Technical specification – AbC-19™ Rapid Test

The AbC-19™ Rapid Test is a single use, in vitro immunochromatographic sandwich assay for the qualitative detection of IgG antibodies against the SARS-CoV-2 trimeric spike protein in capillary whole blood.

The kit contains all the materials required for the procedure in a self-contained kit that includes buffer and all accessories needed to perform the assay and blood collection.

Standard kit contents

Kit comprises a pre-pack and a foiled AbC-19™ Rapid test device.

Pre-pack contents
2 x Medi-Purpose, Inc Safety Lancet G21/2.2mm
1 x SafeTec 5µl black-line Blood Captor (blood collector)
1 x AbC-19™ Running Buffer Blow-Fill Seal Capsule
1 x Waste Bag, black opaque 170x230mm, seal strip. Over printed with "Not Suitable for Recycling"
All assembled into a clear plastic 4" x 5.5" grip-seal bag

The standard kit used in the self-test study was accompanied by an instruction for use leaflet (IFU) tailored for use by UK Biobank participants.

Intended Use: The AbC-19™ Rapid Test is intended to be used to aid the identification of SARS-CoV-2 IgG antibodies using samples of, capillary blood sample obtained through a finger stick blood collection technique.

Intended End User: The AbC-19™ Rapid Test is intended to be used by professional and trained lay- persons. For this study, the AbC-19™ Rapid Test was used for research purposes as a self-test.

Technology: The AbC-19™ Rapid Test is an immunochromatographic sandwich assay based on lateral flow nitrocellulose membrane technology. It is used for the rapid qualitative detection of IgG antibodies to SARS-CoV-2 in human capillary whole blood.

The test strip will show two reaction lines within the viewing window:
Line 1: closest to sample hole, contains immobilized SARS-CoV-2 antigens (Test line (T-line))
Line 2: represents the procedural control (Control line (C-line))

Upon sample application, the conjugated gold particles are rehydrated and react with both non-specific and specific IgG (SARS-CoV-2) antibodies within the sample, forming antibody-coloured complex particles. The addition of the test solution promotes the antibody-coloured particles to travel along the nitrocellulose membrane by capillary action.

Test principle

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 test solution. This mixture is absorbed by the paper strip and will begin traveling across the viewing window from the sample hole.

In the presence of SARS-CoV-2 antibodies the antibody-coloured complex particles will recognize and bind to the immobilized SARS-CoV-2 antigens on the membrane and form an antibody-antigen coloured complex, resulting in the formation of a visible T-line.

In the absence of SARS-CoV-2 antibodies there will be no recognition of the immobilized SARS-CoV-2 antigens and no visible T-line will form.

As the sample continues to flow along the membrane the non-specific IgG antibody-coloured particles will be captured on the control line resulting in the formation of a visible C -line. This line will appear if the test procedure is followed correctly.

The test results can be read in 20 minutes

Interpretation of Results

Once the test has been performed up to two lines can appear on the test. The control (C-line) is present if the test has been performed correctly. In the absence of a C-line the test is invalid and then test should be repeated using a new test device and fresh blood sample. The presence of only a C-line indicates a negative result. The test line (T-line) will only be visible if SARS-CoV-2 IgG antibodies are present in the blood sample. The presence of a T-line and a C-line is a positive result, indicative of previous SARS-CoV-2 infection

Clinical performance

As detailed in the table below a known population of 350 negative EDTA plasma samples and 100 negative serum samples were tested alongside 203 known positive EDTA plasma samples. The positive population of 203 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™ Semi-Q Rapid Test	
		Positive	Negative
ELISA	Positive	199	4
	Negative	2^	448*

*98 pre-pandemic negative serum samples not tested by ELISA

^ 2 pre-pandemic negative serum samples not tested by ELISA

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%)

[a] = Confidence Interval

Conditions that might affect the results

- Re-use of a device. The AbC-19™ Rapid Test is a single use test which cannot be re-used.
- Use of the device after the expiry date.
- Use of a device that has been stored at temperatures less than 15°C of greater than 30°C
- Use of a device that has been exposed to the atmosphere. The test device should not be removed from the packaging until ready to perform. Once the test has been removed, the test should be performed immediately.
- Excess pressure when collecting the sample can cause haemolysis of the red blood cells which may interfere with the results. Squeezing the finger too tightly when collecting the capillary sample should be avoided.
- 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.
- Use of a single puncture site on more than one occasion. This may lead to bacterial contamination and infection.
- User error, for example, the use of too little test solution, or capillary blood sample.
- Incorrect reading of results. Results should be read immediately following the 20-minute wait time. Results should be discarded if read >10 minutes after the 20-minute wait time as they may be inaccurate.