COVID-19 Antibody Test

COVID-19 IgA/IgG/IgM triple antibody rapid test Cassette format

For professional use only

SUMMARY OF THE TEST

INTENDED USE

The test is a qualitative, rapid, lateral flow immunoassay for detection of IgA, IgG and IgM antibodies to SARS-CoV-2 in human blood, serum or plasma, as an aid to diagnosis of active or recent COVID-19 infection in symptomatic or asymptomatic individuals. Test results should be considered in conjunction with other test results and clinical information.

Note. Detection of antibodies does not exclude possibility of re-infection.

SUMMARY & EXPLANATION OF THE TEST

Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) is the viral strain that causes coronavirus disease 2019 (COVID-19). Following infection, the immune system may generate antibodies to fight the infection. The test can detect three types of antibody – immunoglobulin (Ig) A, G and M. Levels of these antibodies develop and decline at different rates within different individuals.

Detection of antibodies indicates the person has been infected with COVID-19.

The immunological response to viral infection can take several weeks and evidence suggests that antibodies to COVID-19 may take several days to appear or in rare cases (<5%) produce no antibodies. Serological testing of an individual before this window period may result in a misleading negative result due to dectectable antibodies not being available in the sample.

This test may not detect COVID-19 infections that happened more than 8 weeks ago. This is because there can be a gradual decline in the number of antibodies in the patient's blood.

If the level of antibodies fall to below detectable levels this will lead to a negative test result. As COVID-19 is a new infection this information is subject to change as research into the virus continues.

To perform the test, 5µl of blood/serum/plasma is applied to the sample well of the test device followed by 2-3 drops of buffer. If COVID-19 antibodies are present, they bind to the test lines. The test result is visually assessed after 10 min. If antibodies are present, red test line(s) appear aligned with the corresponding letter on the device.

PRINCIPLES OF THE TEST

Antibodies in the sample are bound to capture reagents in the test lines as they are transported through the lateral flow strip, and made visible by secondary reagents. A visible test line confirms the presence of IgA, IgG and/or IgM, indicating that the subject has experienced COVID-19 infection and had time to generate antibodies (usually within 4-10 days from onset of infection). The CONTROL line (marked C) turning red confirms that the test has been performed correctly.

LIMITATIONS OF USE

For use with fresh whole blood, plasma or serum samples only.

For reliable results, please carefully follow the instructions provided.

Test results should be used in conjunction with other clinical and patient information.

WARNINGS & PRECAUTIONS

- Do not use if foil pouch is damaged in any way (ie broken seal, tears, holes etc)
- For in vitro diagnostic use only.
- This product is intended for use with fresh blood, plasma or serum samples only.
- Single use. Used tests must not be re-used.
- Do not use after the expiry date printed on the packaging.
- Store at room temperature.
- Dispose of used kit components in clinical waste.

If you have any questions or comments, please contact us on **0845 222 0012** or **+44 (0)1992 815 825** or email **info@biosure.co.uk**

PERFORMANCE CHARACTERISTICS

Time to run test: 10 min.

Percentage positive agreement: A total of 416 samples were tested from symptomatic patients who were PCR positive for COVID-19 antigen. Overall agreement (samples taken 5 to 88 days post symptom onset) was found to be 93.3% (388/416, 95% CI: 90.4 – 95.5%). For samples taken 20 days or more post symptom onset positive agreement was found to be 96.0% (216/225, 95% CI: 92.3 – 98.1%).

Sensitivity: A total of 292 samples were tested from symptomatic patients PCR positive for COVID-19 antigen where the samples were also confirmed as antibody positive by IgG ELISA (Omega Diagnostics). For all samples tested, regardless of time interval post onset of symptoms, sensitivity was found to be 98.3% (287/292, 95% CI: 96.1-99.4%). For samples taken 14-56 days after symptom onset, sensitivity rose to 99.0% (207/209, 95% CI: 96.6-99.9%). For all samples taken at least 20 days after symptom onset, sensitivity was 98.5% (197/200, 95% CI: 95.7- 99.7%).

Specificity: 99.2% (598/603 CI: 98.1%-99.7%).

Negative agreement (pre-COVID-19 outbreak)	Sample number	Reactive	Non-reactive	Negative percent agreement (95% CI)
Sepsis screen	213	3	210	98.6% (95.6% to 99.6%)
Acute respiratory exac-erbation	77	0	77	98.7% (92.89% to 99.97%)
HIV positive	50	0	50	100.0% (91.78% to 100.00%)
Total	340	3	337	99.1% (97.4% to 99.8%)

This COVID-19 Antibody Test was found to be very specific with samples taken before the current COVID-19 pandemic. The specificity of a test is a measure of how likely a test is to give a negative test result when the sample tested does not contain antibodies for COVID-19. The absence of COVID-19 antibodies does not rule out very recent infections.

Negative agreement (Cross reactivity panel)	Sample number	Reactive	Non-reactive	Negative percent agreement (95% CI)
Coronavirus panel	41	0	41	100.0% (91.4% to 100.0%)
High prevalence virus panel	128	2	126	99.4% (94.5% to 99.8%)
Other organisms	80	0	80	100.0% (95.5% to 100.0%)
Auto-antibodies	14	0	14	100.0% (76.8 to 100.0%)
Total	263	2	261	99.2% (97.3% to 99.9%)

This COVID-19 Antibody Test was also tested against a panel of samples taken from people who had been infected with other coronaviruses and other common viruses. A minimal amount of cross re-activity was found with the coronavirus panel and also with some flu viruses.

A positive test result cannot currently be taken to infer immunity or protection from future infection from COVID-19.

OPERATING PROCEDURE

Check kit components

Check product packaging is undamaged and unopened.

Check product is within expiry date.

Do not open the foil pouch until you are ready to perform the test.

MATERIALS REQUIRED BUT NOT PROVIDED

Stopwatch/timer

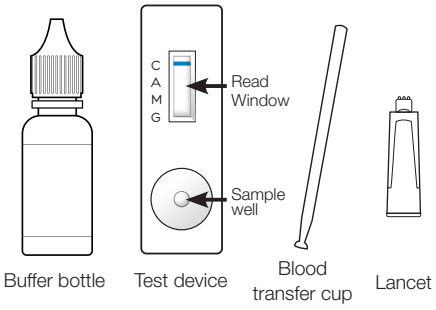
KIT COMPONENTS (ALL SINGLE USE ONLY).

25x Blood collection cups (5ul)

25x Lateral flow test devices

25x Lancets (single use, finger prick)

1x Buffer dropper bottle (contents sufficient for 25 tests)



STORAGE

This product is stable at room temperature (8-25°C).

SAMPLE STORAGE

Fresh *whole* finger prick blood samples must be tested immediately.

If plasma and serum samples are not tested immediately they should be refrigerated 2~8° or freezing is recommended and the samples should be brought to room temperature prior to use.

1. Preparing

Remove the lateral flow device from the foil pouch (ensure that the desiccant sachet is orange, if it is green, discard the test and use a new test device).

Place test device on horizontal flat surface.

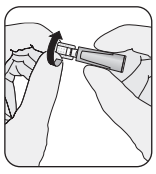
2. Collect sample

Finger prick blood

⚠ **Ensure finger is clean and dry.**

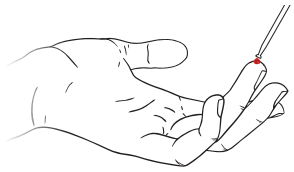
Twist off lancet cap and discard.

DO NOT PULL



Apply lancet. Place lancet firmly against finger tip and press until you hear a click. Gently squeeze to form a round drop of blood.

Touch collection cup onto the round drop of blood. Perform the test immediately.

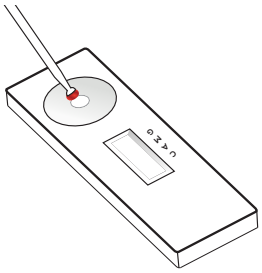


Plasma/serum -

Use collection cup to transfer sample.

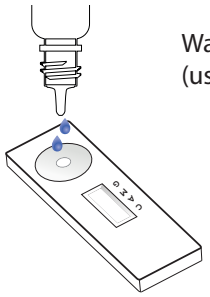
3. Apply fresh blood/serum/ plasma to sample well

Transfer 5ul of sample to the sample well by touching the collection cup into the sample well. Ensure that the droplet is absorbed.



4. Apply buffer solution

Carefully apply 2 drops of buffer solution from the dropper bottle to the sample well. If the test does not run, carefully add 1 more drop. (Seal bottle for subsequent use.)



Wait 10 minutes (use timer).

5. Read the test results

After 10 min have elapsed, inspect the CONTROL line (C) and three TEST lines (A, M, G).

If the test has been performed successfully, the CONTROL line (C) will be visible as a red line.

If the CONTROL line remains blue, or is no longer visible, the test has failed. Dispose of the used test and repeat using a new test device and a fresh sample.

If one or more TEST lines are visible, this indicates presence of antibodies, and suggests that the patient has, or has had, COVID-19.

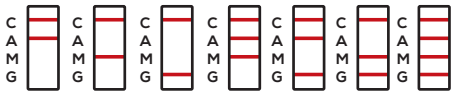
DO NOT READ RESULT AFTER 30 MINUTES

If none of the TEST lines are visible, this indicates absence of antibodies and suggests that the patient has not had COVID-19, or has the infection but has not generated antibodies.

GUIDE TO INTERPRETATION OF TEST RESULTS.

YOU SHOULD READ ANY LINE AS A LINE REGARDLESS OF THE STRENGTH OR INTENSITY OF THE LINE, AS THESE MAY VARY.

POSITIVE (REACTIVE) TEST RESULT



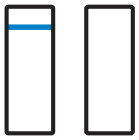
⚠ **Any TEST line A, M and/or G is red = COVID-19 antibodies detected**

NEGATIVE TEST RESULT

⚠ **C CONTROL line is red = test has been performed successfully.**

Absence of A, G and M test lines indicates that these antibodies are not detected

INVALID TEST RESULT



⚠ **C CONTROL line remains blue or is absent = FAILED test. Repeat with new test.**

6. Disposal

All used components and packaging should be disposed of as clinical waste.

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