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Guidance

Coronavirus (COVID-19) serology and viral detection testing: UK procurement overview

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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 outlines how the government considers and assesses offers of serology and viral detection tests for national-level procurement to support the UK's coronavirus (COVID-19) testing strategy.

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

1. How developers apply to the national procurement process

Target product profiles

The Medicines and Healthcare products Regulatory Agency (MHRA) has developed target product profiles (TPPs) (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work) to provide guidance on the features and characteristics of serology tests that the Department of Health and Social Care (DHSC) is seeking to procure with the devolved administrations to support the UK testing strategy.

The TPPs have been developed to help the UK government make decisions around procurement of antibody tests. They might also be used in any local procurement decisions.

The TPPs can also be used by manufacturers developing assays that are likely to meet the UK government requirements.

The TPP for point of care/near patient serology tests has been published.

A TPP for Enzyme Immunoassay (EIA) antibody tests will be published in early June.

A TPP for point of care viral detection testing is expected by the end of June.

These TPPs will continue to be updated to reflect emerging clinical evidence and scientific knowledge.

Registering interest

Test developers can register their interest in the national procurement process if their tests meet the requirements of the relevant TPP.

They should complete the online form (https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19) for each unique test they want to supply.

The form has been designed by the clinical experts on the New Tests Approval Group (Serology) and Viral Detection Tests Approval Group. It has been designed to capture the main clinical and commercial information the government needs to assess the large volume of offers of tests it receives.

2. Initial review of offers (triage)

The online form submissions are reviewed by the clinical and diagnostic experts at either:

- the New Tests Approval Group for serology tests, which meets 3 times a week
- the Viral Detection Tests Approval Group, which meets once a week

Triage is based on a review of the clinical and technical information provided against the MHRA TPP(s) and consideration of the commercial information provided.

At triage, tests are deemed:

- aligned to our current national testing priority needs and progressed for assessment at a national assessment laboratory
- not aligned to our current national testing priority needs and held on file for review in light of any changes to our testing needs
- to currently not have the clinical data required to pass triage but where we recommend that the organisation generates this data

Companies are notified by the New Tests Approval Group or Viral Detection Tests Approval Group whether their technology will be evaluated centrally or if it will be held on file for future reference within 7 working days.

New Tests Approval Group

The New Tests Approval Group consists of representatives from the central evaluation labs (Public Health England (PHE) Oxford), Innovate UK, the government's Serology Taskforce and MHRA, as well as independent scientific advisers.

The group is chaired by Professor Sir John Bell.

Viral Detection Tests Approval Group

The Viral Detection Tests Approval Group consists of representatives from the central evaluation labs (including PHE Frimley, Cumbria), Innovate UK and MHRA, as well as independent scientific advisers.

The group is chaired by PHE.

3. Analytical assessment of offers

For those offers being progressed for centralised assessment, companies will be contacted and requested to send their tests to a named lab for analytical assessment.

We have published papers that outline the assessment methodology for the lateral flow tests and ELISA assays that have been reviewed to date:

- Evaluation of antibody testing for SARS-CoV-2 using ELISA and lateral flow immunoassays (https://www.medrxiv.org/content/10.1101/2020.04.15.20066407v2)
- COVID-19: laboratory evaluations of serological assays (https://www.gov.uk/government/publications/covid-19-laboratory-evaluations-of-serological-assays)

The evaluation protocol assesses antibody tests against a small number of samples first to decide if a further evaluation can take place. This is so that we can evaluate as many lateral flow tests as possible.

This threshold study tests 10 samples (including 9 from polymerise chain reaction (PCR) positive patients with detectable antibody). If 8 or more samples return the expected results, then the test goes forward for further evaluation.

As the constraints around evaluation materials – especially convalescent sera – ease, we're moving towards a system of test developer-led assessment based on standardised, blinded panels for serology tests.

We're developing a standardised POC viral detection evaluation protocol based on a standardised panel being developed by the National Measurement Laboratory. We'll publish more information when available.

4. Procurement

The results of the analytical assessment are reviewed at the New Test Approvals Group once completed. For those technologies that perform at the required level against the relevant TPP, the New Test Approvals Group will consider a recommendation to procure the technology at scale for UK-wide roll-out.

At this point, DHSC's procurement and commercial teams will contact the developer or supplier to discuss the terms under which such a roll-out may occur.

5. Publication of results

We've published:

- data on the ELISA assessments we've conducted (https://www.medrxiv.org/content/10.1101/2020.04.15.20066407v2)
- the results of the first wave of lateral flow test assessments we've conducted (https://www.gov.uk/government/publications/covid-19-laboratory-evaluations-of-serological-assays)

Test developers can provide input into the reports before publication of the results.

From now on, we intend to publish the results of our assessments and will work with test developers to agree the best approach for doing this.