



**External User Test Information for Roche Anti-SARS-CoV-2
Total Assay**

Q-CARD

Q-Card No.: BIO-MP1-8-Q-23	Version No.: 1
Status: Active	Effective Date: 26/10/2020
Author: Chatterton, Wendy	Owner: Joseph, Oneal Copy No: _____

Analyte	Anti-SARS-CoV-2
Laboratory	Health Services Laboratories (HSL) Analytics
Address to send samples	Specimen Reception 60 Whitfield Street London, W1T 4EU
Primary contacts:	Email: HSL@hslpathology.com Phone: +44 (0) 207 307 9400
Accreditation	Awaiting - application submitted to UKAS Internally verified with clinical approval.
EQA participation	UKNEQAS
CE status	Test is CE marked
Sample requirements	Samples must be taken at least 14 days after the onset of symptoms for testing in the Roche Anti-SARS-CoV-2 assay
Minimum volume	2mL blood
Sample type	Serum or EDTA plasma. Gold top gel tube preferred (BD tubes)
Storage	3 days at 15 -25°C (Ambient), 7 days at 2 – 8°C and 28 days at -20°C. (Source Ref: Roche kit insert) Centrifuge samples and store if not shipped same day.
Shipping	Ship at ambient temperature by courier Centrifuge samples and store if not shipped same day.
Courier	Use existing courier set up for sample transport.
Special requirements	Please Do Not send samples in the post unless specifically advised by the laboratory.
Results reporting, Reference range and units of measurement	Qualitative result reported based on a cut off index (COI). See below Negative – SARS-CoV-2 Total Ab Not Detected. No serological evidence of SARS-CoV-2 infection. Consider as susceptible. Please send a combined nose & throat swab for SARS-CoV-2 PCR if current infection is suspected. Positive - SARS-CoV-2 Total Ab DETECTED. Consistent with SARS-CoV-2 at some point. It is not known if presence of antibodies confers protective immunity.
Turnaround time	48 hours from receipt in laboratory.
Methodology	Roche Elecsys Anti-SARS-COV assay Electrochemiluminescence immunoassay (ECLIA) – Total antibody detection
Measurement uncertainty	Available upon request
Suggested repeat test interval (if appropriate)	Please seek clinical advice