

SARS-CoV-2 / COVID-19 Antibodies

Accreditation Status:	UKAS Schedule of Accreditation																		
Date Scheme started:	2020																		
Clinical Applicability:	Detection of antibodies to SARS-CoV-2 / COVID-19 confirming previous infection																		
Analytes:	Antibodies to SARS-CoV-2 as IgG, Total Ig (SER/059)																		
Units for Reporting:	Qualitative and quantitative responses, method dependent																		
Samples Distributed:	Liquid format. Normal and pathological human serum																		
Number of Distributions per year:	6																		
Number of Samples per Distribution:	2																		
Frequency of Distributions:	Every month as outlined in the Distribution Schedule																		
Schedule of Analysis:	Data entry is via the web for the submission of results. Data analysis is commenced 14 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics																		
Data Analysis:	<p>Group Laboratory Trimmed Mean (GLTM) with truncation at 2SD, SD, and CV%. Reports also show method and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. The Designated Value (DV) for calculation of VI is the Method Laboratory Trimmed Mean (MLTM)</p> <p>Chosen Coefficient of Variation for quantitative results is 20%</p>																		
Performance Scoring:	MI scoring and MRVIS																		
Criteria of Performance:	<p>Laboratory performance for the qualitative element of the Scheme is assessed over a running analytical window of 12 Distributions (12 months)</p> <table><tr><td>Good</td><td>OMIS = 0</td></tr><tr><td>Adequate</td><td>OMIS = 1 -2</td></tr><tr><td>Poor</td><td>OMIS = >2</td></tr></table> <p>Individual laboratory performance over a running analytical window of 12 Distributions (12 months) quantitation is expressed in terms of MRBIS, SDBIS and MRVIS</p> <table><tr><td>Ideal</td><td>MRVIS</td><td><50</td></tr><tr><td>Good</td><td></td><td>50 – 100</td></tr><tr><td>Adequate</td><td></td><td>101 – 200</td></tr><tr><td>Poor</td><td></td><td>>200 or SDBIS >200</td></tr></table>	Good	OMIS = 0	Adequate	OMIS = 1 -2	Poor	OMIS = >2	Ideal	MRVIS	<50	Good		50 – 100	Adequate		101 – 200	Poor		>200 or SDBIS >200
Good	OMIS = 0																		
Adequate	OMIS = 1 -2																		
Poor	OMIS = >2																		
Ideal	MRVIS	<50																	
Good		50 – 100																	
Adequate		101 – 200																	
Poor		>200 or SDBIS >200																	
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive distributions																		