New coronavirus 2019-nCoV IgG / IgM detection kit

(colloidal gold method)

【product name】

New coronavirus 2019-nCoV IgG / IgM detection reagent basin (colloidal gold method)

[**Packing specifications**]

25 servings / box, 40 servings / box

【expected usage】

This product uses capture method and colloidal gold immunochromatographic technology for rapid and qualitative detection of 2019-nCoV antibodies in human whole blood, serum and plasma.

[**Inspection principle**]

This product uses capture method and colloidal gold immunochromatography to qualitatively detect nCoV antibodies in human whole blood, or serum. The anti-IgM antigen and, anti-IgG antibody, a murine anti-sheep polyclonal antibody were coated on the cellulose membrane at the detection control line respectively.

when begin to test, If the tested specimen contains IgM antigen, the antigen will be bound to form a complex, and it is bound to the anti-IgM fixed at the detection line . so a purple-red band appears in the line: if the test sample contains IgG , the gold-labeled antibody be bounds to form a complex, there is a purple line at the detection line (IgG) conversely, if no purple-red band appears in the detection area (IgM) (IgG). after the sample being tested ,The control region (C), a purple-red band will be showed. It is a standard for judging whether the chromatography process is normal or expired

[**Main composition**]

1. a test card
2. plastic straws
3. Sample dilution
4.Instruction manual

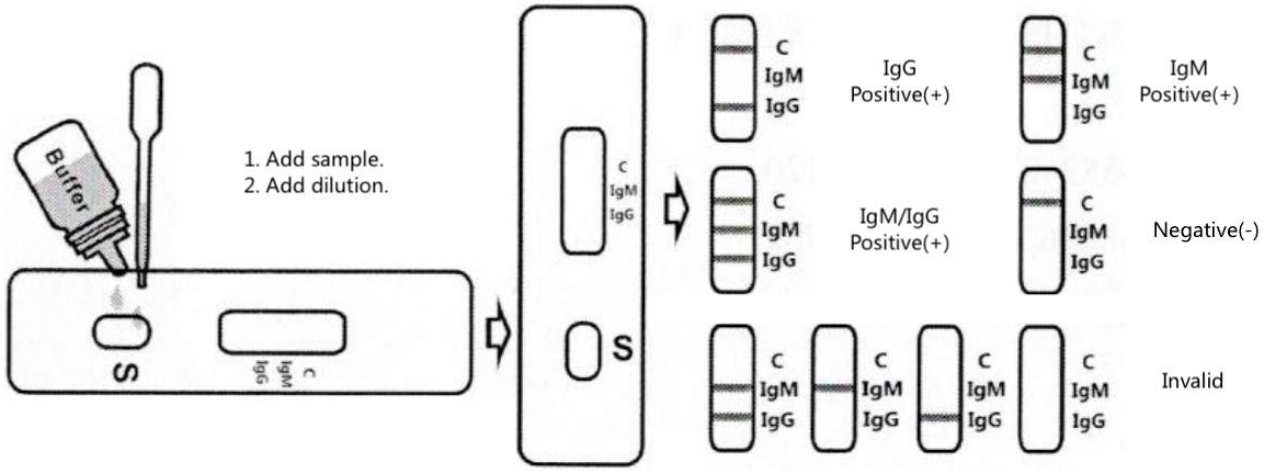
[**Storage conditions and validity**]

Storage conditions:
The original packaging should be stored at 4 ~ 30℃ , and freezing is prohibited.
Validity period: 24 months
Note:The kit should be used as soon as possible within 1 hour after unpacking the aluminum foil bag; it is recommended to use it as soon as possible at ambient temperatures above 30℃ fences or low humidity.please refer to the label for the production stageI and expiration stage II

[**Applicable instruments**]
1. Specimen collector, centrifuge (for plasma only)
2.Timer

[**Sample requirements**]
1. Can detect human whole blood, serum or plasma samples.
2. Collect the collected venous blood in a blood collection tube with EDTA, heparin, and sodium citrate as anticoagulants.
3. Serum / plasma should be separated as soon as possible after sample collection to avoid dissolution and not be stored at room temperature
4. The samples of hemolysis blood cannot be used for testing, and a new set of fresh sample is required.
5. Whole blood samples should be collected and use as soon as possible , anti coagulant should be used within 24 hours, and do not be stored frozen.
6. If the serum / plasma sample is tested within 7 days after collection, the sample must be stored in (2-8 ℃ , if it is more than 7 days, it must be frozen(-20C) Save.
7. For testing, refrigerated samples must be returned to room temperature, and frozen samples must be completely thawed, warmed, and mixed before use. Avoid repeated freeze-thaw cycles.

[**Inspection method**]
I. You must read the instruction manual completely before the patrol test, and return the test kit and sample to room temperature before use. (20C ~ 30C).
2. opened the aluminum foil bag and remove the kit. It should be used within 1 hour.
3. Put the test card on a clean and flat table.
1). Use a plastic pipette to add 1 drop of sample vertically to the sample well (S).
Then add 2 drops of sample dilution (about 70 ul) to S well.
Wait for the test line to appear, read the results within 15 minutes, and judge invalid after 20 minutes.



[**Interpretation of test results**]
Positive (+): three lines appear in both the detection area (IgM)or (IgG) and control line (C). The results showed that the sample is positive has IgG and IgM are in the samples
If only two lines appear. -One line in the detection area (IgM) or (IgG) and control line (C). The results showed that the sample contained only IgM antibody or IgG antibody.
Negative (-): A control line (C)only, and no test line appears in the detection area (IgM) (IgG).
Invalid: No any bands appear in the control area (C). Indicates improper operation or the kit has failed. In this case, read the instructions carefully and retest with a new kit. If the problem persists, stop using this batch of products immediately and contact your local supplier.
Note: The test line of the detection area (IgM) (IgG) can be showed the test line, but but must be within the specified observation time, a very weak color band should be determined as positive result also

[**Limitations of Inspection Methods**]
1. This product is for lab use only, only for detecting human whole blood, serum and plasma samples.
2. This product only provides qualitative detection of 2019-nCoV IgG antibodies or 2019-nCoV IgM antibodies in samples, and cannot be used for quantification. If you need to detect the value of virus, please use professional instruments.
3. Initial screening by users of this product. Any positive test results must be confirmed by confirmatory methods.

【Precautions】

1. All testing operations must comply with the requirements of the Biosafety Code and strictly prevent cross-infection.
2. Use a new pipette for each sample to prevent sample contamination.
3. If the test result is negative and there are clinical symptoms, other clinical methods can be recommended for testing. This product is for research use only and cannot be used as a basis for confirmatory diagnosis.
4. As for the positive result of blood H, the color depth of the color band in the detection area is not completely proportional to the antibody titer in the sample.
5. Samples and all used items should be handled as potentially infectious items.