COVID-19 Human IgM/IgG Rapid Test

Intended Use

This product is a lateral flow immunoassay for the rapid detection of human IgM and IgG antibodies against COVID-19 virus in human whole blood, plasma, or serum. This product is for professional use only.

Background

In 2019, a novel coronavirus was identified as the cause of an outbreak of severe respiratory disease in China. On February 11, 2020, the disease was officially named “Coronavirus Disease 2019” (COVID-19). As the first line of defense against viral infection, human IgM antibody is generated when one becomes infected with the COVID-19 virus. The level of IgM will rise within 2 weeks and then drop; accordingly, a second antibody IgG, which is more protective than IgM antibody, develops within 4 weeks. Therefore, the detection of human IgM/IgG antibodies in blood not only serves as an evidence of viral exposure, but also provides the stage of infection and antibody protection.

Principle

COVID-19 Human IgM/IgG Rapid Test utilizes the technique of chromatography and qualitative immunoassay to detect the presence of IgM and IgG antibodies against COVID-19 virus in human whole blood, plasma or serum. During testing, the blood sample firstly interacts with COVID-19 protein antigen labeled gold nanoparticles in the sample zone. By capillary action, the mixed sample flows across the membrane strip. Human IgM antibodies interact with the anti-human IgM antibody coated in the IgM result zone showing a visible colored line. Similarly, a colored line in the IgG test zone demonstrates the presence of human IgG antibodies. Control line must appear every time to ensure the quality of the sample processing.

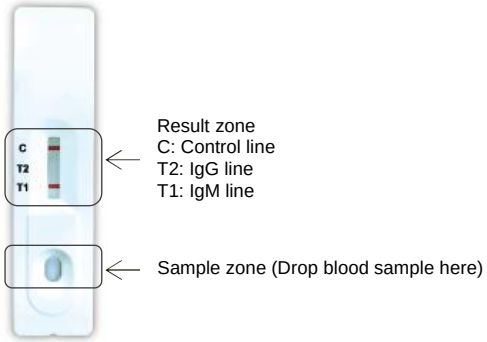
Content

COVID-19 Human IgM/IgG Rapid Test contains Instruction for Use, COVID-19 Testing Strip (Pouch 1), and Sample Buffer (Pouch 2).

Pouch 1: COVID-19 Testing Strip
Pouch 2: Sample Buffer

Pouch 1	Pouch 2
	

The result zone and sample zone of Testing Strip are shown below:



Reagent Ingredients

1. Testing Strip:
- COVID-19 tag fusion protein
- Anti-tag antibody
- Anti-human IgM antibody
- Anti-human IgG antibody

2. Sample Buffer

Expiration Date

Manufactured date, expiration date and lot number are indicated on the packaging. Expiration date is 12 months after the date of manufacture.

Storage Environment

Store product at 15°C - 30°C and avoid direct exposure to sunlight. Do not open until ready to use. Do not freeze or store the product outside the temperature range described above. Do not use it after the expiration date.

Instruction before Usage

1. Operate this product at room temperature 15°C - 30°C.
2. Please read Instruction for Use, Limitations and Precautions carefully before using this product.

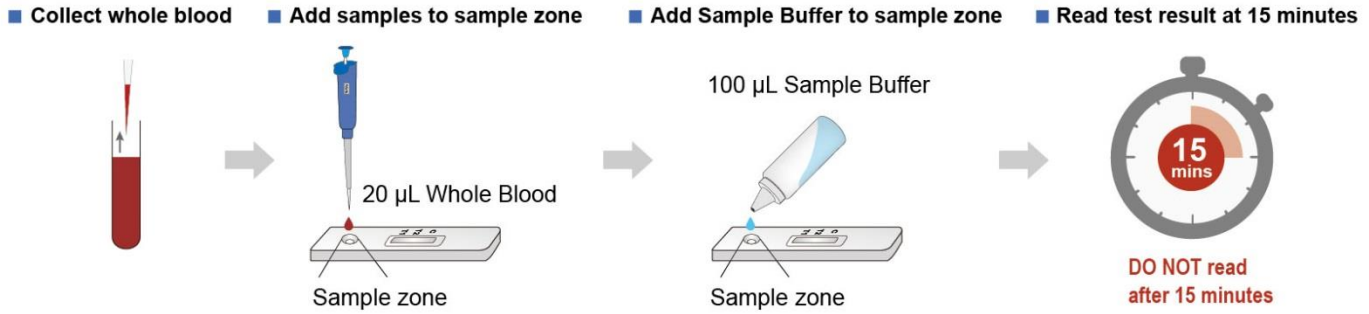
Sample Requirement

Whole blood sample should be used fresh. Plasma or serum sample can be stored at 2°C - 8°C for no more than one week. Bring plasma and serum back to room temperature 15 minutes before use.

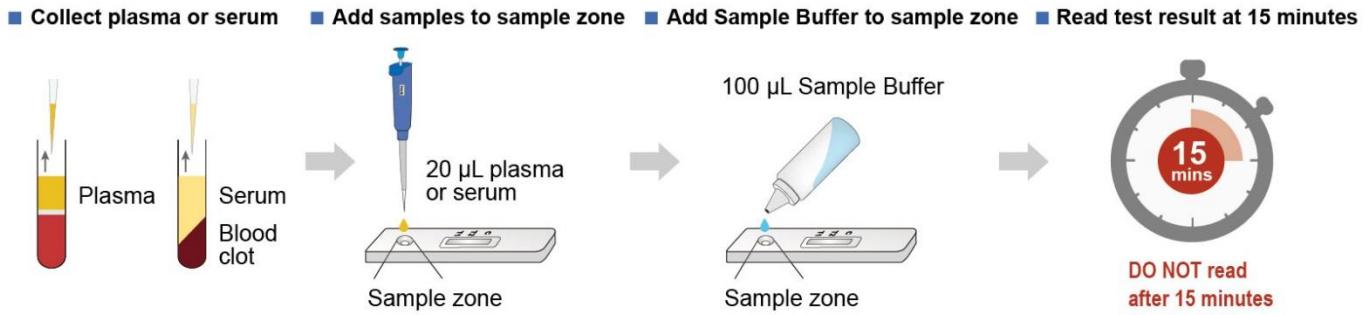
Instruction of Use

1. Take out Pouch 1 and Pouch 2, and adjust to room temperature (15°C - 30°C).
2. Unpack Pouch 1 and take out the Testing Strip. Place the Testing Strip on a balanced surface.
3. Take 20 µL whole blood, 10µL plasma, or 10µL serum with a pipette, and drop the sample into the sample zone of the Testing Strip (DO NOT drop the sample into the result zone).
4. Wait until the sample has fully penetrated the sample zone, unpack Pouch 2 and add 100 µL Sample Buffer to the sample zone of the Testing Strip (DO NOT drop the Sample Buffer into the result zone).
5. Wait 15 minutes for the colored line(s) to appear and then read the result (DO NOT read after 15 minutes).

Using whole blood

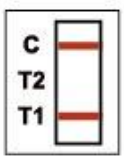
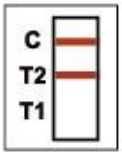
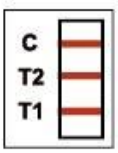
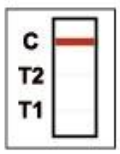
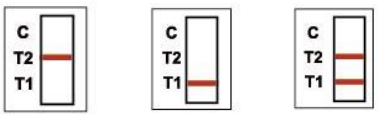


Using plasma or serum



Interpretation of Result

Result zone of the Testing Strip indicates human IgM line (T1 line), IgG line (T2 line) and control line (C line). C line must appear to ensure the quality of sample processing. Please refer to the diagram below for interpretation:

IgM Positive  Colored lines appear in C line and T1 line. Indicate high concentration of COVID-19 IgM in the serum. Please consult a physician for further follow-up.	**IgG Positive**  Colored lines appear in C line and T2 line. Indicate high concentration of COVID-19 IgG in the serum. Please consult a physician for further follow-up.	**IgM and IgG Positive**  Three colored lines appear in C line, T1 line and T2 line. Indicate high concentration of both COVID-19 IgM and IgG in the serum. Please consult a physician for further follow-up.
IgM and IgG Negative  One colored line appears in C line. T1 and T2 line are absent.	**Invalid**  All products are processed follow stringent manufacturing principles. If the C line fails to appear, the test is invalid even if T1 line or T2 line is colored.	

Quality Control

Control line (C line in the above diagram) in the result zone on the Testing Strip serves as an indicator for product validity. Regardless if positive or negative samples, the C line must appear. It will also serve as internal control for sample processing.

Limitations

1. An Emergency Use Authorization (EUA) has been applied to the FDA. This test is under reviewed by the FDA.
2. This product is designed for testing of human IgM and IgG antibodies against COVID-19 coronavirus in human blood samples. Any results derived from other body fluid samples may not be interpreted correctly based on the current criteria.
3. 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.
4. To confirm a positive result, additional tests and clinical evaluation should be conducted under physician's supervision.
5. Positive results may be due to past or present infection with Non-COVID-19 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
6. A negative result does not rule out infection by COVID-19 coronavirus, because antibodies to COVID-19 coronavirus may be absent or low titer at the time of sample collection.
7. If the test result is negative but clinical symptoms persist, complementary tests using other analytical methods are warranted.

Precautions

1. This product is for professional use only.
2. The Product Registration Certificate No. has not been obtained for this product. It is for low complexity testing in laboratories or by healthcare workers at the point-of-care.
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.
5. 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. The product is for single-use only.
7. Clean possible contaminated areas with stringent cleaning procedure after use to avoid infection.

Symbols

	Do not reuse		Do not use if package is damaged		Temperature limit: 15°C - 30°C
	Consult instruction for use		Manufacturer	REF	Catalog number
LOT	Lot number		Use by		Date of manufacture