

## Screening Kit for Detection of IgG/IgM 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 for the qualitative detection of the presence of IgG and/or IgM 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, infection may cause pneumonia, severe acute respiratory syndrome, renal failure and even death. Coronavirus can be excreted through respiratory secretions and transmitted by air droplet. Infection may be caused by contact with infected saliva and sneeze droplets.

### Principle

A Monoclonal Mouse Anti-Human IgG and/or a Monoclonal Mouse Anti-Human IgM conjugated to colloidal gold and embedded in a membrane matrix respectively reacts with the IgG and/or IgM 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. Testing cassette
2. Sample diluent
3. Pipette tips
4. Lancet

Note: Do not interchange reagents from different kits.

### Storage and shelf life

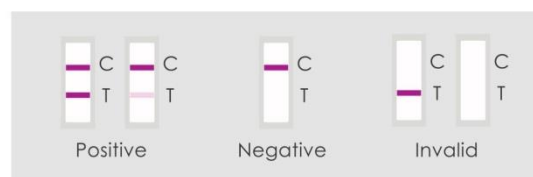
Store at 2~30°C in a sealed dark and dry place. Do not freeze. The shelf life is 18 months from date of manufacturing. Use kit before the expiration date specified on the kit.

### Test procedure

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

1. Open up the test kit. Test kit components include User Manual, Sample diluent, Pipette tips, and Testing cassette.
2. Tear the aluminum foil bag and take out the testing cassette. Place the testing cassette flat on a working surface.
3. Use a one-time disposable cotton swab covered with rubbing alcohol to disinfect the finger from which the blood will be drawn.
4. Use a lancet to prick the finger. It is recommended to use a one-time disposable cotton swab to remove the first blood drop in order to prevent hemolysis.
5. Use a pipette tip to dispense the collected blood to the two testing well on the testing cassette.
6. Dispense 2 drops of sample diluent to each of the two testing wells on the testing cassette.
7. Interpret the result at 15 minutes. Please do not use the result obtained after 20 minutes as false positive results may occur.

## Results Interpretations



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

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

Both IgG Positive and IgM 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.

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**Limitations**

1. This product is a qualitative test of IgG and IgM antibodies to SARS-CoV-2.
2. The result only shows the presence or non-presence of IgG and/or IgM antibody to SARS-CoV-2. The final diagnosis of the patient cannot simply rely on the results of this experiment. Comprehensive judgments must be made combined with clinical examination and additional confirmatory testing.
3. The sensitivity depends on the concentration of IgG and/or IgM antibody to SARS-CoV-2 in the sample. Samples with low antibody concentration may show negative result.

**Note:**

1. This product is only for In vitro screening purposes. Do not use it if damaged or expired.
2. Do not interchange reagents from different lots of kit.
3. Do not use water or purified water as negative control.
4. The testing cassette must be used within 1 hour after taking out the sealed bag. If the surrounding temperature is higher than 30°C or the humidity is high, the cassette must be used immediately after taking out the sealed bag.
5. Applying sufficient amounts of sample diluent 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 sample diluent to the well on the testing cassette.
6. Take appropriate precautions on sample collection, processing, storage, and discarding as well as on reagent uses. **All samples, reagents, and control substances should be handled as infectious substances.**

**Performance Characteristics**

Sensitivity	95.04%
Specificity	100%
Positive Predictive Value (PPV)	100%
Negative Predictive Value (NPV)	98.58%
Accuracy	98.88%

**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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