Guidance

National standardised test performance process for manufacturers of SARS-CoV-2 virus antibody tests

Updated 14 March 2022

Contents

Evaluated antibody tests

This publication is available at 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

This guidance only applies to SARS-CoV-2 (COVID-19) serology antibody tests. It outlines how the government will review and independently evaluate SARS-CoV-2 serodiagnostic antibody assays.

A serodiagnostic antibody assay that successfully completes the standardised test performance process will not lead to a procurement or contract but will result in an independently evaluated serodiagnostic antibody assay.

High-level process

The standardised test performance process follows 6 key steps:

1. Register interest
2. Triage and initial review
3. Preliminary evaluation
4. Assay validation
5. Independent evaluation by UK Health Security Agency (UKHSA)
6. Results endorsement by the Technical Validation Group (TVG) and publication of results

If you have any enquiries regarding this process, please email nibsc@dhsc.gov.uk.

1. Register interest

Manufacturers of SARS-CoV2 (COVID-19) tests for antibody detection can register their interest in the national independent evaluation 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 Profile (TPP) (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work).

> To register your interest in this process, email nibsc@dhsc.gov.uk. Following registration, manufacturers will be sent a questionnaire and non-disclosure agreement (NDA) to complete.

Test manufacturers are required to complete the questionnaire 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.

This process is designed to support manufacturers to develop high-quality serodiagnostic assays as part of our commitment to ensuring high-quality products are available to support the national Test and Trace programme. As a result, information should be provided directly from manufacturers to ensure that the technical information can be confirmed directly with the manufacturer.

For blood-based serodiagnostic, the steps outlined below apply.

For non-blood-based serodiagnostic assays, an alternative validation route will be created as required.

A manufacturer wishing to withdraw their device from the standardised test performance process at any stage should inform nibsc@dhsc.gov.uk.

Please note that once a manufacturer has agreed to progress to the independent evaluation stage this will mean that they have agreed that the results of the independent evaluation will be published.

Sharing of personally and commercially sensitive information

By submitting your data, you are consenting to the information provided in this submission being shared with the relevant triage, review, validation and evaluation groups that form part of DHSC's national test and trace programme.

The information provided will only be used for the above purpose and will not be shared with individuals or groups unconnected to the process.

Your data subject rights are in no way affected.

Read the DHSC data protection policy (https://www.gov.uk/government/organisations/department-of-health-and-social-care/about/personal-information-charter#department-of-health-and-social-care-data-protection-policy)

2. Triage and initial review

The completed registration information and any supporting documents will be reviewed by the Results Oversight Committee.

This triage and initial review is based on a review of the clinical and technical information provided by the manufacturer in the completed questionnaire including:

- the manufacturer holding ISO 13485:2016 covering the registered device
- product use and type
- target analyte
- specimen type, including equivalence between types as appropriate
- output result
- analytical and diagnostic sensitivity and specificity as per MHRA TPP
- confirmation of known cross-reactivity
- regulatory status
- uniqueness of the device

Following the review, tests are deemed to be one of the following:

- aligned to the current national testing priority needs and progressed for completion of the standardised test performance for serodiagnostic antibody assays
- 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
- do not currently have the performance and clinical data required to pass triage but where it is recommended that the organisation generates this data

Manufacturers should expect to receive an outcome within 2 weeks of submission of a completed questionnaire and NDA. This may be longer, subject to the volume of offers that we are reviewing.

3. Preliminary evaluation

Offers that are deemed by the Results Oversight Committee to have met the relevant criteria will be progressed for preliminary evaluation. Manufacturers will be contacted and invited to take part in further technical validation and/or in-service evaluation.

If the manufacturer wishes to proceed, they will be required to:

- complete and sign a Material Transfer Agreement (MTA) with the National Institute for Biological Standards and Control
- procure from NIBSC the British Common Verification Panel, a pre-diluted series of NIBSC's standard for SAR-CoV-2 antibodies, external quality control
- conduct the preliminary evaluation tests in its laboratory using the same batch of devices for all stages
- provide the results of the preliminary evaluation to NIBSC for analysis using the World Health Organization (WHO) scoring system (https://extranet.who.int/pqweb/vitro-diagnostics/performance-evaluation)

4. Assay validation

Results and analysis from the preliminary evaluation that are deemed by the Results Oversight Committee to have met the relevant TPP and align to the current needs of the national Test and Trace programme will be progressed for assay validation. Manufacturers will be contacted and invited to take part in further technical validation and/or in-service evaluation.

If the manufacturer wishes to proceed, they will be required to:

- complete and sign a further MTA with NIBSC
- procure from NIBSC: Common Validation Panel
- conduct the assay validation tests in its laboratory using the same batch of devices for all stages
- provide the results of the assay validation tests to NIBSC for analysis using the WHO scoring system (see the HIV and HBsAg protocols) (https://www.who.int/diagnostics_laboratory/evaluations/alter/protocols/en/)

5. Independent evaluation

Results and analysis from the assay validation that are deemed by the Results Oversight Committee to have met the relevant TPP will be progressed for independent evaluation by UKHSA. Manufacturers will be contacted and invited to take part in further technical validation and/or in-service evaluation.

If the manufacturer wishes to proceed, they will be expected to:

- complete a testing and evaluation agreement with UKHSA
- provide 750 product test kits/assays from a single batch and all required consumables and reagents free of charge for independent evaluation
- provide UKHSA (Colindale) with the technical validation and additional relevant technical information to support the independent evaluation activity including training if needed
- provide relevant legal documents to support the independent evaluation and NDAs where needed
- agree to the results of the process being made publicly available
- confirm that they have immediate availability of sufficient testing kits to allow further independent evaluation and can provide sufficient product volumes, including consumables and reagents, with a lead time of less than one month from order if required

Manufacturers should expect to receive an outcome within 4 weeks of UKHSA receiving a completed agreement and the requisite test kits, consumables and training as appropriate. This may be longer subject to the volume of offers that we are reviewing.

6. Endorsement by the TVG and publication of results

The outcome of the independent evaluation will be reviewed by the Results Oversight Committee with results and recommendations submitted to the TVG, part of DHSC, for endorsement.

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

- central validation labs (including UKHSA Frimley and Cumbria)
- CONDOR (COVID-19 National Diagnostic Research and Evaluation Platform)
- Innovate UK
- academia professional body (Royal College of Pathology)
- MHRA

This group replaces all of the functions of the previous Viral Detection (molecular) Tests Group (VTAG) and, 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 Test, Trace, Contain and Enable (TTCE) programme on the suitability of the solutions and technologies.

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Appeals

If a manufacturer or a distributor acting on their instruction disagrees with the findings or decisions of the Results Oversight Committee at any stage, they may appeal by emailing the Test and Trace independent complaints team at ttsupplierescalation@dhsc.gov.uk with details of their objection and providing supporting data.

Products in the pipeline

The following table provides a snapshot of the number of products currently in the standardised test performance process pipeline for SARS-CoV-2 virus antibody tests as at 6 January 2022 and their status:

Status	Number of tests
Registered interest	69
Currently being evaluated	31
Evaluation concluded or paused	12
Evaluated technology	0

Status	Number of tests
Total	112

Evaluation concluded or paused

The following table provides a snapshot as at 15 March 2021 of the antibody tests that have concluded or paused the standardised test performance process for SARS-CoV-2 virus antibody tests.

Ref	Primary use location	Product type	High-level justification
0000	For example, professional use	For example, lateral flow device	For example, test withdrawn by manufacturer

Publication of results

We will publish links to antibody tests that have been reviewed here.

Evaluated antibody tests

We will publish links to the evaluation reports for each of these antibody tests here.