



The Instruction of Diagnostic Kit for Detection of IgM/IgG Antibody to SARS-CoV-2 (Colloidal Gold)

PACKAGE SIZE

1 test/kit, 10 tests/kit, 20 tests/kit, 50tests/kit and 100 tests/kit.

INTENDED USE

This product is used to qualitative detection of the presence of IgM and/or IgG antibody to SARS-CoV-2 in Human serum, plasma, and whole blood.

The common symptoms are fever, cough, polypnea, and anhelation when infected with SARS-CoV-2. In more serious cases, the infection may cause pneumonia, severe acute respiratory syndrome, renal failure, and even death. Coronavirus can be excreted through respiratory secretions and transmitted by air droplets. Infection may be caused by saliva, sneeze, and contact.

PRINCIPLE

A Monoclonal Mouse Anti-Human IgM and/or A Monoclonal Mouse Anti-Human IgG conjugated to colloidal gold and embedded in each sample pad respectively react with the IgM and/or IgG antibody to SARS-CoV-2 present in whole blood, serum or plasma forming conjugate/ SARS-CoV-2 antibody complex.

As the mixture is allowed to migrate along the test strip, the conjugate/ SARS-CoV-2 antibody complex is captured by recombinant SARS-CoV-2 antigen immobilized on a membrane forming a colored test line in the test region.

COMPONENT

1. Cassette
2. Sample diluent
3. Pipette

Note: Do not interchange reagents from different lot of kit.

STORAGE AND SHELF LIFE

Store at 2~30 °C in a sealed dark and dry place. Do not freeze. The shelf life is 18 months.

SAMPLES REQUIREMENT

- 11 Sample: Serum, plasma or whole blood
- 12 Sample collection
- 13 Collect serum or plasma specimens following regular clinical laboratory procedures. Only those specimens that are clean, clear and with good fluidity can be used for the assay.
- 14 **Those specimens that are hemolyzed, extremely thickened or with very high-fat levels are NOT suitable for the assay.**
- 15 Collect whole blood specimens following regular clinical laboratory procedures. Anticoagulant tube with EDTA or Sodium Citrate must be used for collecting whole blood samples.
- 16 Collect peripheral blood following regular clinical laboratory procedures. The first drop blood should be removed by a dry cotton ball.

2. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 7 days of collecting. The specimen should be stored at -80°C or lower if not used within 3 months. Avoid freezing and thawing the specimens more than 2-3 times.

3. Transportation: Samples must be transported in seal and refrigeration.

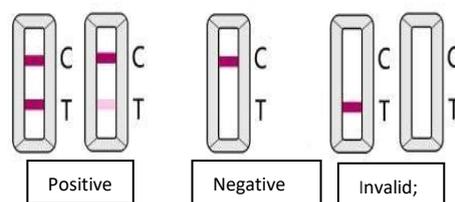
TEST PROCEDURE

Read the instruction carefully before use. Bring the Cassette, Sample Diluent and samples to room temperature.

Dispense 10ul serum/plasma/whole blood into each sampling well of Cassette. Then Dispense 100ul Sample diluent into each sampling well of Cassette

Interpret the result at 15 minutes. Please do not judge the result after 20 minutes.

RESULTS INTERPRETATION



IgM Positive: IgM test band and control band appear on the membrane.



IgG Positive: IgG test band and control band appear on the membrane.

Both IgM Positive and IgG Positive: IgG test band, IgM test band and control band appear on the membrane

Negative: Only the control band appears on the membrane.

Invalidity: No control band appears on the membrane.

Note: Within the specified time, regardless of the depth of the color, even if only a very weak band should also be judged as positive results.

Limitations

1. This product is a qualitative test of IgM antibody to SARS-CoV-2.
2. The result only shows the presence or non-presence of IgM to the SARS-CoV-2. The final diagnosis of the patient can not simply rely on the results of this examination, the comprehensive judgments must be made combined with further clinical examination.
3. The sensitivity depends on the concentration of IgM antibody to SARS-CoV-2 in the sample. Samples with low concentration may show negative results.

Performance

Positive control

All 5 positive controls should show positive results.

Negative controls

All 10 negative controls should show negative results.

Limitation

4 samples, L1, L2, L3 and L4 were tested. L1, L2 and L3 show positive result and L4 shows negative result.

Repeatability

2 Controls, Q1 and Q2, are tested in 10 times. The results should be positive and the color is identical.

Note:

1. The product is only for In vitro diagnosis. Please operate under instructions. Do not use it after the expired and/or damaged.
2. Do not interchange reagents from the different kit lot.
3. Do not use water or purified water as a negative control.

The cassette must be used within 1 hour after taking out the sealed bag. If the surrounding temperature is higher than 30°C or the high humidity, The cassette must be used immediately after taking out the sealed bag.

4. Applying a sufficient amount of samples diluents is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after 30 seconds, add one more drop of diluents.
5. The collection, processing, storage, discarding of the sample and the use of the reagent in the kit should take appropriate precautions. All the samples, reagents, and control substances should be handled as infectious substances.

References

[1] Na Zhu. A Novel Coronavirus from Patients with Pneumonia in China, 2019. The new England journal of medicine. January 24, 2020.

Manufacturer

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