IgM/IgG

Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

Model:10 Test Sets/Kit 20 Test Sets/Kit

[Product Name]

Generic Name: Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)

[Intended Use]

This product is used for in vitro qualitative detection of Coronavirus (SARS-CoV-2) IgM/IgG antibody in human serum, plasma and whole blood samples.

[Test Principle]

This product contains one IgM test cassette and one IgG test cassette. The IgM test uses colloidal gold immunochromatography technology to detect the Coronavirus (SARS-CoV-2) IgM antibody. The anti-human IgM antibody labeled by colloidal gold is coated on the conjugate pad. Meanwhile, on the cellulose nitrate membrane, the antigens of Coronavirus (SARS-CoV-2) are coated in the test area, and goat anti-mouse antibody is coated in the control area. While testing, the IgM antibody in the test sample (the specific IgM antibody to Coronavirus (SARS-CoV-2) and non-specific IgM antibody) binds with the colloidal gold labeled anti-human IgM antibody and forms an immune complex. The immune complex moves along the membrane through chromatography. If there is specific IgM antibody to Coronavirus (SARS-CoV-2) in the test sample, it will be captured by the antigens coated in the test area, forming a visible band (test line); The free colloidal gold conjugate or immune complex continues to move forward, and binds specifically with the goat anti-mouse antibody coated in the control area, forming a visible band (control line). If the test sample doesn't contain any Coronavirus (SARS-CoV-2) IgM antibody, only a control line will appear. The IgG test uses colloidal gold immunochromatography technology to detect the Coronavirus (SARS-CoV-2) IgG antibody. The anti-human IgG antibody labeled by colloidal gold is coated on the conjugate pad. Meanwhile, on the cellulose nitrate membrane, the antigens of Coronavirus (SARS-CoV-2) are coated in the test area, and goat anti-mouse antibody is coated in the control area. While testing, the IgG antibody in the test sample (the specific IgG antibody to Coronavirus (SARS-CoV-2) and non-specific IgG antibody) binds with the colloidal gold labeled anti-human IgG antibody and forms an immune complex. The immune complex moves along the membrane through chromatography. If there is specific IgG antibody to Coronavirus (SARS-CoV-2) in the test sample, it will be captured by the antigens coated in the test area, forming a visible band (test line); The free colloidal gold conjugate or immune complex continues to move forward, and binds specifically with the goat anti-mouse antibody coated in the control area, forming a visible band (control line). If the test sample doesn't contain any Coronavirus (SARS-CoV-2) IgG antibody, only a control line will appear.

[Components]

No.	Components	Packaging Specification	
		10 Tests	20 Tests
1	IgM test cassette On the cellulose nitrate membrane, the test area is precoated with recombinant antigens of the Coronavirus (SARS-CoV-2), while the control area is precoated with the goat anti- mouse antibody. The fiberglass is precoated with the mouse anti-human IgM antibody labeled by colloidal gold	10 Tests	20 Tests
2	IgG test cassette On the cellulose nitrate membrane, the test area is precoated with recombinant antigen of the Coronavirus (SARS-CoV-2), while the control area is precoated with the goat anti- mouse antibody. The fiberglass is precoated with the mouse anti-human IgG antibody labeled by colloidal gold	10 Tests	20 Tests
3	Pipette	10pcs	20pcs
4	Sample diluent buffer solution containing sodium chloride	3 mL×1pc	3 mL×2pcs

Note: Components from the different batches can't be mixed up for use.

[Materials required but not provided]

1. Timer
2. Container for collecting samples

[Storage and shelf life]

1. Store at 2～30°C. The shelf life is temporarily set as 6 months.
2. Keep dry and keep in dark place.
3. The test should be finished within 30 minutes after the aluminum foil bag is unsealed. In case of the ambient temperature above 30 °C or the humidity above 70%, it should be used as soon as possible.
4. The manufacture date and expiry date can be found in the label of the kit.

[Sample Collection, handling and storage]

1. The product can be used for testing serum, plasma or whole blood samples.
2. The plasma or whole blood sample to be tested can be anticoagulated with sodium citrate, EDTA-K_2 or heparin sodium.
3. Samples with hemolysis, high viscosity, high fat, bacteria growth or contamination are not suitable for this product.
4. Serum or plasma samples can be stored at 2-8 °C for 7 days. For long term storage, the samples should be kept at - 20 °C to avoid repeated freezing and thawing. The whole blood sample is recommended to be tested within 5days and stored at 2-8 °C. Frozen storage is prohibited.

[Test Procedures]

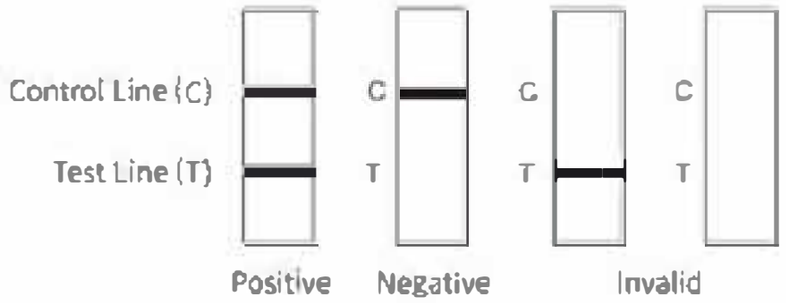
1. Preparation
   a) Take out the tested samples and the test kit needed from the storage condition and allow them to reach the room temperature.
   b) Take out the test cassette from the packaging bag and put it on a dry surface.
2. Testing
   a) Sample addition
   For serum / plasma sample: add 10μL of serum or plasma sample

into the sample well (S) of IgM test cassette and IgG test cassette, and add vertically 2 drops (about 100μL) of sample diluent.

For whole blood sample: add 20μL of whole blood sample into the sample well (S) of IgM test card and IgG test card, and add vertically 2 drops (about 100μL) of sample diluent.

b) Within 1-15 minutes after sample addition, the result can be interpreted as positive while both the control line and test line appear. If only the control line appears and the test line does not appear in 15 minutes, the result can be interpreted as negative. It is invalid to read result after 15 minutes.

[Interpretation of Test Result]



1. Positive result:

a) IgM positive, IgG positive: IgM test cassette appears both control line (C) and test line (T); IgG test cassette appears both control line (C) and test line (T).

b) IgM positive, IgG negative: IgM test cassette appears both control line (C) and test line (T); IgG test cassette appears only control line(C), but no test line (T).

c) IgM negative, IgG positive: IgM test cassette appears only control line(C), but no test line (T); IgG test cassette appears both control line (C) and test line (T).

2. Negative result: IgM test cassette appears only control line(C), but no test line (T); IgG test cassette appears only control line(C), but no test line (T).

3. Invalid result: If IgM and/or IgG test cassette appears no control line(C), no matter whether the test line (T) appears or not, the test result is invalid. A repeat test should be done in case of invalid result appears.

[Limitations of the Test Procedures]

1. The product can only be used for in vitro test of individual' s serum, plasma or whole blood samples.
2. A Coronavirus (SARS-CoV-2) infection may not be excluded if the test result is negative.
3. The test result is only for clinical reference and should not be regarded as the only reference for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, physical signs, medical history, other laboratory tests (especially etiology test), treatment response and epidemiological information.
4. In patients with impaired immune function or receiving immunosuppressive therapy, the value of serological antibody test is limited.
5. IgM antibody positive not only occurs in primary infection, but also in secondary infection.
6. The IgM and IgG antibody of Coronavirus (SARS-CoV-2) which this product targets does not directly reflect the presence of Coronavirus (SARS-CoV-2) in the sample.

[Warnings and Precautions]

1. The product is for in vitro diagnosis only.
2. Operation and interpretation of the result must be carried out in strict accordance with the insert.
3. The product is intended for qualitative test, and it cannot get a quantitative result.
4. The kit should be used within the shelf life.
5. The test cassettes and pipettes are for single use and cannot be reused.
6. Because of the difference in titers of the samples, the test line will show different color intensity, all of which indicate a positive result. The color intensity of the test line cannot be used as a reference base for determining the antibody titer in the sample.
7. Before testing, the samples stored at low temperature shall stand to reach the room temperature and be well mixed.
8. An inactivation of 56°C incubation for 30 minutes does not influence the test result.
9. Samples and wastes must be handled as potential infectious sources, and the desiccant in the aluminum foil bag is inedible.

【Manufacturer】
Name: Zhuhai Livzon Diagnostics Inc.
Address: No. 266 Tongchang Road, Xiangzhou District, 519060 Zhuhai, Guangdong, P. R. China
Contact: Tel: +86-0756-8919728 Fax:+86-0756-8204052

【EU Representative】
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Contact: Tel: +49-40-2513175 Fax: +49-40-255726

Glossary of Symbols

	Manufacturer
EC REP	Authorized Representative
IVD	*In Vitro* diagnostic medical device
LOT	Batch Code/Lot Number
	Date of Manufacture
	Temperature limit
Σ	Contains sufficient for <n> Tests
	Use By/Expiry Date
CE	CE marking according to IVD Medical Devices Directive 98/79/EC
	Consult instructions for Use
	Sample Diluent
	Biological risks

This test is provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

· 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.

· Not for the screening of donated blood