Department of Health & Social Care

Industry call for end-to-end serology testing

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Introduction

- Request is for an industry solution that can deliver a high throughput, end-to-end process that integrates home-based blood sampling with lab processing using an ELISA or equivalent antibody test at a specificity >98% and sensitivity >95%.

- The solution should be able to deliver at least ten thousand tests a day in the first instance with the potential to rapidly scale by mid-July.

- Any proposals submitted on behalf of an industry consortia should nominate a lead organisation to act as a single point of contact with HM Government and proposals should be submitted by Thursday 14th April.

- Proposals should be in the region of 15 pages/slides and should cover the following questions:

    - Describe the end-to-end process you can deliver and clearly indicate the role each partner will play.

    - What is the current status and technical performance of your assay? Primary data should be provided on as many of the technical specifications as possible.

    - What blood collection method will you use now and in the future?

    - How will your proposed end-to-end process be managed logistically from beginning to end (e.g. test assigned to being processed in the lab)?

    - How will you manage the blood processing at high volumes to transfer samples to testing machinery?

    - What is your capability and capacity to scale up testing, to 10k/day, 50k/day and beyond and to what time-line?

    - How will you approach establishing a robust value chain to procure and supply the components and reagents at the required volume?

    - What digital systems will you have in place/ build to allow sample tracking and how will you interface with the NHSX digital portal for tests to be sent to individuals and results returned?

    - Costs should be included for the total end-to-end process broken down by stage where possible and include the split between set up and ongoing costs.

Technical requirements

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

Parameter	Essential	Desirable
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 method that meets the regulatory requirements	Whole blood from finger prick processed as compatible with downstream and sensitivity requirements. Or equivalent method that meets the regulatory 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.

Key areas for consideration