

SARS-CoV-2 IgM/IgG Test Kit
(Immunochromatographic Assay)

【Product name】

SARS-CoV-2 IgM/IgG Test Kit (Immunochromatographic Assay)

【Packing specification】

Cat#: EGIVD008, Cassette: 50 pcs/box

【Intended Use】

This test kit is used to qualitatively detect the novel coronavirus (SARS-CoV-2) antibodies in human serum, plasma and venous whole blood samples in vitro. The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. If the test result is positive, further confirmation is needed. Negative test result cannot rule out the possibility of infection.

The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the condition in combination with the clinical manifestations of patients and other laboratory tests.

When performing the novel coronavirus laboratory test, the Technology Guide for Conducting Novel Coronavirus Infection Laboratory Test and other requirements should be followed, to ensure biological safety.

【Principle】

This Immunochromatographic Assay Test Kit contains an IgM antibody test strip and an IgG antibody test strip, each comes with a test line and a control line. When the sample is added to the sample well of the cassette, the sample travels on the strips and separates. When the sample contains SARS-CoV-2 antibodies in concentrations above or equal to the minimum detection limit, the antibodies combine with black microsphere labeled Mouse anti-Human IgM monoclonal antibodies/black microsphere labeled Mouse anti-Human IgG monoclonal antibodies to form immune complexes that are captured by recombinant S protein fixed to the assay line, and the detection line turns black; when the sample does not contain IgM/IgG antibodies, the detection line does not show colour. The control line should be black regardless of the colour of the detection lines. A colourless control line indicates an invalid test result, and the sample needs to be retested.

【Composition】

	Test cassette, sample diluent, dropper
1	Test cassette: consists of SARS-CoV-2 IgM/IgG test strips and a plastic box; the test strip is made of nitrocellulose membrane, sample pad, conjugate pad, absorbent paper and PVC board. Specifically, the nitrocellulose membrane is coated with neo coronavirus protein and goat anti-mouse IgG polyclonal antibodies, and the conjugate pad contains anti-human IgM/IgG secondary antibodies
2	sample diluent
3	dropper

【Storage and Expiry date】

- The shelf life of kit is 12 months when stored sealed and away from light at 4-30°C.
- Once the inner package is opened and the kit is kept at room temperature (10°C~30°C), please use in 1 hour.
- Production Date and Expire date please see the label and package.

【Apparatus】None

【Specimen】

This kit can work on whole blood, serum and plasma. The sample can be venous blood or fingertip blood (pinch the puncture site, puncture by a sterile blood needle, then press a dry cotton ball on the wound for a moment).

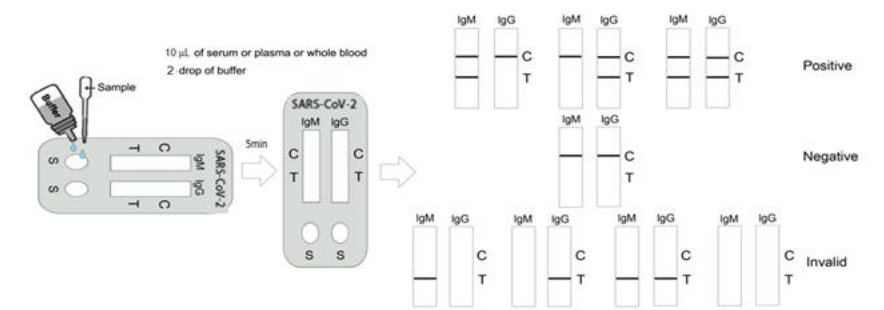
Serum/plasma sample collection: serum and plasma should be separated as soon as possible after collection to avoid hemolysis. The separated serum and plasma

should be tested within 8 hours as soon as possible. If they cannot be used in time, they should be stored at 2°C~8°C for an utmost of 3 days. If storage for more than 3 days is needed, they should be refrigerated at -20 °C for an utmost of 9 days. Before test, restore them to room temperature. Avoid repeated freeze-thaw. Samples with severe hemolysis and thermal inactivation are not recommended to be used.

Venous blood collection: collect blood with an anticoagulant tube, or add an anticoagulant (heparin, EDTA salt, sodium citrate are recommended) into the blood vessel, then add the blood sample and shake it well for later use. It can be stored at room temperature for 8 hours. If it cannot be tested immediately, it can be stored at 2~8 °C for 7 days. Venous whole blood samples stored for over 7 days are not suitable for this reagent.

【Test Procedure】

- Take out the cassette and the sample diluent, and restore to room temperature.
- Open the cassette package, and lay the cassette flat horizontally on the table.
- Absorb 10 μL of sample (serum/plasma/whole blood) and add to the sample well, then immediately add ~100 μL (around 2~3 drops) sample diluent.
- 5 minutes later, read the results. Do not read the results after 10 minutes.



【Interpretation of the Results】

- Negative: If only control line (C) shows color, while test lines for IgM and IgG antibody test strips remain colourless, this means no SARS-Cov-2 IgM/IgG antibodies are detected and the result is negative.
- Positive:
IgM antibody test strip: if both the control line and the test line show colour, that means SARS-Cov-2 IgM antibodies are detected, and the result is SARS-Cov-2 IgM antibody positive.
IgG antibody test strip: if both the control line and the test line show colour, that means SARS-Cov-2 IgG antibodies are detected, and the result is SARS-Cov-2 IgG antibody positive.
- Invalid: if control line(C) fails to appear, then no matter test line G/M appear or not, the result is invalid and new test is needed.

【Warnings and precautions】

- Restore the sample diluent and cassette to room temperature before the test
- Strictly follow the instructions for use.
- Wait for the colour line(s) to appear. Read the results at 5 minutes. Results read later than 10 minutes are invalid.
- Do not use high hemolysis and lipid blood samples

【Performance indicators】

- Detection rate for positive reference materials: should be 5/5
- Detection rate for negative reference materials: should be 10/10
- Limitation of detection (LOD): the LOD reference S1 shall test negative, and S2 and S3 shall test positive
- Repeatability: test 2 repeatability reference materials (J1~J2) for 10 times each, all results should be positive

【Warnings and precautions】

- This product is a disposable in vitro diagnostic reagent. Please avoid repeated use. Do not use expired products.
- Avoid test environment where the temperature is too high. Cassettes and sample diluents stored at a low temperature shall be used after they restore to the room temperature to avoid moisture absorption.
- The used cassette, sample diluent, droppers and so on shall be regarded as biomedical waste and be properly disposed of.
- The desiccant in the aluminum foil compound packaging bag should not be

- taken orally.
- Do not use repeatedly frozen thawed samples. When testing, please restore the sample temperature to room temperature
 - The test samples should be regarded as infectious agents. When conducting tests, please follow the laboratory standards for infectious diseases, and observe biosafety practices.
 - As with all diagnostic reagents, the final diagnosis should be made by the doctors after comprehensively considered all the indicators and clinical symptoms.
 - If you have any question or suggestion about using this reagent, please contact the manufacturer

【Label legends】

	Shelf life		Refer to the Instructions for use
	Production Lot No.		In Vitro Diagnostic Device
	Production Date		Temperature Limit: Store only at the designated temperature range.

【Biography】

N/A

【Basic temperature】

Registrant/Manufacturer: Anhui Enhe Biotechnology Co., Ltd.

International Distributor: Nanjing EnoGene Biotech Co., Ltd.

Website: www.enogene.com

Order: order@enogene.com

CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

CERTIFICATE

ZERTIFIKAT

RIOMAVIX

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Anhui Enhe Biotechnology Co., Ltd

ADDRESS: Area D, 5th floor, building 5, Mingzhu Industrial Park, Hefei high-tech zone, Anhui Province, China

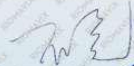
The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: SARS-CoV-2 IgM/IgG Test Kit (Immunochromatographic Assay)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is RPS/706/2020


Executive Director



Issue date: 7/MAY/2020
Cert. No.: R20200512



Riomavix S.L.

Calle de Almansa 55, 1D, Madrid 28039 Spain