

2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based)

Datasheet (Version 1.0)

PRODUCT NAME

2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based).

CATALOG NUMBER & SIZE

50 tests / kit.

INTENDED USE

This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). It is suitable for qualitative detection of IgG / IgM antibodies in human serum, plasma, whole blood, and finger prick blood.

2019-Novel Coronavirus belongs to the new coronavirus of the genus β , which has an envelope, the particles are round or oval, often polymorphic, and the diameter is 60-140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). After infection with 2019-nCoV, the common symptoms are fever, fatigue, dry cough, dyspnea etc. Some severe patients appear the symptoms including acute respiratory distress syndrome, septic shock, metabolic acidosis that is difficult to correct, and coagulation disorders. Some patients have mild symptoms and no fever. Most of patients have a good prognosis, while a few are in critical condition or even die.

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. The level of IgM antibody begins to rise within 1 week and achieves the peak at 2-3 weeks after the initial infection. While the IgG appears later than IgM (usually in 14 days after infection) and achieves the peak at 5 weeks, lasting for 6 months or even several years. When the antibody titer of patients in the convalescence period is 4 times (or more than 4 times) higher or lower than that in the acute period, which has clinical diagnostic significance for virus infection.

PRINCIPLE OF DETECTION

This product is based on capture and solid-phase immunochromatography methods for determination. The specimen (whole blood / serum / plasma / finger prick blood) flows from the blood separator through to the conjugate release pad (which occurs the conjugation reaction between IgM / IgG antibody in the specimen and the antigen colloidal gold of 2019-nCoV to form an immune complex of IgM / IgG antibody and colloidal gold-labeled antigen) due to capillary action. Then migrate to a capture zone of nitrocellulose membrane-immobilized antibody (mouse-anti-human IgM antibody, T1 line) to form an immune complex of colloidal gold-labeled antigen, IgM antibody and mouse-anti-human IgM antibody, thereby generating a T1 red line. The unreacted immune complex continues to flow upward, will be captured by the mouse-anti-human IgG antibodies (T2 line) to form an immune complex of colloidal gold-labeled antigen, IgG antibody and mouse-anti-human IgG antibody, thereby generating a T2 red line. The remaining uncaptured immune complex moves upward, combining with C line (quality control line) to indicate the completion of this reaction.

Components

Components	Ingredients
Detection Card	Aluminum foil pouch, desiccant, test strip and plastic card. Test strip composing blotting paper, nitrocellulose membrane, specimen separator, colloidal gold-labeled pad and PVC. T1 line (Test line) coating 1.0 mg/mL mouse-anti-human IgM antibody. T2 line (Test line) coating 1.0 mg/mL mouse-anti-human IgG antibody. C line (quality control line) coating 1.0 mg/mL actin protein C. Conjugate release pad containing 40 OD 2019-nCoV antigen-colloidal gold conjugate complex.
Specimen Dilution	HEPES Buffer containing casein (0.1 M), 5 mL/bottle.
Dropper	According to different packing specifications: 10 droppers /pack, 50 droppers/pack.

Note: Do not interchange the components from different batches.

STORAGE & SHELF LIFE

This kit should be stored at 4°C~30°C for 18 months in a sealed condition. Once the inner packaging of strip is opened (4°C~30°C, humidity < 65%), it must be used in 1 hour.

SAMPLING & HANDLING

- Suitable specimen type: serum, plasma, whole blood and finger prick blood.
- Sediment and suspended matter in the specimen may affect the test result. It should be removed by centrifugation at 3000g for 10 minutes.
- Severe hemolytic, lipemic and turbid specimens should not be used.
- Whole blood/plasma specimens can be treated with heparin sodium or EDTA anticoagulant. After specimen collection, the test should be completed within the same day. If not, please store it as the following protocol:
For whole blood specimens, store at 2°C~8°C for 3 days.
For Serum/plasma specimens, store at 2°C~8°C for 7 days, or at < -20°C for 12 months.
For finger prick blood specimens, it is recommended for immediate use after collection and do not freeze and avoid heating to inactivate specimen.
- Specimens must be fully restored to room temperature (18°C-28°C) before testing. Freeze-preserved specimens should be completely melted, reheated and mixed thoroughly before use.