Product Description

Device: SARS-CoV-2 IgG/IgM Rapid Test

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1 Summary and explanation of the test

Coronavirus (SARS-CoV-2) Belongs to the genus Nestovirus, Coronaviridae, and is divided into four genera: α, β, γ and δ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. The δ gene include nightingale coronavirus HPU11, thrush coronavirus HPU12, munia coronavirus HPU13. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus(SARS-CoV-2) (2019) , it’s an important pathogen of human respiratory infections. Among them, a SARS-CoV-2 was discovered in 2019 due to Wuhan virus pneumonia cases. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. Can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

2 Product model and composition

SARS-CoV-2 IgG/IgM Rapid Test has 1/5/10/20 /25 /40 /50 model.

Figure 4.1 product

The components of the product include test card, extract, instruction, desiccant.

The test card consists of gold standard pad, sample pad, absorbent paper, nitrocellulose film and plastic card. The main components of the extract are phosphate

buffered saline and preservative.

3 Intended use and method of use

3.1Intend use

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus(SARS-CoV-2) in human whole blood, serum or plasma.

This test is intended to be used as a screening test and as an aid in the diagnosis of infection with Novel Coronavirus. Any reactive specimen with the SARS-CoV-2 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

3.2 method of use

3.2.1Bring the specimen and test components to room temperature if refrigerated or frozen. Place the test device on a clean, flat surface and label specimen number

3.2.2Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 10 μL) of whole blood (include finger blood),serum, plasma into the sample well,making sure that there are no air bubbles. Then add 1-2drops (about 70-100 μL) of Sample Diluent immediately.

3.2.3Set up timer. Results can be read in 15 minutes. Don't read result after 15 minutes.

POSITIVE RESULT:

In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of *SARS-CoV-2* IgG antibody. The result is positive.

In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of *SARS-CoV-2* IgM antibody. The result is positive.

In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-*SARS-CoV-2,* The result is also positive.

***NOTE:** Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

NEGATIVE RESULT:

If only the C band is present, the absence of any burgundy color in the both test bands (IgG and IgM) indicates that no *SARS-CoV-2* antibody is detected in the specimen. The result is negative.

INVALID RESULT:

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands. Repeat the assay with a new device.

4 Product technical principle

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant SARS-CoV-2 antigen conjugated with colloid gold (SARS-CoV-2 conjugates) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgG and IgM bands) and a control band (C band). The IgG band is pre-coated with monoclonal anti-human IgG for the detection of IgG anti- SARS-CoV-2, IgM band is pre-coated with reagents for the detection of IgM anti- SARS-CoV-2 and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 IgM antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored IgM band, indicating SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored IgG band, indicating a SARS-CoV-2 IgG positive test result.

Absence of any test bands (IgG and IgM) suggests a negative result. The test card also contains a quality control band C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. The quality control band is a color band of the quality control antibody immune complex. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.