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InstantRapid® SARS-CoV2 IgG IgM Test

Instructions for Use

The InstantRapid® SARS-CoV-2 IgG IgM Test is an immunochromatographic assay intended for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma from individuals with current or prior COVID-19 infection.

INTRODUCTION

The InstantRapid® SARS-CoV-2 IgG IgM Test is intended for use as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The InstantRapid® SARS-CoV-2 IgG IgM Test should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate and high complexity test and as applicable, Point of Care (POC) testing. Results are for the detection of SARS CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Patients may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of The InstantRapid® SARS-CoV-2 IgG IgM early after infection in unknown.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for InstantRapid® SARS-CoV-2 IgG IgM Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay as appropriate.

The InstantRapid® SARS-CoV-2 IgG IgM Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY

This product is used for in vitro qualitative detection of SARS-CoV2 IgG/IgM antibodies in human serum/plasma/whole blood. Coronavirus (CoV) belongs to the Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. Genera α, β are only pathogenic to mammals, genera γ mainly causes infection in birds. 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. There are 7 types of human coronavirus (HCoV) that cause human respiratory disease: HCoV-229E, HCoV- OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV2, which are the important pathogens of human respiratory infections. SARS-CoV2 may cause COVID-19 which first appeared in Wuhan China in November 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, which can rapidly develop into severe pneumonia, respiratory failure, and acute respiratory distress syndrome, septic shock, multiple organ failure and severe acid-base metabolism disorders, which can even become life-threatening. SARS-CoV2 is also named 2019-nCoV.

PRINCIPLE

The reagent utilizes the principle of capture reaction and combines with colloidal gold immunochromatography. The test card contains: a colloidal gold-labeled recombinant SARS-CoV2 antigen and gold markers for quality control antibodies; nitrocellulose membrane with two test lines (G and M lines); and one quality control line (C line). The M line is fixed with a monoclonal anti-human IgM antibody for detecting the SARS-CoV2 IgM antibody. The G line is fixed with a reagent for detecting the SARS-CoV2 IgG antibody. The C line is fixed with a quality control antibody.

When an appropriate amount of the test sample is added into the sample reservoir of the test card, the sample will be move forward along the test card under the capillary action. If the sample contains IgM antibody, the antibody will bind to the colloidal gold-labeled SARS-CoV2 antigen. The immune complex will then be captured by anti-human IgM antibodies immobilized on the membrane, forming a purple-red M line, showing a positive SARS-CoV2 IgM antibody result. If the sample contains IgG antibodies, the antibodies will bind to the colloidal gold-labeled SARS-CoV2 antigen. The immune complex will then be captured by IgG antibodies immobilized on the membrane, forming a purple-red G line, indicating a positive SARS-CoV2 IgG antibody result. If the test line G and M are not colored, a negative result is displayed. The test card also contains a quality control line C, which should appear regardless of whether there is a test line. The quality control line C is the color belt of the quality control antibody immune complex. If the quality control line C does not appear, it indicates that the test result is invalid, and the sample shall be retested with another test.

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MATERIALS SUPPLIED

1 x Test. Each test cassette is packed in a pouch with a disposable dropper and a package of silica;

1 x Assay buffer

1 x Lancet

1 x Instructions for Use

PRECAUTIONS

1. For in-vitro diagnostic use.
2. Must not use kit beyond the expiration date.
3. Do not mix components from kits with different lot number.
4. Avoid microbial contamination of reagents.
5. Use the test as soon as possible after opening to protect it from moisture.

SPECIMEN COLLECTION AND STORAGE

The Test can be stored at any temperature between 2-30℃. Do not freeze. The stability of the kit under these storage conditions is 18 months. The test card should be used within 1 hour after opening the inner package to prevent the failure of detection due to moisture absorption.

SAMPLE REQUIREMENT

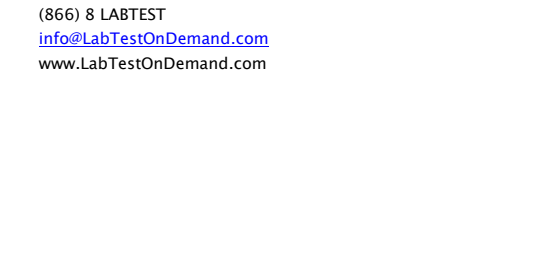
1. This kit can be used for the detection of serum/plasma/whole blood samples. Include plasma or whole blood samples prepared from clinically used anticoagulants (EDTA, heparin, sodium citrate)
2. Separate serum as soon as possible during sample collection to avoid hemolysis. The sample can be stored for 5 days at 2 ~ 8℃. Long-term preservation should be frozen below -20 ℃, avoid repeated freezing and thawing. Anticoagulated whole blood samples should not be stored for more than 72 hours at room temperature and not more than 7 days at 2-8 ℃.
3. The refrigerated/frozen sample should be returned to room temperature and mixed evenly before testing. When clearly visible particulate matter is present in the sample, it should be centrifuged to remove sediment before testing.
4. If the sample contains a large amount of lipid, hemolysis or turbidity, do not use it, so as not to affect the test result.

TEST PROCEDURE

Preparations: Allow all reagents and samples to equilibrate to room temperature before proceeding with the test. Write the specimen number on the cassette and sample preparation device.

Procedure:

1. Remove the test device from its protective pouch, lay it on a dry and clean flat surface, and label the device with patient or specimen number.
2. Use a micropipette or a dropper to take 10μl of serum or plasma and 20μl whole blood sample, directly into the well, and then add the 2 drops (about 70-100ul) assay buffer into the well. Start the timer.
3. Leave the test at room temperature and read the results within 15 minutes. Do not read result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the above illustration)

Negative: One pink line appears in control line C, and no G and M line in test region. Which showing that no SARS-CoV2 IgG/IgM was detected and the result was negative.

Positive:

1. If C line and M line appear in the test region, it means that SARS-CoV2 IgM antibody was detected and the result was positive for IgM antibodies.
2. If C line and G line appear in the test region, it means that SARS-CoV2 IgG antibodies was detected and the result was positive for IgG antibodies.
3. If C line, M line and G line appear in the test region, it means that SARS-CoV2 IgG and IgM antibodies was detected and the result was positive for IgG and IgM antibodies.

Invalid: If the quality control line C is not observed, it is invalid regardless of whether the detection line is displayed, and the test should be repeated.

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PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A total of 208 samples from susceptible subjects were tested by the InstantRapid® SARS-CoV-2 IgG IgM Test and by PCR test. Comparison for all subjects is shown in the following table. Taken together the InstantRapid® SARS CoV-2 IgG IgM Test had a Positive Percent Agreement and Negative Percent Agreement of 96.4% (95% CI: 90.3%-98.6%) and 98.7% (95% CI: 94.5%-99.6%).

Method		PCR		Total Results
	Results	Positive	Negative	
InstantRapid® SARS CoV-2 IgG IgM Test	IgG+/IgM+	15	O	15
	IgG-/IgM+	12	0	12
	IgG+/IgM-	26	2	28
	IgG-/ IgM-	2	151	153
Total Results		55	153	208

Relative sensitivity: **96.4%** (95%CI:*90.3%-98.6%)

Relative specificity: **98.7%** (95%CI:*94.5%-99.6%)

Accuracy: **98.1%** (95%CI:*93.8%-99.3%)

*Confidence Intervals

Clinical Evaluation: A total of 571 samples from susceptible subjects were tested by the InstantRapid® SARS-CoV-2 IgG IgM Test and by PCR test. Comparison for all subjects is shown in the following table. Taken together the InstantRapid® SARS CoV-2 IgG IgM Test had a Positive Percent Agreement and Negative Percent Agreement of 92.7% (95% CI: 87.6-96.2%) and 98.8% (95% CI: 97.2%-99.6%).

Method		PCR		Total Results
	Results	Positive	Negative	
InstantRapid® SARS CoV-2 IgG IgM Test	IgG+/IgM+	115	O	115
	IgG-/IgM+	12	2	4
	IgG+/IgM-	26	3	29
	IgG-/ IgM-	12	401	413
Total Results		165	406	571

Positive Percent Agreement **92.7%** (95% CI: 87.6-96.2%)

Negative Percent Agreement **98.8%** (95% CI: 97.2%-99.6%)

Accuracy **97.1%**

Precision

Intra-Assay Within-run precision has been determined by using 20 replicates of five specimens: a negative, a SARS-CoV2 IgM low titer positive, a SARS-CoV2 IgM high titer positive, a SARS-CoV2 IgG low titer positive and a SARS-CoV2 IgG high titer positive. The negative, a SARS-CoV2 IgM low titer positive, a SARS-CoV2 IgM high titer positive, a SARS-CoV2 IgG low titer positive and a SARS-CoV2 IgG high titer positive values were correctly identified 100% of the time.

Inter-Assay Between-run precision has been determined by 20 independent assays on the same five specimens: a negative, a SARS-CoV2 IgM low titer positive, a SARS-CoV2 IgM high titer positive, a SARS-CoV2 IgG low titer positive and a SARS-CoV2 IgG high titer positive. Three different lots of the One Milo InstantRapid® SARS-CoV2 IgG IgM Test have been tested over a 3-month period using negative, a SARS-CoV2 IgM low titer positive, a SARS-CoV2 IgM high titer positive, a SARS-CoV2 IgG low titer positive and a SARS-CoV2 IgG high titer positive specimens. The specimens were correctly identified 100% of the time.

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Cross-reactivity The InstantRapid® SARS-CoV2 IgG IgM Test has been tested for HAMA, RF, Influenza A/B antibody and Adenovirus antibody positive specimens. Theoretically, there is no cross reaction with MERS CoV, and there may be cross reaction with SARS CoV.

ATTENTION

1. Before carrying out any test, the operating instructions must be read completely. The kit can be kept at room temperature. The experimental environment should be kept at a certain humidity and sheltered from wind to avoid carrying out the experiment at a high temperature.
2. The reagent stored at low temperature should be balanced to room temperature before use.
    1. Appropriate biosafety assurance procedures should be in place for substances containing and suspected of having sources of infection. The following are relevant considerations:

        a. Handle samples and reagents with gloves;

        b. Do not take samples with your mouth;

        c. Do not smoke, eat, drink, beautify or treat contact lenses while handling these items;

        d. Disinfect spilled samples or reagents with disinfectant;

        e. Disinfection and treatment of all sample reagents and potential contaminants in accordance with local regulations;

        f. All components of the kit remain stable until the expiration date under the condition of proper treatment and preservation, and cannot be used beyond the expiration date of the kit.
3. The degree of color depth of the detection line is not necessarily related to the titer of the object to be measured in the sample.
4. Do not replace the ingredients in this kit with those in other kits.
5. No samples of hemolysis can be tested. Do not use turbid contamination samples for detection.
6. Do not dilute the sample after testing, or you may get inaccurate results.
7. This kit will show negative results under the following conditions: when the titer of the SARS-CoV2 antibody in the sample is lower than the minimum detection limit of the kit, or the SARS-CoV2 antibody has not appeared at the time of sample collection.
8. Samples containing higher titers of heterophilic antibodies or rheumatoid factors may affect expected results.

The following information should be included in patient reports to healthcare providers:

Limitations of the Procedure:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- This test is not for the screening of donated blood.

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