

# Coronavirus (COVID-19) Antibody Testing

## Briefing Paper

### Humber Directors of Public Health

#### Key Messages:

- Tests are available to identify if an individual is currently infected with COVID-19 or if they have previously been infected with COVID-19.
- COVID-19 is a new disease and the lasting immunity or ability to become infected with COVID-19 again requires further research.
- If an individual tests positive for COVID-19 antibodies, this does not mean they are immune from further infection and must adhere to social distancing and self-isolation guidance.
- This document will be continuously updated to reflect national guidance and the most recent COVID-19 research.

#### 1. Purpose:

As part of the UK Government 5-pillar testing strategy, coronavirus (COVID-19) antibody testing became available to NHS staff and patients from 28 May 2020. Testing to diagnose current cases of COVID-19 and to identify individuals who have previously been infected with the virus is imperative to develop our understanding of the virus, COVID-19 epidemiology and to help inform national decisions about control measures.

This paper considers the two types of tests available for COVID-19 and how these results should be interpreted.

#### 2. Coronavirus (COVID-19) Antigen PCR Testing:

The coronavirus (COVID-19) antigen PCR test determines whether an individual is currently infected with COVID-19. The test involves taking a swab of the patient's nose or throat and processing the sample to look for fragments of the virus genetic material.

The PCR test is the method being used for diagnosis of COVID-19. The test is sensitive and able to test if the patient/individual is shedding virus fragments. The test does not indicate if the virus is "viable" (i.e. live and can cause infection) or "not viable" (i.e. dead and cannot cause infection).

##### 2.1 PCR Test Results:

A positive result indicates an individual is most likely currently infected with COVID-19.

A negative result indicates an individual is most likely not infected with COVID-19. Essential workers, particularly health and social care workers, must conduct a local risk assessment before returning to work if they have been tested for COVID-19 but had a negative result. More information on the accuracy and reliability of the PCR test is available in the 'Directors of Public Health Humber, Coast and Vale Testing for COVID-19 Briefing Paper'.

Some individuals have been found to shed virus genetic material at a low level for a number of weeks following infection and so may intermittently test positive and negative. Current evidence has identified that individuals with laboratory-confirmed COVID-19 diagnosis are not considered to be infectious beyond 14-days from the initial onset of symptoms. Further guidance on this is anticipated from Public Health England and the Department of Health and Social Care imminently.

### **3. Coronavirus (COVID-19) Antibody Testing:**

Antibodies are disease specific proteins which are produced by the body to protect it from infection (i.e. provide immunity). The COVID-19 antibody test is a serological test which processes blood samples from individuals to look for the COVID-19 antibodies (anti-SARS-CoV-2). The test is used to identify whether an individual has had a COVID-19 infection.

#### *3.1 Accuracy:*

Public Health England (Porton Down) and researchers from the University of Oxford and Oxford University Teaching Hospitals NHS Foundation Trust were commissioned by the Department of Health and Social Care to evaluate several commercial blood tests that look for SARS-CoV-2 antibodies.

Over a three-week period, four SARS-CoV-2 antibody assays were evaluated. Antibody test sensitivity (the true positive rate) was evaluated on 536 positive samples from adult individuals with laboratory-confirmed COVID-19 infection more than 20 days post-symptom onset. Antibody test specificity (the true negative result) was evaluated on 994 pre-pandemic (2015-2018) blood samples from unique, health individuals.

SARS-CoV-2 antibody test evaluation results showed a sensitivity (true positive rate) of 92.7-98.1% and a specificity (true negative result) of 98.6-99.9%.

Antibody testing kits are newly developed and further research is required to understand the long-term immunity to COVID-19.

#### *3.2 Interpretation of antibody results:*

The result of an antibody test can either be positive (i.e. antibodies present), negative (i.e. no antibodies) or equivocal (i.e. inconclusive).

##### *3.2.1 Positive test result:*

A positive results means an individual has been exposed to COVID-19 at some time and their body has produced antibodies in response.

There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection. Therefore, individuals are possibly at on-going risk of infection even with a positive antibody result.

Everyone must follow social distancing and personal protective equipment (PPE) guidance irrespective of their antibody status.

[Appendix 1](#) provides examples of specific scenarios where a positive antibody result may be obtained.

##### *3.2.2 Negative test result:*

A negative result means an individual has no COVID-19 antibodies (anti-SARS-CoV-2) present in their blood sample.

[Appendix 2](#) provides examples of specific scenarios where a negative antibody result may be obtained.

### *3.2.3 Equivocal test result:*

Equivocal test results are obtained when the antibody response is weakly reactive and renders the test difficult to interpret. These test results are difficult to interpret and a repeat antibody test is recommended after four weeks.

[Appendix 3](#) provides examples of specific scenarios where an equivocal antibody test result may be obtained.

## **4. Further reading and useful resources:**

The following papers and resources provide further explanation and guidance relating to testing for COVID-19 and the implications of test results:

- Directors of Public Health Humber, Coast and Vale Testing for COVID-19 Briefing Paper
- Public Health England, 2020. Evaluation of sensitivity and specificity of four commercially available SARS-CoV-2 antibody immunoassays. Available [here](#).
- Department of Health and Social Care, 2020. Coronavirus (COVID-19): antibody tests. Available [here](#).
- UK Government, 2020. Coronavirus (COVID-19): scaling up testing programmes. Available [here](#).

**Appendix 1:** Examples of specific scenarios when a positive antibody test result may be obtained.

Positive antibody test result scenario	Scenario interpretation
Positive result in someone who had a positive PCR test > 14 days ago	<ul style="list-style-type: none"> <li>Confirms the individual had COVID-19 in the past</li> </ul>
Positive result in someone who had a positive PCR test <7 days ago	<ul style="list-style-type: none"> <li>This indicates acute infection with COVID-19 and the individual, their household and other close contacts must self-isolate in accordance with national guidelines.</li> </ul>
Positive test in someone with COVID-19 symptoms in the last 7 days	<ul style="list-style-type: none"> <li>This indicates acute infection with COVID-19</li> <li>The individual should have a PCR test</li> <li>The individual, their household and other close contacts must self-isolate in accordance with national guidelines.</li> </ul>
Positive result in someone with previous COVID-19 symptoms but never had a PCR test to confirm diagnosis	<ul style="list-style-type: none"> <li>Result indicates the individual has been exposed to COVID-19 and their body has responded by producing antibodies.</li> </ul>
Positive test in someone who has not had previous symptoms nor a positive PCR test	<ul style="list-style-type: none"> <li>Most likely the result indicates the individual was an asymptomatic case at some point in the past</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>The result could also mean that the individual currently has COVID-19 or has only recently had COVID-19 infection <ul style="list-style-type: none"> <li>A PCR swab test will be recommended to diagnose if the individual currently has COVID-19</li> <li>This scenario is not anticipated to be common</li> <li>An individual may continue to work with PPE and social distancing whilst waiting for the PCR result</li> <li>If the PCR result is positive, they must follow self-isolation guidance</li> <li>If the result is negative it is likely to mean the individual was an asymptomatic case in the past</li> </ul> </li> </ul>
<b>Source:</b> NHS Barts Health Trust	

**Appendix 2:** Examples of specific scenarios when a negative antibody test result may be obtained.

Negative antibody test result scenario	Scenario interpretation
Negative test in someone who has not had previous symptoms nor a positive PCR test	<ul style="list-style-type: none"> <li>• This means the individual has not been infected with COVID-19</li> </ul>
Negative test in someone with COVID-19 symptoms in the last 7 days	<ul style="list-style-type: none"> <li>• Result may occur if the individual is tested early in their illness and the body has not had enough time to produce antibodies to the COVID-19 infection.</li> <li>• The best results are obtained when tested 4-6 weeks after an infection</li> </ul>
Negative result in someone with previous COVID-19 symptoms but never had a PCR test	<ul style="list-style-type: none"> <li>• Result may indicate the individual has been infected with a different virus (not COVID-19).</li> <li>• Some individuals may have been infected/exposed to COVID-19 but never developed a measurable immune response. <ul style="list-style-type: none"> <li>○ COVID-19 is a new disease and its effects of the immune system and different individuals is still to be understood fully.</li> </ul> </li> <li>• A result may indicate that the individual has been tested early in their illness and the body has not had enough time to produce antibodies in response to the COVID-19 infection. <ul style="list-style-type: none"> <li>○ The best results are obtained 4-6 weeks after an infection.</li> </ul> </li> </ul>
Negative result in someone who had a positive PCR test < 6 weeks ago	<ul style="list-style-type: none"> <li>• A result may indicate that the individual has been tested early in their illness and the body has not had enough time to produce antibodies in response to the COVID-19 infection. <ul style="list-style-type: none"> <li>○ The best results are obtained 4-6 weeks after an infection.</li> </ul> </li> <li>• Some people may have been exposed to COVID-19 but never developed a measurable immune response.</li> <li>• It is worth having a repeat antibody test at least 6 weeks after the PCR test</li> </ul>
Negative result in someone who had a positive PCR test > 6 weeks ago	<ul style="list-style-type: none"> <li>• Some individuals may have been infected/exposed to COVID-19 but never developed a measurable immune response. <ul style="list-style-type: none"> <li>○ COVID-19 is a new disease and its effects of the immune system and different individuals is still to be understood fully.</li> </ul> </li> </ul>
<b>Source:</b> NHS Barts Health Trust	

**Appendix 3:** Examples of specific scenarios when an equivocal antibody test result may be obtained.

Equivocal antibody test result scenario	Scenario interpretation
Equivocal result in someone who had a positive PCR test <7 days ago	<ul style="list-style-type: none"> <li>Result likely indicate early antibody production during an acute infection with COVID-19 and the individual, their household and close contacts must self-isolate in accordance with national guidance.</li> </ul>
Equivocal test in someone with COVID-19 symptoms in the last 7 days	<ul style="list-style-type: none"> <li>Result may indicate early antibody production during an acute infection with COVID-19</li> <li>A PCR test should be conducted and the individual, their household and close contacts must self-isolate in accordance with national guidance.</li> </ul>
Equivocal result in someone who had a positive PCR test >14 days ago	<ul style="list-style-type: none"> <li>Antibody result is difficult to interpret. A repeat antibody test is recommended after four weeks.</li> </ul>
Equivocal result in someone with previous COVID-19 symptoms but never had a PCR test	<ul style="list-style-type: none"> <li>Antibody result is difficult to interpret. A repeat antibody test is recommended after four weeks.</li> </ul>
Equivocal test in someone who is has not had previous symptoms nor a positive PCR test	<ul style="list-style-type: none"> <li>Antibody result is difficult to interpret. A repeat antibody test is recommended after four weeks.</li> </ul>
<b>Source:</b> NHS Barts Health Trust	