects the test results.

Specimen acceptance/rejection criteria

Pre-examination sample suitability and integrity is important to the final test result that is reported by the laboratory and/or to the safety of laboratory staff. As a result, the laboratory will **reject** the specimen and not proceed with analysis of samples if the following criteria listed below are not present.

Sample

Essential labelling requirements

- NHS, CHI or Health and Care Number, Hospital number
- Patient's full name or unique coded identifier
- Date of birth and/or hospital number

Desirable labelling requirements

- Date and time of collection (essential)
- Identification of person taking the sample (essential for BT)
- Nature of sample, including qualifying details, e.g. left, distal etc. especially if more than one sample per request is submitted
- For time study samples, such as PD fluids, time of collection of each sample is essential.

Specimens

Request Form (either paper or electronic)

Essential labelling requirements

- NHS, CHI or Health and Care Number*, Hospital number
- Patient's full name or unique coded identifier
- Date of birth and/or hospital number
- Gender
- Patient's location and destination for report
- Patient's consultant, GP or name of requesting practitioner
- Investigation(s) required
- Clinical information including relevant medication
- Date and time sample collected
- Practitioner's contact number (bleep or extension)

Desirable labelling requirements

- Patient's address including postcode

*Use of the NHS number, on paper and electronic patient records, is now a mandatory requirement included within the NHS Operating Framework 2008/9. Patient data should be used to identify the sample up to the point where an NHS or CHI Number is allocated, whereupon this becomes the primary identifier.

Rejection criteria

- Any unlabelled/ partially labelled samples will not be accepted for processing.
- Any samples received labelled with pre-used requests will not be accepted for processing. Repeat samples will be needed.
- Samples delayed for receipt > 24h in the laboratory are not suitable for analysis and therefore will be discarded
- Samples from multiple patients should not be sent in one bag and if in such cases there is evidence of spillage they will be discarded and the requester informed.
- Samples received with needles attached to tubes will be discarded.
- All sample conditions such as specific temperature requirement should be followed i.e. if temperature

of the samples need to be maintained at 4°C or body temperature for e.g. cryoglobulins these instructions should be followed. Please refer to pathology test finder for sample requirements.

Specimen transport

All RRLs have regular scheduled transport runs provided by TDL Collect (the company courier service) to carry samples for the centralised departments (special chemistry, Immunology, Virology, Microbiology and Molecular Pathology) to the Halo.

Each RRL receives its specimens by means of services provided by the Trusts, apart from some GP services which are serviced by TDL Collect.

All Trusts operate a pneumatic tube system (PTS) or air chute which connects the wards/clinics and emergency departments to the laboratory. There is usually a separate tube between the emergency department and the laboratory to enable fast receipt and processing of samples. There are local policies in place for the use of the PTS or air chute.

Royal Free Hospital

Samples can be delivered using the pneumatic air chute system or in person (including hospital porters).

Some specimens MUST NOT be sent via the air chute because this will affect the test result.

Routine Haematology, Blood Transfusion and Immunology

All samples can be sent via the air chute.

Cytopathology or Histopathology

No samples must be sent via the air chute.

Clinical Biochemistry

The following samples must NOT be sent via the air chute

- Samples for Ammonia or Blood Gas
- CSF and Urine (universal or sterile pot)
- Samples on ice or heat
- Samples shielded from light

Virology & Microbiology

None of the following samples (in universals or pots) must be sent via air chute

- Biopsies
- CSF
- Bone marrow or Fluid samples

Haemophilia (Specialist coagulation)

The below specialist coagulation samples must not be sent via the air chute when the following tests have been requested.

Note: Samples for Platelet studies (aggregometry, Lumiaggregometry, and platelet nucleotides) and whole blood assays – IMPACT R, PFA-100 and ROTEM must be hand-delivered to the laboratory as soon as possible after collection (within two hours of venepuncture).

| SAMPLE | EPR TEST CODE ON LABEL (WINPATH TEST CODE) |
|--|--|
| 2.7mL Citrate Blood sample (Light Blue top) | CADP, CADR (PFA-100) |
| 2.7mL Citrate Blood sample (Light Blue top) or 10mL Sarstedt Monovette (Green Lid) | PAGG (PAGG) |
| 2.7mL Citrate Blood sample (Light Blue top) or 10mL Sarstedt Monovette (Green Lid) | CHRN (CHRN) |
| 2.7mL Citrate Blood sample (Light Blue top) | IMPR (IMPR - Impact R) |
| 2.7mL Citrate Blood sample (Light Blue top) or 10mL Sarstedt Monovette (Green Lid) | NUCS (NUCS) |

Where samples can be sent ensure you:

- Place the specimen bag into a pod. Note: Specimens that are not sent in a pod will break and leak
- Close the pod securely and place in the station
- Enter the destination code (see table)
- Send

| DESTINATION CODE | DEPARTMENT | OUT OF HOURS CODE |
|------------------|---|-------------------|
| 591 | Haemostasis (Haemophilia) | 885 |
| 885, 595 | Rapid Response Laboratory Biochemistry, Haematology & Routine Coagulation | 885 |
| 596 | Blood Transfusion | 885 |
| 885, 595, | Microbiology | 885 |
| 885, 595 | Immunology | 885 |
| 885, 595 | Virology | 885 |

In the event of a spillage or breakage in the air tube system, contact the site Estates Department and log this as an incident on DATIX.

If there are problems with the pneumatic air chute during working hours Monday to Friday 9:00am to 4:30pm, please call the Estates Department on extension 33254 and log the incident as urgent. For out of hours (4:30pm-8am), contact the shift technicians on extension 34106 or bleep 71-1111.

Delivery in person (includes Hospital porters)

Place the specimen in a leak-proof, sealed plastic biohazard bag designed for specimen transport and deliver as soon as possible to Central Specimen Reception.

Specimens

| COLLECTION TIME | FROM | TIME DELIVERED TO CENTRAL RECEPTION |
|-----------------|-------------------|-------------------------------------|
| 9.15 | Concourse | 9.45 - 10:00 |
| 10.30 | R/Clinics | 11:00 - 11:15 |
| 11.30 | Concourse/Clinics | 12.00 - 12:15 |
| 14.00 | Concourse/Clinics | 14.45 - 15:00 |

There is point-to-point Chute from phlebotomy to SRA for the delivery of routine samples. Any samples that require special transport conditions are delivered from the phlebotomy room at the point the sample is taken.

Transport of specimens out of normal working hours

Samples that are collected by phlebotomists will be delivered to the RRL on weekends and bank holidays from 09:00-12:00. Outside of these times, specimens should be sent via the air chute, delivered in person or arranged through the general portering services.

University College London Hospital

Pneumatic (vacuum) tube system (PTS)

- There is a dedicated chute from A/E to the RRL and a second chute linked to several wards and locations.
- Designated carriers (PODs) must be used at all times.
- Tissue and biopsy samples should not be delivered by PTS.
- The Trust Estates departments (Interserve/ CBRE) are responsible for the pneumatic tube system. All faults or incidents are reported via hospital switchboard: 020 3456 7890 .
- Instructions for use and destination station codes are displayed by each station.

UCH at Westmoreland Street is not on the PTS and hourly scheduled courier runs transport samples to the RRL.

Samples from GP practices must be sent via UCLH Trust transport on the next available collection during the working day.

If a significant delay in sample transportation to the laboratory is anticipated, please discuss with laboratory staff, as sample deterioration may limit the viability of results.

Barnet General Hospital

Hospital porters

Hospital porters will collect samples from wards or outpatient phlebotomy and take them to the RRL.

Pneumatic (vacuum) tube system (PTS)

- There is a dedicated chute from A/E to the RRL and a second chute linked to several wards and locations.
- Designated carriers should be used at all times.
- Tissue and biopsy samples should not be delivered by PTS.
- The Trust Estates department (Equans) is responsible for the pneumatic tube system. All faults or incidents should be reported to the Trust Estates provider on ext. 64123 or via hospital switchboard out of hours.
- Instructions for use and destination station codes are displayed by each station.

Hand delivery

- Specimens can be delivered directly to the laboratory. If these are urgent, they must be handed directly to staff and signed in the log.
- Patients can drop off their own samples at the laboratory.

GP specimen transport

GP patients are either bled at the Barnet phlebotomy department or out in the community at their own, or nearby, surgeries. TDL Collect, the company courier service, is responsible for collecting these specimens and delivering them to the laboratory in a timely manner.

Transport-related queries should be directed to the Courier department on 020 7307 7373.

Chase Farm Hospital

The RRL at Barnet General Hospital provides Pathology services to Chase Farm Hospital, however there is a small laboratory on the lower ground floor which has a Blood Transfusion fridge and a small sample reception. There is a PTS from some wards/clinics, or samples are brought by porters. An hourly shuttle service between the laboratory at Chase Farm Hospital and the RRL at Barnet General Hospital is provided Mondays to Fridays from 08:00 to 20:00 by TDL Collect. Weekend couriers, if required, are organised by ward/departmental staff via third party providers.

North Middlesex University Hospital

Hospital porters

Hospital porters will collect samples from wards or outpatient phlebotomy.

Pneumatic (vacuum) tube system (PTS)

- There is a dedicated chute from A/E to the RRL and a second chute linked to several wards and locations.
- Designated carriers should be used at all times.
- Tissue and biopsy samples should not be delivered by PTS.
- The Trust Estates department (Bouygues) is responsible for the pneumatic tube system. All faults or incidents should be reported to Bouygues on ext. 2596 or via hospital switchboard out of hours.
- Instructions for use and destination station codes are displayed by each station.

Hand delivery

- Specimens can be delivered directly to the laboratory. If these are urgent, they must be handed directly to staff and signed in the log.
- Patients can drop off their own samples at the laboratory.

GP specimen transport

GP patients are bled at local phlebotomy hubs. The Hospital Estates department (sub-contracted to Medirest) is responsible for collecting these specimens and delivering them to the laboratory in a timely manner. Transport-related queries should be directed to Medirest (0208 887 2220).

Supplies

HSL Facilities Management provide support for consumables and reagents to laboratories and wards, departments and GPs – the extent of this service depends on the individual contracts between HSL and the Trusts.

Barnet/Chase Farm

bcf.pathologystores@hslpathology.com – GPs can use this address to order externally.

North Middlesex Hospital

GPs order supplies by use of formstack (https://pathologyforms.formstack.com/forms/nmuh_pathology_supplies_order_form)

Royal Free Hospital

The only supplies currently being provided by HSL are Blood Culture kits to the wards and QFit Test kits for GP's.

UCL Hospitals

Orders are sent to suppliesgroup@tdlpathology.com Blood cultures via TDL Collect couriers directly from the Halo; UCLH and CNWL practices only. Formstack order at https://pathologyforms.formstack.com/forms/uch_pathology_supplies_order_form is completed internally by FM (Lab Support).

Drivers delivering specimens from GP surgeries will collect the supplies and deliver to the practices. Within the hospital, Supplies may be delivered to the wards, or pre-ordered goods may be collected from the FM stores in the Pathology department (NNUH and Barnet only).

Specimens

Request procedures

HSL is contracted to provide results on an urgent and routine basis. There are contractually-defined lists of urgent tests and their target turnaround times (TATs) for each RRL, and these are monitored on a daily basis by laboratory staff and reported on formally at the HSL Board, at Laboratory Operations Committees, Clinical Pathology Advisory Committees and Operational Management Group meetings every month.

Urgent requests

The laboratory defines urgent samples as those where the results are required for immediate patient management. For each individual contract there is a defined list of locations from which samples are always treated as urgent; procedures for requesting urgent testing from other locations differ slightly depending on the Trust.

Barnet/Chase Farm

- A&E/AAU
- CC North and South
- Mulberry Ward
- Victoria Ward
- Maternity Delivery Room
- Starlight Ward (Paediatric and Transitional Care)
- Paediatrics Special Care Unit
- OPAU
- Pre-chemo samples

North Middlesex Hospital

- A&E
- Critical Care
- Ambulatory Care
- Neonatal ICU
- Labour Ward

Royal Free Hospital

- A&E/ 2NA/Urgent Care
- MAAU
- IRCU
- Lyndhurst Rooms
- ICU
- Clinic 6 (Haematology only)
- 11 South (Haematology only)
- Oncology (only if patient awaiting chemotherapy)
- Pre-chemo samples in a bag labelled 'pre-chemo priority'
- SCBU/NNU (BUT not routine paediatric samples)

UCL Hospitals

- A&E
- AAU
- ITU
- Haematology Wards
- Oncology (only if patient awaiting chemotherapy)
- Pre-chemo samples
- SCBU/NNU (BUT not routine paediatric samples)

Royal Free London

Other urgent samples:

- Samples phoned to extension 38851 help desk option 2 (Hampstead) and requested as urgent prior to sending sample to the laboratory.
- Samples delivered by clinicians directly to laboratory staff and identified to laboratory staff as urgent
- Any requests for blood gases, ammonia, lactate, CSF protein, CSF glucose.

Barnet/Chase Farm

- Samples phoned to 65037 (Barnet), 51786 (Chase Farm) and requested as urgent prior to sending sample to the laboratory

Please note: Samples requested as urgent on EPR or on the specimen bag (unless specifically requested to do so by the laboratory) will not be treated as such.

Urgent results are usually communicated by telephone, therefore in order to effectively communicate abnormal urgent results the bleep number/telephone number of the clinician requesting the test is required.

If a clinician is offsite outpatient/ward/GP setting and require urgent Contact RFH switchboard and ask them to contact extension 38851 help desk option 2 (Hampstead) or phone 65037 (Barnet).

Provide the laboratory with the details of the patient whose sample you wish to be processed urgently and what tests you would like to request.

Make the request in the usual way ensuring that you have provided a telephone number or bleep number by which the lab can contact you should the results be abnormal. Please note results will be available within 1 hour of the samples receipt by the laboratory.

Package the sample which requires urgent processing separately and make it clear on the packaging that the sample is urgent. Arrange transport of the sample to the laboratory.

North Middlesex University Hospital

Samples from certain locations, such as A/E, will be automatically processed urgently.

For other locations, order comms requests should only be marked as urgent where they are required for the immediate management of the patient. Urgent samples from other locations must be sent in red bags.

It is essential to telephone a Microbiology Consultant before sending an urgent Microbiology request. To prevent delay, it is good practice to telephone Blood Transfusion for all urgent requests.

Requesting additional tests ('add-on' requests)

Under certain circumstances, it is possible to add tests on to samples that are already in the laboratory, but this will depend on sample stability, tube type and, for some tests, there will be timing restrictions. There may not be sufficient specimen to perform the additional tests. Investigations are best performed on fresh primary specimens and where possible, any non-urgent investigations should be deferred until a further phlebotomy episode is being performed.

The availability of a sample for further analysis cannot be guaranteed owing to limits imposed by refrigerated storage space, even if the analyte required is stable for weeks at a time.

It will not always be possible to add on a test if the analyte requested is sufficiently unstable that any result provided would be inaccurate (eg Troponin 24h), or if the quality of the sample is such (haemolysed, lipaemic, icteric) that the result would be inaccurate.

Please note that standard sample retention time will differ according to the nature of the original request. The laboratory will be able to advise if a sample is still in storage and appropriate to the test required to be added retrospectively. Where the laboratory receives a request for an add-on that cannot be fulfilled the user will be advised through the standard laboratory report.

Blood Transfusion accepts additional test and blood component requests over the telephone depending on the sample validity of 72 hours (7-day sample validity is also applicable at UCLH). Blood component requests made by telephone must be made by medical staff, qualified midwives or trained and authorised practitioners.

All requests for urgent add-on tests [only tests that will change management immediately and in our urgent test repertoire] should be requested by contacting the Laboratory. All requests should include the following information; Name of Patient, DOB, Hospital Number, Name of test to be added, Date and time of sample, Contact number/bleep of requestor.

Add on tests requested urgently should be available within 2 hours (if appropriate) of the time the telephone request is received. For non-urgent add on tests requested during working hours, results should be available within 24 hours of the time the email request is received. Requests for add on tests that must be sent to a referral laboratory, or be processed by our specialist sections may take longer.

Chemistry/Haematology samples are not suitable for use when requesting additional testing for virology/serology due to the potential for cross-contamination of samples during the original analysis.

At Royal Free there is an add-on email address for routine requests. This will be monitored Monday to Friday 09:00 – 17:00. rf.biochemhaemaddon@nhs.net

At North Middlesex there is an add-on email address for routine requests. This will be monitored 24/7. nmhp pathology.addonrequests@nhs.net

At Barnet there is an add-on email address for routine requests. This will be monitored Monday to Friday 09:00 – 17:00. rf-tr.barnetlab.helpdesk@nhs.net

At UCLH, there is an email for routine add-on requests, monitored Monday – Friday 09:00-17:00. uclh.enquiry.biochemhelpdesk@nhs.net

Results

All results are recorded on the HSL LIMS (Laboratory Information Management System) Winpath. This is interfaced with the electronic patient record of the local Trust:

Barnet/Chase Farm

EPR-RFG

Royal Free

EPR-RFG

North Middlesex

Careflow

UCL Hospitals

EPIC

As soon as results are authorised on Winpath they are transmitted to the Trust systems and are available for viewing by clinical staff.

GPs in all catchment areas can be set up to use the electronic requesting and resulting system T-Quest. Please contact the IT helpdesk on helpdesk@tdlpathology.com.

Providing the GP surgery has been set up to request and receive results via T Quest, results will be electronically downloaded. Requests for missing GP results or requests for copies can be made to the email addresses shown below. These will be re-transmitted electronically or emailed as appropriate.

Each RRL operates a helpdesk for results enquiries:

Royal Free London

Helpdesk: 020 3758 2070

GP results: Rf.pathologyenquiries@nhs.net

UCL Hospitals

Hospital patients: 020 3447 9405
uclh.enquiry.biochemhelpdesk@nhs.net (24/7)

GP and General Enquiries: 020 3447 9953
uclh.pathology@nhs.net

NB: Service is Mon-Fri 09:00-17:00

Barnet/Chase Farm

Helpdesk: 020 8216 4885
rf-tr.barnetlab.helpdesk@nhs.net

North Middlesex

Enquiries: 020 8887 2484
northmid.pathology@nhs.net

A harmonised service for duty biochemist advice is provided from the Halo Building for all clinical users of the RRLs. Clinical Scientists, Chemical Pathologists and Chemical Pathology Registrars from all sites participate in one rota. The involvement of a larger pool of specialists with a wider expertise, both scientific and medical, provides comprehensive clinical support for Biochemistry.

The contact details for this service are:

Telephone: 020 3908 1362
Email: duty.biochemist@hslpathology.com

Please use the email for non-urgent enquiries; it is monitored and responded to at a frequency of not more than 90 minutes between the hours of 09:00 and 17:00 Monday-Friday. For more urgent issues please use the telephone contact.

Critical/Abnormal results

Results falling outside of predefined limits (set by the Royal College of Pathologists) will be phoned to the requesting clinician, GP surgery or patient location as appropriate. See below.

Outside of normal working hours, GP results will be phoned to the relevant deputising service; hospital results will be phoned to a member of the hospital's medical team.

Critically abnormal results will be communicated to the requesting clinician at all times where contactable.

Where not contactable, or out of hours:

- Inpatients - the ward will be contacted
- Outpatients - will be bleeped to the Medical Registrar
- GP results will be telephoned to the NHS emergency service 111.

If contact cannot be made, the local on-call Chemical Pathologist will be alerted (via switchboard).

RRL Haematology Phoning Limits

| TEST | LOWER LIMIT | UPPER LIMIT |
|--|--|-------------|
| Haemoglobin (g/L) | <80 | >180 |
| WBC | <1.0 | >30.0 |
| Malarial Parasites | Positive Ag Screen, Parasitaemia % for P. falciparum | |
| Platelets | ≤50 | >600 |
| INR | >4.5, | |
| APTT Ratio | >6.0 | |
| Fibrinogen | <1.0 | |
| Blood Film shows evidence of Blast Cells or diagnosis suggesting of AML/CML/ALL/DIC | | |

North Middlesex University Hospital

| HAEMATOLOGY TEST | RESULT |
|--|---|
| Wbc | > 50 x 10 ⁹ /L |
| Neutrophils | <0.5 x 10 ⁹ /L |
| Hb. | <60 g/L |
| Hb. (Males) | >200 g/L |
| Hb. (Females) | >180 g/L |
| Platelets | >1000 x 10 ⁹ /L |
| Platelets | <20 x 10 ⁹ /L |
| Malaria | All Positive results |
| Any suspected Acute Leukaemia (irrespective of WBC) | All new cases reported to Haem clinical team |
| Special Haematology | New major Haemoglobinopathy reported to Haem clinical team |
| Coagulation (non-warfarin patients) | PT >40 APTT >50 |
| Coagulation (patients on anti- coagulants) | PT >120s / INR > 5. APTT >80s / APTTR > 6 |
| D-Dimer | >550ug/L FEU |

Results

Clinical Biochemistry: Critically abnormal results that will be communicated to the requesting clinician at all times where contactable

| ANALYTE (SERUM/PLASMA) | ACTION LIMITS | | COMMENTS | |
|---|---------------|-------------|---------------------------------------|--|
| | LOWER LIMIT | UPPER LIMIT | | |
| Sodium | mmol/L | 120 | 155 | ≤ 130 if < 16yrs |
| Potassium | mmol/L | 2.5 | 6.5 7.1 (pre-haemodialysis sample) | Exclude renal patients. Exclude haemolysis, old samples and EDTA contamination. |
| Urea | mmol/L | | 30 | ≥ 10 if < 16yrs |
| Creatinine | mmol/L | | 350 | ≥ 120 in < 14 years and ≥ 200 in older children (≥ 14 and < 16) |
| Acute Kidney Injury (Royal Free/Barnet/Chase Farm only) | | | | |
| AKI-1 Only if K > 6.0 mmol/L. Primary Care: If out of hours (OOHs) GP OOHs service or communication next day to GP | | | | |
| AKI-3 All new occurrences | | | | |
| AKI-2 All new occurrences | | | | |
| (AKI) - For patients with previous results AKI-2 triggers to be followed. | | | | |
| Glucose | mmol/L | 2.5 | 25 | ≥ 15 if < 16yrs |
| Adjusted Calcium | mmol/L | 1.8 | 3.0 | |
| Magnesium | mmol/L | 0.4 | 2.5 | |
| Phosphate | mmol/L | 0.3 | | |
| AST | U/L | | 15 x upper limit of normal (ULN) | 10 x ULN if < 16yrs |
| ALT | U/L | | 15 x ULN | 10 x ULN if < 16yrs |
| Total CK | U/L | | 5000 | ≥ 2000 if < 16yrs |
| Amylase | U/L | | 500 | |
| Triglyceride | mmol/L | | 20 | |
| Carbamazepine | mg/L | | 25 | |
| Digoxin | ug/L | | 2.5 | Check timing > 6hrs after dose. If Potassium < 3.0mmol/L, this should be phoned with high digoxin result. |
| Lithium | mmol/L | | 1.5 | |
| Phenobarbitone | mg/L | | 70 | |
| Phenytoin | mg/L | | 25 | |
| Theophylline | mg/L | | 25 | |
| CRP | mg/L | | 300 | ≥ 100 if < 16yrs |
| Ammonia | umol/L | | 100 | |
| Conjugated Bilirubin | umol/L | | 25 | Neonates only |
| Bicarbonate | mmol/L | 10 | | |

| ANALYTE (SERUM/PLASMA) | | ACTION LIMITS | | COMMENTS |
|---------------------------|--------|---------------|-------------------------------------|---|
| | | LOWER LIMIT | UPPER LIMIT | |
| Cortisol | nmol/L | 50 | If 9am Cortisol | Unless part of dexamethasone suppression test |
| Ethanol | mg/L | 100 | 4000 | |
| FT4 | pmol/L | | 40 | |
| TSH | mU/L | | 50 | |
| Cyclosporin | ug/L | | 500 (Renal) 600 (BMT) | |
| Tacrolimus | ug/L | | 25 (Inpatients) 20 (Outpatients) | |
| Bile Acids | umol/L | | 20 | Ante-natal indications only |
| Urate | umol/L | | 340 | Ante-natal indications only |

* Croal B, The Communication of critical and unexpected pathology results.
Royal College of Pathologists. Document No. G158. Published: October 2017.

Specialist Services

Lipid Clinics (at Royal Free London only)

The department has a long-standing interest in the management of lipid disorders including familial hypercholesterolaemia. The department hosts a nationally recognised specialist clinical and laboratory service for the management of inherited lipoprotein disorders as well as complex lipoprotein abnormalities and their investigation. It is renowned for providing an integrated service for the management of familial hypercholesterolaemia, with cascade testing supported by clinical nurse specialists. There is also a paediatric service.

Supra Regional Assay Service (SAS) for Cardiovascular Biomarkers (at Royal Free London only)

The SAS service for cardiovascular biomarkers supports the investigation of complex lipoprotein abnormalities. Senior clinicians for the SAS centre can be contacted for advice on appropriate investigations. The centre also supports research and development through a research laboratory. We work with several collaborators both nationally and internationally on projects related to cardiac biomarkers and lipoprotein metabolism.

Any R and D enquiries should be directed to HSL R&D department contact Siddra Noureen at siddra.noureen@tdlpathology.com. Senior staff are always happy to discuss and advise on the appropriate choice of tests as well as providing clinical advice.

Andrology (At North Middlesex and Barnet Hospitals only)

The department operates an appointment only policy for the acceptance of semen samples for analysis. Patients who wish to use the service may book appointments on the following numbers:

North Middlesex University Hospital

020 8887 2925

Barnet General Hospital

020 3912 0366

Appointments can be made hourly from 08:30 to 12 noon Monday to Friday. **Samples can only be accepted if booked as it is a requirement of the Human Embryology and Fertilisation Authority that only one specimen is dealt with at a time.**

Semen analysis is performed on a specimen of semen produced after a minimum of two days' and a maximum of 5 days' abstinence from sexual intercourse. A pre-produced specimen must be brought to Pathology Specimen Reception at the appointed time. It must be collected directly into a pre-weighed specimen container (provided from Specimen Reception) and maintained at body temperature (keep in trouser pocket). **The specimen must be delivered to the laboratory within 50 minutes of collection.**

There are no facilities at North Middlesex Hospital for specimen collection. There are no facilities at Barnet.

Results are available:

- Post vasectomy: after 1 day
- Infertility: after 4 days

HSL Special Coagulation

The HSL Special Coagulation Laboratory, located at the Royal Free Hospital, is a dedicated laboratory that provides a specialist haemostasis and thrombosis diagnostic and treatment monitoring service for patients with inherited or acquired bleeding and thrombotic disorders. We serve a wide population.

Laboratory services include:

- A highly specialised laboratory service offering a range of tests for the definitive diagnosis of congenital and acquired bleeding and thrombotic disorders. This service includes:
 - A full repertoire of tests for the work-up of inherited and acquired bleeding disorders.
 - Standard and non-replacement treatment monitoring and factor inhibitor detection assays for patients with Haemophilia, von Willebrand's disease and other Rare Bleeding Disorders.
 - A full repertoire of tests-for the work up of inherited and acquired thrombophilias.
 - All types of anticoagulation treatment monitoring.
- A rapid access laboratory service to many specialist tests through prior discussion with the Haemophilia Registrar or Consultant at the Royal Free Hospital.
- A laboratory reference service for other Haemophilia treatment units.
- An evening out-of-hours on-call service to cover specialist coagulation tests required for an urgent diagnosis or treatment monitoring.
- A confirmation laboratory reference service for other laboratories.
- A national educational service for clinicians, clinical scientists, biomedical scientists and medical personnel invited to the department to receive training through International Haemophilia Training Centre (IHTC) programmes and fellowships.
- A clinical trial and contract research service, which includes clinical trials of therapeutic materials and analysis and validation of new methodologies.

HSL Special Coagulation is a UKAS Accredited Medical Laboratory (9345).

Urgent requests

During laboratory working hours urgent requests need to be marked clearly on the sample request.

Out-of-hours and urgent requests must be discussed with the Royal Free Hospital Haemophilia and Thrombosis Consultant on-call.

Specialist coagulation tests offered out-of-hours include those required for:

- Diagnosis of inherited or acquired haemophilia
- Quantification of clotting factor Inhibitors
- Urgent treatment monitoring in patients with haemophilia and other bleeding disorders
- Factor assay measurement for 'urgent' investigations of isolated prolonged Activated Partial Thromboplastin Time (APTT) and Prothrombin Time (PT) tests.
- Urgent anticoagulant levels (including LMWH, UFH, Danaparoid (Orgaran) anti Xa levels, Fondaparinux (Arixtra), Apixaban, Rivaroxaban and Edoxaban levels).
- Heparin-induced thrombocytopenia (HIT)
- Antithrombin levels in patients on l-asparaginase treatment

See below for contact details and arrangements in place when sending urgent requests (i.e. those requests whose results are required for immediate patient management).

The laboratory will endeavour to report all urgent tests within the published turnaround times. In addition, please call the laboratory for results of urgent tests.

Location

The HSL Special Coagulation Laboratory is located on the first floor, Royal Free Hospital Medical School building next to the Peter Samuel Hall, Hampstead site.

HSL Special Coagulation, Haemophilia and Thrombosis Laboratory
Floor 1
Royal Free Hospital
Pond Street
London
NW3 2QG

Special Coagulation

Opening times

The Laboratory is open between 09:00 and 17:30 Monday to Friday, and 09:00 and 17:00 at weekends and public holidays.

At other times please contact the On-call Consultant for the Haemophilia Centre via the Royal Free Hospital Switchboard 020 7794 0500 if the on-call BMS is required.

Contacts during working hours

Tel: Direct (020 7830 2274) or via Royal Free Hospital (RFH) Switchboard 020 7794 0500 ext. 34485, 34484 (BMS) or Bleep 71-1811 (Haematology Specialist Registrar).

Email: rfh.haemophilia@hslpathology.com (only for non-urgent query use).

Contacts out-of-hours

By arrangement with the on-call Haematology Specialist Registrar and Haemophilia Consultant via RFH Switchboard (020 7794 0500).

On-Call BMS Air call number: 340, contact via RFH Switchboard (RFH Switchboard 020 7794 0500).

Staff/Key personnel

CLINICAL STAFF

| | | |
|--|-----------------------------------|--------------------------------|
| Consultant Haematologist and Co-Centre Director and Clinical Lead for Coagulation for Royal Free and HSL | Professor Pratima Chowdary | 020 7794 0500 Ext. 35921 |
| Consultant Haematologist | Professor Keith Gomez | 020 7794 0500 Ext. 35561 |
| Consultant Haematologist and Associate Professor at University College London | Dr Paul Batty | 020 7830 2068 |
| Specialist Registrar for clinical advice | | 020 7794 0500 Bleep 71-1811 |

LABORATORY STAFF

| | | |
|--|---------------------|--|
| Laboratory Head of Department (Special Coagulation, Haemophilia) and HSL Scientific Lead Coagulation | Anne Riddell | 020 7830 2274 Ext. 34484 |
| Quality Manager | Obi Mpamugo | 07976 792436 |
| Laboratory enquiries/results | | 020 7830 2274 (Direct) 020 7794 0500 Ext 34484, 34485 or 34239 |

Preparing patients

It is essential that the person responsible for preparing the patient and collecting the specimen ensures that they check the requisition form for the requested tests and:

- Explains the reason for the specimen being taken.
- Correctly determines the identity of the patient prior to collection by asking the patient to verbally provide their name and date of birth and confirm this by checking their details on the request form or their wristband as appropriate.
- Checks the patient meets particular conditions prior to sample collection such as:
 - Pre-determined times or at timed intervals
 - Cessation of medication
- Obtaining consent from the patient. Note: Patients presenting themselves with a request form at the point of sample collection or providing a sample themselves to their healthcare provider will be viewed as providing implied consent.
- Assembling the specimen collection bottles and supplies e.g., sharps bin, needles, cotton wool and alcohol swab gloves etc. – needed to carry out the procedure within safe and easy reach.
- Wearing gloves, collecting the specimen and labelling the specimen container.
- Packaging and transporting the specimen containers following the appropriate guidelines for specimen collection.

Specimens

Guidance on specimen collection

A properly collected specimen is critical to quality test results.

- When collecting blood samples for Platelet Studies, it is recommended that you use 10ml green cap Sarstedt S-Monovette® Citrate 0.107M (3.2%) tubes.
- When collecting blood samples for all other special coagulation tests:
 - For RFH and Barnet Hospital patients, prepare the patient and collect the samples following the Royal Free Trust 'Taking blood (venepuncture)' guidelines which provides information on blood collection tubes, order of draw to avoid cross contamination of additives between tubes (coagulation samples must be collected first), and mixing of tubes following collection.
 - Collect the blood sample into light blue capped sodium citrate vacutainer tubes which contain 0.109M (3.2%) sodium citrate as anticoagulant.
 - Immediately and gently mix the blood inside the tube 3-4 times to form the plasma. Note: insufficient sample collection or too vigorous mixing can result in inaccurate test results and the need to re-draw.
- For all other locations prepare the patient and collect the venous blood samples for special coagulation tests according to local guidelines on venepuncture.

Specimen labelling

Each specimen container must be labelled:

- At the time of collection i.e., next to the patient when the sample is taken.
- With the correct barcode label (pre-printed label with accession numbers generated by an information system).
- With a single label placed on it.
- With a label whose information matches the information on the accompanying request form. See Sample rejection / acceptance criteria for essential and desirable sample labelling requirements.

Note:

NEVER label the specimen bag.

NEVER wrap the request form around the specimen bottle as a specimen label.

Specimens

For requests made using EPR (Royal Free Hospital) or EPR2 (Barnet Hospital, Edgware Community Hospital)

Place the EPR specimen label along the length of the tube, as straight and as far up as possible without touching the cap of the tube, so that the analysers can read the label.

It is imperative that the label quality is checked prior to labelling the specimen bottles as poor-quality barcodes cause delays and introduce the risk of errors in the laboratory.

Request forms

A completed request form (electronic or manual) must accompany each patient sample with the details on the specimen label matching the details on the corresponding request form.

Either complete:

- Royal Free London users
 - EPR or EPR2 request (Royal Free London NHS Foundation Trust internal electronic order comms system)
 - A manual request form in the event of downtime. The form can be accessed at <https://freenet2.royalfree.nhs.uk/sites/menu/group-clinical-services/SitePage/88305/downtime-forms>
- GPs – tQuest request (GP order comms system)
- External Users – local request forms

All requests should be completed with all relevant information, including:

- NHS number (or Hospital number)
- Patient name (last name and first name)
- Date of birth
- Gender
- Ward or clinic
- Requesting doctor with contact number – the signature, bleep and/or contact number of the requesting doctor must also be completed.
- Clinical details
- Tests requested
- Date and time sample taken

- Consultant
- Consent (where appropriate)
- Paper request forms should include the signature/initial of the person collecting the samples, confirming that they have verified the patient details on the label matches the patient details on the test requisition and that the specimen has been drawn.

Specimen packing and transport

- Place the labelled specimen container in a plastic specimen mini-grip bag, which is available on the wards, in the clinics and from central stores, and seal.
- Each specimen bag must only contain samples from one patient (DO NOT mix patient samples).
- Place the matching requisition in the outside pouch of the bag.

Royal Free Hospital requirements

Send the specimen promptly to the laboratory or to the collection point. For guidance on the most appropriate means of transporting specimens please see below.

Delivery using the RFH pneumatic air chute system

- Where samples can be sent using the pneumatic air chute system, place the specimen bag into a pod. This will prevent any breaks or leaks. In the event the pod is visibly defective (e.g., the lid will not close, or the housing is cracked), please DO NOT remove any defective pods from circulation and inform the Estates Team so that they can organise for replacement carrier(s) to be obtained for the relevant clinical area.
- Close the pod securely and place in the station.
- Enter destination code 591 when transporting samples during normal working hours and code 885 when sending samples out-of-hours.
- Press: Send (PTT).

Note: Samples for Platelet studies (aggregometry, lumiaggregometry and platelet nucleotides) and whole blood assays – IMPACT R, PFA-200 and ROTEM – **MUST NOT** be sent via the air chute. These must be hand-delivered to the laboratory as soon as possible after collection (within 2 hours of venepuncture).

Delivery in person (including RFH hospital porters)

Place the specimen in a leak-proof sealed plastic biohazard bag designed for specimen transport and drop off at the collection point or deliver as soon

as possible to the laboratory.

Note: When transporting samples for PAI-1 antigen levels, place the specimen container in crushed ice and deliver to the laboratory.

See the table below for collection times during routine working hours from the Royal Free Hospital Trust wards / departments / clinics.

| Collection time | From | Time delivered to Central Reception |
|-----------------|---------------------|-------------------------------------|
| 9.15 | Concourse | 9.45 – 10:00 |
| 10.30 | Concourse / Clinics | 11:00 – 11:15 |
| 11.30 | Concourse / Clinics | 12.00 – 12:15 |
| 14.00 | Concourse / Clinics | 14.45 – 15:00 |

Note: Samples transported out of hours are to be delivered to the Rapid Response Laboratory Specimen Reception.

GPs and community clinics

Blood samples to be collected and placed in a biohazard bag which will be delivered to Royal Free Hospital Pathology Reception (Floor 1) or directly to the Haemophilia and Thrombosis Laboratory (Floor 1) via courier.

External users (excluding GPs, community clinics, etc.)

- If a delay is expected with transportation of citrated blood samples to the laboratory, the sample should be double-spun, separated, frozen within 4 hours of collecting the sample from the patient and transport frozen.
- Frozen plasma should be sent in polystyrene boxes with dry ice, sealed, placed into specimen bags and delivered by courier.
- By post: Blood samples which are considered to be Category B Biological Substances are assigned to UN3373 and must be packaged according to the Dangerous Goods ADR (Road) Packing Instruction 650 for transport.
- If there is any concern that the material being sent does not meet UN3373 (including most category 3 and 4 pathogens), the laboratory must be contacted for advice before sending.

- Place the labelled primary specimen container into a plastic specimen mini-grip bag together with sufficient absorbent material (e.g., tissue paper or cotton wool), to absorb the blood in the event of a leak, and seal.
- Each specimen bag must only contain samples from one patient (DO NOT mix different patient samples in the same specimen bag).
- Place the matching requisition in the outside pouch of the bag and place this into the secondary packaging with sufficient cushioning material to secure the primary container within the secondary container.
- Close / seal the secondary container.
Note: Where multiple primary receptacles need placing in single secondary packaging, they must be separated using cushioning material to prevent contact between them.
- The transport of pathology samples from external locations to the Royal Free Hospital is provided by City Sprint Ltd. When the courier presents you with a diagnostic substances UN3373 transport bag or box (i.e., outer packaging), place the secondary container into the transport bag/box.
- Where single or multiple secondary containers are placed into the UN3373 transport bag ensure that these are cushioned to secure the secondary packaging within the outer packaging – thus preventing movement during transportation.
- Ensure the outer packaging is sealed before it leaves your premises.

Factors affecting test performance

Factors that significantly affect the performance of the examination or interpretation of results

- Underfilled or overfilled citrate tubes so that the ratio of anticoagulant to blood is less or greater than 1:9.
- Clotted samples.
- Haemolysed samples as a result of mixing tubes too vigorously, using the wrong size tube, using the wrong size needle or when the blood is drawn too slowly.
- Heparin-contaminated samples (unless for monitoring heparin levels).
- Presence of DOACS (unless for monitoring) – e.g. Rivaroxaban, Apixaban, Edoxaban, Dabigatran, Argatroban.
- Presence of anti-platelet or non-steroidal drugs prior to platelet function testing (unless used for the detection of the drug).
- Out-of-date citrate tubes.
- Samples for coagulation tests greater than 4 hours old.
- Samples for INR greater than 6 hours old.
- Chylomicrons causing lipaemic samples can interfere with the measurement of platelet aggregation studies and therefore the test should not be performed shortly after a fatty meal.
- Patient samples with low platelet counts ($<80-100 \times 10^9/\text{dL}$) for platelet function investigations. When platelet investigations are required for patients with platelet counts $<80 \times 10^9/\text{L}$, please inform the laboratory.
- Factors affecting platelet function can include:
 - Foods: e.g., garlic, alcohol, onions, peppers and ginger affect platelet function.
 - Drugs: A comprehensive list for patient preparation is outlined in the BSH Clinical and laboratory diagnosis of heritable platelet disorders in adults and children: a British Society for Haematology Guideline (2021) (<https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.17690>)
 - Examples include:
 - Non-steroidal anti-inflammatory drugs – aspirin; reversible cyclooxygenase inhibitors such as indomethacin, ibuprofen, sulindac and naproxen.
 - Antibiotics, penicillins, cephalosporins, nitrofurantoin, Miconazole Thienopyridines – Ticlopidine, clopidogrel.
- GPIIb/IIIa antagonists – Abciximab, tirofiban, eptifibatide.
- Drugs that affect platelet cAMP levels – Prostacyclin, iloprost, dipyridamole, cilostazol.
- Anticoagulants and fibrinolytic agents – heparin, streptokinase, tissue plasminogen activator, urokinase, e-aminocaproic acid.
- Cardiovascular drugs – nitroglycerin, isosorbide dinitrate, propranolol, nitroprusside, nifedipine, verapamil, diltiazem, quinidine.
- Volume expanders – Dextran, hydroxyethyl starch.
- Psychotropic drugs and anesthetics – psychotropic drugs: imiprimine, amitriptyline, nortryptaline, chlorpromazine, flufenazine, trifluoperazine and haloperidol.
- Anesthetics – dibucaine, tetracaine, metycaine, cyclaine, butacaine, nepercaine, procaine, cocaine, plaquenil and halothane.
- Chemotherapeutic agents – Mithramycin, daunorubicin, BCNU.
- Miscellaneous drugs – serotonin antagonists, antihistamines, Radiographix contrast agent, foods and food additives.

Patients should be advised to avoid taking these medications for up to 14 days before the test, asked about their current medication and diet prior to obtaining blood samples for these tests.

Sample rejection/acceptance criteria

Samples or request forms will be rejected if they are received without the minimum essential identification criteria listed below and as a result the details on the sample label cannot be matched with the details on the request form.

- Essential labelling requirements on the sample bottle
 - NHS, CHI or Health and Care Number
 - Patient's full name or unique coded identifier
 - Date of birth and/or hospital number
 - Date and time
- Desirable labelling requirements on the sample bottle
 - Nature of sample, including qualifying details, e.g., baseline, pre-level, post-level, left, distal etc. especially if more than one sample per request is submitted
- Essential labelling requirements on the request form
 - NHS, CHI or Health and Care Number
 - Patient's full name or unique coded identifier
 - Date of birth and/or hospital number
 - Gender
 - Patient's location and destination for report
 - Patient's consultant, GP or name of requesting practitioner
 - Investigation(s) required.
- Desirable labelling requirements on the request form
 - Clinical information including relevant medication (which is sometimes essential e.g. treatment monitoring, platelet aggregation requests, LMWH, UFH and DOAC monitoring test requests)
 - Date and time sample collected (which is sometimes essential, e.g. treatment monitoring, platelet aggregation requests, LMWH, UFH and DOAC monitoring test requests)
 - Patient's address including postcode
 - Practitioner's contact number (bleep or extension).

Samples will be rejected if they are unlabelled, mislabelled, have a label which has illegible information or have a label whose information does not match the information on the request form.

Other factors that will cause sample rejection:

- Citrated blood samples for coagulation testing that are filled above the maximum or below the minimum fill line etched in the sample tube. A minimum of 90% and maximum of 110% fill is required to have an appropriate ratio of blood to anticoagulant/plasma otherwise the samples are subject to unpredictable dilution and anticoagulation effects which would invalidate the test results.
- Citrated blood collection tubes that are used past their expiry date.
- Samples that are haemolysed.
- Samples that are clotted.
- Samples that are received leaking and the container is found to be damaged.
- The wrong sample type has been received for a given investigation or the sample has been collected in the wrong sample bottle.
- Citrated whole blood samples for Anti Xa assays (LMWH, UFH, Fondaparinux, and Danaparoid levels) which are greater than 2 hours old.
- Citrated whole blood samples received after 4 hours of collection for clotting screens, APTT, FV and FVIII and after 6 hours of collection for PT/INR.
- Citrated blood samples received for specialist coagulation testing (Bleeding state work ups – Factors II, V, VII, VIII, IX, XI, XII, VWF:Ag, VWF:RCo, VWF:CB, Platelet Aggregation and Lumiaggregometry studies, Platelet Function Analysis on PFA-200, FVIII, FIX, FXI, FV Inhibitor Tests, Pro-thrombotic (Thrombophilia testing) – protein C (PC), protein S (PS), Antithrombin (AT), APC-R ratio, other tests plasminogen, antiplasmin, PAI-1, tPA, ROTEM, Thrombin generation, Lupus Anticoagulant, DOAC (Rivaroxaban, Apixaban, Edoxaban, Dabigatran, Argatroban levels), which fulfil the above criteria and are received more than 4 hours after collection.
- Frozen plasma aliquots that have thawed in transit due to incorrect transport conditions (delay in transit, lack of dry ice, etc.).

Sample rejection/acceptance criteria

- Whole citrated blood samples for Platelet Studies (Platelet aggregation, Lumiaggregometry and platelet nucleotide tests) and ROTEM testing which have been sent via the pneumatic tube and in some cases by forms of motorised transport (motorcycle courier). These samples should be delivered by hand to the Haemophilia and Thrombosis Laboratory (RFH) or via the dumb waiter from the RFH Haemophilia and Thrombosis centre.
- Whole citrated blood samples for PAI-1 antigen analysis which are not delivered on crushed ice.

The laboratory will contact the requestor informing them that the sample will be rejected and will not be processed, giving the reasons for the rejection and request for a repeat sample to be collected and sent. Details of the conversation will be documented in the patient record in the LIMS system WinPath.

Note: Laboratory staff are NOT allowed to:

- Amend the details on the sample or request form.
- Return samples if the laboratory is contacted by the Ward/Clinical area stating that they wish to relabel the specimen, as the integrity of the specimen cannot be guaranteed in such cases. Instead a repeat specimen MUST be obtained and sent to the laboratory.

Where the date on the printed label differs from today's date the requestor can be contacted to confirm the collection date and staff are allowed to enter the information onto WinPath.

Requesting additional tests

Requesting additional tests (add on requests)

Under certain circumstances, it is possible to add tests onto samples that are already in the laboratory, but this will depend on sample stability, tube type and, for some tests, there will be timing restrictions. There may not be sufficient specimen to perform the additional tests. Investigations are best performed on fresh primary specimens.

Additional requests may be received by phone or in person (see contact information). As much information as possible should be provided – for example, to which sample should the tests be added. This will minimise the risk of tests being added to the wrong sample, resulting in unnecessary delays to patient management.

Where the laboratory receives a request for an add-on that cannot be fulfilled the user will be notified.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|---|--|-------------------------------|--------------------------|------------------------|
| Activated Partial Thromboplastin Time (APTT) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 4 hours |
| Activated Protein C ratio with Factor V deficient plasma | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| ADAMTS 13 IgG Activity[#] | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 1 day | No special instructions. | 4 hours |
| ADAMTS 13 Inhibitor[#] | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 1 day | No special instructions. | 4 hours |
| Antithrombin Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Antithrombin Antigen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Apixaban Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| APTT 50/50 Mix | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 4 hours |
| APTT Inhibitor Screen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 1.0mL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| APTT Ratio for UFH Monitoring | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 2 hours |
| Argatroban Level - Direct Thrombin Inhibitors | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Chromogenic Factor VIII (Biophen) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Chromogenic Factor VIII (Coamatic - Bovine Factors) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Chromogenic Factor IX | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Chromogenic Nijmegen FVIII Bethesda | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

[#] All tests are carried out by HSL Special Coagulation unless otherwise noted with [#] where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|--|---|-------------------------------|--------------------------|------------------------|
| Clauss Fibrinogen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citratd plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 4 hours |
| Dabigatran Level - Direct Thrombin Inhibitors | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Dalteparin | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Danaparoid Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 2 hours |
| Edoxaban Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Emicizumab Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Enoxaparin Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Factor II - Extrinsic One Stage PT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor V - Extrinsic One Stage PT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor V Leiden G1691A and Prothrombin (FII) G20210A gene mutations | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 1 week / 1 day (urgent) | No special instructions. | N/A |
| Factor VII - Extrinsic One Stage PT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor VIII - Intrinsic One Stage APTT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor VIII Inhibitor | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

All tests are carried out by HSL Special Coagulation unless otherwise noted with # where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|---|---|-----------------------------|--------------------------|------------------------|
| Factor IX Antigen (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks | No special instructions. | 4 hours |
| Factor IX Inhibitor | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor IX - Intrinsic One Stage APTT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor IX using Synthafax APTT Reagent | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor X - Extrinsic One Stage PT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor XI - Intrinsic One Stage APTT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor XI Antigen (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks | No special instructions. | 4 hours |
| Factor XI Inhibitor | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor XII - Intrinsic One Stage APTT Assays | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Factor XIII Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Factor XIII Antigen (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Fibrinogen Antigen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Fondaparinux Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 2 hours |
| FVII Antigen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

All tests are carried out by HSL Special Coagulation unless otherwise noted with # where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|---|---|-----------------------------|---|------------------------|
| Glycoprotein Ib (RFH users only)# | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 7 days | Please pre-arrange with the Laboratory, collect a Healthy control at the same time as Patient sample | 4 hours |
| Glycoprotein IIb/IIIa (RFH users only)# | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 7 days | Please pre-arrange with the Laboratory, collect a Healthy control at the same time as Patient sample | 4 hours |
| High Molecular Weight Kininogen HMWK (Fitzgerald Trait) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Low Molecular Weight Heparin (Anti-Xa) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 2 hours |
| Lupus Screen - Dilute Russell Viper Test and Confirmation | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 2 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Lupus Screen - Silica Clot Time and Confirmation | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 2 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| PFA-200 (Collagen/ADP Closure Time (seconds)) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 4 hours | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Test analysis must be completed within 4 hours of venepuncture. | 4 hours |
| PFA-200 (Collagen/Epinephrine Closure Time (seconds)) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 4 hours | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Test analysis must be completed within 4 hours of venepuncture. | 4 hours |
| PIVKA# | Serum sample (Red Top Tube) | 14 days | Sample must be protected from light | 4 hours |
| Plasmin Inhibitor Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Plasminogen Activator Inhibitor-1 Antigen (PAI-1 Ag) (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | Place the specimen container in crushed ice and transport to the Laboratory immediately for processing | 4 hours |
| Plasminogen Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

All tests are carried out by HSL Special Coagulation unless otherwise noted with # where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|--|--|--------------------------|---|------------------------|
| Platelet Aggregate Size Surface Coverage (IMPACT-R) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 4 hours | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Test analysis must be completed within 4 hours of venepuncture. | 4 hours |
| Platelet Aggregation (Light Transmission Aggregometry) | Whole blood (BD Light Blue Citrate); 5 x 2.7ml, or 3x4.5mL, or 1x10mL Sarstedt Monovette | 4 hours (Report 2 weeks) | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Test analysis must be completed within 4 hours of venepuncture. | 4 hours |
| Platelet Factor 4 IgG Heparin Induced Thrombocytopenia Screen HIT | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Platelet Lummiaggregometry | Whole blood (BD Light Blue Citrate); 5 x 2.7ml, or 3x4.5mL, or 1x10mL Sarstedt Monovette | 4 hours (Report 2 weeks) | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Test analysis must be completed within 4 hours of venepuncture. | 4 hours |
| Platelet Nucleotides | Whole blood (BD Light Blue Citrate); 5 x 2.7ml, or 3x4.5mL, or 1x10mL Sarstedt Monovette | 4 hours (Report 2 weeks) | The samples, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. Platelet Lysate preparation must be completed within 4 hours of venepuncture. | 4 hours |
| Porcine FVIII Inhibitor | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| PreKallikrein (Fletcher Trait) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Protein C Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Protein C Antigen (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Protein S Activity | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

All tests are carried out by HSL Special Coagulation unless otherwise noted with # where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|--|--|-------------------------------|--|------------------------|
| Protein S Free | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| Protein S Total (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 2 weeks / 1 day (urgent) | No special instructions. | 4 hours |
| Prothrombin F 1+2 | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 month | Please discuss with the Laboratory | 2 hours |
| Prothrombin Time (PT) / INR | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 6 hours |
| Reptilase Time | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 4 hours |
| Rivaroxaban Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| ROTEM | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 1 day | The sample, once collected, must be kept at room temperature and hand delivered to the Haemophilia Laboratory immediately. | 4 hours |
| Thrombin Generation Assay | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 2 weeks | Please discuss with the Laboratory | 4 hours |
| Thrombin Time | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen single spun Citrated plasma 500µL x 1 aliquot | 6 hours / 2 hours (urgent) | No special instructions. | 4 hours |
| Thrombin-Antithrombin Complexes | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 1 month | Please discuss with the Laboratory | 2 hours |
| Tinzaparin Level | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 4 hours |
| Tissue Plasminogen Activator (t-PA) Antigen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 2 weeks | No special instructions. | 2 hours |
| Unfractionated Heparin (Anti-Xa) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citrated plasma 500µL x 1 aliquot | 24 hours | No special instructions. | 2 hours |
| Vitamin K1* | Serum sample (Red Top Tube) | 14 days | Sample must be protected from light | 4 hours |

* Whole blood stability from venepuncture at room temperature.

All tests are carried out by HSL Special Coagulation unless otherwise noted with # where it will be referred to an external testing laboratory (test not on TDL/HSL scopes of accreditation).

Reference ranges for tests will be indicated on the report.

Special Coagulation tests

| TEST NAME | SAMPLE REQUIREMENT | TAT/ URGENT TAT | SPECIAL INSTRUCTIONS | WHOLE BLOOD STABILITY* |
|-------------------------------------|---|-----------------------------|------------------------------------|------------------------|
| VWF Activity Latex | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| VWF Antigen (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 10 days / 1 day (urgent) | No special instructions. | 4 hours |
| VWF Antigen Latex | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 week / 1 day (urgent) | No special instructions. | 4 hours |
| VWF Collagen Binding (ELISA) | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 10 days / 1 day (urgent) | No special instructions. | 4 hours |
| VWF Inhibitor Screen | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 2 weeks | Please discuss with the Laboratory | 4 hours |
| VWF Multimer | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 month | No special instructions. | 4 hours |
| VWF Ristocetin o-factor | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 10 days / 1 day (urgent) | No special instructions. | 4 hours |
| VWFXVIII Binding | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL External Requests: Frozen double centrifuged Citratd plasma 500µL x 1 aliquot | 1 month | No special instructions. | 4 hours |
| Warfarin Level[#] | Whole blood (BD Light Blue Citrate), 2.7mL or 4.5mL | 14 days | No special instructions. | 4 hours |

* Whole blood stability from venepuncture at room temperature.

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Reference ranges for tests will be indicated on the report.

HSL Virology

HSL Virology provides a modern, rapid and fully comprehensive clinically-led diagnostic and reference service. Clinical services include transplantation, HIV medicine, genito-urinary medicine, infectious diseases, stem cell and solid organ transplant, haematology and oncology, renal dialysis, hepatology, obstetrics and gynaecology, paediatrics, neurology and occupational health.

The service is highly automated, and has an extensive repertoire of serological- and molecular-based tests. It can identify a wide range of viral infections, and monitor viral load levels in patients undergoing antiviral treatments for infections such as HIV 1 and 2, hepatitis B, hepatitis C and cytomegalovirus. We provide a multiplex viral respiratory molecular assay, and a multiplex viral gastroenterology molecular assay to assist in the management and control of infection in the clinical setting.

We also provide an antiviral drug resistance service for patients undergoing treatment for HIV, hepatitis B, hepatitis C and cytomegalovirus, serve as a national reference centre for the diagnosis of congenital cytomegalovirus infection – testing neonatal blood from Guthrie cards – and carry out DNA testing for bacteria associated with sexual health.

This department is a leading site for the training of biomedical scientists, clinical scientists and medical doctors including FY2 trainees and specialty registrars. The department also holds the IBMS pre- and post-registration training approval for completion of the IBMS Registration Portfolio and Specialist Diplomas. HSL Virology is a UKAS Accredited Medical Laboratory No. 8169.

Staff /Key personnel

CLINICAL STAFF

| | | | |
|--------------------------------------|---------------------|---------------------|---------------|
| Clinical Specialty Lead for Virology | Gee Yen Shin | geeyen.shin@nhs.net | 020 3447 8991 |
|--------------------------------------|---------------------|---------------------|---------------|

LABORATORY STAFF

| | | | |
|--|---------------------------|---|-------------------------|
| Quality Manager for Molecular Pathology, Genetics, Virology and IT | Shelley Chaytor | shelley.chaytor@hslpathology.com or shelley.chaytor@nhs.net | 020 7307 7373 Ext: 3508 |
| Molecular Virology Operations Manager | Melanie Turner | melanie.turner@hslpathology.com | 020 7307 7373 Ext: 3508 |
| Molecular Virology Scientific Lead | Dr Paul Grant | Paul.Grant@hslpathology.com | 020 7307 7373 Ext: 3508 |
| Senior BMS in Serology | Quincy Kusi-Appouh | Quincy.Kusi-Appouh@hslpathology.com | 020 7307 7373 Ext 3140 |
| Virology Service Manager | Wendy Chatterton | wendy.chatterton@hslpathology.com | 020 7307 7373 Ext:3241 |

Molecular microbiology (Sexual health)

CLINICAL STAFF

| | | | |
|--|--------------------|---------------------|---------------|
| Clinical Specialty Lead for Microbiology | Robin Smith | Robin.smith@nhs.net | 020 7794 0500 |
|--|--------------------|---------------------|---------------|

LABORATORY STAFF

| | | | |
|----------------------------------|------------------------|---------------------------------|-------------------------|
| Quality Rep for STI NAAT service | Simon Stevenson | Simon.stevenson@hslpatholgy.com | 020 7307 7373 Ext: 3516 |
|----------------------------------|------------------------|---------------------------------|-------------------------|

General enquiries

Phone: 020 7307 9400

Email

Antiviral Resistance

Molecular.sequencingEnquiries@hslpathology.com

Molecular Pathology (non HIV,HCV, HBV)

Molecular.Virology@hslpathology.com

Blood Borne Viruses PCR (HIV, HCV, HBV)

BBVLab@hslpathology.com

Automated Serology

Automated.Serology@tdlpathology.com

Manual Serology

Viral.Serology@hslpathology.com

Out of hours service

For Molecular Virology, out of hours laboratory testing service is not available on after 5.30pm Mon-Fri, and after 5pm on Saturdays, Sundays and Bank Holidays.

For urgent serology, out of hours testing or for clinical advice, please contact the on-call relevant site Virology Consultant via the switchboard:

Barnet & Chase Farm: 020 8216 4600

North Middlesex: 020 8887 2000

Royal Free: 020 7794 0500

UCLH: 020 3456 7890

For services relating to the molecular STI and urgent out of hours bacterial serology services please use above numbers but ask for the Microbiologist consultant on-call.

Virology specimens

See page 14 for general information on ordering tests, and specimen collection, packaging and transport.

Labelling

The specimen must be labelled with the patient details as on the request form.

Please ensure that electronically created barcodes are placed down the length of the specimen container, not wrapped round it.

Please note that unlabelled samples, or samples with insufficient unique identifiers cannot be processed and will be discarded. Sex cannot be used as a unique identifier.

Containers

Blood should be taken either without anticoagulant (for general serology) or with the appropriate anticoagulant (for most molecular testing; see below). Please contact the laboratory if you are uncertain about the appropriate blood container.

Swabs for virological investigations should be placed immediately in viral transport medium (VTM). Do not use charcoal or microbiology swabs. Please use the VTM provided in the NPS (3ml) and universal viral swab packs (2ml).

Other specimens are collected in generic sterile containers available in wards and clinics or from central stores.

Transport to the Laboratory

Biological Substances; Category A infectious substances must be assigned to UN 2814 or UN 2900, as appropriate, Category B, Clinical Specimens, Diagnostic Specimens, UN 3373

All specimens should be in individual bags to protect them from external contamination.

Key Factors affecting the performance of the test/interpretation of the results.

- Haemolysed, lipaemic and out of date sample containers may give inaccurate test results. EDTA Bloods for HIV Viral Load should be received in the lab within 6 hours of blood collection.
- Heavy blood contaminated CSF may produce results that do not reflect the content of the CSF, but rather what is present in the blood.
- Insufficient sample volume in the STI Aptima tube.

Request procedures

ROYAL FREE LONDON NHS TRUST (ALL SITES)

All routine specimens should be sent to the Central Pathology Reception (SRA) on the 1st floor of the main Royal Free Hospital Building or the Barnet site Rapid Response laboratory, or blood specimens and dry swabs can be sent through the pod system direct to SRA. Respiratory swabs and Faeces must be walked down to the SRA or left for the porters to collect.

For all urgent requests during the laboratory opening hours (Mon-Fri 8am to 5.30pm) the Consultant Virologist, Specialty Registrar, or Section managers should be contacted to discuss the availability of tests. The specimens should be brought directly to the SRA and not left for the porters to deliver.

For requests on Saturdays, Sundays and Bank Holidays (testing available 9am-5pm molecular, 24/7 serology) contact the Medical Virologist on-call via switchboard. All tests will have to be urgently couriered to the core laboratory from the SRA after booking and there has to be sufficient time to process the test within the opening hours.

Where possible please order test request(s) using EPR or TQuest.

If unable to use the system, send a purple or orange Virology request form with the test request(s) and clinical details.

The following request forms will still be required:

- Multipart single pathology request form: For GPs
- Specialised requests forms: For HIV, HCV, HBV, CMV and Influenza resistance drug resistance testing, CMV Guthrie Card testing.

There must be at least 3 unique patient identifiers on both the requests and the specimens.

For patients suspected with unusual viruses like Dengue, Hanta, West Nile and Chikungunya, please give travel history, dates and clear clinical details. This is required by the referral laboratory where the samples are sent and analysed.

Additional Requests

Please call the laboratory during routine working hours for additional tests. Additional tests can be added onto the original sample for Molecular Virology/Blood Borne Virus PCR within one week of sample receipt, Serology specimens are available for 7 days, unless they are an antenatal sample, transplant or needlestick.

UCLH

All routine specimens from the main hospital sites and Mortimer Market should be sent to the Rapid Response Laboratory (RRL) specimen reception area (SRA) which is located in 60 Whitfield Street.

For all urgent requests during the laboratory opening hours (Mon-Fri 8am to 5.30pm), the Consultant Virologist, Specialty Registrar, or Section leads should be contacted to discuss the availability of tests. The urgent specimens should be brought/sent directly to the SRA and marked clearly.

For urgent requests on Saturdays, Sundays and Bank Holidays (testing available 9am-5pm molecular, 24/7 serology) contact the Medical Virologist on-call via switchboard. All tests will have to be urgently couriered to the core laboratory after booking at the SRA and there has to be sufficient time to process the test within the opening hours.

All tests for virology should be ordered through the EPIC system; Please ensure that there are sufficient clinical details available on the requests either electronic or paper to allow the team to be able to identify the requirements, for testing this is especially important if the samples are to be sent to referral laboratories for specialist testing. Ensure that all the questions asked within the Epic request system are answered.

HTLV viral load testing on either blood or CSF must reach the referral hospital within 24 hours of being drawn. Therefore this test cannot be added onto stored samples.

For HIV, HCV or HBV resistance specimens, it is important to include any information on the patients' treatment regime or if they are treatment-naive.

Request procedures

NORTH MIDDLESEX

All routine specimens from the main hospital sites should be sent to the Rapid Response Laboratory (RRL) specimen reception area located on the North Middlesex Site.

For all urgent requests during the laboratory opening hours (Mon-Fri 8am to 5.30pm) the Consultant Microbiologist, Specialty Registrar, or Section leads should be contacted to discuss the availability of tests. The urgent specimens should be brought/sent directly to the SRA and marked clearly.

For urgent requests on Saturdays, Sundays and Bank Holidays (testing available 9am-5pm molecular, 24/7 serology) contact the Medical Microbiologist on-call via switchboard. All tests will have to be urgently couriered to the core laboratory after booking from the SRA and there has to be sufficient time to process the test within the opening hours.

All tests for virology should be ordered through the Medway system; Please ensure that there are sufficient clinical details available on the requests either electronic or paper to allow the team to be able to identify the requirements, for testing this is especially important if the samples are to be sent to referral laboratories for specialist testing. Ensure that all the questions asked within the Medway request system are answered.

OTHER USERS

All other users of services must ensure that samples are sent to the hospital sites that you have agreed prices/have SLAs with.

Samples must be received with clear requests with clinical details, and clearly labelled specimens.

ALL USERS

Any additional requests for tests to be added to samples which have been stored must be requested by email (see contact emails above), with sufficient information to positively identify the sample/patient to which these tests are to be added.

Specialities

Within the Virology Department, there are four main diagnostic sections; Virus Detection, Virus Serology, Molecular HIV and Hepatitis, and Anti-viral Drug Resistance.

Molecular Virology (Floor 5)

This section uses Real-time PCR techniques for the detection of viral nucleic acid in clinical samples. PCRs routinely performed in the Virology Department are for the detection of:

- Adenovirus (Qualitative & Quantitative)
- Herpesviruses (HSV 1 & 2, VZV, (Qualitative), CMV, EBV (Qualitative & Quantitative), HHV6 (Quantitative), HHV8 (Qualitative & Quantitative))
- Enterovirus
- Parvovirus B19
- Respiratory viruses (RSV, Influenza A/B, Parainfluenza 1/2/3/4, Rhinovirus, Human Metapneumovirus, Enterovirus, Adenovirus, and Coronavirus, parechovirus)
- Influenza A typing
- MERS-CoV
- COVID-19 PCR (SARS-CoV-2)
- Gastroenteritis (Sapovirus, Norovirus type I and II, Rotavirus, Astrovirus, Adenovirus and Adenovirus Group F)
- BK PCR Quantitative
- Qualitative JC PCR
- HIV-1 Proviral DNA
- HIV-2 genome detection and viral load
- Hepatitis E RNA Quantification
- Hepatitis D RNA Quantification
- Viral CSF panel (available viruses: CMV, HHV6, Enterovirus, Parechovirus, VZV PCR, HSV 1 & 2 PCR)
- 16 & 18S sequencing
- Genital Ulcer PCR (Syphilis, HSV 1 & 2)

Viral Serology (Floors 1 and 2)

This section detects viral antibodies (IgG and IgM) and antigens in patient serum using manual and automated assays and are split over two floors depending on whether it is a manual or automated process:

Floor 1 Automated

- COVID-19 Total Antibodies (SARS-CoV-2)
- HIV 1 & 2 Ag /Ab screening, HIV 1&2 Ag/Ab confirmation
- HBsAg screening, HBsAg confirmation and HBsAg quantification
- HB 'e' markers Ag and Ab
- HB core Total and IgM
- HBsAb
- HCV Ab screening, HCV Ab confirmation
- HCV Ag screening
- Hepatitis D total antibody
- Hepatitis A Total and IgM
- CMV IgM, IgG and Avidity
- Rubella IgM and IgG
- Human T-lymphotropic virus (HTLV) 1 & 2 IgG
- VZV IgG
- HSV 1 & 2 IgG
- Epstein Barr Virus (EBV) VCA IgG, IgM and EBNA IgG
- Parvovirus IgM and IgG
- Measles IgM and IgG
- Mumps IgM and IgG

Floor 2 Manual

- HSV type specific IgG
- Hepatitis E IgM and IgG

Specialities

Blood-borne Virus Laboratory, floor 2

This section detects either RNA or DNA in patient samples allowing the quantification of virus levels.

- Hepatitis B viral load
- Hepatitis C viral load
- Hepatitis C Genotyping (performed on floor 5)
- HIV-1 viral load in Plasma and CSF
- HIV-1 qualitative PCR

Anti-viral Drug Resistance, floor 5

This section looks for mutations that confer resistance to specific types of drugs in the viruses present in patient samples.

- HIV drug resistance (NRTIs, NNRTIs, PIs, Fusion inhibitors, Integrase inhibitors)
- HIV genotypic tropism assay
- Hepatitis B genotyping and drug resistance
- Hepatitis C genotyping and drug resistance, including NS3, NS5a and NS5b
- CMV Ganciclovir resistance. UL97 and UL54

Molecular microbiology (Sexual health)

The department tests for DNA from:

- *Chlamydia trachomatis*
- *Chlamydia trachomatis* serovars L1, L2 & L3 (lymphogranuloma venereum)
- *Mycoplasma genitalium*
- *Neisseria gonorrhoea*
- *Trichomonas vaginalis*

And mRNA from:

- Human Papillomavirus

For *Ureaplasma urealyticum/parvum* and *Gardnerella vaginalis*, see the TDL Lab Guide.

For Herpes Simplex Virus 1 and 2, and syphilis, see above.

Samples

Testing cannot be performed on swabs which have charcoal or gel additives in the tubes or Roche PCR swabs, as these are inhibitory to the PCR processes.

Acceptable samples types are swabs (preferably in Aptima tubes) from appropriate body sites, 1st catch urines in sterile containers and Thinprep.

Chlamydia trachomatis

Allow 6 weeks before re-testing to avoid picking up the DNA from a previous infection.

Lymphogranuloma venereum (LGV)

Investigation for possible LGV symptoms is by PCR swab taken from the rectum and penis. If LGV infection is suspected in female patients, cervical and vaginal PCR swabs should be taken. Samples are first tested for chlamydia. If chlamydia is detected, LGV is suspected and if requested, the same swab samples can be tested for LGV as an additional test. Sexual contact partners should also be checked.

Mycoplasma genitalium

M. genitalium cannot be cultured for diagnostic testing. Partner testing is advised for current partners only. Rectal infections are common, and appear to be an important reservoir for resistance. BASHH guidance is that all patients must return for test of cure at 3–5 weeks. BASHH also recommends treatment with Resistance Guided Therapy – testing for *M. genitalium* with macrolide resistance determination.

Neisseria gonorrhoea

Individual PCR swabs from each site should be taken to screen for gonorrhoea. Partners should be treated at the same time with retesting after two weeks to confirm clearance – test of cure is recommended following treatment for gonococcal infections.

Trichomonas vaginalis

Infected women who are sexually active have a high rate of reinfection, thus re-screening at 3 month post treatment could be considered.

Human papillomavirus

The Human papillomavirus test helps healthcare providers detect the presence of abnormal cervical cells, and the HPV assays identify high-risk HPV mRNA that is indicative of the HPV infections most likely to lead to cervical disease. ThinPrep samples are the only samples which can be processed for HPV.

Virology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|----------|---|
| 16s bacterial sequencing | Cultures/Isolates/Fluids/ Biopsies | 7 days | All isolates and category 3 pathogens must be heat inactivated prior sending to the laboratory. |
| 18s fungal sequencing | Cultures/Isolates/Fluids/ Biopsies | 7 days | All isolates and category 3 pathogens must be heat inactivated prior sending to the laboratory. |
| Adenovirus by PCR | A / PCR swab / Green Viral swab / 60ml container | 7 days | |
| Adenovirus DNA Quantitation by PCR | 6ml EDTA | 48 hours | |
| Alphavirus Investigations [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| Arbovirus Antibodies/Abs [#] | 6ml Clotted blood / 6ml EDTA | 21 days | Clinical history must be provided. Provide details of travel history. |
| BK Polyoma Virus by PCR (quantitative) | 6ml EDTA blood / Random Urine | 5 days | |
| Bone marrow donor screen | 3 x 6ml EDTA | 72 hours | |
| Chagas Disease Serology (S.American Trypanosomiasis) T. Cruzi [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| Chikungunya Virus Abs [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| CMV DNA Quantitation (by PCR) | 6ml EDTA blood or 4.8ml Citrated blood | 48 hours | |
| CMV DNA by PCR (Urine) | Random Urine | 48 hours | |
| CMV DNA by PCR (other) | Biopsy, saliva, ETA | 48 hours | |
| CMV DNA by PCR (Guthrie/Dried blood spots) | Guthrie card / dried blood spot | 7 days | |
| CMV Resistance | 2 x 6ml EDTA whole blood | 10 days | |
| Coronavirus - COVID-19 IgG Antibody (SARS-CoV-2) | SST / Serum B | 24 hours | Contact the laboratory for patient self-collection sample kits. |
| Coronavirus - COVID-19 PCR (SARS-CoV-2) | PCR Swab (nasal/pharyngeal) | 36 hours | Contact the laboratory. |
| CSF Screen by PCR (CMV, EBV, HSV, VZV, Enterovirus, Parechovirus) | CSF | 48 hours | |
| Cytomegalovirus (CMV-DNA) Amnio | Ammotic fluid | 48 hours | |
| Cytomegalovirus (IgG/IgM) Antibodies | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Cytomegalovirus IgG Avidity | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Dengue Fever PCR [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| Epstein-Barr Virus (EBV) Antibodies VCA IgG/IgM and EBNA IgG | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| EBV DNA quantitative PCR | 6ml EDTA / 4.8ml Citrated blood | 48 hours | |
| Gastro-Intestinal PCR (Adenovirus, Astrovirus, Rotavirus, Norovirus, Sapovirus.) | Stool / Faecal | 48 hours | |

Virology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---------------------------------------|----------|--|
| Genital Ulcer PCR (HSV, Syphilis) | 6ml Clotted blood / 6ml EDTA blood | 21 days | |
| Travel Fever Viral Screen | 3ml Copan UTM swab | 48 hours | |
| Hantavirus Serology/PCR [#] | 6ml Clotted blood / 6ml EDTA blood | 10 days | Clinical history must be provided. Provide details of travel history. |
| Hepatitis (Acute) Screen | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis A (IgM) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis A Immunity (Total) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis A RNA by PCR [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| Hepatitis B 'e' Antigen and Antibody | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B (PCR) Genotype | 6ml Clotted blood / 6ml EDTA blood | 10 days | |
| Hepatitis B Core Antibody - IgM | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B Core Antibody - Total | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B DNA (Viral load) | 6ml Clotted blood / 6ml EDTA blood | 60 hours | |
| Hepatitis B Immunity | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B Profile | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B Resistant Mutation | 6ml Clotted blood / 6ml EDTA blood | 10 days | |
| Hepatitis B Surface Antibody | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B Surface Antigen | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis B Surface Antigen Quantification | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis C Antibodies | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis C Antigen (Early detection) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Hepatitis C Genotype | 6ml Clotted blood / 6ml EDTA blood | 10 days | |
| Hepatitis C NS3 Resistance | 2 x 6ml EDTA whole blood | 10 days | |
| Hepatitis C NS5a Resistance | 2 x 6ml EDTA whole blood | 10 days | |
| Hepatitis C NS5b Resistance | 2 x 6ml EDTA whole blood | 10 days | |
| Hepatitis C RNA (Viral Load) | 6 ml EDTA whole blood / Clotted blood | 60 hours | |
| Hepatitis Delta total Antibody | 6ml Clotted blood / 6ml EDTA blood | 3 days | |
| Hepatitis Delta RNA (Viral load) | 6ml EDTA whole blood | 5 days | |
| Hepatitis E RNA (Quantitative PCR) | 6ml EDTA whole blood | 72 hours | |
| Hepatitis E IgG/IgM | 6ml Clotted blood / 6ml EDTA blood | 5 days | |
| Herpes Simplex I/II Antibody Profile (IgG) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Herpes Simplex 1 and 2 IgG Typing | 6ml Clotted blood | 7 days | |
| Herpes Simplex I/II by PCR (Swab) | 3ml Copan UTM swab / EDTA blood | 48 hours | |

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--|----------|------------------------------------|
| HIV 1 Proviral DNA | 6ml EDTA whole blood from adults or at least 1ml EDTA whole blood from neonatal patients | 7 days | |
| HIV Screening: HIV1& 2 Abs/p24 Ag (4th Gen) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| HIV-1 Avidity (RITA/STARHS) [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. |
| HIV-1 Genotypic Resistance (Integrase) | 2 x 6ml EDTA tubes | 10 days | Information Drug regimens required |
| HIV-1 Genotypic Resistance (RT & Protease) | 2 x 6ml EDTA tubes | 10 days | Information Drug regimens required |
| HIV-1 PCR Qualitative | 6ml Clotted blood | 60 hours | |
| HIV-1 RNA Viral Load by PCR | 6ml EDTA tube | 60 hours | |
| HIV-1 Tropism | 2 x 6ml EDTA tubes | 10 days | Information Drug regimens required |
| HIV-2 Proviral DNA | 6ml EDTA whole blood from adults or at least 1ml EDTA whole blood from neonatal patients | 21 days | |
| HIV-2 RNA (Quantitative or Qualitative) by PCR | 6ml EDTA whole blood | 21 days | |
| HIV-2 drug resistance [#] | 2 x 6ml EDTA | 21 days | |
| HTLV 1& 2 Abs. (Human T Lymphotropic Virus Type I-II) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| HTLV by PCR [#] | 6ml EDTA whole blood | 21 days | |
| Human Herpes Virus 6 by quantitative PCR | 6ml EDTA whole blood | 5 days | |
| Human Herpes Virus 8 (HHV8) by qualitative/quantitative PCR | 6ml EDTA whole blood | 5 days | |
| Human Parvovirus B19 - Quantitative DNA PCR [#] | 6ml EDTA whole blood | 2 weeks | |
| JC Polyoma Virus by PCR | 6ml EDTA whole blood / CSF | 5 days | |
| Measles Antibodies (IgG) Immunity | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Measles Antibodies (IgM) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | Clinical history must be provided. |
| Measles PCR | Buccal swab | 48 hours | |
| Measles, Mumps, Rubella (MMR) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Monkey Pox PCR | 3ml Copan UTM swab | 48 hours | |
| Mumps Antibodies (IgG) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Mumps Antibodies (IgM) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Mumps PCR [#] | Swab | 21 days | |
| Needle Stick Injury Profile | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Neurological Viral PCR | CSF | 48 hours | |
| Neurological Viral Screen | 6ml Clotted blood / 6ml EDTA blood | 48 hours | |

Virology tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|--|---|----------|---|
| Parvovirus Antibodies (IgM) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Parvovirus Quantitative DNA by PCR | 6ml EDTA whole blood | 5 days | |
| Parvovirus IgG Antibodies | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Polio Virus 1, 2, 3 Antibodies [#] | 6ml Clotted blood / 6ml EDTA blood | 15 days | Clinical history must be provided. |
| Rabies Antibody [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical and travel history must be provided. |
| Respiratory PCR (RSV, Influenza A, Influenza B, Parainfluenza 1-4, Coronavirus, Rhinovirus, Human Metapneumovirus, Enterovirus, Adenovirus, Parechovirus) | PCR swab / NPA / BAL / NPS / ETA | 48 hours | |
| Rubella Antibody (IgG) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Rubella Antibody (IgM) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Rubella Avidity [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | |
| Rubella PCR [#] | EDTA whole blood / Amniotic Fluid | 21 days | |
| Torch Screen | 6ml Clotted blood / 6ml EDTA blood | 48 hours | |
| Transplant screen donor antibody screen | 6ml Clotted | 24 hours | |
| Varicella Zoster - DNA | 6ml EDTA whole blood / 3ml Copan UTM Swab | 72 hours | |
| Varicella zoster Antibodies (IgG) | 6ml Clotted blood / 6ml EDTA blood | 24 hours | |
| Viral Eye by PCR (HSV/VZV/ADENO) | 3ml Copan UTM swab or dry PCR swab | 72 hours | |
| Vesicular Rash by PCR | PCR swab / 6ml EDTA tube | 48 hours | |
| West Nile Virus Abs [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |
| West Nile Virus PCR [#] | 6ml Clotted blood / 6ml EDTA blood | | Clinical history must be provided. Provide details of travel history. |
| Zika Abs IgM and IgG - Antibody detection from 15 days [#] | 6ml Clotted blood / 6ml EDTA blood | 5 days | Clinical history must be provided. Provide details of travel history. |
| Zika RNA by PCR [#] | 6ml Clotted blood / 6ml EDTA blood | 21 days | Clinical history must be provided. Provide details of travel history. |

Molecular microbiology (Sexual health) tests

| TEST NAME | SAMPLE REQUIREMENT | TAT | SPECIAL INSTRUCTIONS |
|---|--------------------|-----------|--|
| Chlamydia (PCR swab) | PCR | 2 days | |
| Chlamydia (Thin Prep) | TPV | 2 days | |
| Chlamydia (Urine) | FCRU | 2 days | |
| Chlamydia/Gonorrhoea (PCR Swab) | PCR | 2 days | |
| Chlamydia/Gonorrhoea (Rectal) | PCR | 2 days | |
| Chlamydia/Gonorrhoea (Thin Prep) | TPV | 5 days | |
| Chlamydia/Gonorrhoea (Throat) | PCR | 2 days | |
| Chlamydia/Gonorrhoea (Urine) | FCRU | 2 days | |
| Chlamydia/Gonorrhoea/Trichomonas by PCR | FCRU/PCR/TPV | 2 days | |
| Gonorrhoea (PCR swab) | PCR | 2 days | |
| Gonorrhoea (Thin Prep) | TPV | 2 days | |
| Gonorrhoea (Urine) | FCRU | 2 days | |
| Haemophilus ducreyi by PCR | PCR | 7 days | |
| HPV (mRNA HR-HPV) (ThinPrep) | TPV | 2-3 days | |
| Lymphogranuloma Venerium (LGV) | PCR* | 1-2 weeks | LGV can be added to a positive chlamydia sample using the same swab if requested within 4 days of receipt of result. |
| Macrolide Resistance Test (Mgen) | FCRU/PCR | 1-2 weeks | |
| Mycoplasma genitalium by PCR | FCRU/PCR/TPV | 2 days | |
| N. Gonorrhoea | TPV | 2 days | |
| Trichomonas vaginalis by PCR | FCRU/PCR/TPV | 2 days | |

Request Forms

- TDL Genetics Request Form
- TDL Genetics Consent Form
- HSL Oncogenomics Request Form
- HSL Haemophilia and Thrombosis Request for Genetic Status Form
- TDL Genetic Request Form
- TDL Request Form
- HSL Virology Guthrie CMV Request Form

TDL GENETICS LTD

The Halo Building
1 Mabledon Place
London WC1H 9AX
Tel: 020 7307 7409
Fax: 020 7307 7350
Email: tdlgenetics@tdlpathology.com

CLINICIAN

Doctor
Address
Tel
Email

Additional copy of results to:

TAP1929C/02-12-21/V16

| | | | | | | |
|----------|--|-------|--|------------|------------------|-----------|
| SURNAME | | | | DOB or AGE | Patient Ref. No. | Gestation |
| FORENAME | | TITLE | | | | |

Clinical Details – include reason for test request and family history
(Please complete this box – details are crucial for analysis and interpretation)

| | |
|-------------------------------|---|
| Identified gender | <input type="checkbox"/> M <input type="checkbox"/> F |
| Biological sex (if different) | <input type="checkbox"/> M <input type="checkbox"/> F |

PRENATAL NT: Risk: Abnormal U/S Findings:

No of fetuses:

| | | |
|---|--|---|
| <p>PRENATAL ASSAYS</p> <p><input type="checkbox"/> Amnio PCR <input type="checkbox"/> Amnio Karyotype <input type="checkbox"/> Amnio PCR & Karyotype <input type="checkbox"/> αFP <input type="checkbox"/> CVS PCR <input type="checkbox"/> CVS Karyotype <input type="checkbox"/> CVS PCR & Karyotype <input type="checkbox"/> Microdeletions BOBs <input type="checkbox"/> Prenatal Microarray (Array CGH) <input type="checkbox"/> UPD specify chromosome _____</p> <p>Please ensure options* below are completed.</p> <p>*Fetal sex to be reported Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>*p.F508del Cystic Fibrosis Only available as part of Amnio/ CVS PCR: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>*Fee for these options is included in test price.</p> | <p>POSTNATAL ASSAYS</p> <p><input type="checkbox"/> Blood PCR (T13, T18, T21, X and Y) <input type="checkbox"/> Chromosome Analysis Karyotype – blood <input type="checkbox"/> Chromosome Analysis Karyotype from G banded slide <input type="checkbox"/> Postnatal Microarray (Array CGH) <input type="checkbox"/> Chromosome Analysis Karyotype of Solid Tissue/Products of Conception** Reflex to aneuploidy BOBs in the event of culture failure</p> <p>BACs on Beads (BOBs)</p> <p><input type="checkbox"/> Microdeletion/Duplication Syndromes All (or select individual tests below) <input type="checkbox"/> Di George/VCFS <input type="checkbox"/> Miller-Dieker <input type="checkbox"/> Cri du Chat <input type="checkbox"/> Williams <input type="checkbox"/> Wolf-Hirschhorn <input type="checkbox"/> Smith-Magenis <input type="checkbox"/> Products of Conception Aneuploidy BOBs**</p> <p>** Material from miscarriage samples can be returned upon request at the time of referral. Please instruct if required. Full details of sensitive disposal can be found in the lab guide.</p> | <p>DNA ASSAYS</p> <p><input type="checkbox"/> CF (139 Mutations) <input type="checkbox"/> Haemochromatosis mutations – C282Y,H63D <input type="checkbox"/> Y Chromosome Microdeletion <input type="checkbox"/> Paternity Testing <input type="checkbox"/> DNA Identity Profile <input type="checkbox"/> Uniparental Disomy <input type="checkbox"/> Factor II Prothrombin <input type="checkbox"/> Factor V Leiden <input type="checkbox"/> MTHFR – C677T, A1298C <input type="checkbox"/> Duchenne Muscular Dystrophy <input type="checkbox"/> Spinal Muscular Atrophy <input type="checkbox"/> Prader Willi/Angelman methylation</p> <p>Zygosity Testing <input type="checkbox"/> Apo E Genotype <input type="checkbox"/> HLA Tissue Typing (A,B,Cw,DR,DQ Coeliac/Narcolepsy) Please specify _____ <input type="checkbox"/> HLA B27 <input type="checkbox"/> DNA extraction and storage For 3 years unless otherwise stated</p> |
|---|--|---|

Other tests:

PROFILES

Male Genetic Reproductive Profile
Y Chromosome Microdeletion DNA Studies / Cystic Fibrosis Carrier Screen / Chromosome analysis (Karyotype)

Iron Overload Profile
Iron / Total Iron Binding Capacity / Ferritin / Haemochromatosis mutation

Ashkenazi Jewish Carrier Screen (see lab guide for details)

Pan Ethnic Carrier Screen (see lab guide for details)

Fee to be paid by: Dr Patient

Patients address and telephone number (essential information if patient to pay)

Address

Town/City Postcode

Contact telephone number

Laboratory notes:

Tick if a Letter of Guarantee is required

| | | | | | | | | | | | | |
|-------------------------------|-------------|-------|-----|----------|--------|-----------------------------------|----|-------|-----|-----|--------|----------------------------|
| For Practice Use Only: | | | | | | For TDL Genetics Use Only: | | | | | | Date/Time received: |
| EDTA | LH | AMNIO | CVS | POC | OTHERS | EDTA | LH | AMNIO | CVS | POC | OTHERS | |
| | | | | | | | | | | | | |
| Sample Date | Sample Time | | | Analysis | | | | | | | | |

Consent Form



**TDL
GENETICS**

The Halo Building, 1 Mabledon Place, London WC1H 9AX
Tel: 020 7307 7409 Fax: 020 7307 7350
Email: tdlgenetics@tdlpathology.com

PATIENT OR GUARDIAN

Please cross-out where applicable.

I consent /do not consent to be tested for the genetic test/tests which have been explained to me.

I consent /do not consent for the results of this test to be available to assist in testing other family members.

I consent /do not consent for DNA from this sample to be stored.

I consent /do not consent for DNA to be used anonymously for relevant research.

Signed _____

Date ____ / ____ / ____

DOCTOR

I have explained the purpose of obtaining a blood or tissue sample for genetic testing.

Signed _____

Date ____ / ____ / ____

This consent form is for use with diagnostic testing. It is important to think through the implications of genetic testing for other family members. Certain family studies may reveal information regarding paternity. We strongly recommend genetic counselling for predictive testing in disorders such as Huntington's Disease or inherited cancers. Please contact our Consultant if you have queries about consent or counselling issues.

OncoGenomics Request Form



HEALTH SERVICES
LABORATORIES

Please deliver sample and form to:

HSL Analytics LLP, OncoGenomics, Level 6, 1 Mabledon Place, Flaxman Terrace, London WC1H 9AJ

Contact details: Dr Elisabeth Nacheva, The Halo Building, Level 7, 1 Mabledon Place, London WC1H 9AX

Email: oncogenomics@hslpathology.com | e.nacheva@ucl.ac.uk | elisabeth.nacheva@nhs.net

Phone: 020 3908 1314 (office) | 020 3908 2308 (lab) Mobile: 07714 721579

CLINICIAN

Hospital: _____ Consultant: _____

Doctor for enquiry: _____ Department: _____

Contact/Bleep no.: _____

PATIENT

Hospital number: _____ Ward: _____

Surname: _____ Department: _____

Forename: _____ Gender: Male Female

Date of birth: _____ Patient status: In/Out NHS/Private

SAMPLE

Sample date: _____ Time: _____

Sample type: **Bone Marrow** **Blood** **Other** (please specify) _____

DISEASE

Diagnosis: _____ FAB classification: _____

Disease status: **Presentation** **Remission** **Relapse** **Persistent** **Post treatment**

Post transplant Date of transplant: _____

Type and sex of donor: _____

Other (please specify): _____

FOR CYTOGENETIC USE ONLY

Lab no.: _____ Date and time of receipt: _____

Cell count: _____ x10⁶ per ml Volume of sample : _____ ml

Cultures: _____

ON **ONC** **SYN** **Direct culture** **3D** **3D+PHA** **3D+TPA** **IL2DS30**

MACs **Lympho prep (FISH only)** **Other** _____



All tests are accredited under UKAS standard ISO 15189:2012.
For the full scope of accreditation please refer to the
UKAS website <http://www.ukas.com>

Haemophilia and Thrombosis Request for Genetic Status



HEALTH SERVICES
LABORATORIES

**Haemophilia and Thrombosis Laboratory, Health Services Laboratories
The Halo Building, 1 Mabledon Place, London, WC1H 9AX**

Email: Bilal Jradeh – Bilal.Jradeh@hslpathology.com Tel: 020 7307 7409

Patient information

| | | | |
|-------------------------------|------------------|--|----------|
| Name: | | Family no.: | Lab no.: |
| Hospital no.: | Gender: | Family name (surname of first family member diagnosed) | |
| DOB: | Ethnic origin: | | |
| Sample taken (date and time): | | Sample type: | |
| Requested by: | | Email (nhs.net address preferred): | |
| Consultant: | Hospital/Clinic: | Contact no.: | |

| | |
|--|--|
| Please sign this box to confirm documentation of consent: Signature: _____ | SAMPLES WILL NOT BE PROCESSED IF THIS IS LEFT BLANK |
|--|--|

Factor levels and clinical synopsis

Family tree (Please refer to the symbols overleaf and try to include 3 generations)

**If these results are required urgently please discuss with the laboratory on the number above.
Samples from family members may be sent together but details must be recorded overleaf.**

Haemophilia and Thrombosis Request for Genetic Status


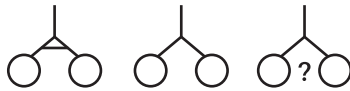



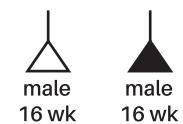




















If samples on other family members are included please record their details here

| | | |
|---------------|---------|--|
| Name: | | Relationship to Proband / Pedigree Position: |
| Hospital No.: | | Factor Levels and Clinical Synopsis: |
| DOB: | Gender: | |

| | | |
|---------------|---------|--|
| Name: | | Relationship to Proband / Pedigree Position: |
| Hospital No.: | | Factor Levels and Clinical Synopsis: |
| DOB: | Gender: | |

Further information

Pedigree symbols (Ref: AM JHum Genet 1995; 56:745-52)

| | | | |
|--|---|---|---|
| Male / Female / Unknown Sex |    | Twins (MZ, DZ and uncertain) |    |
| Clinically affected |    | Ongoing pregnancy |  EDD |
| Multiple siblings (if number not known, put <i>n</i>) |   | Miscarriage (unaffected, affected) (sex, gestation) |  male 16 wk  male 16 wk |
| Deceased (with age died) |  d.63y | Termination (unaffected, affected) |   |
| Proband (index, propositus, proposita) |  | Stillbirth (with gestation) |  SB 32 wk |
| Consultand |  | Consanguinity |  |
| Carrier of recessive condition (usually clinically asymptomatic, e.g. Haemophilia) |   | Partners now separated |  |
| Heterozygous for partially penetrant condition (e.g. FXI deficiency) |   | | |

FOR LABORATORY USE ONLY

Date and time received: _____ Sample type: _____

| |
|----------|
| Comment: |
|----------|

Genetic Request



THE DOCTORS
LABORATORY

In order to provide an efficient service for Genetic Requests, please complete the following:

PATIENT DETAILS

Surname: _____

First name: _____

Date of Birth: _____ Gender: M F

Patient number: _____

Ethnic origin: _____

Gestation (if applicable): _____ weeks

REFERRING DOCTOR

Name: _____

Address: _____

Tel: _____

Email: _____

TEST REQUEST

Disease name: _____

Gene(s) to be analysed: _____

Test for: Diagnosis Carrier screening Known family variant

Clinical symptoms: _____

Family history: _____

Please state any family gene variant(s) if known: _____

Please also provide copies of any relevant genetic or pathology (ie. haematology) reports.

INFORMED CONSENT

PATIENT OR GUARDIAN

Please tick as applicable:

- | | | |
|------------------------------------|---|--|
| <input type="checkbox"/> I consent | <input type="checkbox"/> I do not consent | to be tested for the genetic test(s), which have been explained to me |
| <input type="checkbox"/> I consent | <input type="checkbox"/> I do not consent | for the results of this test to be available to assist in testing other family members |
| <input type="checkbox"/> I consent | <input type="checkbox"/> I do not consent | for DNA from this sample to be stored |
| <input type="checkbox"/> I consent | <input type="checkbox"/> I do not consent | for DNA to be used anonymously for relevant research |

Signed: _____ Date: _____

DOCTOR/GENETIC COUNSELLOR

I have explained the purpose of obtaining a blood or tissue sample for genetic testing.

Signed: _____ Date: _____

This consent form is for use with diagnostic testing. It is important to think through the implications of genetic testing for other family members. We strongly recommend genetic counselling for predictive testing in disorders such as Huntington's Disease or inherited cancers. Please contact our Consultant if you have queries about consent or counselling issues.

Fee to be paid by Patient/Other. **PLEASE PROVIDE ADDRESS DETAILS**

Insurance Co.

Membership No.

Patient address

Fee to be paid by
Doctor/Clinic as above

TAP4157E/18-10-23/V6

Postcode

Contact telephone number



HSL Virology Guthrie CMV Form

Newborn Screening Dried Bloodspot

| | |
|---------------------------|--|
| Bloodspot Sample Number: | |
| Specimen Collection Date: | |
| Name on Bloodspot Card: | |
| NHS Number: | |
| D.O.B: | |
| Mother's Name: | |
| Date Sample Sent to HSL: | |

Copies of Report to Sender and Requesting Clinician

| | |
|-----------------------------------|--|
| Sender (& Address): | |
| Requesting Clinician (& Address): | |
| Please Send Invoice To: | |

Please send this form with Guthrie Card to:

**UCLH Virology Sample Reception
UCLH Rapid Response Laboratory
60 Whitfield Street
London
W1T 4EU**

Health Services Laboratories
The Halo Building
1 Mabledon Place
London
WC1H 9AX

T +44 (0)20 7307 9400
E hsl@hslpathology.com
www.hslpathology.com