USER MANUAL

Product Name:

- **Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test**

Product reference:

- SERO-CoV-2.2

Packaging specifications:

- 1 box containing:
  - 25 tests
  - 1 bottle of migration solvent
  - 1 instruction manual

Storage conditions and validity:

The kit must be stored at a temperature of 2~30°C and is valid for 12 months.
After unpacking the aluminium bag, please use it as soon as possible.

Usage specifications:

This in vitro kit is used for the qualitative detection of IgM and IgG antibodies to Novel Coronavirus (SARS-CoV-2 or covid-19) in human serum, plasma or whole blood.

Novel Coronavirus 2019, abbreviated to SARS-CoV-2 (or covid-19), is a new strain of coronavirus discovered in the human body. Symptoms of the virus include fever, fatigue, dry cough and progressive dyspnea. In severe cases, symptoms include acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction that cannot be reversed. The human-to-human transmission capacity of the virus has been confirmed. The shortest incubation period of the virus is only one day, while the longest incubation period is 14 days. Incubating patients are contagious and there is no specific treatment for the disease at the moment. Once infected with a new virus, the body's immune system begins to defend itself and, after a certain period of time, to produce antibodies. In general, IgM antibodies appear within 1-2 weeks and IgG antibodies within 4 weeks.

Requirements:

1. The test is suitable only for human serum, plasma and whole blood samples (EDTA, Heparin Sodium and Sodium Citrate Anticoagulant are recommended for plasma/wholesale blood).
2. Samples should be used as soon as possible after collection; if not used immediately, serum/plasma samples may be stored at 2-8°C for 5 days; if long-term storage is required, they should be stored at -20°C; and whole blood samples should be stored at 2-8°C to avoid hemolysis.

Test principle:

The principle of the test is based on immunochromatography and the reaction between IgM/IgG antibodies present in the sample and the SARS-CoV-2 antigen labelled with colloidal gold on a cellulose membrane.

The IgM/IgG antibody present in the sample binds to the recombinant colloidal gold labeled 2019-nCoV antigen present in the binding buffer to form a complex which diffuses forward along the nitrocellulose membrane.
It then binds to an anti-human IgM/IgG antibody attached to the nitrocellulose membrane test line (M/G line) to form a red-violet band, showing the IgM/IgG antibody SARS-Cov-2. The deeper the color of the band on the M/G line, the higher the concentration of the SARS-Cov-2 IgM/IgG antibody in the sample will be.
To monitor the effectiveness of the Test Card, a quality control line (C line) is set up. For the test to be validated, the C-line must show color development or the test result will be considered invalid.

Test Steps:

1. Remove the test sample and the required reagents from the storage environment and equilibrate to room temperature;

2. Unpack the foil pouch, remove the test card and place it on a horizontal table;

3. Place approximately 30 µL of whole blood, vertically into the sample well of the Test Card and immediately add 2 drops (approximately 70µL) or add 70µL of Sample Diluent using a pipette;

4. Start timing and determine the result within 15 to 30 minutes

Interpretation of test results:

1. **Negative result:**

   If only one line appears in the C level and there is no band development in the M line and the G line, no IgM/lgG SARS-CoV-2 antibodies are detected and the result is determined to be negative (as shown in the figure below).

2. **Positive results:**

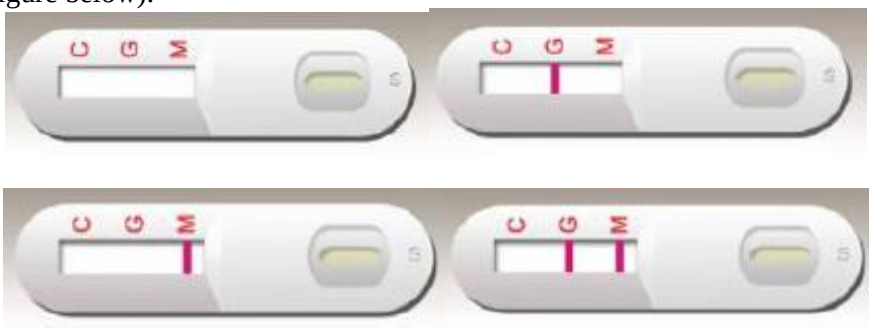
a. If both line C and line M show band development, this means that an IgM SARS-CoV-2 antibody is detected and the result is determined to be IgM positive (as shown in the figure below).

b. If both line C and line G show band development, this means that an IgG SARS-CoV-2 antibody is detected and the result is determined to be IgG positive (as shown in the figure below).

c. If line C, line M and line G all show band development, this means that both IgM and IgG SARS-CoV-2 antibodies are detected and the result is determined as IgM positive and IgG positive (as shown in the figure below).

3. Invalid results:

If line C does not appear, (no band development), it means that the test is invalid (as shown in the figure below).



At this point, the absence of line C indicates a malfunction or damage to the test card.
Please read the instructions again carefully and perform the test with a new Test Card.
If the problem persists, discontinue use of this product batch immediately and contact the supplier.

Limits of the test method:

Test results should be determined within 15 to 30 minutes after addition of the specimen.

Precautions:

1. This kit is intended to be used for in vitro diagnostic purposes only.
2. Before use, please equilibrate the samples and the corresponding reagents to room temperature. To prevent the Test Card from being affected by moisture, please use the Test Card within 30 minutes after unpacking.
3. Do not use any sample diluent that is not compatible with this reagent.