CORONAVIRUS (COVID-19) TESTING

The UK life sciences industry, from multinational organisations to smaller companies, has mobilised in an unprecedented way to tackle the significant global challenge of COVID-19 and has played a critical role in supporting the NHS.

Diagnostic testing is a crucial part of healthcare. Tests can help to identify when patients are ill and how a virus is spreading, as well as preventing it from spreading further. Testing also reduces unnecessary hospital admissions, saving the NHS time and money in the long-term.

As SARS-CoV-2 – the virus which causes COVID-19 – is a new virus, diagnostic tests have had to be developed from a standing start. Within months, a number of tests have been evaluated and fast-tracked for use through worldwide regulatory bodies, including the US' FDA and the EU's CE marking system. COVID-19 testing in the UK is regulated by the MHRA, which has laid down target product profiles with a set of mandatory specifications for each test type according to its use.

Strong partnership working between industry and Government is ensuring that at this most critical time anyone who has symptoms of COVID-19, and some people without symptoms, can get a free test to check if they have the virus.

Antibody testing is also being offered to NHS and social care staff and their families, and to some NHS inpatients and care home residents, as well as blood donors.

FAQ

1. What types of tests have been made available?

There are two types of diagnostic tests for COVID-19:

1) **Virus** (nucleic acid) test (also known as PCR testing)

   This tests for presence of the genetic signature (RNA) of SARS-CoV-2, the virus which causes COVID-19.

   The tests being used by the NHS are CE marked, meaning that the test complies with EU safety rules and can be made available in markets including the UK.

   A swab is used to collect a sample from inside the nose or back of the throat of an individual.

   The test is initiated by a healthcare professional and performed in specific laboratories, a list of which is here.

Presence of the virus can be confirmed within a matter of hours. This type of test is available across the UK for anyone experiencing symptoms.

Virus (or PCR tests) are important as they can indicate if a person needs to continue to self-isolate or if they can return to work.

2) **Antibody** (serological) test

Lab-based antibody tests

This tests if an individual has previously been exposed to a COVID-19 infection and has developed antibodies.

A number of antibody tests are CE marked and have been evaluated by Public Health England.

These tests are currently initiated by a healthcare professional who collects a blood sample and is performed in specific laboratories.

More research is needed to understand the link between antibodies and immunity from getting the virus again. However, antibody tests are still important as they can give scientists and government a better understanding of the spread of the virus.

Antibody tests for community use

Validation of emerging antibody tests for use in community settings, for example 'finger prick' tests taken at home, is currently underway at a variety of global centres.

The current view from Public Health England and the MHRA is that use of these products is not advised and the government is not offering 'finger prick' tests at present, as there is not yet enough information on the accuracy of these types of tests

2. Are the tests accurate?

Virus (nucleic acid testing)

Nucleic acid testing makes use of a biochemical process, the polymerase chain reaction (PCR), a powerful and highly sensitive method for the amplification and subsequent detection of very small amounts of genetic information - in this case RNA from just a few SARS-Cov-2 viral particles. Although highly sensitive and specific, the technology is reliant on the quality of the sample.

Once initiated by a healthcare professional, testing can take a matter of hours to complete and is safe and robust. The technology lends itself to high-end automation, allowing large numbers of samples to be processed at specific laboratories with minimal handling by a technician.

Nucleic acid testing can only identify patients with active infection. Individuals within the recovery period of COVID-19 illness might not have detectable virus and will test negative.

Antibody (serological testing)

Antibody tests' accuracy is measured in terms of clinical specificity and clinical sensitivity.

Specificity indicates how precisely the tests finds the exact COVID-19 antibodies that it is looking for in each test sample, rather than seasonal coronavirus. A high specificity is vital in evaluating the reliability of an antibody tests.

The sensitivity indicates the number of false negatives. You would expect to see the level of sensitivity improve the longer the interval between antibody test and infection. This is because the immunological response to viral infection can take several weeks and evidence suggests that antibodies to COVID-19 may take 10-14 days to appear [Okba et al; Liu et al; Li et al]. Serological testing of an individual before this (known as the window period) will result in an unhelpful negative result.

Infection with SARS-CoV-2 will invoke an immune response in most cases. The detection of virus-specific antibodies - IgM, IgA and IgG - is important to identify individuals infected with SARS-Cov-2 regardless of symptoms. The detection of high affinity antibodies including IgG may indicate immunity to subsequent infection by the same virus and will provide a measure of how many people have been infected in the absence of nucleic acid testing results.

3. Are the tests safe?

The MHRA requires all manufacturers of test kits for professional use to contact them so that they can advise if a testing product can be placed on the market. There are a number of lab-based tests that have received the CE mark, which indicates the test conforms with health, safety and environmental protection standards for products sold in Europe. There are currently no antibody tests for home use that have received the CE mark, and it is illegal to supply such products. More information can be found here.

4. Who is providing these tests?

A number of companies from the life sciences industry, both multi-national organisations and smaller companies, have mobilised in an unprecedented way to make tests available. The collective response has enabled the NHS to increase testing capacity across the UK.

5. How are the tests evaluated?

All diagnostic tests, including the virus and antibody tests for COVID-19, are rigorously evaluated in the UK. This evaluation may include:

- CE marking – this means that the test complies with EU safety rules and can be made available in markets including the UK.
- Manufacturer's evaluation – tests carried out by the manufacturer to determine the specificity and sensitivity of its tests.
- Independent evaluation – for example by Public Health England or other centrally funded organisations such as CONDOR.

- Third-party studies – for example by universities or research laboratories.

6. Who can get the tests?

At the moment, anyone who has symptoms of COVID-19, and some people without symptoms, can get a free test to check if they have the virus.

Antibody testing is also being offered to NHS and social care staff, and to some NHS inpatients and care home residents.

7. How are the laboratories prioritising testing?

The Royal Collage of Pathologists has issued guidance which outlines a range of measures that laboratories can use to prioritise work, and release staff, facilities, equipment and reagents to cope with the viral outbreak and maximise SARS-CoV-2-19 testing capacity.