Technical specification – Fortress Fast test

Fortress Fast COVID-19 Home Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human 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:
1x COVID-19 lateral flow test device
1x Owen Mumford Unistick Touch - contact activated lancet - 21G
1x Owen Mumford Unistick Touch - contact activated lancet - 23G
1x 5ml buffer bottle, teat and lid, containing 1ml buffer
1x sterile cotton ball
1x alcohol-free wipe
1x small plaster

The standard kit used in the self-test study was accompanied by an instructions for use leaflet (IFU) developed for the REACT 2 programme and tailored for use in UK Biobank.

Intended Use: The Fortress Fast Test is intended to be used to aid the identification of SARS-CoV-2 IgG and IgM antibodies using samples of fresh, human capillary whole blood obtained through a finger stick blood collection technique.

Intended End User: The Fortress Fast Test is intended to be used by professionals and lay people with no knowledge of self-testing.

Technology: The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow solid phase immunochromatographic assay for the rapid qualitative and differential detection of IgG and IgM antibodies to SARS-CoV-2 in human capillary whole blood, serum or plasma. The test uses anti-human IgM antibody (test line IgM), anti-human IgG antibody (test line IgG) and rabbit IgG antibody (control line C) immobilised on a nitrocellulose strip. The burgundy-coloured conjugate pad contains recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates). When a specimen followed by assay buffer is added to the sample well, if IgM and/or IgG antibodies are present it will bind to COVID-19 conjugates and make an antigen antibodies complex. This complex migrates through the nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilised antibody (anti-human IgM and/or anti-human IgG), the complex is trapped and forms a burgundy-coloured band which confirms a reactive test result. The test results can be read in ten minutes.

Clinical performance

Clinical performance characteristic	Fortress Fast COVID-19 Home Test	
	IgG	**IgM**
Specificity	98.8%	96.0%
Sensitivity	98.4%	95.2%

Limit of detection

The limit of detection of the Fortress Fast COVID-19 Home Test (Whole Blood) is a dilution rate of 1:32.

Conditions that might affect the results

- Re-use of a device. The Fortress Fast COVID-19 Home 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 2°C or greater than 30°C.
- Use of a device that has been exposed to the atmosphere for longer than one hour.
- Excess pressure 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 Fortress Fast COVID-19 Home 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 much or too little test solution, or capillary blood.
- Incorrect reading of results. Results should be read immediately following the 20-minute wait time. Results should be discarded if read >5 minutes after the 10-minute wait time as they may be inaccurate.