COVID-19 IgG/IgM Rapid Test

INTENDED USE

The COVID-19 Rapid test kit is a One Step Test for Novel Coronavirus (COVID-19) IgG/IgM antibody (Colloidal Gold) detection and is intended for the qualitative detection of COVID-19 IgG and IgM antibody in serum or plasma samples of pneumonitis patients or suspected cases.

PRINCIPLE

The test uses mixed recombinant 2019-nCoV nucleocapsid protein (N protein) and spike protein (S protein) both conjugated with colloidal gold and anti-human IgM and IgG antibody coated on different test lines respectively.

a) Serum/plasma→+Gold-labeled recombinant COVID-19 N protein and S protein will bind with 2019-nCoV IgM or IgG antibody in sample → Form marked antigen-antibody complexes (Red colour)

b) These marked antigen-antibody complexes (red colour) move to the test card detection zone by capillary action. → Marked antigen-antibody complexes will be captured on different test lines by Anti-Human IgG and IgM antibody resulting in purplish red streaks on the testlines.

CONTENTS & PACKAGE DETAILS

1. A test card consists of: A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad, nitrocellulose membrane with two test lines , the control line, absorbent paper and liner.

2. Sample diluent composition: Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

PACKAGE DETAILS

Product Catalog Number	A03
Package specifications	20 test/box
Sealed pouch with desiccant	20 packs with 1 test of Dr. Protector COVID-19 IgG/IgM antibody test card
Sample Diluent	3ml per bottle
User Manual Guide	1 piece / box

Note: Do not mix or interchange different batches of kits.

STORAGE & STABILITY

Store the test card at 2-35℃ with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

SPECIMEN COLLECTION AND PREPARATION

1. Sample should be human serum, plasma.

***Fingertip blood and whole blood, other body fluid and samples may cause incorrect or inaccurate results.**

2. Serum test:

Venous blood should be collected under sterile condition in no any anticoagulant blood collection tube.

3. Plasma test:

Venous blood should be collected under sterile condition in EDTA blood collection tube

4. Serum or plasma should be tested within 4 hours after blood collection in room temperature. If testing will be delayed, serum and plasma may be stored up to 48 hours at 2-8 ℃ or stored for 3 months at -20 ℃ before testing. Do not heat the samples and discard hemolyzed samples.

PROCEDURE

1. Collect specimens according to user manual.

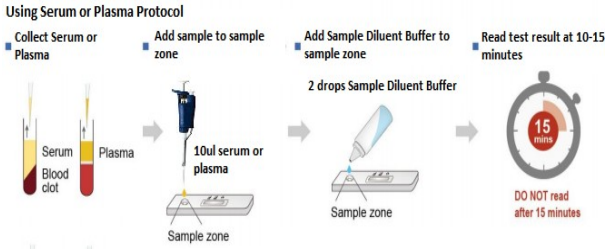
2. Test card, sample and reagent should reach to room temperature (15-30 ℃) before test.

3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

4. Put the test card on a clean table, horizontally placed.

5. Using sample transfer pipette, deliver sample (10 μL of serum or plasma sample into the sample port on the test card. Then add 2 drops of sample diluent immediately into sample zone.

6. Read the results visually at 10-15 minutes. The result cannot be read if over 15 minutes reaction time.



QUALITY CONTROL (QC)

1. Control line (C line in the above diagram) in the result zone on the Testing Strip serves as an indicator for product validity.

2. Regardless if positive or negative samples, the C line must appear. It will also serve as internal control for sample processing.

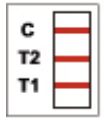
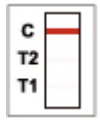
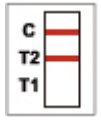
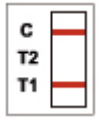
3. Clean and clear background of Testing Strip is served as internal control for negative result. If colour appearance on background which affect result observation will be define as invalid result.

LIMITATIONS

1. This product only indicates the qualitative level of IgM and IgG antibodies against COVID-19 coronavirus and should not be used as the sole criteria for the diagnosis of COVID-19. Quantitative values of IgM and IgG antibodies cannot be determined by the test

2. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

RESULT

Antibody Result	Observation Result	Antibody Result	Observation Result
IgG and IgM Positive		IgG and IgM Negative	
IgG Positive		IgM Positive	
Invalid Result			

PRECAUTIONS

1. This product is for in-vitro diagnostics use only.

2. Clean possible contaminated areas with stringent cleaning procedure after use to avoid infection.

3. Please check the expiration date before use. Do not use the product beyond expiration date.

4. Leave all components in their sealed pouches until use. Discard the product if not used immediately after unpacking pouches to avoid changes in product quality that may affect the test result.

4. Please follow the Instruction for Use and use it immediately after unpacking pouches. No interruption is allowed. Do not use methods not described in the Instruction for Use.

6. Discard the test strip and tips into infectious waste when after use.

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