SARS-CoV-2 IgG/IgM Rapid Test (Colloidal Gold)

【Catalog Number】

REF CoV19-GM

【Package Size】

☐ 1 Test/box ☐ 20 Tests/box

【Intended Use】

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow immunoassay test intended for in vitro, qualitative, detection and differentiation of SARS-CoV-2 IgM and IgG antibodies in human serum, plasma or whole blood. The kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or earlier infections. At this time, it is unknown for how long antibodies persist following the infection and if the presence of antibodies confers protective immunity.

The kit should not be used as a basis for the diagnosis or exclusion of the SARS-CoV-2 infection, and is not suitable for general population screening.

The usage of this kit is limited to medical institutions (not for the home use).

【Test Principle】

1. The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow immunoassay type test to detect SARS-CoV-2 IgM/IgG antibodies in biological samples. The test cassette contains colloidal gold-labeled SARS-CoV-2 recombinant protein that binds to SARS-CoV-2 IgM or IgG antibodies to form a complex;
2. G-line (IgG detection line) is coated with mouse anti-human IgG that captures the SARS-CoV-2 IgG positive complex, and a red purple line will be generated to indicate the sample is SARS-CoV-2 IgG positive, otherwise the sample is SARS-CoV-2 IgG negative or below the limit of detection;
3. M-line (IgM detection line) is coated with mouse anti-human IgM that captures the SARS-CoV-2 IgM positive complex, and a red purple line will be generated to indicate the sample is SARS-CoV-2 IgM positive, otherwise the sample is SARS-CoV-2 IgM negative or below the limit of detection;
4. C-line (control line) is a built-in control line that captures control substrates and generates a red purple line to indicate the whole procedure is standardized and under control.

【Contents of the Kit】

1. Materials contained in the kit:

Content	1 Test/pack	20 Tests/box
Cassette	1×1	1×20
Sample Dilution	1×300uL	20×300uL
Pipette Dropper	1×1	1×20
Package Insert (IFU)	1×1	1×1

2. Materials not provided but required:
   Lancet | Alcohol wipes | Gloves | Timer

【Storage and Handling】

1. Store at +2 to +30°C in a dry place and avoid direct sunlight. Do not freeze.
2. In case of prolonged time after opening the inner package, the test cartridge may fail due to environmental moisture absorption. Please, use the test within 1 hour.

【Sample Requirements】

1. Suitable for human serum, plasma and whole blood samples;
2. Serum or plasma samples are collected from vein via conventional methods and obtained via proper centrifugation; suitable anticoagulants include sodium heparin, EDTA or sodium citrate;
3. Collected samples are recommended to be tested immediately, serum/plasma samples can be stored at 2-8°C for 5 days, at -20°C for long-term storage. Avoid repeated freeze-thaw cycles.
4. Avoid samples with large amounts of lipids, apparent hemolysis or turbidity.

【Test Method】

Components of the kit should be used only warmed up to the room temperature (25°C±5°C) as follows:

1. Remove the test strip from the sealed package, mark it, if needed, and lay it flat on the working surface;
2. Transfer 10μL of the sample into the sample well vertically, and add 2 drops of sample dilution (roughly 100μL) into the sample well immediately;
3. Read the result within 10-15 minutes.

Note: Do not interpret the result after 15 minutes, for long-term preservation please take photos.

【Quality Control】

1. Each test cassette has a built-in control. A red

colored line in the detection window at the Control line can be considered an internal positive procedural control.

2. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed.

【Interpretation of Results】

Total of three detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.

1. Negative Result

If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

2. Positive Result, M only

If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

3. Positive Result, G only

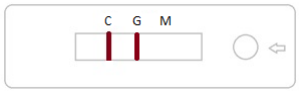
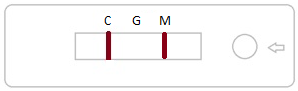
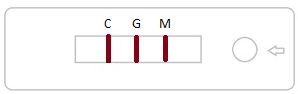
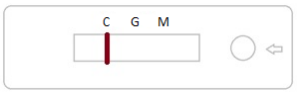
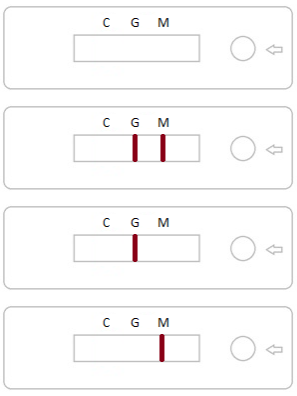
If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

4. Positive Result, G and M

If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

5. Invalid Result

If the quality control line (C) is not visible, then that the result is invalid and a re-test is required.

POSITIVE RESULT	
Visible C-line and G-line indicates SARS-CoV-2 IgG positive	
Visible C-line and M-line indicates SARS-CoV-2 IgM positive	
Visible C-line, G-line and M-line indicates SARS-CoV-2 IgG and IgM positive	
NEGATIVE RESULT	
Visible C-line indicates SARS-CoV-2 IgG and IgM negative	
INVALID RESULT	
Invisible C-line indicates that the result is invalid and a re-test is required	

Note: The color depth of line is related to the concentration of test substrates, the result should be determined by the appearance of the colored line regardless of the color intensity.

【Performance Characteristics】

Specificity & Sensitivity Study

600 samples including 319 negative and 281 positive SARS-CoV-2 RT-PCR confirmed samples were tested and compared to RT PCR test results.

Table1. IgG/IgM Specificity and Sensitivity Test Results

SARS-CoV-2 IgG/IgM Rapid Test Results	SARS-CoV-2 RT-PCR Test Results		Total
	Positive	Negative	
Positive Result, IgM only	45	5	50
Positive Result, IgG only	109	0	109
Positive Result, IgM and IgG	92	0	92
IgG and IgM Negative	35	314	349
Total	281	319	600

The results for IgG or IgM demonstrate a specificity of 98.43% (314/319), and a sensitivity of 87.54% (246/281).

Table2. IgG Specificity and Sensitivity Test Results

SARS-CoV-2 IgG/IgM Rapid Test Results	SARS-CoV-2 RT-PCR Test Results		Total
	Positive	Negative	
Positive Result, IgG only	109	0	109
Positive Result, IgM and IgG	92	0	92
IgG and IgM Negative	35	314	349
Total	236	314	550

The results for IgG demonstrate a specificity of 100%

(314/314) and a sensitivity of 85.17% (201/236).

Table3. IgM Specificity and Sensitivity Test Results

SARS-CoV-2 IgG/IgM Rapid Test Results	SARS-CoV-2 RT-PCR Test Results		Total
	Positive	Negative	
Positive Result, IgM only	45	5	50
Positive Result, IgM and IgG	92	0	92
IgG and IgM Negative	35	314	349
Total	172	319	491

The results for IgM demonstrate a specificity of 98.43% (314/319) and a sensitivity of 79.65% (137/172).

Cross-Reactivity Study

No cross reaction with other coronaviruses or other viruses has been found, such as human coronaviruses (hku1, OC43, nl63 and 229E), SARS coronavirus and MERS coronavirus; H1N1 (new H1N1 influenza virus (2009), seasonal H1N1 influenza virus), H3N2, H5N1, h7n9, influenza B Yamagata, Victoria, respiratory syncytial virus A, B, parainfluenza virus 1, 2, 3, rhinovirus a, B, C, adenovirus 1, 2, 3, 4, 5, 7, 55, enterovirus a, B, C, D, human lung virus, EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella zoster virus; also no cross reaction with bacterial cells as Mycoplasma pneumoniae and Chlamydia pneumonia has been detected.

【Limitations】

1. This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other bodily fluids or secretions.
2. This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.
3. Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.

【Warnings and Precautions】

1. This product is a one-time consumable in vitro diagnostic device that should be used strictly in accordance with this user manual, test should not be reused, or used if damaged or expired.
2. Load sample as soon as possible after removing the test strip from the sealed package as environmental moisture absorption may cause failure.
3. Fresh samples are highly recommended.
4. Wear protective clothing, gloves and mask for safety.
5. Desiccants packed in aluminum foil bag should not be taken orally.

【Disposal of the Device】

The test samples shall be regarded as infectious products, and the handling of reagents and samples shall be in accordance with the operation specifications valid for infectious materials; attention shall be paid to the biosafety operation rules and regulations. All samples and reagents used shall be in accordance with the specifications for infectious medical waste.

【Contact Information】

CE

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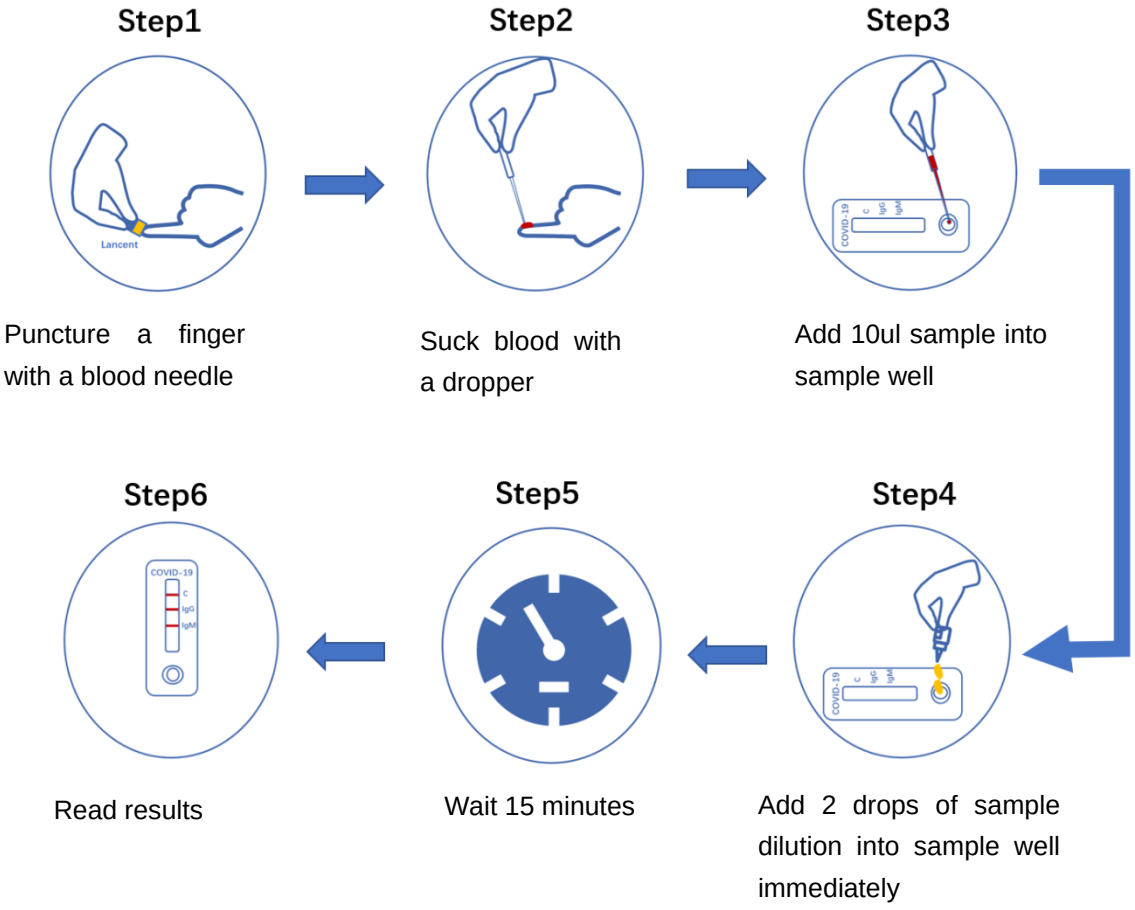
	Manufacturer
EC REP	Authorized EU Representative
	Date of Manufacture
	Use-by date
LOT	Batch Code
REF	Catalogue Number
	Consult Instructions for use
IVD	In Vitro Diagnostic Medical Device
	Do not re-use
	Temperature limit

Finger Stick/Whole Blood Sampling Procedure



Serum/Plasma Testing Procedure