COVID-19(SARS-CoV-2) IgG/IgM Rapid Lateral Flow Test (colloidal gold-based)

Intended use:

AIVD COVID-19(SARS-CoV-2) IgG/IgM Rapid Test 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).

Description:

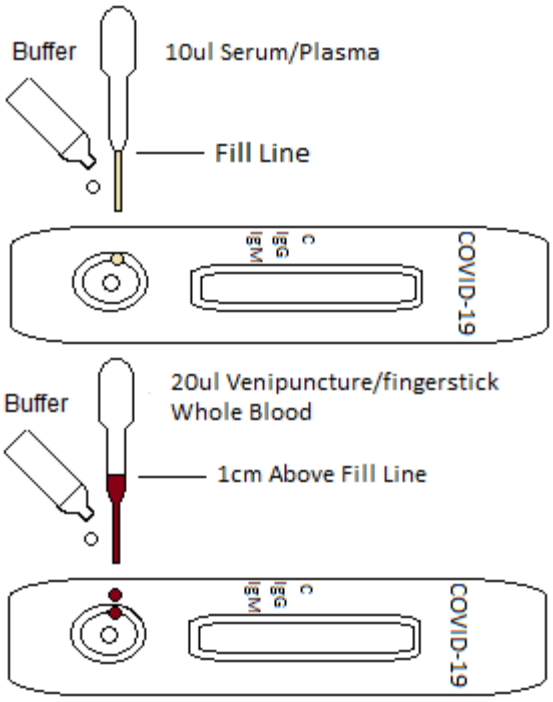
Novel coronavirus pneumonia (NCP) or SARS-COV-2, that was officially named by the WHO as “Corona virus disease 2019” (COVID-19), is a respiratory infection caused by a new virus that was first identified in late 2019.

IgM/IgG Rapid Kit can specifically detect IgM and IgG antibodies of COVID-19, covering the entire course of infection and recovery period of patients. This approach improves the overall diagnosis of COVID-19 in both acute and recovery phases of illness.

This kit utilizes the principle of colloidal gold immunochromatography to qualitatively detect the new coronavirus (COVID-19) IgG / IgM antibodies in human serum and plasma. Lateral flow immunochromatographic assay provides an easy workflow, short turnaround time, and rapid diagnosis of COVID-19 suspected patients.

This method does not require expensive medical instruments and consumables. Just take the specimen and add it to the sample well, and then add the required amount of a diluent. The IgG / IgM antibodies in the sample will interact with the colloidal gold-labeled COVID-19 recombinant antigen on the conjugate pad. Then the conjugate pad will release re-solubilized conjugate onto the nitrocellulose membrane. The nitrocellulose membrane (NC membrane) diffuses it forward.
As the sample moves along the device binding reagents situated on the nitrocellulose membrane bind to the target at the test line. If the sample contains a COVID-19 IgG antibodies, they will bind to the colloidal gold-labeled novel coronavirus recombinant antigen, diffuse forward, and then react with the anti-human IgG antibodies immobilized on the NC membrane detection line (T2 line). Similarly, if the specimen contains IgM antibodies to COVID-19, the antibodies will react with antigen-coated particles, the conjugate migrate laterally forward, and cause a colored line (T1 line). The darker the color of colloidal gold on the test line, the higher the concentration antibodies to COVID-19 in the sample.

As a procedure control, there is a quality control line (C line), this line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred, otherwise the test result is invalid.



Accuracy:： > 90%

Specificity: 97%

Storage Conditions：
Store at + 2 - 30 °C

Specimen requirements:

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 should be used as soon as possible after collection; if not used immediately, serum / plasma samples can be refrigerated at 2-8 ° C for 5 days. n case of long-term storage, it shall be frozen below -20°C, and repeated freezing and thawing shall not exceed 3 times. Samples should be balanced to room temperature (15 minutes), mix the specimen before testing.

3. It is recommended to test the whole blood specimen immediately after blood collection. Do not use the specimen after long-term storage.
4. If the sample contains a large amount of lipid, hemolysis or turbidity, please do not use it to avoid affecting the test results.

Basic Protocol:

1. Remove the test specimen, required reagents from storage conditions, and equilibrate to room temperature.
2. Unpack the aluminum foil bag, place the test horizontally on the table and number it.
3. Add 10ul serum, plasma or whole blood sample to the sample well with a pipette or a dropper. Slowly add 2 drops of sample dilution (about 60uL) to the sample well.
4. Read the results within 10-15 minutes after adding the sample, and the results will be invalid after 30 minutes.

Please note:

The amount of a sample and dilution should be adjusted according to the width of the customer's test strip.

The above amounts: 10ul of sample and 60ul of dilution are suggested for 4mm wide test strip.