

Media Q&A- antibody testing

Top lines

- Antibody testing is a key part of the Government's testing programme and will play an increasingly important role as we move into the next phase of responding to this epidemic.
- In order to better understand the role that an antibody test could play in our response to the epidemic, we need to improve our understanding of how the immune system responds to the virus that causes Covid-19.
- We do not currently know how long an antibody response to the virus lasts, nor whether having antibodies means a person cannot transmit the virus to others.
- Our understanding of the virus will grow as new scientific evidence and studies emerge.

What is antibody testing?

Antibody testing is a key part of the Government's testing programme and will play an increasingly important role as we move into the next phase of responding to the coronavirus pandemic.

Antibody testing can tell someone whether they have had the virus that causes Covid-19 in the past, by analysing a blood sample. It differs from virus testing (PCR), which can tell someone whether they have the virus currently.

What does an antibody (or serological) test do and how does it differ to a virus test (PCR test)?

Antibody test:

Antibody tests are used to detect antibodies to the virus as a marker of past infection. The test works by taking a blood sample and testing that sample for the presence of antibodies.

A positive test result indicates that you have previously had the virus and have developed some form of immune response.

However, we do not yet know how long the antibody response lasts, so we don't know how long it might help your body resist the virus. And we don't know whether having antibodies means one cannot transmit the virus to others.

PCR test/virus test:

In contrast, a PCR test aims to find out if you **currently have** the virus. A positive result does not necessarily indicate that you will go on to develop antibodies to the virus and an immune response. It is possible that around 10% of people who test positive will not develop an immune response.

What do antibody test results mean?

A positive antibody test demonstrates that someone has developed antibodies to the virus. The presence of antibodies signals that the body has staged an immune response to the virus.

Covid-19 is a new disease, and our understanding of the body's immune response to it is limited. We do not know, for example, how long an antibody response lasts, nor whether having antibodies means a person cannot transmit the virus to others.

Our understanding of the virus will grow as new scientific evidence and studies emerge.

An antibody test result can only tell an individual whether or not they have had the virus in the past. Antibody tests are also being used currently in surveillance studies, to understand what proportion of the population have already had the virus.

What is the point of antibody testing if you know so little about immunity?

Antibody testing has a critical role to play in helping us to learn about the level and length of immunity following infection and how the virus is spreading across the country. Public Health England (PHE) are currently undertaking a study, called the SIREN study, of 10,000 healthcare workers to establish if antibodies indicate any kind of immunity to Covid-19.

What types of antibody tests are the UK government developing?

The government is currently pursuing two main testing devices:

- A. 'Lab-based tests' (immunoassays), which require blood samples to be processed in NHS and other laboratories.
- B. 'Self-use finger-prick tests' (lateral-flow tests) for use within a community setting, and which do not require any lab processing.

'Self-use finger-prick tests' indicate the presence of antibodies in the blood. However, generally, they only provide this information on a 'yes/no' scale. These tests, currently in development, could potentially be deployed in greater numbers if a reliable version can be found.

In contrast, 'lab-based' tests tend to provide more detailed results, for example regarding the amount or concentration of antibodies. Although this type of test is more detailed, it is harder to scale-up, and currently requires a blood sample taken by a professional.

What do you know about the nature and duration of an immune system response to the virus?

There is no strong evidence yet to suggest that those who have been proven to have had the virus are immune. This is the position of the WHO.

It is a fair assumption, based on what we know about other viruses, that those who get the virus will be immune or resistant, at least for a limited period of time.

If you are usually healthy and your first illness was so severe you were prioritised for a virus (PCR) test and the result was positive, you will probably have developed some short-term immunity to the virus.

We do not know how long an antibody response lasts, nor whether having antibodies means one cannot transmit the virus. So it is an assumption that there is immunity, albeit a sensible one, and an assumption that if proven to have had the virus, you do not transmit.

What is the government doing to improve understanding of the virus and the immune response to the virus?

The Government is conducting some of the biggest seroprevalence surveys in the world, using lab-based tests to monitor the number of people in the sample cohorts that are presenting an antibody response and how this changes over time.

If you test positive for antibodies, can you ignore lockdown restrictions?

No. There is no evidence yet to suggest that those who have been proven to have had the virus are immune. This is the position of the WHO. You should continue to comply with social distancing measures and government guidelines.

Aren't you already doing antibody testing as part of surveillance?

Yes, the Government is already using antibody tests as part of several surveillance studies. We are conducting some of the biggest surveys in the world, using lab-based tests to find out what proportion of the population have already had the virus. This work includes 4 major surveillance studies with Public Health England (PHE), the Office for National Statistics (ONS), IPSOS MORI with Imperial College London and UK Biobank, designed to understand the current and future prevalence of infection in the wider population. We will be able to share further details of the results of these studies in due course.

What are you doing on developing a home-based antibody test?

The Government is working to develop scalable solutions for at home testing (lateral flow tests) as well as lab-based testing (lab-based serology / immunoassay testing) to assess whether a person has had the virus which causes Covid-19.

The Government is backing efforts to develop a homegrown lateral flow test. A business consortium, UK Rapid Test Consortium (UK-RTC), including Oxford University, Abingdon Health, BBI Solutions and CIGA Healthcare has launched, in order to design and develop a new home antibody test.

Are there home-based antibody tests you can purchase online safe to use?

There are now some regulated, safe, and accurate antibody tests available to buy privately online. The science of immunity remains uncertain, though we are making progress every

day. There is no strong evidence yet to suggest that those who have been proven to have had the virus are immune. The value of antibody tests therefore is currently limited to answering the question of whether someone has had the virus or not. If you receive a positive antibody result it does not mean that you are immune, or that you cannot pass on the virus to others. You must continue to comply with social distancing measures and government guidelines.

[If pushed on whether people should buy them: Individuals can make their own choices on whether to purchase an antibody test kit. Should they choose to do so, they should ensure that it is CE marked (which determines it is regulated and safe to use, but is not a guarantee of quality or accuracy) and appraise themselves on the details of the test's accuracy levels. It is important that anyone who takes an antibody test notes that there is no strong evidence yet to suggest that those who have been proven to have had the virus are immune, or that you cannot pass the virus on to others. It also does not mean that you can ignore social distancing measures.]

When do you think finger-prick antibody tests will be made available for public use?

The results from the first evaluation of home-use antibody tests (now published) have shown that, of the tests the Government has looked at so far, none have reached the standard required to be rolled out for individual, at-home use. The Government is backing efforts to develop a homegrown test. A business consortium, UK Rapid Test Consortium (UK-RTC), including Oxford University, Abingdon Health, BBI Solutions and CIGA Healthcare has launched, and is currently designing and developing a new home-use antibody test to determine whether people have had the virus. We will continue to assess all options and maintain a validation process for any potentially viable tests available on the market. Confidence in antibody tests needs to be established before being rolled out as part of a national programme of testing. According to Patrick Vallance, Chief Scientific Adviser: 'The accuracy of tests is so important that if it means a delay to get there, that delay is worth having.' This is an emerging area of science and technology. In normal circumstances development of a test like this would take 6 months. However, we are optimistic that a test can be developed much sooner than this.

Who will get the finger-prick tests first?

Home-use antibody tests will form one part of the Government's ongoing testing strategy, alongside lab-based antibody tests and virus testing. Confidence in any antibody tests needs to be established before being rolled out as part of a national programme of testing. According to Patrick Vallance, Chief Scientific Adviser: 'The accuracy of tests is so important that if it means a delay to get there, that delay is worth having.' The Government is considering its rollout plans for antibody testing and will be making announcements in due course.

How reliable do the 'self-use finger-prick tests' need to be before they will be approved for use in the UK?

The criteria for clinical specificity is set deliberately high. In a test with low specificity, there is an unacceptable risk that a person is incorrectly told that they have developed an immune response. They may consequently be exposed to infection and be at risk of illness and may

also pass that infection on to others that they come in contact with. This is particularly a concern in people from a high-risk group, or a group which is directly exposed to vulnerable persons.

Our experts are clear that an unreliable test is worse than no test. Hence, the Chief Medical Officer strongly discourages organisations and individuals purchasing their own unvalidated antibody tests.

Antibody lab-tests programme rollout

Testing programme Q&A

Why are you starting in the NHS / care sector - Why aren't you rolling out this test most widely now?

We believe a national antibody testing programme may provide a critical role in the next phase of this pandemic. However, the science of immunity remains uncertain, though we are making progress every day. There is no strong evidence yet to suggest that those who have been proven to have had the virus are immune. If you receive a positive antibody result it does not mean that you are immune, or that you cannot pass on the virus to others. You must continue to comply with social distancing measures and government guidelines. The value of antibody tests is therefore currently limited to answering the question of whether someone has had the virus or not. This is why we are starting the national roll-out in the NHS and care sector where there is a clear need to know who has had the virus.

Are non-clinical staff eligible ie cleaners and trust office staff?

This test will be offered to all NHS staff regardless of their role, NHS regions in England will roll out the test prioritising according to local needs.

The 7 NHS regions will roll it out and prioritise staff on a regional basis so they may be tested in a different order in different areas, depending on the local arrangements, but it will roll out quickly.

How is the care sector getting tested? When will it be available?

For care workers, we will be phasing this offer in by geography and will agree with local leaders the best place in the country to start and co-design the implementation. This will then be rolled out across England.

Who tests the care sector?

We are reviewing the best options for the care sector but it is likely to include trained professionals going to care homes to take the blood samples from those who would like to take part. The details will be confirmed soon.

Will the results of the antibody test mean changes to the PPE guidance?

No, if someone tests positive, they still need to follow social distancing measures and appropriate use of PPE.

A positive test result for antibodies, whichever test is used, does not currently mean that the person being tested is immune to Covid-19. There is also no firm evidence that the presence of antibodies means someone cannot be re-infected with the virus or will not pass it on to someone else.

How many tests will be delivered to the DAs?

The UK Government has arranged supplies of tests on behalf of the devolved administrations, and each devolved nation is deciding how to use its test allocation and how testing will be prioritised and managed.

What's the timeline for rollout?

For NHS staff and patients, blood will be taken in NHS hospital settings. For NHS staff, within each region, the tests will be prioritised according to local needs and concerns – we aim to get through all NHS staff who would like a test as quickly as possible.

Where inpatients are currently having a blood test as part of their assessment they will also be asked whether they would like an antibody test alongside other tests. Where patients are attending as a day patient and a blood test is part of their assessment the antibody test will also be offered.

For care staff, separate arrangements are being made to carry out testing in social care settings, where staff will be asked whether they would like a test, and tests offered to social care residents based on clinical advice.

Who will be responsible locally for deciding which areas get care home tests first?

For care staff, the testing programme will be rolled out in a phased way across regions in England. We will agree with local leaders the best place in the country to start the programme and we will work with them to decide how this is implemented. Care home staff will be tested using a separate phlebotomy service, which will be able to take blood at their place of work.

Will all NHS staff have access straight away?

For NHS staff, within each region, the tests will be prioritised according to local needs and concerns – we aim to get through all NHS staff who would like a test as quickly as possible. Blood will be taken in NHS hospital settings.

Are community pharmacists included?

Yes, community pharmacists will be included in the NHS staff testing.

Why is the NHS national but care homes are geographical?

The care sector is currently taking part in the rollout of PCR testing which is being offered to all staff and residents and will determine if they have the virus. This is a priority for our care homes and we want to introduce the Antibody testing in parallel but in a phased way to allow for both to be implemented in a timely manner.

How will the geographical phasing work for care homes? Where are the areas?

We will discuss with regional and local leaders the phasing of Antibody testing based on local priorities.

Does social care staff include everyone working in the sector (i.e. not just those in care homes)?

We will start with those in Care Homes and look at widening to all staff.

How will the tests actually be carried out in care homes?

Care home staff are likely to be tested by a separate phlebotomy service, which will take blood at their place of work.

Broadly how soon will people get results?

This is going to be different from hospitals to care homes - as quick as 4 hours in the lab but we don't know about the logistics of taking blood, getting to path lab and returning results yet for sites outside of the NHS - would not want to commit to a time yet

Within the NHS is there systematic prioritisation for those writing with the most vulnerable people (eg cancer units) or is that decision made at a local level?

For NHS staff, blood will be taken in NHS hospital settings. Within each region, the tests will be prioritised according to local needs and concerns – we aim to get through all NHS staff who would like a test as quickly as possible.

Regional NHS testing leads will make decisions of prioritisation based on local needs.

How will the antibody tests fit with existing testing? Will people be tested for both if they have the antibody test?

Antibody and swab (PCR) tests fulfil different purposes, and it is unlikely someone would be given both tests at the same time.

Antibody tests are used to detect antibodies to the virus as a marker of past infection. The test works by taking a blood sample and testing that sample for the presence of antibodies.

A positive test result indicates that you have previously had the virus and have developed some form of immune response.

However, we do not yet know how long the antibody response lasts, so we don't know how long it might help your body resist the virus. And we don't know whether having antibodies means one cannot transmit the virus to others.

In contrast, a PCR test aims to find out if you currently have the virus. A positive result does not necessarily indicate that you will go on to develop antibodies to the virus and an immune response. It is possible that around 10% of people who test positive will not develop an immune response.

The NHS will continue to offer testing to symptomatic staff and their household/family members with the PCR swab test. Someone with active symptoms of COVID-19 would not be offered the antibody test, and we would wait 21 days after symptoms to test for antibodies.

How / where will the tests be carried out?

For NHS staff, blood will be taken in NHS hospital settings.

Where inpatients are currently having a blood test as part of their assessment they will also be asked whether they would like an antibody test alongside other tests. Where patients are attending as a day patient and a blood test is part of their assessment the antibody test will also be offered.

For NHS staff, within each region, the tests will be prioritised according to local needs and concerns – we aim to get through all NHS staff who would like a test as quickly as possible.

Separate arrangements are being made to carry out testing in social care settings, where staff will be asked whether they would like a test, and tests offered to social care residents based on clinical advice.

Could you use the Pillar 2 network for antibody testing?

There are already significant phlebotomy services within the NHS that will enable us to test NHS patients and staff. Only trained clinical staff can take blood.

Where does lab capacity for these tests come from? How will lab capacity be provided if rollout beyond NHS?

The NHS England existing pathology laboratory network will process these tests.

How / when will individuals receive the results of lab-based tests? Where will these results be stored?

Results will be communicated to patients alongside other blood test results by their clinician. Results will be stored on a patient's GP record.

Is the programme UK wide, or just England?

The UK Government has arranged supplies of tests on behalf of the devolved administrations, and each devolved nation is deciding how to use its test allocation and how testing will be prioritised and managed.

What will the test results be used for? Will they be shared?

Patient results remain confidential.

Who will be given priority access to these tests?

Antibody tests will be prioritised for NHS and care home staff. Clinicians will be able to request the tests for patients in both hospital and social care settings if they deem it appropriate.

NHS staff will have blood taken in NHS hospital settings. Where inpatients are currently having a blood test as part of their assessment they will also be asked whether they would like an antibody test alongside other tests. Where patients are attending as a day patient and a blood test is part of their assessment the antibody test will also be offered. For NHS staff, within each region, the tests will be prioritised according to local needs and concerns – we aim to get through all NHS staff who would like a test as quickly as possible.

Separate arrangements are being made to carry out testing in social care settings, where staff will be asked whether they would like a test, and tests offered to social care residents based on clinical advice.

Can anyone book one of these tests or have them done at their GP?

No. Antibody tests will be prioritised for NHS and care home staff. Clinicians will be able to request the tests for patients in both hospital and social care settings if they deem it appropriate.

Is it compulsory to have one of these tests if you go to hospital?

All blood tests are consented to by the patient or guardian - having an antibody test will not be compulsory.

Roche/Abbott and other suppliers Q&A

Can you confirm that the Roche/Abbott test has been approved by PHE? When did this happen?

The test was independently evaluated by Public Health England at its reference laboratory at Porton Down. This evaluation will inform Government/NHS decisions on rolling out antibody testing.

Is Roche/Abbott supplying the antibody tests you'll be using on the programme?

The government is in conversation with a number of potential suppliers.

Roche and Abbott are producers of two tests that have already been evaluated by PHE and found to be accurate. But more tests are currently going through the validation process, so they will not be the only suppliers used in the programme.

How long did it take to evaluate the Roche/Abbott antibody test?

PHE started the evaluation within days of receiving test kits from Roche and Abbott and the evaluations and reports were each completed within 5 days.

Why did PHE need to clear the Abbott/Roche antibody test, given it had already received Europe's CE mark?

CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. PHE's evaluation was to confirm the sensitivity and specificity of the test as reported by Roche and to inform the decisions and recommendations of the cross-government group tasked by DHSC with overseeing the triage process for new tests.

What is the PHE validation process anyway?

PHE conducts evaluations for its own use and to inform the decisions and recommendations of the cross-government group tasked by DHSC with overseeing the triage process for new tests

Scientific experts at PHE have been evaluating a number of lab-based antibody assays, including those produced by Roche and Abbott, using blood serum samples.

The results are shared with the manufacturers for their information. However, evaluation work is ongoing and the results will be published once all work has been completed and the results have been thoroughly reviewed

PHE is not a regulator and so does not have any role in approvals for tests for use in the UK. The Medicines and Health Products Regulatory Agency is the national regulator for medical tests and any test can legally be marketed and deployed in the UK once it receives a CE mark.

What is the accuracy rate for the Roche test?

The test is one of the most reliable on the market, with the manufacturer reporting 100% sensitivity (14 days post PCR confirmation) and over 99.8% specificity.

What is the accuracy rate for the Abbott test?

The test is one of the most reliable on the market, with the manufacturer reporting 100% sensitivity (14 days post PCR confirmation) and over 99.6% specificity.

How does it work?

The test requires a blood sample to be taken by a qualified healthcare professional and processed in a laboratory.

Hospitals and reference laboratories can run the test on fully-automated equipment already widely installed by Abbott Laboratories and Roche Diagnostics at sites across the UK. Existing NHS pathology lab networks will be used.

The high specificity indicates how precisely this test finds the exact antibodies to the virus that causes COVID-19 it is looking for in each test sample. The test helps identify both immunoglobulin M (IgM) antibodies – which are produced by the body in the initial fight against the infection – and immunoglobulin G (IgG) antibodies – which remain longer in the body.

Are you working to verify other tests or is that it now?

We of course continue to monitor and assess all tests that pass through our triaging process.

Immunity Certificates/Passports Q&A:

Will you introduce “immunity passports” for those who have positive antibody tests and, if so, when?

In order to fully understand the potential of certification in the next phase of our national response to this pandemic, we first need to improve our understanding of how the immune system responds to infection with the COVID-19 virus.

COVID-19 is a **new disease** and the science around “immunity” to the virus remains uncertain. We do not, for example, know how long an antibody response to the virus lasts nor whether having antibodies means one does not transmit the virus to others.

In order to gain answers to these critical scientific questions, the UK Government is conducting some of the biggest seroprevalence surveys in the world – using lab-based tests to monitor the number of people that are presenting an antibody response and how this response changes over time.

Follow up questions and answers (if pushed):

Is the Government doing work to find out answers to these scientific questions?

- Yes. The Government is conducting some of the biggest seroprevalence surveys in the world, using lab-based tests to monitor the number of people in the sample cohorts that are presenting an antibody response and how this changes over time.

Are you saying you do not intend to introduce “certificates?”

- We first need to improve our understanding of the science around immunity in order to fully understand the potential of certification in our response to this pandemic.

If you do roll-out certificates, what steps would you take to ensure privacy concerns are address?

- As with the NHSx contract tracing app, if we deemed it possible to introduce a “certification” system, we would of course ensure privacy was put at the heart of this system too.

Would these certificates be app-based and use facial recognition?

- To borrow Matthew Gould, CEO of NHSX’s words to the Commons Science and Technology Select Committee on the 28 April 2020, “the tech cart cannot come before the horse” – we need to work out what the science enables us to do before we work out what technology might underpin a system of certification”.

Is it true that Onfido, the UK-based firm specialising in verifying people’s identities using facial biometrics, are in talks with ministers about creating health passports?

- The government has been approached by a number of companies offering us technology solutions in the certification space. However we are not planning, nor have I seen any plans to use facial recognition.

Is antibody testing key to easing existing NPIs?

- Antibody testing has a critical role to play in helping us to learn about the level and length of immunity following infection and how the virus is spreading across the country.