COVID-19 Total Ab Device

PRODUCT CODE: COVID010 / COVID020

THE PRODUCT IS INTENDED FOR PROFESSIONAL USE ONLY

COVID010	COVID020
10 Tests	20 Tests
STORE AT 2 - 30°C	
INSTRUCTIONS FOR USE	
FOR IN-VITRO DIAGNOSTIC USE ONLY	

IVD For In Vitro Diagnostics Use Only
LOT Lot Number
REF Catalogue Number
Storage Temperature
Expiry Date (Year / Month)
Warning, Read Enclosed Documents
Instructions For Use
Manufactured By

INTENDED USE

Fortress COVID-19 Total Ab Device is a single use, rapid device for qualitative detection of total antibodies against 2019 novel coronavirus (SARS-CoV-2) in human serum, plasma or whole blood specimens. The kit is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease 2019 (COVID-19).

SUMMARY

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death.

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 novel coronavirus, formerly known as 2019-nCoV and now known as SARS-CoV-2, is a new strain of coronavirus that was first identified during an outbreak in Wuhan, China which started in December 2019.

PRINCIPLE OF THE ASSAY

Fortress COVID-19 Total Ab Device employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens corresponding to SARS-CoV-2 are dry-immobilized at the end of nitrocellulose membrane strip. SARS-CoV-2 antigens are bound at the Test Zone (G & M) and antibodies are bound at the Control Zone (C). When the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in specimen, SARS-CoV-2 antibody will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (G & M) where they are captured by the SARS-CoV-2 antibody generating a visible red line. If there is no SARS-CoV-2 antibody in specimen, no red line is formed in the Test Zone (G & M). The gold conjugate will continue to migrate alone until it is captured in the Control Zone (C) by the antibodies aggregating in a red line, which indicates the validity of the test.

KIT CONTENTS:

Test Cassette:

COVID-19 Total Ab Device in plastic cassette packed in foil pouch for single use only.

Diluent Buffer:

4ml per vial. The Diluent Buffer can be stored at room temperature.

Others:

- Instructions for use

Materials required but not provided:

Clock or timer, specimen collection container, centrifuge, biohazard waste container, safety lancets and alcohol pads.

SPECIMEN COLLECTION

1. Human serum, plasma or whole blood samples are used for this test. Plasma or whole blood samples containing EDTA, sodium citrate or heparin can be used for this test. Whole blood samples can be venous whole blood, or fingertip blood.

2. Samples containing suspended fibrin or aggregates and severe haemolysis (haemoglobin content greater than 400mg/L) cannot be detected, but jaundice (bilirubin content less than 1.71mmol/L) and hyperlipemia triglyceride content less than 170mmol/L) can be detected.

3. Serum and plasma samples can be refrigerated at 2-8°C for one week; In case of long-term storage, it shall be frozen below -15°C, and repeated freezing and thawing shall not exceed 3 times. Samples should be left at room temperature before use (15 minutes), mix the specimen before testing.

4. It is recommended to test the whole blood specimen immediately after blood collection. Do not use the specimen after long-term storage.

STORAGE AND STABILITY

COVID-19 Total Ab Device can be stored at room temperature (2-30°C, do not freeze!).

PRECAUTIONS AND SAFETY

COVID-19 Total Ab Device is for *In Vitro Use Only*
FOR PROFESSIONAL USE ONLY

1. This reagent is only used for in vitro testing, and the operation should be carried out in strict accordance with the instructions. Make sure that the test is not expired (EXP Date indicated on the kit box). The detection card cannot be reused.
2. Do not use the samples that have been sitting for too long, and hence contaminated by bacteria and have peculiar smell, so as to avoid non-specific reactions caused by contamination of samples with bacteria.
3. Due to the different intensity of the positive samples, the red strip of the test line (G & M) can show different colour depth. During the specified observation time, even a very weak ribbon, regardless of its colour, should be judged as a positive result.
4. All the waste and specimen should be treated as infectious in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal. The desiccant in aluminium foil bag cannot be takeninternally.
5. At room temperature, the test card should be used within 30 minutes after it is taken out of the package to avoid prolonged exposure to humid air (humidity > 60%), which may affect the test result. If the kit is stored at 2-8°C, the reagent should be left at room temperature (30 minutes) before starting the test, then open the aluminium foil bag for use.
6. During the test, the test device should be laid flat on the work top, so as not to cause the sample chromatography speed to be faster (or slower) and affect the test result.
7. Always interpret the results under good light conditions to avoid misreading the test results.

ASSAY PROCEDURE

Place the cassette on flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately (within 15 minutes) after opening.

1. **For whole blood / serum / plasma specimens:** Open the pouch and add 5-10µl of specimen into the specimen window (S). Immediately add **two drops** of diluent buffer into the buffer window B.
2. Read the results within 15 minutes after specimen and buffer loading.

RESULTS

Quality Control: One red line will always appear next to the Control Zone (C) indicating the validity of the test.
Invalid test run: If no red line appears, the test is invalid

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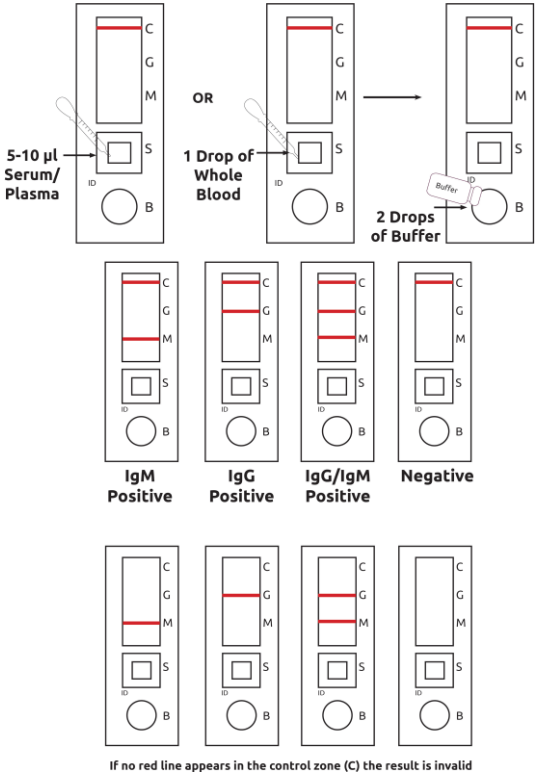
- discard the test and repeat with new specimen and new cassette.

Reactive Results (Positive Results): One red line appears next to the Test Zone (G OR M) which indicates that antibodies to SARS-CoV-2 have been detected through using this test. The red line next to G indicates presence of IgG Antibodies and the red line next to M indicates presence of IgM Antibodies. Red lines next to the G & M indicate the presence of IgG and IgM antibodies.

Non-reactive Results: If no red line appears next to the Test Zone (G & M) this indicates that no antibodies to SARS-CoV-2 have been detected with this test. However, this does not exclude the possibility from infection with SARS-CoV-2.

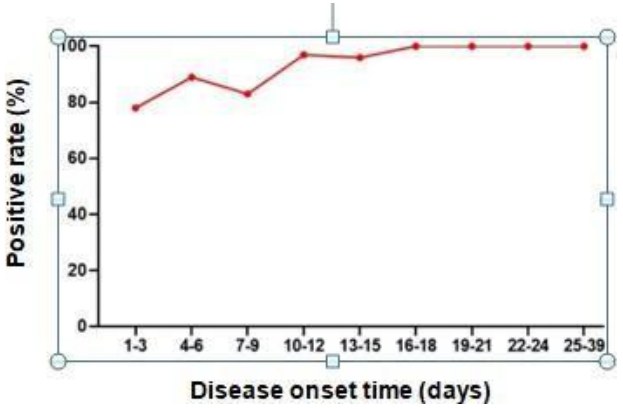
The reactive result obtained with COVID-19 Total Ab Device alone cannot be the final diagnosis of COVID-19. Any reactive results must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all reactive specimens with other tests is required to confirm any reactive result.



PERFORMANCE DATA

1. Sensitivity and specificity: clinical validation study of COVID-19 Total Ab Device was conducted in 2020 in China and Iran. 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals were tested. The kit demonstrated the sensitivity of 95.6% (131/137) and the specificity of 95.2% (199/209).

2. Samples were collected from COVID-19 confirmed cases with clinical symptoms, laboratory abnormalities or pulmonary imaging manifestations. No tests have been performed on specimens from latent infections or patients in the incubation period. It was observed that the detection rate of the kit was closely related to the time of disease onset, the kit showed higher positive detection rate in specimens from patients with delayed onset. Therefore, the interpretation of the test results should consider the specimen's collection time.



LIMITATIONS

1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information.
2. Negative test results of this reagent do not rule out the possibility of SARS-CoV-2 infection. Patients with impaired immune function or receiving immunosuppressive therapy have limited serological antibody levels. Antibodies in samples are destroyed or inactivated; and the limitation of the reaction principle of immunochromatography; It is recommended that the patient should be re-examined within 7 to 14 days. During re-examination, the samples collected last time should be tested in parallel to confirm whether there is serological Yang rotation or significant increase in titre.
3. This reagent cannot be used as a quantitative reagent.
4. This reagent is only used for the detection of human serum, plasma or whole blood samples.

FAST LABORATORY DIAGNOSTICS
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