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COVID-19 IgG and IgM Detection Kit

Cat# COV1004

Upon receipt, store at RT.

TESTING PRINCIPLE

The novel coronavirus antibody was detected by IgG and IgM and indirect principle and colloidal gold immunochromatography. The test card contains:

- 1) Binding pad: colloidal gold-labeled recombinant 2019 novel coronavirus antigen and quality control antibody;
- 2) NC membrane: coated with detection lines (G or M lines) and a quality control line (C line). M-line coated with mouse anti-human IgM monoclonal antibody for detection of 2019 novel coronavirus IgM antibodies; G-line coated with mouse anti-human IgG monoclonal antibody for detection of 2019 novel coronavirus IgG antibodies; C-line coating with quality control antibody.

When an appropriate amount of test sample is added to the sample hole of the test card, the sample will move forward along the test card. If the sample contains an IgM antibody, the antibody will bind to the colloidal gold-labeled virus antigen, and the immune complex will be on the M line. It forms a sandwich complex with the coated anti-human IgM monoclonal antibody, showing a purple-red M line, suggesting that the 2019 novel coronavirus IgM antibody is positive.

If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled 2019 novel antigen, and the immune complex will form a sandwich complex with the coated mouse anti-human IgG monoclonal antibody at the G line, showing a purple red G line, Suggesting that the 2019 novel IgG antibody is positive.

If the test lines G and M are not colored, a negative result is displayed. The test card also contains a quality control line C. The fuchsia quality control line C should appear regardless of whether a test line appears. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again.

PACKAGE INFORMATION

10 person/box

MAIN COMPONENT

- 1. #COV1002 IgM Detection card
- 2. #COV1003 IgG Detection card
- 3. Sample diluent (500 µl/vial)
- 4. Disposable dropper (1 ml)



EXPECTED USAGE

This product is used to qualitatively detect IgG and IgM antibodies of 2019 novel coronavirus in human serum, plasma, whole blood or fingertip blood.

STORAGE CONDITION AND VALIDITY

The detection reagent shall be stored in a dry place away from light at room temperature (2°C -30°C), and shall not be frozen

Validity: 12 months

SAMPLE REQUIREMENT

- 1. The reagent is applicable to whole blood (venous blood or fingertip blood), serum or plasma. The whole blood/ plasma/ serum samples have no requirements for commonly used clinical anticoagulants (such as EDTA, heparin and sodium citrate, etc.).
- 2. Immediately after the specimen is collected, shake it up and down 5-10 times without shaking.
- 3. The sample should be tested immediately after collection. If it cannot be detected in time, it should be stored under low temperature conditions: the sample can be stored at $2 \sim 8$ °C for 48 hours, and frozen at -20°C for 3 months.
- 4. Samples with severe hemolysis or hyperlipidemia may affect the results.

STEPS

- 1. If the reagent is stored in a refrigerator at 2-8°C, remove the reagent card and equilibrate at room temperature for more than 30 minutes.
- 2. Open the inspection card aluminum foil bag. Remove the test card and place it horizontally on a table.
- 3. Use pipette to aspirate sample (serum, plasma or whole blood) and add 20 μ l to the sample hole of the test card, and then add 200 μ l sample dilution solution immediately.
- 4. Read the result at 15min. Results after 20 minutes are invalid.

INTERPRETATION OF TEST RESULTS

- 1. Negative results: If only the quality control line C shows color and neither the G nor M test lines develop color, no 2019 novel coronavirus IgG/IgM antibody is detected, and the result is negative.
- 2. Positive results:
 - 2-1 IgM detection card: If the two lines (quality control line C and detection line T) develop color, then the new coronavirus IgM antibody is detected, and the result is positive for the new coronavirus IgM antibody.
 - 2-2 IgG detection card: If the two lines (quality control line C and detection line T) develop color, then the new coronavirus IgG antibody is detected, and the result is positive for the new coronavirus IgG antibody.
- 3. Invalid result: If the quality control line C does not develop color, regardless of whether the test line



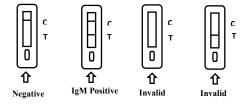
develops color, the result is invalid, and the test needs to be performed again.

PRECAUTIONS

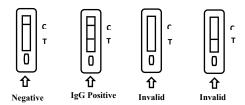
- 1. Please equilibrate the sample dilution and test card to room temperature (more than 30 min) before testing.
- 2. Testing is performed strictly in accordance with the instructions.
- 3. The results must be interpreted at 15 minutes.
- 4. Do not use highly hemolyzed and lipemia samples.

THE RESULTS OF INTERPRETATION

IgM detection card:



IgG detection card:



PRODUCT USE LIMITATION

These products are intended for research use only.

