learn | prepare | care

COVID-19 Antibody Test

You might have some questions to ask, we have tried to think of some here. We will also be able to answer your questions on your pre-test screening call.

1. How accurate is this test and how much does it matter?

This BIOPANDA test is more accurate than many antigen or other antibody tests. Many antigen PCR tests have very low accuracy rates and have further issues such as the potential for cross contamination of samples.

https://nymag.com/intelligencer/2020/06/how-accurate-are-covid-19-tests.html

2. Is the test CE approved for testing by healthcare professionals?

The CE mark is for point of care vitro finger prick capillary use by a Health Care Professional. The test can only be performed and evaluated by a Health Care Professional such as a nurse, paramedic or pharmacist and **cannot be sold directly to the public to self-test.**

3. What is the test actually testing for?

The COVID-19 rapid antibody test is a finger prick test which identifies if the body has developed an antibody response to a COVID-19 infection.

4. Does the test tell you if you have an active COVID-19 infection?

No. The test is not a viral test to identify if you currently have COVID-19. The test is a highly sensitive and a very reliable marker of past infection.

5. Is the test specific to COVID-19 or will antibodies to other Coronavirus show a positive result?

The test is highly specific for COVID-19. Evaluation found it had a 98.3% Specificity which means that less than 17 in 1000 positive tests might be false positives due to other reasons such as other coronaviruses.

6. What is the difference between IgM and IgG (these are the antibodies that might be picked up on the test)?

IgM antibodies are the body's initial immune response that help the body fight off infection.
IgG antibodies are the body's secondary immune response that remain in the blood to fight off infection.

PharmaDoctor (distributer) terms state the requirement for the tests on the public to only be carried out **21 days after symptoms have subsided**. By leaving 21 days the more accurate IgG can be used to identify a patient's antibody response.

7. How accurate is the test's IgG response?

No test can be 100% accurate however, the BIOPANDA finger prick test is highly accurate. The manufacturer quotes the following accuracy data:

IgG Specificity	98.3%
IgG Sensitivity @ 21 days+	99.9%*

Specificity = The % of people who will test correctly negative for COVID-19 antibodies
Sensitivity = The % of people who will test correctly positive for COVID-19 antibodies

8. What is the incidence of false results?

At 21 days post symptoms, the test is >99.9%* accurate at detecting IgG antibodies and has 98.3% specificity in producing a correct negative test result.

9. If the test gives a positive result does this mean I have had COVID-19 before and can I catch it again?

There is currently no evidence that the presence of antibodies protects you from being infected by the virus again or possibly passing on the infection again. All patients being tested should be told that the presence of antibodies does not infer immunity and to continue following Government guidelines in maintaining vigilance, practicing social distancing and isolating when appropriate.

10. What is the benefit of having the test?

For now, it is for no other reason than a confirmation that you have had/not had COVID-19. Feedback is that people simply want peace of mind that they have had COVID-19 and recovered.

A positive test does not mean that you will have immunity, or any improved resistance should you catch the virus again. However, it does confirm that you have most likely been through a coronavirus infection and built up antibodies for COVID-19.

11. If antibodies don't mean I am immune, why have the test?

It is up to the individual if they want to be tested. Some people may want to do the test to find out if it was coronavirus that they had previously contracted when they may have experienced symptoms. Knowing you have had the virus before may give peace of mind that your body managed to successfully fight off the virus.

12. The Government say that there is no accurate antibody test that is approved to use other than the NHS testing programme. Why is this test ok?

The Government has requested that Public Health England (PHE) evaluate tests for their national testing program. PHE has conducted some evaluation of antibody tests but have only identified the ROCHE and ABBOT tests to be suitable for any national program. Both PharmaDoctor and BIOPANDA have submitted requests for the test to be evaluated by PHE. To date, PHE has not evaluated the BIOPANDA test and not asked for the test to be submitted for evaluation.

13. Does PHE not evaluate tests?

Public Health England 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 (MHRA) is the national regulator for medical tests. The MHRA only accredit manufacturer's CE certification however, the MHRA do not evaluate or approve the actual tests or devices themselves.

Any test can legally be marketed and deployed in the UK once it receives a 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. A CE mark is applied by manufacturers to devices which meet the requirements of medical device regulations.

14. What is the law with regards approving tests and how they can be used?

It is a common misconception that PHE need to evaluate COVID-19 tests before they can be used.

PHE is not a regulator and so does not have any role in approvals for tests for use in the UK private market. The Government has asked PHE to evaluate tests for use in the UK's national program, but this does not mean that tests must be evaluated by PHE in order to be used.

15. If a patient is positive for IgM antibodies does that mean the patient is infectious?

Presence of IgM antibodies can be detected for some time after the infection has been fought off. IgM is usually only detected once the patient has built up enough antibodies and this is usually in the post-infectious stage. We request patients to be tested at least 21 days after the onset of symptoms and at least 28 days after contact with a symptomatic individual, in order to ensure that they are no longer infectious. Although a test result detecting IgM ONLY, can potentially be a marker of the patient fighting the virus and may be infectious if they are 21 days post infection, this is very unlikely.

If IgM only is presented, we would question the patient on when they first felt ill, their symptoms and when they stopped. The Government advises a 7-day quarantine for coronavirus. However, the individual should continue isolation if they are still presenting the following symptoms:

- a high temperature or feeling hot and shivery
- a runny nose or sneezing
- feeling or being sick
- diarrhoea
- loss of appetite
  https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/how-long-to-self-isolate/

16. What is the regulatory requirement to use a test?

The Medicines and Health Products Regulatory Agency (MHRA) is the national regulator for medical tests. The MHRA only accredits the manufacturer's CE certification however, they do not evaluate or approve the actual tests or devices themselves.

Any test can legally be marketed and deployed in the UK once it receives a 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. A CE mark is applied by manufacturers to devices which meet the requirements of medical device regulations.

The BIOPANDA tests are CE certified by the manufacturer. The CE certificate and documentation have been reviewed by the MHRA who have authorised the test for sale to Health Care Professionals only.

17. Did the MHRA stop companies from supplying finger prick tests?

This relates to the ROCHE and ABBOT tests which are CE certified for intravenous blood collection by Health Care Professionals and for lab evaluation only. The MHRA confirmed that capillary blood samples are not to be used for these types of tests. The BIOPANDA test differs from these ROCHE and ABBOT tests as it has been CE certified as a point of care finger prick blood test to be performed and evaluated by Health Care Professionals only (capillary blood sample is allowed and no lab evaluation is required).

The MHRA guidance clearly states:
"Some UK providers such as high street pharmacies and private healthcare providers offer COVID-19 antibody testing for members of the public…

collecting a finger prick blood sample into a small container following a set of instructions. The container is then sent to a laboratory for analysis…

The laboratory tests are CE marked and safe for use on blood drawn from the vein by a healthcare professional, but have not yet been validated by the manufacturer of the test to be used with a finger prick blood sample...

We are contacting providers of the antibody testing services and the laboratories running these tests. We are asking them to temporarily stop offering these tests for sale until the regulatory and safety concerns have been resolved."

https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-patients-the-public-and-professional-users-a-guide-to-covid-19-tests-and-testing-kits

18. Does Public Health England (PHE) not advise against the use of tests?

The Public Health England (PHE) advice does not rule out antibody testing services provided in a clinical setting by Health Care Professionals who can provide suitable assistance to patients to ensure they are fully informed.

The PHE Statement: *"COVID-19: rapid point of care tests for use in community pharmacies or at home"* – first published 25th March, advises against the use of rapid point of care antibody tests. https://www.gov.uk/government/publications/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home

Despite developments since the published date, the advice has not changed since and

may not be up to date. In part, the advice conflates different types of tests and is not specific to any test.

- Their first bullet point states that there are different types of tests – this is not advice but simply a statement.

- Their second point raises concerns, due to the lack of, *"information on the accuracy of these rapid point of care tests, or on how a patient's antibody response develops or changes during COVID-19 infection. It is not known whether either a positive or negative result is reliable."* – Since the first publication, there is now published information on the accuracy of the BIOPANDA rapid point of care tests. There are also statistics of regional rates of infection which allow for a clearer understanding of probable reliability for positive and negative rates.

- Their third point does not even relate to antibody testing, instead questions the evidence of the suitability of tests to diagnose COVID-19 infection. Antibody tests such as the BIOPANDA test are not designed to 'diagnose COVID-19 infection' (that is what an antigen test is designed to do) but are designed to test if someone has previously had a COVID-19 infection. For this reason, this statement is not relevant to the BIOPANDA antibody tests.

Underlying the above points is a concern that the general public may not understand the full implications of testing and subsequently change their behaviour after testing. PHE is against the use of the tests "at home" by the public, and indeed the MHRA has indicated that no test that has yet been authorised for home use. The omission of doctors or other Health Care Professionals, concurs that trained professionals can legally perform and evaluate tests. Also, that they are suitably trained to deliver the relevant information relating to testing and COVID-19. It is important that the public are suitably informed about immunity and infection advice, test accuracy and the importance of following Government advice and regulations relating to the Coronavirus pandemic.

19. How does the evaluation of the BIOPANDA test compare to the ROCHE and ABBOT tests?

There has not been any published study that has compared the ABBOT and ROCHE lab-based test or the BIOPANDA finger prick point of care test. However, we can look at the separate evaluations that have been made of each test and how many COVID-19 samples were used in each evaluation:

- The PHE evaluation of the ROCHE test used a total of 93 samples of COVID-19 positive serum samples.

- The PHE evaluation of the ABBOT test used a total of 96 samples of COVID-19 positive serum samples.

- PHE has not evaluated BIOPANDA's test.
- BIOPANDA's own evaluation used 239 samples each from unique patients, both symptomatic and asymptomatic but with a PCR-confirmed COVID-19 infection, to review the tests specificity.
- BIOPANDA's own evaluation also used 60 extra unique blood samples without COVID-19 infection, to review the tests sensitivity.
- ROCHES own evaluation used a total of 204 samples from 69 symptomatic patients with a PCR-confirmed COVID-19 infection, to review the ROCHE test for specificity.

https://www.biopanda.co.uk/php/products/rapid/infectious_diseases/covid19.php

https://diagnostics.roche.com/content/dam/diagnostics/Blueprint/en/pdf/cps/Elecsys-Anti-SARS-CoV-2-factsheet.pdf

https://www.sciencemediacentre.org/expert-reaction-to-phe-laboratory-evaluations-of-roche-and-abbott-antibody-tests/

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/890566/Evaluation_of_Abbott_SARS_CoV_2_IgG_PHE.pdf

https://www.gov.uk/government/publications/covid-19-laboratory-evaluations-of-serological-assays

https://www.cebm.net/covid-19/covid-19-roche-antibody-test-14th-may/

20. How does the BIOPANDA test compare to the ROCHE and ABBOT tests?

The ROCHE and ABBOT tests have various different published data available whereas the BIOPANDA test only has the manufacturer's own published evaluation.

Taking the Eurofins County Pathology evaluations published on the Babylon Health website:
https://www.babylonhealth.com/coronavirus/covid-19-antibody-test
All evaluations below are from the IgG antibody marker and relate to tests like the ROCHE and ABBOT tests:

- 98.5% sensitivity.

This means that among 1000 people who have had COVID-19, 985 of them will correctly test positive.
For 15 of these 1000 people who have had COVID-19, the result will come back negative - this is called a false negative. This means that 15 out of 1000 people will think they do not have antibodies to COVID-19, but in fact they do.

- 99.5% specificity.

This means that among 1000 people who have not had COVID-19, 995 of them will correctly test negative.
For 5 of these 1000 people who have not had COVID-19, the result will come back positive - this is called a false positive. This means that 5 out of 1000 people will think they have antibodies to COVID-19, but in fact they don't.

So how does this compare with the Pharmadoctor HCP antibody tests you may ask, e.g. the BIOPANDA tests?

- >99.9%* sensitivity.

This means that among 1000 people who have had COVID-19, almost 100% of them will correctly test positive.
For less than 1 of these 1000 people who have had COVID-19, the result will come back negative - this is called a false negative. This means that less than 1 person out of 1000 people will think they don't have antibodies to COVID-19, but in fact they do.

- 98.3% Specificity.

This means that among 1000 people who have not had COVID-19, 983 of them will correctly test negative.
For 17 of these 1000 people who have not had COVID-19, the result will come back positive - this is called a false positive. This means that 20 out of 1000 people will think they have antibodies to COVID-19, but in fact they don't.
It should be noted that regardless of the test result (+ve or -ve), people should continue following the Government's advice, practice social distancing wherever possible and isolate when appropriate.

21. Why does the Government require a highly sensitive test?

It is problematic to evaluate the immunity levels of a population using a national program as the numbers being tested are so large. If you had a test with a Specificity rate of 99.0% you may think it is very accurate. However, this would mean that the test would produce 10 false positives for every 1000 and if you tested a population with a true infection rate of just 2 in every 1000 within, then you would have 5 false positives for every real positive. It is for these reasons that highly specificity accurate tests are required for any national program.

* Current BIOPANDA 99.9% accuracy evaluation was for 21 days post infection. Evaluations conducted by all manufacturers are based on samples taken in hospital. When tested within the community on patients with mild or no symptoms, the sensitivity may vary and likely be lower.