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Guidance

National technical validation process for manufacturers of SARS-CoV-2 (COVID-19) tests

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This publication is available at https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview

This guidance only applies to SARS-CoV-2 (COVID-19) viral detection and antigen tests.

This guidance outlines how the government will triage, review and evaluate offers of viral detection and antigen tests to support the National Test and Trace programme.

Whether or not a test developer or supplier explores national-level procurement via this process, they are still able to supply tests with the relevant regulatory authorisation to UK customers.

High-level process

The technical validation process involves 6 keys steps:

1. Register through the online form
2. Triage of online form by scientific advisor
3. Inital review by Scientific Expert Panel
4. Technical and in-service evaluation
5. Decision by the Technical Validation Group
6. Procurement discussion[footnote 1]

Registering interest

Manufacturers of SARS-CoV-2 (COVID-19) tests for viral detection and antigen tests, excluding home based kits, can register their interest in the national procurement process if their test meets, or are intended to meet in the case of tests under development, the requirements of a relevant Medicines and Healthcare products Regulatory Agency (MHRA) Target Product Profiles (TPPs) (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work).

Test manufacturers are invited to complete the online form (https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19) for each test they want to supply. The form captures the main clinical and commercial information required to triage the large volume of offers received.

As part of our commitment to acquiring high-quality products for the National Test and Trace programme, information should be provided directly from the test manufacturers. This ensures that the technical information can be confirmed directly with the manufacturer.

If you have been contacted proactively by another government department who are already reviewing your offer, please do not complete an online unless specifically requested to do so.

Further procurement opportunities, including the National Microbiology Framework, which supports the UK testing strategy set out by the Secretary of State for Health and Social Care, can be found on:

- TED (Tenders Electronic Daily) (https://ted.europa.eu/udl?uri=TED:NOTICE:263375-2020:TEXT:EN:HTML)
- Contracts finder (https://www.contractsfinder.service.gov.uk/)

Triage

The online form submission and any supporting documents are reviewed by a scientific advisor to categorise the type of test and refer it through appropriate validation and evaluation route.

For all viral detection and antigen tests, excluding non-machine based Lateral Flow Technology (LFT) and home testing kits, the steps outlined below apply.

For any non-machine based LFT and home testing kits, an alternative technical validation route will be required (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices).

Initial review of offers

The online form and supporting documents are initially reviewed by a member of the Scientific Expert Group. The Scientific Expert Group is made up experts in technologies, viral testing and infectious disease. This a subgroup of the Technologies Validation Group (TVG). The Group undertakes a detailed assessment of the information on the solutions and technologies that have been submitted.

The initial review is based on a review of the clinical and technical information provided by the manufacturer against the MHRA TPPs (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work). Following the review tests are deemed to be one of the following:

- aligned to the current national testing priority needs and progressed for national validation and evaluation
- not aligned to the current national testing priority needs and held on file for review in case of any future changes to our testing needs
- not to currently have the performance and clinical data required to pass triage but where it is recommended that the organisation generates this data

Companies should expect to receive any outcome from the Scientific Expert Group within 2 weeks. This may be longer subject to the volume of offers that we are reviewing.

Technical validation and in-service evaluation

Offers that are deemed by the Scientific Expert Group to have met the relevant TPP and align to the current needs of the National Test and Trace programme will be progressed for technical validation and in-service evaluation. Manufacturers will be contacted and invited to take part in further technical validation and/or in-service evaluation.

As part of the technical validation process and/or in-service evaluation manufacturers will be matched with a validation laboratory. The manufacturer will be expected to:

- provide product samples and all required consumables and reagents free of charge for validation and evaluation
- provide the laboratories undertaking the technical validation with additional relevant technical information to support the validation activity
- provide the relevant legal documents to support the technical validation and in-service evaluation, and non-disclosure agreements, where needed
- agree to the results of the process to be made publicly available
- confirm that they have immediate availability of sufficient testing kits to allow further in-service evaluation and can provide sufficient product volumes, including consumables and reagents, with a lead time less than one month from order

Technical validation

The technical validation includes, but is not limited to, a bio-safety assessment, lower dynamic range analysis and an initial test accuracy assessment. The information generated at this stage will be compared to the TPP. Products that meet the technical validation criteria may progress to an in-service evaluation.

See further information about the technical validation protocol (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/technical-validation-protocol-for-sars-cov-2-nucleic-acid-detection).

In-service evaluation (for example, hospitals and care homes)

Tests will be performed by the intended user in the relevant setting to develop real-world evidence. This evaluation is tailored to the setting and the type pf test. It typically includes consideration of installation (for example, does the equipment require specialist installation or calibration) and usability factors (for example, does the result require any interpretation and, if yes, how skilled does the user need to be to interpret the result?)

Review by the Technical Validation Group

The outcome of the technical validation and in-service evaluation will be reviewed by the Technical Validation Group (TVG).

The TVG includes a range of experts in technologies, viral testing and infectious disease, including representatives from the:

- central validation labs (including Public Health England (PHE), Frimley, Cumbria)
- CONDOR (COVID-19 National Diagnostic Research and Evaluation Platform)
- Innovate UK
- academia professional body (Royal College of Pathology)
- Medicines and Healthcare products Regulatory Agency

This group replaces all of the functions of the previous Viral Detection (molecular) Tests Group (VTAG) and the for new serology technologies, the work previously undertaken by the New Tests Advisory Group (NTAG).

TVG reviews the outcome of all of the validation and evaluations and makes recommendations to the wider COVID-19 TTCE programme on the suitability of the solutions/technologies.

Procurement

For those technologies recommended by the TVG, the DHSC commercial team will invite those developers or suppliers to take part in a competitive procurement. In emergency circumstances the contract will be let via Direct Award.

Products in the pipeline (TVG)

The following table provides a snapshot of the number of products currently in TVG pipeline (as at 17 December 2020) and their status:

Validation stage

Status	Number of tests

Status	Number of tests
In early stages of validation	11
Currently being validated or evaluated	13
Validation concluded or paused	82
Validated technology	11
Total	117

Validation concluded or paused

TVG reference	Primary use location	Product type	High-level justification
10	Near patient test or point of care test	PCR	Product withdrawn from validation by the supplier
25	Laboratory	PCR	Product withdrawn from validation by the supplier
92	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
67	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
75	Laboratory	PCR	Assay does not provide additional capacity to meet DHSC's current needs
86	Laboratory	RT-PCR	End-to-end solution and validation routed to an alternative team
98	Laboratory	PCR	Multiplex assay and validation sits outside of DHSC (to be performed locally)
11	Laboratory	PCR	Product currently research only, with significant transportation constraints
38	Laboratory	PCR	Further information requested but has not been provided to enable validation
65	Laboratory	PCR	Solution not viable within the timelines required to support with DHSC surge capacity
68	Point of care test	PCR	Assay does not provide additional capacity to meet DHSC's current needs

TVG reference	Primary use location	Product type	High-level justification
9	Near patient test or point of care test	PCR	Product withdrawn from validation by the supplier
95	Point of care test	Antigen tests	Validation paused to clarify assay performance. In addition, contradictory statements in the IFU on the assay
4	Near patient test	Bespoke	Multiplex assay and validation sits outside of DHSC (to be performed locally)
18	Point of care test	Direct LAMP	Assay does not meet TPP Standards for sensitivity. Biosafety concerns also noted
29	Point of care test	Microelectronics and microfluidics	Product is not ready for market – very early stages of development
5	Point of care test	PCR	Rejected for commercial reasons following the commencement of validation activities.
60	Near patient test or point of care test	PCR	More specific information on the performance of the assay required and not provided
58	Point of care test	PCR	Supplier unable to provide staffed solution
31	Laboratory	RNA LAMP	Product is not ready for market – very early stages of development
77	Laboratory	RNA LAMP	Assay does not provide incremental capacity to meet DHSC's current needs
85	Laboratory	LAMP	Limited use case due to clinical performance and assay being laboratory
22	Near patient test	Direct LAMP	Protocol being updated by the company to improve clinical performance
28	Laboratory	RNA and Direct LAMP	Resilience and scalability concerns
21	Near patient test	RNA and Direct LAMP	Product not market ready – reliability issues and does not meet TPP standards
82	Laboratory	RNA LAMP	Use cases restricted and not adding any to additional testing capacity

TVG reference	Primary use location	Product type	High-level justification
59	Laboratory	RNA and Direct LAMP	Resilience and scalability concerns
7	Near patient test	LAMP	Supplier non-engagement, difficulty in obtaining technical data
70	Point of care test	Direct LAMP	Product is not ready for market – very early stages of development
72	Point of care test	RNA LAMP	Did not meet TPP Standards on sensitivity, concerns of throughput
97	Laboratory	Lateral flow	Additional information on the performance of the assay requested but not provided to date
74	Near patient test	Antibody	Assay does not provide additional capacity to meet DHSC's current needs
45	Point of care test	Biosensor (that is, lateral flow)	Being validated by a separate team
44	Point of care test	POCT	Assay does not provide additional capacity to meet DHSC's current needs
42	Point of care test	Biosensor (that is, lateral flow)	Non-responsive supplier
43	Laboratory	Mass spectrometry	Validated as a part of a broader pilot (different validation route)
51	Laboratory	Digital sequencing test	Product not market ready – does not meet TPP standards and has reliability issues

Publication of results

The following technologies have been reviewed:

- ELISA (enzyme-linked immunosorbent assay) assessments (https://www.medrxiv.org/content/10.1101/2020.04.15.20066407v2)
- first wave of lateral flow test and non-machine based LFT assessment (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/lateral-flow-devices-results)
- first wave of lateral flow test assessments (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/lateral-flow-devices-results)

- first wave of laboratory assessments of molecular tests (https://www.gov.uk/government/publications/covid-19-phe-laboratory-assessments-of-molecular-tests)

Validated technology

Read the validation reports (https://www.gov.uk/government/publications/coronavirus-covid-19-serology-and-viral-detection-tests-technical-validation-reports) for each of these products.

Company	Product	Format	Limit of detection	Sensitivity	Specificity
Optigene	Genie® HT and Genie® III	RNA RT-LAMP on swabs	1,000 copies/ml	97% (CI 93% to 99%)	99% (CI 99% to 100%)
Optigene	Genie® HT and Genie® III	RNA RT-LAMP on saliva	1,000 copies/ml	82% (CI 68% to 91%)	100% (CI 99% to 100%)
Optigene	Genie® HT and Genie® III	Direct RT-LAMP on swabs	1,000 copies/ml	72% (CI 64% to 78%)	100% (CI 99% to 100%)
Optigene	Genie® HT and Genie® III	Direct RT-LAMP on saliva	1,000 copies/ml	80% (CI 72% to 85%)	100% (CI 98% to 100%)
Diagnostics for the Real World	SAMBA II SARS-COV-2 Test	POCT combined extraction and RT-PCR	250 copies/ml	98.8% (CI 95%)	100% (CI 95%)
LGC Group Ltd	End- point PCR (EPCR)	Extracted RT-PCR with endpoint detection	50 copies/ml	98.68% (CI 97.86% to 99.24%)	98.56% (CI 97.55% to 99.23%)
Horiba	POCKIT™	Central Nucleic Acid Analyzer	2440 copies/ml	95.75% (95% CI 91.0% to 98.1%)	97.7% (95% CI 95.2 to 99.0%)
QuantuMDx	SARS-CoV-2 Nucleic Acid Detection	RT-PCR	500 copies/ml	98.9% (97.1 to 99.6)	99.1% (97.6 to 99.6)
Oxford Nanopore	LamPORE	RNA RT-qPCR	20 copies/ml	99.57% (95% CI 98.46 to 99.99%)	99.40% (95% CI 99.28 to 99.50%)

Other technologies that have been validated will be added to the table once the manufacturer has consented to publication.

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1. Commercial and supply chain conversations will commence earlier in the process and happen in parallel through the relevant process.

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