

Instructions of COVID-19 IgM/IgG Test Kit (Colloidal Gold)

【Product Name】

COVID-19 IgM/IgG Test Kit (Colloidal Gold)

【Specifications】

25 tests/kit, 50 tests/kit

【Intended Use】

This kit is suitable for the qualitative detection of COVID-19 IgM/IgG antibodies in human serum, plasma and whole blood samples. It can be used for rapid screening of carriers of the COVID-19 virus that are symptomatic or asymptomatic.

【Detection Principle】

The COVID-19 IgG/IgM test kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by sample diluent is added to the sample well, IgM and/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen-antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG), the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

【Components】

The components of the test kit are test cards and sample diluent. The test card is mainly composed of mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-rabbit IgG antibody fixed on the nitrocellulose membrane, and colloidal gold-labeled COVID-19 recombinant antigen and rabbit IgG antibody fixed on glass fiber conjugate pad.

Components		Specification / Quantity	
		25 tests/kit	50 tests/kit
Test Card	Mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-rabbit IgG antibody fixed on the nitrocellulose membrane	1 test/bag 25 bags/kit	1 test/bag 50 bags/kit
	Colloidal gold-labeled COVID-19 recombinant antigen and rabbit IgG antibody fixed on glass fiber conjugate pad		
	Absorbent Paper		
Sample Diluent (pH8.0 Tris-Hcl)		1 bottle/kit (5ml)	1 bottle/kit (5ml)

Note: The components in different batches cannot be used interchangeably.

【Storage and Expiry date】

1. Keep test kits in a cool and dry place at 2 ~ 30°C. Do not freeze. The Kits are valid for 18 months. The test card and sample diluent should be used up in 1 hour after opening the package (opening temperature 10 ~ 30°C, humidity 25% ~ 95%).

2. The date of production and the term of use are labeled.

【Sample Requirement】

1. This kit is suitable for serum, (EDTA anticoagulation, heparin anticoagulation, sodium citrate anticoagulant 1:9) plasma, venous whole blood and fingertip blood samples. Fresh samples are recommended.

2. Sample collection: The whole blood/fingertip blood collected from the vein must be sterile, separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. The separated serum and plasma samples can be stored at 2 ~ 8 °C within 7 days if not run immediately. If long-term storage is required, please store at - 20 °C for periods less than 3 months. Samples can be frozen and thawed for 3 times. Whole blood samples can be stored at 2 ~ 8 °C within 7 days. Bring samples to room temperature prior to testing.

【Test Assay】

1. Bring the test card to room temperature prior to testing. Remove the test card from the sealed foil pouch and use it as soon as possible. Place the test card on a clean and level surface.

2. Venous blood collection: Add 10 µl of serum/plasma/15 µl of whole blood sample to the sample well, and then add two drops of diluent (about 80 µl) to the sample well. Avoid air bubbles.

3. Fingertip blood collection: Lancets used to collect fingertip blood. Transfer 1 drop of whole blood (about 15 µl) to the sample well, and then add two drops of diluent (about 80 µl) to the sample well. Avoid air bubbles.

4. The results can be interpreted in 10 minutes. Results measured after 20 minutes are invalid and should be discarded.

【Result Interpretation】

1. Positive result:

a. Positive result of COVID-19 IgG: Both the test line (G) and the quality control line (C) are colored. The test line (M) does not develop color.

b. Positive result of COVID-19 IgM: Both the test line (M) and the quality control line (C) are colored. The test line (G) does not develop color.