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:	Qualitative responses are recorded for antibodies to SARS-CoV-2 as IgG and as Total Ig and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Group Laboratory Trimmed Mean (GLTM) with truncation at 2SD, SD, and CV%. Reports also show method and manufacturer specific statistics. Chosen Coefficient of Variation for quantitative results is 20%
Performance Scoring:	MI scoring
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

Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive distributions