Atlas Medical CE

COVID-19 IgG/IgM Rapid Test
(Whole Blood /Serum/Plasma)

IVD *For In-Vitro diagnostic and professional use only*

2 - 30°C Store at (2-30 ℃)

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a test rapid for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma.

INTRODUCTION

COVID-19 is an interspecies infectious disease that is caused by a novel coronavirus with a nucleocapsid of helical symmetry that envelopes a positive single stranded RNA genome. Infection by this virus is zoonotic; which means it can be transmitted between species. Symptoms, however, vary drastically. In humans, the novel coronavirus causes acute respiratory tract complications that can range from mild to lethal. Symptoms most commonly include; fever, dry cough, fatigue, sputum production, sore throat, and headache. Infected individuals usually show signs of infection within 2 to 14 days of exposure, and will recover without the need for special treatment. Elderly, diabetic, immuno-compromised, and those patients with cardiovascular conditions, for instance, are at higher risk of developing severe responses to the virus, such as pneumonia, kidney failure, and even death.

The 1960s witnessed the discovery of human coronaviruses. Other members of the family have emerged since, including SARS-CoV in 2003, HCoV NL63 in 2004, HKU1 in 2005, MERS-CoV in 2012, and the novel SARS-CoV-2 in 2019. According to the European Centre for Disease Prevention and Control, the COVID-19 virus spreads primarily through common substances of human origin that include bodily fluids, such as mucus and saliva.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette is an antibody-capture immunochromatographic assay for the simultaneous detection and differentiation of IgM & IgG antibodies to COVID-19 virus in human serum, plasma, and/or whole blood samples. COVID-19 virus-specific antigens are conjugated to a colloidal gold and deposited on the conjugate pad. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized on two individual test lines (IgG and IgM) of the nitrocellulose membrane. The IgM line is closer to the sample well and followed by the IgG line. When the sample is added the gold-antigen conjugate is rehydrated and the COVID-19 IgM and/or IgG antibodies, if any in the sample, will interact with the gold conjugated antigen. The immunocomplex will migrate towards the test window until the test zone (IgG/IgM) where they will be captured by the relevant anti-human IgM and/or anti-human IgG , forming a visible pink line, indicating positive results. If COVID-19 antibodies are absent in the sample, no pink line will appear in the test lines (IgG and IgM), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

MATERIALS

MATERIALS PROVIDED

- Test cassette.
- Buffer.
- Dropper.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Timer.
- Centrifuge.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Never smoke, drink, or eat in the assay laboratory.
- The test cassette should remain in the sealed pouches until use.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
- This package insert must be read completely before performing the test.
- Do not interchange the buffer and test cassettes of different lots.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The tests are packaged in the sealed pouch at room temperature or refrigerated 2-30°C.
- The test cassette is stable through the expiration date printed on the sealed pouch.
- Do not freeze.
- The test cassette must remain in the sealed pouch until use.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The COVID-19 Rapid Test Cassette can be performed using whole blood ,serum or plasma.
2. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days. For long term storage, specimens should be kept at -20°C.
4. Allow sample to reach room temperature before proceeding. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations.
6. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (18-25°C) before use.

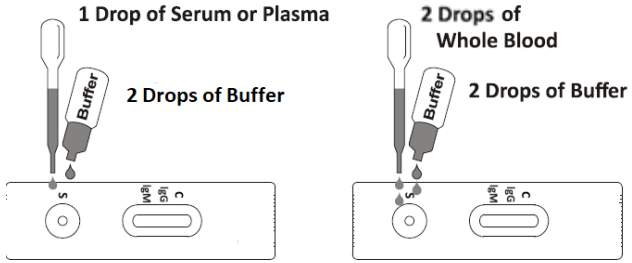
1. Take the test cassette from the sealed pouch.
2. Place the test cassette on a clean and level surface.

For serum or plasma specimen:

3. Hold the dropper and transfer **1 drop of serum or plasma (approximately 10 µL)** to the specimen well of test Cassette，then add **2 drops of buffer (approximately 90µL)** and start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.

For whole blood specimen:

4. Hold the dropper and transfer **2 drops of whole blood (approximately 20 µL)** to the specimen well, then **add 2 drops of buffer (approximately 90 µL),** and start the timer. See illustration below.
5. Wait for the colored line(s) to appear. The result read after 15 minutes. Do not interpret results after 30 minutes.



INTERPRETATION OF RESULT

(PLEASE REFER TO THE ILLUSTRATION BELOW)

POSITIVE: **Three lines appear**. One colored line should always appear in the control line region (C) and another two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

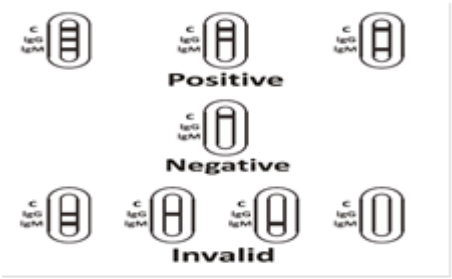
IgM Positive: Along with line in Control region (C), a line appears in IgM region.

IgG Positive: Along with line in Control region (C), a line appears in IgG region

NOTE: The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of 2019-nCoV antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line regions (IgM and IgG).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms adequate membrane wicking.

LIMITATIONS

- The COVID-19 Rapid Test Cassette is for qualitative detection of antibodies in human whole blood, serum or plasma.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting antibodies against COVID-19 virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Cassette was compared with a leading commercial ELISA. The study included 368 specimens for IgG and IgM.

IgG Results

Method		ELISA Results		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	74	2	76
	Negative	3	103	106
Total Results		77	105	182

Sensitivity: 96.1% (95%CI*: 91.8%~100%)
Specificity: 98.1% (95%CI*: 95.5%~100%)
Accuracy: 97.2%(95%CI*: 94.8%~99.6%)
* Confidence Interval

IgM Results

Method		ELISA Results		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	76	4	80
	Negative	5	101	106
Total Results		81	105	186

Sensitivity: 93.8%(95%CI*:88.6%~99.1%)
Specificity: 96.2%(95%CI*:92.5%~99.9%)
Accuracy: 95.1%(95%CI*:92%~98.2%)

* Confidence Interval

2. CROSS -REACTIVITY

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity with materials pathogens and the weak cross reactivity is observed with SARS-CoV-Antibody.

3. INTERFERING SUBSTANCES

The following potentially interfering substances were added to SARS-CoV-2 negative and positive specimens.

SUBSTANCE	CONCENTRATION
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	2 g/dL
Hemoglobin	1000 mg/dL
Bilirubin	1 g/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Creatine	20 mg/dL
Albumin	2 g/dL
Oxalic acid	60 mg/dL
Ethanol	1%
Uric Acid	20 mg/ml

- None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

- World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if the package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry