

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, IgM, IgA, Total Ig		
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:	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)		
	Chosen Coefficient of Variation for quantitative results is 20%		
Performance Scoring:	MI scoring and MRVIS		
Criteria of Performance:	Laboratory performance for the qualitative element of the Scheme is assessed over a running analytical window of 12 Distributions (12 months)		
	Good	OMIS = 0	
	Adequate	OMIS = 1 -2	
	Poor	OMIS = >2	
	Individual laboratory performance over a running analytical window of 12 Distributions (12 months) quantitation is expressed in terms of MRBIS, SDBIS and MRVIS		
	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		