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COV Test kit Instructions

March 2020

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3. English Specification

A novel coronavirus 2019-nCoV IgM test kit (latex method)

【 Product Name】

Generic name: novel coronavirus 2019-nCoV IgM test kit (latex method) specification

【 Package Specification】

1 person / bag, 5 person / bag, 10 person / bag, 20 person / bag, 1 person / box, 5 person / box, 10 person / box, 20 person / box, 25 person / box, 30 person / box, 40 person / box, 50 person / box, 100 person / box, 200 person / box.

【Intended Use】

The novel coronavirus novel coronavirus 2019-nCoV IgM antibody can be used for clinical diagnosis of new coronavirus 2019-nCoV infection.

Coronavirus is a large virus family, which is known to cause cold, Middle East respiratory syndrome (mers) and severe acute respiratory syndrome (SARS) and other serious diseases. Coronaviruses belong to coronaviridae and coronavirus. Coronavirus is a positive strand RNA virus with envelope, which only infects human, mouse, pig, cat, dog and poultry vertebrates. In the report of the Ninth International Committee of virological classification, the coronaviridae is divided into three genera: α, β and γ. The coronavirus is discharged from the body through respiratory secretions, transmitted through mouth fluid, sneeze, contact, and air droplets.

2019 the novel coronavirus, the "2019-nCoV", was discovered in 2019 in Wuhan, and was named by WHO in January 12, 2020. A novel coronavirus is a new strain of coronavirus that has never been found in human body before.

【Test Principle】

A novel coronavirus 2019-nCoV specific epitope antigen was immobilized on the cellulose nitrate membrane and was made up of a color latex labeled anti human IgM antibody release pad and other reagents. A novel coronavirus 2019-nCoV antibody in human serum / plasma / whole blood was detected by latex immunochromatography and capture principle.

During the detection, the blood sample is added to the sample adding hole of the kit. The sample is first mixed with the anti human IgM marked by the color latex on the release pad, and then chromatographed on the nitrocellulose membrane. If the novel coronavirus novel coronavirus 2019-nCoV antibody is contained in the sample, these antibodies are first combined with the latex labeled anti human IgM. When the mixture is chromatograph on the nitrocellulose membrane, it will be captured by the detection line (T line) of the new coronavirus 2019-nCoV antigen, and form a color emulsion labeled antibody complex to human IgM- antibody, thus a red appears on the T line. Line, positive result. If the novel coronavirus 2019-nCoV antibody is not found in the blood, the red line will not form on the detection line (T line), which is negative. The quality control line (line C) on the reagent card is covered with Goat anti mouse antibody. Under normal circumstances, the red line should appear on the quality control line during the test to prove that the reagent card works normally.

【Main Components】

1) a novel coronavirus 2019-nCoV IgM test kit.
2) 1 sample pipette per person;
3) 1 bottle of sample diluent per box;
4) Instruction manual: 1 copy.

【 Storage Conditions and Validity】

Store at 4-30 C° in dark for 12 months without freezing.

【 Sample Requirements】

1) The applicable sample type of this test kit is serum / plasma / whole blood.

2) The whole blood was extracted by clinical laboratory standard method, and the serum or plasma was separated. Hemolysis was avoided as much as possible during the treatment.

3) Samples should be tested as soon as possible after collection to avoid long-term storage at room temperature. If the serum or plasma samples cannot be detected immediately, they can be stored at 2-8 C°.

4) The sample must be returned to room temperature before testing.

【 Test Method】

1) Please read the instruction manual carefully before testing.

2) Take out the reagent card, test sample and control, etc., and use it after the room temperature is restored. When everything is ready, tear open the aluminum foil bag of the kit, take out the reagent card and place it on the horizontal table.

3) Sample addition:

Whole blood sample: add 2 drops of whole blood vertically to the sample adding hole with sample adding pipette, and then add 1-2 drops of sample diluent.

Serum / plasma sample: use a pipette to drop 1 drop vertically into the sample hole, and then add 1-2 drops of sample diluent.

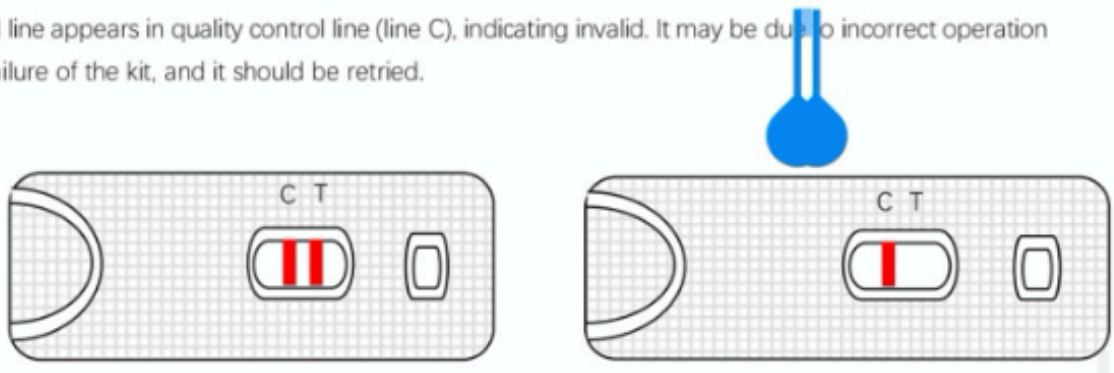
4) Timing observation: judge the result 10 minutes after sample addition, do not observe the result 20 minutes later.

【 Interpretation of Test Results】

Positive: quality control line (line C) and detection line (line T) each have a red line. The novel coronavirus 2019-nCoV antibody was found in the samples.

Negative: only quality control line (line C) has a red line, while test line (line T) has no red line. The novel coronavirus 2019-nCoV antibody or novel coronavirus 2019-nCoV antibody were lower than the detection level.

Invalid: no red line appears in quality control line (line C), indicating invalid. It may be due to incorrect operation or failure of the kit, and it should be retried.



【Limitations of Detection Methods】

The test results of this product can only be used as an assistant for doctors or other diagnoses.

【Product Performance Index】

1. Detection limit: the detection limit reference is used for detection, and the results are all positive.

2. Precision: test the same sample 5 times, the test results are consistent and the color is uniform.

3. Compliance rate of yin and Yang:

Positive coincidence rate: the positive coincidence rate of three positive reference samples was 100%;

Negative coincidence rate: the negative coincidence rate was 100% for 10 negative references.

4. Interference test:

When the bilirubin content in the sample to be tested is less than 200mg / L, there is no interference to the test results; when the cholesterol in the sample to be tested is less than 2500mg / L, there is no interference to the test results; when the hemoglobin in the sample is less than 2500mg / L, there is no interference to the test results; the rheumatoid factor (RF) positive, hepatitis B, hepatitis C and hepatitis E samples have no interference to the test results.

【Precautions】

1) This product is only used for external detection.

2) If it is suspected that the sample is contaminated, it shall be re sampled for testing.

3) Do not use expired kits.

4) All samples in the test shall be treated as infectious substances.