SUMMARY OF THE TEST

Intended Use

The BioSURE COVID-19 IgG Antibody Self Test is a qualitative test for the detection of neutralising IgG antibodies to SARS-CoV-2 (COVID-19), to be used by untrained lay users as a self-test to aid in the determination of immune response to previous infection with SARS-CoV-2 (COVID-19) or full vaccination, from samples of fresh whole blood obtained through finger stick sample collection.

The assay is intended to be used by persons who have had symptoms of COVID-19 infection or full vaccination, at least 14 days previously. The test results should be considered in conjunction with other clinical information of other test results.

This test should not be used for diagnosis of current COVID-19 infection.

A positive test result does not guarantee that you are now immune from possible future infection.

Helpful tips

- If you normally wear spectacles you should wear them whilst testing.
- It is recommended that you perform the test in a well lit area.
- Before starting, wash your hands and ensure that they are clean and dry.

Limitations of the test

- The BioSURE COVID-19 IgG Antibody Self Test will only indicate the presence of neutralising IgG antibodies to COVID-19, an indicator of prior infection or an immune response to full vaccination, and MUST NOT be used for the diagnosis of current COVID-19 infection.
- You should not take any decision of medical relevance with regard to your condition without first consulting a healthcare professional.
- Your lancet and test will ONLY work once.

Meaning of symbols used

CE 0483 — CE Mark

Legal Manufacturer

2°C – 30°C — Store between 2-30ºC

IVD — For in vitro diagnostic use only

For single use only

LOT — Lot Number

REF — Catalogue or Part Number

Instructions for use provided. Please read carefully.

Warnings and Precautions

Expiry date

EC REP — Authorised Representative in the European Union

Bibliography

[1] https://www.who.int/director-general/speeches/detail/who-director-general-sstatement-on-ihr-emergency-committee-onnovel-coronavirus-(2019-ncov)

[2]https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines

[3]https://www.thelancet.com/article/S0140-6736(20)32137-1/fulltext

[4]https://www.imperial.ac.uk/mrc-globalinfectious-disease-analysis/covid-19/report-34-ifr

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Warnings and precautions

REMEMBER: An incorrect test result may lead to situations were you could be at higher risk of infection. Some people are at increased risk of severe symptoms. If you have any of the following indications, antibody testing may not be suitable:

- have been told by your doctor that you are clinically extremely vulnerable
- had an organ transplant
- having chemotherapy or antibody treatment for cancer
- having an intense course of radiotherapy for lung cancer
- having targeted cancer treatments that can affect the immune system
- have blood or bone marrow cancer or had a bone marrow or stem cell transplant in the past 6 months or are still taking immunosuppressant medicine
- have been told by a doctor you have a severe lung condition
- have a condition that means you have a very high risk of getting infections
- are taking medicine that makes you much more likely to get infections (such as high dose steroids or immunosuppressants)
- have a problem with your spleen or your spleen has been removed (splenectomy)
- are an adult who is having dialysis or has severe long-term kidney disease

This test is for use only with human blood.

Not suitable if you have a bleeding disorder.

Do not use if the foil pouch is damaged or if the expiry date has passed.

Do not open the pouch until you wish to test.

Do not read your result more than 1 hour after performing the test.

If the buffer solution comes into contact with your eye, wash with a large amount of water. If the eye becomes irritated or painful, contact your doctor.

If you mistakenly swallow the buffer solution, wash your mouth out with a large amount of water. If your mouth becomes irritated or you start to feel unwell, contact your doctor.

Whilst every effort has been taken to ensure the safe design of your test, once used, it will contain a very small sample of your blood, so you must dispose of it safely.

BioSURE
COVID-19 IgG Antibody Self Test

At the end of December 2019, several cases of pneumonia were reported in Wuhan City, China to the World Health Organization (WHO). In January 2020, WHO declared the outbreak a public health emergency[1]. The infection, now commonly known as COVID-19, is an infectious disease caused by the SARS-CoV-2 virus. A lot has been understood about the virus and the effect on people's health and, while it remains largely untreatable, vaccines have since been developed and approved[2]. It is now widely agreed that infection causes a detectable and lasting immune response[3].

The COVID-19 virus is primarily spread between people via respiratory droplets when an infected person coughs or sneezes. Most infected people experience loss of smell, a new persistent dry cough, a fever or other flu like symptoms. Most infected individuals (80%) recover, but complications may include pneumonia-like symptoms and severe acute respiratory problems. In high income countries the virus may be deadly for around 1%[4] of people, with the over 60s at increasing risk.

Your BioSURE COVID-19 IgG Antibody Self Test device comprises a paper test strip inside a plastic barrel and a pre-filled pot of buffer solution. The test is performed by applying a small drop of blood to the tip of the test device and inserting this tip into the buffer pot. The sample is absorbed by the paper strip. When the test is completed two red lines, the test and control lines, can appear on the strip. The test line will only appear if you have antibodies to COVID-19 in your blood. The control line will only become visible if sufficient human blood is applied and the test has run correctly.

The test does not detect the virus directly but detects IgG antibodies to the virus that are part of the body's response to infection or vaccination.

IMPORTANT

Your test...

Can ONLY tell you if you have detectable levels of neutralising antibodies to COVID-19. It CANNOT tell you if you are now immune.

MATERIALS PROVIDED

1 x BioSURE COVID-19 IgG Antibody Self Test Pouch containing: 1 x BioSURE COVID-19 Ab Test, 1 x lancet, 1 x plaster and 1 x desiccant pack (DO NOT EAT), a pictorial instruction for use with results reading tray, this product insert and a disposal bag.

Storage

- This test should be performed at room temperature (8 to 30°C).
- This test can be stored at room temperature (15 to 25°C). It can, but does not need to be, stored in refrigerated conditions (2-8°C).
- If stored in the fridge, the test should be allowed to return to room temperature before using.
- Do not store above a radiator or in direct sunlight.
- The test must be used within 30 minutes of opening the pouch.

TEST METHOD

Tear open the pouch and remove the contents.

Remove the buffer pot from the end of your test device and place it in the round hole in the tray.

Remove the cap from the end of your lancet and discard. Place the red pad of the lancet against the side of the tip of your finger. Press the lancet down until it clicks (it won't hurt!) You may need to gently massage your finger to make a round, well formed drop of blood, approximately 2-3mm across.

Touch the tip of your test device into the drop of blood. You will see the tip automatically fill with enough blood. Ensure the tip is completely filled.

Push the tip of your test device into the buffer pot, through the foil lid. Push it right down to the bottom of the buffer pot until it won't go any further, leave the test standing.

Start timing 20 minutes.

After the 20 minutes, lay your test down in the cut out shape in the tray and read your result.

How will I know if my test has run correctly?

The BioSURE COVID-19 IgG Antibody Self Test has an inbuilt Sample Control Line to show that the test has run correctly and you have applied enough blood. If the Control Line does not appear, your test has not worked. This is known as an "invalid" result. Please discard your test and retest with a new device. If the control line appears, you know that the test has run correctly.

REQUIRED BUT NOT PROVIDED

Clock, watch, or other timing device

Frequently Asked Questions

How does the test work?
Your test uses technology very similar to a pregnancy test: 1 line on the test is a negative result, 2 lines is a positive result. Your test detects neutralising IgG antibodies in your blood sample that are specific to SARS-CoV-2 (COVID-19), not the virus itself.

What is an antibody?
When your body detects something harmful (like a bacteria or a virus) your immune system starts to produce antibodies to defend your body .

What is the 'window period'?
This is the time between infection, or vaccination, and when your test can correctly give a positive result. During this period someone could get a negative test result if they have not yet produced enough neutralising antibodies to be detected by the test.

Why should I wait until 2 weeks after my symptoms before testing?
People produce antibodies at different rates and at different times after becoming infected. Most people have made these antibodies within 10 days and around 95% of people in 17 days, some people produce them much later. It is thought that around 5% of people will not create detectable levels of neutralising antibodies.

How accurate is my test?
Extensive studies have shown that this test is extremely accurate when performed correctly, at the right time:

- It has a proven clinical sensitivity (how reliably the test will give a true positive result for people who have antibodies to SARS-CoV-2) of 98.2%, i.e. 982 in every 1,000 people who have antibodies will be correctly identified.
- It has a proven clinical specificity (how reliably the test will give a negative result for people who have do not have IgG antibodies to SARS-CoV-2) of at least 99.7%. This means that on average only 3 in every 1,000 people who test but have not had the SARS-CoV-2 virus will be incorrectly identified as having antibodies.

RESULTS

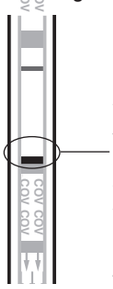
(Also see over the page, 'Reading your result')

When the test is completed, two lines can appear on the test strip. The upper line (the Control Line) will only become visible if you have performed the test correctly. The lower line (the Test Line) will only become visible if you have detectable levels of neutralising IgG antibodies to SARS-CoV-2 in your blood. If you only see the Control Line, the test result is negative. If you see the Control Line AND the test line, the test result is positive.

These lines can only appear in the positions shown in the diagrams but can vary in strength or intensity. You should read any line in these positions as a line, regardless of it's strength or intensity.

A positive test result does not guarantee that you have developed immunity to COVID-19 or that you are protected from future infection.

Warning



You may see a faint red mark appear here.

THIS IS FROM YOUR BLOOD SAMPLE, IT IS NOT A LINE.

Disclaimer – Whilst every effort has been taken to ensure the diagnostic ability and accuracy of this product, the product is used beyond the direct control of the Manufacturer or Distributor and as such the result may be affected by environmental factors and / or user error. A person who is the subject of the test should consult a healthcare professional for further confirmation of the result.

Warning – The Manufacturer and/or Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect test result, whether positive or negative, as indicated by this product.

I can't find the buffer pot...
You will find it at the top of your test device, at the other end from the tip. Remove it and place it in the tray.

The lancet won't click…
The lancet is designed to only work once. You may have already clicked the lancet by mistake.

Will using the lancet hurt?
Not really. It is best to take the sample from the side of the tip of your finger as there are less nerve endings there.

Does it matter which finger I take blood from?
No, the blood will be the same from whichever finger you take it from.

How does the tip fill up?
The device automatically sucks 2.5µL of blood into the tip by capillary action. You can see when the tip has filled with blood.

My test hasn't started to run
The tip of the device must be fully inserted into the buffer pot. Make sure the tip has been pushed right to the bottom of the buffer pot. You may need to push quite hard until it won't go in any further.

When will I get my result?
You can read your test result 20 minutes after completing the test procedure. You should not read your test result more than 1 hour after running your test. This could give you an incorrect result.

Why does the test have to stand up?
The test is designed to run standing upright. You will know if the test has run correctly and whether you have applied enough blood when the control line appears on the test strip.

What happens if my test falls over?
Stand your test up as soon as possible. Your test should still work. You will know that your test has run correctly by the appearance of the Control Line. If the Control Line does not appear, you should consider your test to be invalid and you will need to test again with a new device.

How do I dispose of my test?
To dispose of your test, simply place all components back into the box and secure in the disposal bag provided.
It can now be thrown away with your general household waste.
This item is not suitable for recycling.

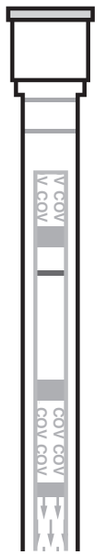
Reading your result

2 lines can appear on your test: the Control Line (C) and the Test Line (T). These lines can only appear in the positions shown in the diagrams. You should read **any** line in these positions as a line regardless of their strength or intensity.

After 20 minutes, lay your test in the space below and compare it with the pictures.

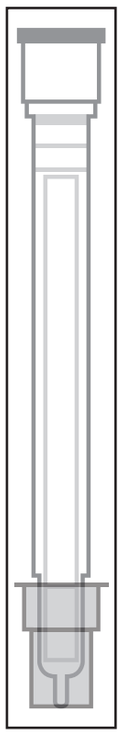
A positive test result means you have detectable levels of neutralising IgG antibodies to COVID-19 in your blood. However, this does **NOT** mean that you are now immune or protected from future infections.

1 LINE
(C)

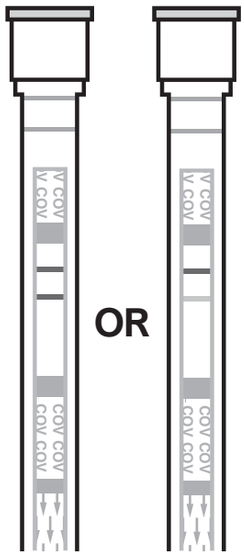


Your test result is NEGATIVE

YOUR TEST



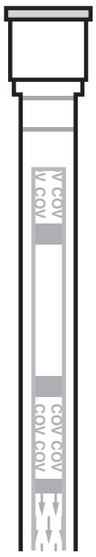
2 LINES
(C and T)



OR

Your test result is POSITIVE

NO CONTROL LINE (C)



Your test did NOT work

Intended Use

The BioSURE COVID-19 IgG Antibody Self Test is intended to be used by untrained lay users as a self-test to aid in the detection of neutralising antibodies to SARS-CoV-2 due to prior infection with SARS-CoV-2 (COVID-19) or an immune response to vaccination, from samples of fresh, whole blood obtained through a finger stick blood collection technique. The test works by detecting neutralising IgG antibodies to SARS-CoV-2 and does not directly detect the virus. The test can only detect an immune response if the person testing has created a sufficient quantity of the correct class of antibody to the virus. Currently, scientific evidence does not imply that the presence of antibodies confers immunity or protection from further infection. Research is ongoing and our understanding of the effects, treatments and immunity to COVID-19 will change.

BIOLOGICAL PRINCIPLES OF THE TEST

The BioSURE COVID-19 IgG Antibody Self Test is a qualitative immunochromatographic rapid test contained in a novel test housing ('the barrel'). The test contains a solid-phase membrane, the test strip, which is pre-coated with SARS-CoV-2 peptides. The test also contains gold nanoparticles that are conjugated to protein that binds to human IgG antibodies. The strip includes a control line, above the test line, which appears red if the test has been performed correctly and sufficient sample and buffer has been added to the test. Once the sample and buffer have been applied to the test, the gold-conjugate particles are resolubilised and can bind to antibodies to SARS-CoV-2, if present in the sample. These newly formed complexes migrate along the test strip towards the Test Line. At the Test Line, the immobilised SARS-CoV-2 trimeric spike peptides can capture the labelled anti-SARS-CoV-2 antibodies. The captured complex becomes visible as a red/pink line. The Control Line can only appear if the test has been performed correctly and the sample has migrated fully through the test.

PERFORMANCE CHARACTERISTICS

DIAGNOSTIC SENSITIVITY:

Diagnostic sensitivity of a qualitative test, such as the BioSURE COVID-19 IgG Antibody Self Test, is a measure of how well the test correctly detects the presence of the condition or analyte. It is usually given as a percentage and is determined by performance evaluation. It is calculated by dividing the number of positive test results by the total number of true positive samples. The higher the sensitivity, the better the test is at correctly identifying persons with a condition. In these studies, "true positive" samples were obtained from patients who had previously tested positive for COVID-19 by RT-PCR and were found to have COVID-19 specific antibodies by CE Marked Enzyme Linked Immunoassay. Diagnostic sensitivity is calculated as 98.2% (425/433, 95% CI: 96.4-99.2%).

Sample type	Study ID#	Number of True positive samples (n)	BioSURE COVID-19 IgG Ab Self Test Positive	BioSURE COVID-19 IgG Ab Self Test Negative
RT-PCR +ve AND EIA for Ab	2	304	297	7
RT-PCR +ve AND EIA for Ab	3	102	102	0
External SARS-CoV-2 reference panels	5	27	26	1

POSITIVE PERCENTAGE AGREEMENT WITH RT-PCR:

When considered against only against RT-PCR positive test results, the assay detected 93.7% (238/254, 95% CI: 90.0-96.4%) of previous infections.

ANALYTICAL SENSITIVITY: The test has been shown to be able to detect samples containing 45 RBD IgG Binding Antibody Units/ml. (Study ID# 5)

Evaluation ID#	Testing Site
1	Specificity testing - pre-pandemic HIV positive samples, BioSure (UK) Limited, United Kingdom
2	Evaluation of [BioSURE COVID-19 IgG Antibody Self Test], United Kingdom
3	Early Pandemic Samples, BioSure (UK) Limited, United Kingdom
4	Pre-pandemic samples, Abingdon Health, United Kingdom
5	Evaluation with external QC and WHO reference panel, BioSure (UK) Limited, United Kingdom
6	Cross reactivity of {BioSURE COVID-19 IgG Ab Self Test], United Kingdom

DIAGNOSTIC SPECIFICITY:

Diagnostic specificity of a qualitative test such as the BioSURE COVID-19 IgG Antibody Self Test, is a measure of how well it correctly detects the absence of a condition. It is usually given as a percentage and is determined through performance evaluation. It is calculated by dividing the number of negative test results by the total number of true negative samples. The higher the specificity, the more reliable a positive result. Diagnostic specificity of 99.7% (615/617, 95% CI: 98.8-99.99%).

Sample type	Study ID#	No. of negative samples (n)	BioSURE COVST Negative	No. of positive samples (n)	BioSURE COVST Positive
Pre-pandemic HIV Positive samples	1	69	69	0	0
Known negative evaluation	2	223	222	0	1
Pre-pandemic samples	4	100	100	0	0
Performance evaluation: early pandemic samples	3	14	14	102	102
Cross reactivity panel	6	211	210	41	42
All studies		617	615	143	144

SPECIFICITY

The ability of a diagnostic test to correctly discriminate between previously infected and non-infected individuals is a function of the ability of the device not to be affected by the presence of analytes unrelated to the condition. Evaluations have been undertaken with both naturally occurring and contrived samples to ensure that the performance of the test device is not affected by the presence of common possible exogenous and endogenous interferents and potentially cross reacting co-morbidities. There is no cross reactivity with other coronaviruses.

Possible interferents	COV Positive samples	BioSURE COVST Positive	COV Negative samples	BioSURE COVST Negative
Whole blood	8	8	5	5
High haematocrit	3	3	3	3
Cholesterol	3	3	3	3
Triglyceride	3	3	3	3
Bilirubin	3	3	3	3
Hyper IgM	3	3	3	3
Hyper IgG	3	3	3	3
Caffeine	3	3	3	3
Biotin	3	3	3	3
Aspirin	3	3	3	3
Paracetamol	3	3	3	3
Ibuprofen	3	3	3	3

Cross Reactivity	BioSURE COVST Negative Results	BioSURE COVST Positive Results[1]
Human coronavirus:		
229E	5	0
OC43	5	0
HKU1	5	0
NL63	5	0
High prevalence virus panel*	49	0
Other organisms giving similar symptoms**	38	0
Pregnant women	21	0
Auto-antibodies***	45	1

[1] 1 positive was with a sample known to be Systemic Lupus Erythematosus (SLE) positive.
*Adenovirus (n=5), Epstein-Barr Virus (n =5), Haemophilus influenzae (n=5), Influenza A (n=5), Influenza B (n=6), Parainfluenza (n=5), Rhinovirus (n=12), Respiratory Syncytial Virus (n=6)
**Bordatella pertussis (n=6), Enterovirus (n=6), Group A strep (n=6), M tuberculosis (n=10), HIV (10)
***Rheumatoid factor (n=20) and SLE (n=25)