Guidance

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

Updated 14 March 2022

Contents

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, antigen and antibody tests to support the national Test and Trace programme.

For any non-machine based LFT and home testing kits, an alternative technical validation route (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) will be required.

For all antibody tests, an alternative technical validation route will be required.

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. Initial 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, antigen and antibody tests 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).

Antigen test manufacturers are invited to complete the online form (https://support-covid-19-testing.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.

Antibody test manufacturers are invited to join the Dynamic Purchasing System (DPS) for antibody devices (https://health-family-contract-search.secure.force.com/ProSpend__CS_ContractPage?SearchType=Projects&uid=a074J000007FUgJQAW&searchStr=&sortStr=Recently+Published&page=1&filters=). Please note that joining the Dynamic Purchasing System does not guarantee that any orders will be placed with a supplier and is not a contract to provide goods to the department. Only once an invitation is issued and awarded will a contract be formed. It will only cover the specific requirement needed by that invitation.

Antibody test manufacturers are invited to seek independent evaluation of their tests. See the national standardised test performance process (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/national-standardised-test-performance-process-for-manufacturers-of-sars-cov-2-virus-antibody-tests) for more information.

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 form unless specifically requested to do so.

Further procurement opportunities that support the UK testing strategy set out by the Secretary of State for Health and Social Care, can be found on 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 (/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 (/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 of 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 UK Health Security Agency, 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 that suit use cases with unmet demand, the DHSC commercial team will invite those developers or suppliers to take part in a competitive procurement either via mini-competition or via appropriate frameworks.

Products in the pipeline (TVG)

The following table provides a snapshot of the number of products currently in TVG pipeline (as at 11 January 2022) and their status:

Validation stage

Status	Number of tests
In early stages of validation	0
Currently being validated or evaluated	8
Validation concluded or paused	129
Validated technology	24
Total	161

Validation concluded or paused

The 'Products in the pipeline (TVG): validation concluded or paused' table is on the main Assessment and procurement of coronavirus (COVID-19) tests page (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests).

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.

The performance results are based on the specific assay version described in the validation reports. Subsequent changes to the assay may result in deviation from these results and therefore the product will need to be locally verified for consistency as part of routine deployment.

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	QPOC SARS-CoV-2 assay	Direct molecular, LOD	1,000copies/ml	80.0 (95% CI 72.1-86.2)	98.5% (95% CI 96.5-99.4)

Company	Product	Format	Limit of detection	Sensitivity	Specificity
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%)
Nonacus	VirPath Sars-CoV-2 Multiplex qRT-PCR	qRT-PCR	250 to 500 copies/ml	98.40% (95.34% to 99.45%)	98.90% (97.70% to 99.65%)
Abbott	ID Now	Direct Isothermal Assay	<1,000 copies/ml	Nasal Swabs 89.5% (95% CI 83.2 to 93.7%), Nasopharyngeal 93.2% (85% CI 84.3 to 97.5%)	Nasal Swabs 98.4% (95% CI 96.5 to 99.3%), Nasopharyngeal 98.1% (95% CI 95.7 to 99.2%)
LumiraDx	POC rapid COVID-19 Ag test	POC	~62,500 copies/ml Claimed 32 TCID 50/ml	83.8 (95% CI 76.4 to 89.2%).	98.7% (95% CI 97.2 to 99.4%).
Primer Design Ltd	PROmate	Direct qRT-PCR	960 copies/ml	91.3% (95% CI 87.1 to 94.3)	99.0% (95% CI 97.8 to 99.6)
DNA Nudge	DNA Nudge	POC (non-extracted) RT-PCR	5,000 copies/ml	82.1% (95% CI 77.7 to 85.7)*	99.1% (95% CI 98.4-99.5%
Certest Biotech	Viasure	qRT-PCR	<1,000 copies/ml (20 genome copies per reaction)	99% (95% CI 96 to 99%)	100% (95% CI 98 to 100%)
Randox	Rapid PCR	PCR	725 copies/ml	99% (95% CI 96 to 99%)	100% (95% CI 99 to 100%)
Thermo Fisher	Taqpath	PCR	250 GCE/ml	100% (95% CI 98 to 100%)	100% (95% CI 99 to 100%)
BD Veritor	BD Veritor™ System	POC	1.4 x 102 TCID50/ml	85.2% (95% CI 79.1 to 89.8)	98.4% (95% CI 96.2 to 99.4)

Company	Product	Format	Limit of detection	Sensitivity	Specificity
VMD Health (UK) and Alveo Technologies Inc	be.well™	POC	<100copies/ml	95.3% (95% CI 90.6 to 97.8)	97.0% (95% CI 94.5 to 98.4)
Roche Cobas	SARS CoV-2	Extracted RT-PCR	50 copies/mL	99.4% (95% CI 96.5 to 99.9)	100% (95% CI 97.8 to 99.9)
Roche Cobas Liat	SARS CoV-2 + Influenza A/B	Extracted RT-PCR	50 copies/mL	97.6% (95% CI 94.1 to 99.1)	99.2% (95% CI 98.4 to 99.6)
Cepheid	Xpert® Xpress SARS-CoV-2 assay	Extracted RT-PCR	10 to 100 copies/mL for N gene and 100 to 1,000 copies/ml for E gene	99.5% (95% CI 98.2 to 99.9)	99.1% (95% CI 97.3 to 99.7)

*There is a range of sensitivities across validation sites. Please see the full report.

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.