FOR RESEARCH PURPOSES ONLY

UK-RTC

AbC-19™ RAPID TEST

Information & Instructions Leaflet

Video Guide

For additional guidance on how to perform the AbC-19™ Rapid Test please watch our short instruction video.

To access the video scan the QR code below or visit:

https://www.youtube.com/watch?v=WqT2z8jCEHs

Symbol Key

- For research purposes only
- LOT Batch code
- REF Catalogue number
- Contains sufficient for <n> tests
- Consult the instructions for use
- Temperature limit
- Manufacturer
- Date of manufacture
- Do not re-use
- Use-by-date
- Keep out of sunlight
- Do not use if packaging is damaged
- STERILE R Sterilized using irradiation

1. Intended Use

The AbC-19™ Rapid Test is a single – use test for the detection of IgG antibodies in human capillary whole blood.

When the body is invaded by harmful bacteria or viruses, the immune system responds by producing disease-specific antibodies. These antibodies help fight the infection and in some instances provide protection against future infections (immunity).

Using a blood sample from a finger-stick puncture the AbC-19™ Rapid Test will identify the presence of antibodies produced in response to the SARS-CoV-2 virus (the virus responsible for COVID-19 disease), signifying a recent or previous infection by the virus.

2. Intended End User

The AbC-19™ Rapid Test is intended to be used for research purposes as a self-test.

3. Background

The SARS-CoV-2 virus is a member of the Coronavirus family (CoV). In humans this virus family is capable of causing illnesses that range from the common cold, to more severe conditions such as severe acute respiratory syndrome (SARS) and COVID-19 disease.

Symptoms of COVID-19 can vary but most commonly include a fever, tiredness, dry cough, shortness of breath, loss of taste and smell and difficulties breathing. Some patients are asymptomatic and show no symptoms.

Antigen and antibody tests are currently the two main types of tests being used to test for COVID-19 disease. Antigen tests are able to detect the presence of the virus and confirm whether a patient is currently infected. In contrast, an antibody test does not identify the virus itself but measures the body's immune response to the invading virus, by detecting the presence of the disease-specific antibodies.

The immune response typically involves an initial production of short-lived Immunoglobulin M (IgM) antibodies, followed by a second response and the production of Immunoglobulin G (IgG) antibodies and in some people Immunoglobulin A (IgA).

The AbC-19™ Rapid Test detects IgG antibodies. Current evidence suggests these antibodies become detectable sometime between 4-19 days after the onset of symptoms. For symptomatic patients, it is recommended that the AbC-19™ Rapid Test should be performed **after day 14 of showing symptoms**. The AbC-19™ Rapid Test is also suitable to be used by patients with no COVID-19 symptoms. It is not known how long IgG antibodies for SARS-CoV-2 are present in the blood, but they typically persist for several months.

4. Limitations

The AbC-19™ Rapid Test is to be used for research purposes only.

The AbC-19™ Rapid Test has been validated for use with blood samples obtained from a finger- stick puncture. **No other sample types should be used.**

The AbC-19™ Rapid Test indicates the presence of SARS-CoV-2 IgG antibodies and should not be used as the sole criterion for the confirmation /exclusion of SARS-CoV-2 infection or confirmation of immunity against COVID-19.

If the IgG antibodies for SARS-CoV-2 are present but below the detection limit of the test, the AbC-19™ Rapid Test may give a false negative result. This could happen if the test is performed less than 14 days after the first signs of infection. Other contributing factors towards a false negative include a weakened immune system.

As with all tests, it is possible to obtain a false positive result, meaning the SARS-CoV-2 IgG antibodies have been incorrectly identified as present. The AbC-19™ Rapid Test has been extensively tested against a large number of known negative samples and has been found to give very few false positive results.

5. Disclaimer

The manufacturer 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.

Do not make any medical or personal safety decisions based on the results of this test without consulting your doctor first.

6. Storage & Handling

Store the AbC-19™ Rapid Test kit in a cool, dry place between 5-30°C, away from direct sunlight. Do not store on or above a radiator.

Do not touch the test with wet hands. Dry hands thoroughly prior to taking the blood sample.

Do not remove the test from its packaging until ready to perform. Once the test has been removed please perform the test immediately.

The test should be performed at **room temperature** (15-25°C).

Do not use the AbC-19™ Rapid Test if the box or kit contents are damaged.

7. Test Principle

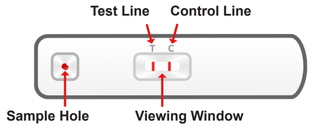
Only a small amount of blood is required to perform the test. Using the provided lancet a small blood sample is obtained from a finger-stick puncture and collected via the provided blood collector.

The test is performed by applying the collected blood to the sample hole, followed by the application of the provided test solution. Once applied this mixture is absorbed by the paper strip and will begin traveling down from the sample hole and across the viewing window.

If SARS-CoV-2 antibodies are present within the blood sample these disease-specific antibodies will attach themselves to the first line, the test line (T-line), resulting in the formation of a visible red line.

In the absence of SARS-CoV-2 antibodies, no attachment will occur at the T line, resulting in no visible line at the T-line position.

The second line to appear is an internal control line (C-line). This line will only appear if the test procedure is followed correctly.



8. Warnings & Precautions

Please read the instructions provided carefully before performing the test. Failure to follow the test procedure could lead to inaccurate results.

The AbC-19™ Rapid Test is a single use in vitro diagnostic (for use outside of the body) test which cannot be re-used.

Blood samples must not be taken from fingers on the side affected by a mastectomy.

It may not be possible to obtain a blood sample using a finger-stick puncture if suffering with poor peripheral circulation (e.g. suffering with peripheral edema).

The lancet remains sterile until the cap is removed.

Do not remove the cap or use the lancet until you are ready to start the test and complete in full.

The lancet contains a needle. Please keep out of reach of anybody under the age of 16 and pets. If any of the kit materials are swallowed, seek medical advice immediately.

The test kit contains small parts and should be kept out of the reach of children under the age of 3.

Do not use a single puncture site more than once; this can lead to bacterial contamination and infection.

This test is not suitable for use by anyone suffering with a blood coagulation disorder or under the age of 8.

Children between 8 and 16 should not perform the test without adult supervision.

The kit materials are not considered dangerous according to the 2012/18/EU and 1272/2008 Directives.

Whilst every effort has been taken to ensure the accuracy of this product, as the product is used beyond the direct control of the manufacturer the result may be affected by environmental factors and/or user error should the instructions not be followed.

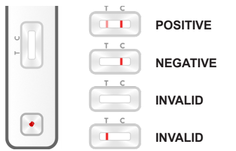
9. Interpretation of Results

Once the test has been performed up to two lines can appear on the test.

The line furthest away from the sample hole is the control line (C-line). The C- line is always present if the test has been performed correctly. The C-line must be present when reading the results. In the absence of a C-line the test is invalid and the result must not be used. The test will need to be repeated using a new test device and fresh blood sample.

The presence of only a C-line indicates a **NEGATIVE** result.

The line closest to the sample hole, the test line (T-line), will only be visible if you have SARS-CoV-2 IgG antibodies present within the blood sample. The presence of a T-line alongside a C-line is a **POSITIVE** result, indicative of a recent or previous SARS-CoV-2 infection.



The absence of any lines or the presence of the T-line alone indicates the test has not been performed correctly. The results of the test are invalid and must not be used. The test will need to be repeated using a new test and fresh blood sample.

We do not currently know if antibodies present in your blood will protect you from getting COVID-19 again. Do not make any medical or personal safety decisions based on the result of this test, which is being done for research purposes only.

10. Performance Characteristics

As detailed in the table below a known population of 450 negative EDTA plasma samples were tested alongside 203 known positive samples. The positive population of 203 EDTA plasma samples were obtained from donors at least 14 days after the onset of COVID-19 symptoms and were verified as positive using a commercial IgG SARS-CoV-2 ELISA kit.

		AbC-19™ Rapid Test	
		Positive	Negative
ELISA	Positive	199	4
	Negative	2^	448*

* 98 pre-pandemic negative samples not tested by ELISA

^ 2 pre-pandemic negative samples not tested by ELISA

Clinical Sensitivity and Specificity is as follows:
Positive Predictive Agreement (Sensitivity): 98.03% (95% CI[a] : 95.03% - 99.46%)
Negative Predictive Agreement (Specificity): 99.56% (95% CI[a] : 98.40% - 99.95%)

Key: [a] = Confidence Interval

Cross reactivity:

Known positive serum samples from other viral infections were tested as follows (value in square brackets refers to the number tested): Seasonal Coronavirus (HCoV-NL63 [x5] and HCoV-229E [x5]), Influenza A [x5], H5N1 Influenza [x1], Influenza B [x6], Respiratory Syncytial Virus (RSV) [x6], Haemophilus influenzae type b [x5] and Bordetella pertussis [x1]. No cross reactivity was observed, with all tests demonstrating a negative result using the AbC-19™ Rapid Test.

Interference: A range of substances were tested using the AbC-19™ Rapid Test for positive and negative interference. No false positives or false negatives were recorded at the concentrations in the table below.

Substance	Upper limit of normal serum levels mg/dL	Level Tested mg/dL
Unconjugated Bilirubin	2	40
Cholesterol (total)	<200	400
Triglyceride	200	1500
IgG	1400	4,200
IgM	250	750
Haemoglobin	17.5	1000
Biotin	0.117	0.351
Acetaminophen (paracetamol)	5.2	15.6
Acetylsalicylic acid (asprin)	1	3
Ibuprofen	7.3	22
Caffeine	3.6	11

References

Guarner J. Three emerging coronaviruses in two decades the story of SARS, MERS, and now COVID-19. Am J Clin Pathol. 2020. March; 153 (4): 420–5.

Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet. 2020. February; 395 (10223): 497–506.

Bénézit F, Le Turnier P, Declerck C et al. Utility of hyposmia and hypogeusia for the diagnosis of COVID-19. Lancet Infect Dis. 2020. April; S1473-3099 (20): 30297-8

Chaplin DD. Overview of the Immune Response. J Allergy Clin Immunol. 2010. Feb; 125 (2 Suppl 2): S3–23.

Clem AS. Fundamentals of Vaccine Immunology. J Glob Infect Dis. 2011. Jan-Mar; 3 (1): 73–78.

Long Q, Liu B, Deng H, et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med. 2020. April; 26: 845–848.

Hortensius J, Slingerland RJ, Kleefstra N, et al. Self-Monitoring of Blood Glucose: The Use of the First or the Second Drop of Blood. Diabetes Care. 2011. Mar; 34 (3): 556–560.

Procedures and devices for the collection of diagnostic capillary blood specimens; approved standard 6th edition. CLSI Standard, GP42- A6.

WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva: World Health Organization; 2010. 7, Capillary sampling. Available from: https://www.ncbi.nlm.nih.gov/books/NBK138654/.

Turn page for step-by-step instructions >

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When to test?

If you currently have symptoms of COVID-19, it is recommended to wait **at least 14 days** after the onset of symptoms before using the AbC-19™ Rapid Test.

Symptoms of COVID-19 may include:

- **A high temperature**
- **A new continuous cough**
- **A loss or change to sense of smell or taste**

Before you start...

Read the step-by-step instructions several times until you are confident you understand each stage.

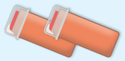
For additional guidance, watch our short instruction video. Website link on front page.

Ensure hands are warm.

Ensure good hydration by having a drink before performing the test.

KIT CONTENTS PROVIDED

1x Test



2x Sterile Single Use Lancets

1x Blood Collector

1x Instructions

1x Test Solution
*(Contains 3-4 drops)

1x Waste Bag

ADDITIONAL MATERIALS NEEDED:

Plaster

Tissue

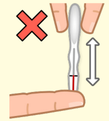
Timer

HELPFUL TIPS

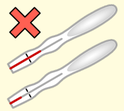
Perform the test at **room temperature** (15-25°C) in a well-lit area.

When performing the test, lie the test on a clean flat surface.

Use the spare lancet if you have problems getting enough blood for the sample.



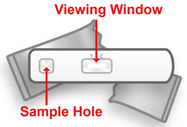
DO NOT hold the blood collector vertically when collecting the blood.



DO NOT over-fill or under-fill the blood collector.

STEP 1: PREPARE

1. Prepare by washing hands with nothing but soap and **warm water.** Dry thoroughly. Do not apply any hand cream or hand sanitiser.

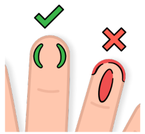


2. Open foil pouch and remove test. Discard silica gel packet.

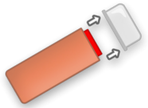
STEP 2: SAMPLE

Do not use a single puncture site more than once. This can lead to bacterial contamination and infection.

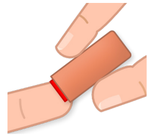
3. Blood should be collected from ring or middle finger of the non-dominant hand.



4. The finger stick puncture should be performed on the **side of the fingertip** (just off centre), marked by the green area.

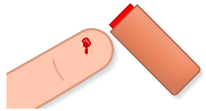


5. To perform the finger-stick puncture, first remove the protective cap from the lancet. Do not remove the lancet cap until you are ready to perform the test and complete in full.



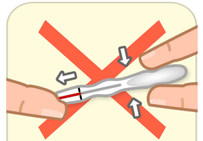
6. Place the **raised red platform** against the side of the fingertip. Apply gentle and steady pressure for 2-3 seconds until a click is heard.

STEP 3: COLLECT

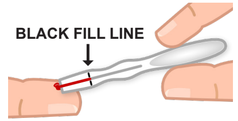


7. Wait a few seconds for a drop of blood to form. If a drop does not form very gently squeeze the sides of the finger.

Ensure a good size drop of blood has formed before collecting the blood sample.



When collecting the blood sample **DO NOT** squeeze the bulb or push the blood collector into the puncture site.



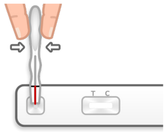
8. Holding the blood collector horizontally at a slight angle, gently touch the tip to the blood drop. The blood will automatically be drawn up the blood collector to the black fill line.

Once collected the blood will begin to clot. Move to step 4 without delay.

It may be necessary to use the tissue and apply pressure to prevent continued bleeding from the puncture site.

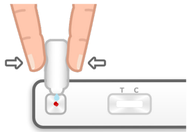
STEP 4: RUN TEST

Always add the blood sample first before adding the test solution.



9. Holding the blood collector straight, **gently touch the centre of the sample hole with the tip** and squeeze the bulb carefully to add the blood to the test.

10. Do not shake the test solution before using. Twist and turn the top of the test solution to break the seal.



11. Apply the test solution to the sample hole on the test, one drop at a time, until there is no test solution remaining (3-4 drops).

12. Wait 20 minutes before reading the results.

STEP 5: RESULTS

Read the results immediately following the 20 minute wait time. Reading too late can give inaccurate results.

13. After 20 minutes look at the viewing window to interpret your results. You will see one of the following combinations of lines...

Lines can only appear in the positions shown, but the colour intensity of the test lines can vary. Provided you have a C-line a visible T-line of any intensity should be interpreted as a positive.

2 Lines (T and C) = POSITIVE

1 Line (C) = NEGATIVE

No Lines or 1 Line (T) = INVALID

INTERPRETATION OF RESULTS

NEGATIVE RESULT: A negative result indicates that a measureable immune response to the SARS-Cov-2 Spike protein has not been detected.

POSITIVE RESULT: A positive result indicates that a measureable immune response to the SARS-Cov-2 Spike protein has been detected.

IMMUNITY: It is still unknown whether the production of antibodies offers any immunity to COVID-19. A positive result should therefore not be interpreted as immunity to COVID-19.

Please continue to follow government COVID-19 legislation and guidelines, and do not change your behaviour based on your test result. For current government guidelines about COVID-19, please visit: **https://www.gov.uk/coronavirus**

STEP 6: DISPOSAL

14. Place all kit materials in the waste bag, seal and place in the general waste. **Press and click any unused lancets before disposing of them.**

IMPORTANT: The AbC-19™ Rapid Test is not suitable for recycling.

FURTHER ASSISTANCE

A replacement kit can be requested by logging into the UK Biobank website at https://biobank.ndph.ox.ac.uk/members/ and clicking on "Replacement kit". Here you can provide details about any problems encountered with your antibody testing kit.

If you had an adverse reaction, were harmed as a result of undertaking the test, or had any other problems please contact our Participant Resource Centre on 0800 0 276 276.