Technical specification for end-to-end serology testing

Parameter	Essential	Desirable
Target Population	Individuals >10 days following onset of symptoms	Individuals >10 days who were asymptomatic
Scale	capable of 10-30k samples/day/site capable of <5 day turnaround time	capable of >50k samples/day capable of <3 day turnaround time
Assay Type	Immunoassay qualitative	Immunoassay quantitative
Blood collection/ sample Matrices	Home testing blood product compatible with downstream automation	As per essential requirement
Analyte Target	To include IgG antibodies to SARS-COV2	To include IgG antibodies to SARS-COV2
Other Assay Design Considerations	Appropriate Internal and External quality control samples and external quality assessment samples. To ensure precision and accuracy.	As per essential requirement
Precision	<10% CV	<5% CV
Sensitivity *	95% (95% CI)	98% (95% CI)
Specificity *	98% (95% CI)	98% (95% CI)
Sample volume for immunoassay	Compatible with home sample collection and logistics	Compatible with home sample collection and logistics
Cross Reactivity	No cross-reactivity against other coronavirus -SARS, MERS, seasonal coronavirus etc.	As per essential requirement
No Interference to	EDTA plasma, HAMA, RF, Trigylcerides	EDTA plasma, HAMA, RF, Trigylcerides
Limit of Detection	To be provided upper and lower end	As per essential requirement
Error rate	<10% end to end	<5% end to end

Sample handling

Sample acquisition environment	Home	As per essential requirement
Sample Type	Whole blood from finger prick processed as compatible with downstream and sensitivity requirements. Or equivalent	Whole blood from finger prick processed as compatible with downstream and sensitivity requirements. Or equivalent

	method that meets the technical requirements	method that meets the technical requirements
Sample Collection	Method for safely collecting sample from patients and safe disposal of collection device.	Method for safely collecting sample from patients and safe disposal of collection device.
Stability of Sample Between Collection and Preparation	No cold chain required.	No cold chain required.
Digital requirements	Must interface with the HMG portal for tests to be assigned and results given	As per essential requirements

*The assay can be tested on other samples at proposal stage but will need to meet these criteria in the NHS/ PHE/MHRA validation process on appropriate samples before any final decision is made by HMG.