



CORONAVIRUS (COVID-19) TESTING

The Government has confirmed that COVID-19 testing capacity will increase.

The life sciences industry, both multi-national organisations and smaller companies, has mobilised in an unprecedented way to make tests available. As SARS-CoV-2, the virus which causes COVID-19, is a new virus, tests have been developed from a standing start and fast-tracked for use through worldwide regulatory bodies such as the US' FDA and the EU's CE marking system.

Strong partnership working between industry and Government, is ensuring that at this most critical time, the NHS can accurately test every member of its staff and patients. This includes provision of the multitude of additional materials required to take, preserve and prepare patient samples for testing.

Inevitably, with the urgent and unprecedented demand for the new antigen tests across the world, demand is out-stripping supply. A balance needs to be struck between rolling out at rapid speed and ensuring testing can be delivered reliably across the UK.

Laboratories and testing equipment of companies have been offered-up to supplement NHS/Public Health England capacity. The availability of additional testing facilities must be explored urgently.

We would urge the prioritisation of antigen testing to those who are showing clear symptoms requiring hospitalisation, and to develop testing protocols for healthcare workers and other key workers currently in self-isolation to enable them to return to work more quickly, where appropriate.

In the coming weeks, government will need to prepare for the next phase of the COVID-19 response. Attention therefore must turn to antibody testing to complement antigen testing. It is paramount that effort is directed to support innovators who are working in this field, to enable a secure supply chain of high quality, validated products.

FAQ

1. What types of tests will be available?

There are two types of test:

1) **Antigen** (nucleic acid test)

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

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.

2) **Antibody** (serological test)

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

It can also be performed in specific laboratories but also can be adapted into a testing format for community use.

Validation of emerging antibody tests for use in community settings is currently underway at a variety of global centres.

The [current view](#) from Public Health England is that use of these products is not advised.

2. Are the tests accurate? Do they pass on safety requirements?

In terms of safety, 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. They have confirmed that there are no CE marked tests for home use, and it is illegal to supply such products. More information can be found [here](#).

In terms of accuracy:

Antigen (nucleic acid testing)

Nucleic acid testing makes use of a biochemical process, the polymerase chain reaction, 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, testing can take a matter of hours to complete and is safe and robust. The technology lends itself to high-end automation, allowing the processing of large numbers of samples 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)

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. Detectable IgG antibodies 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.

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.

3. Which tests are prioritised?

At this moment, the priority is to test healthcare workers and those patients requiring hospitalisation for the presence of SARS-CoV-2 using the antigen test.

Testing the general population to see whether they have been exposed to SARS-CoV-2 will be very important, using the antibody test.

It might be possible to allow presumed immune key workers to come out of self-isolation and return to work. This may be done when the virus has reached its peak and we are beyond the current crisis phase, or when an assay has been identified that is both accurate and in high enough numbers to be logistically effective.

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.