CE

COVID-19 IgM/IgG Antibody Rapid Detection Kit (Colloidal Gold)

【Product Name】

COVID-19 IgM/IgG Antibody Rapid Detection Kit(Colloidal Gold)

【Specification】

One test/package; 1 test/kit; 5 tests/kit; 10 tests/kit; 20 tests/kit; 25 tests/kit; 30 tests/kit; 40 tests/kit; 50 tests/kit.

【Intended Use】

The kit is used for the in vitro qualitative detection of COVID-19 IgM/IgG antibodies in human serum, plasma or whole blood samples. The kit can be used as a supplementary test index for suspected cases with a negative nucleicacid test for the COVID-19 or used in conjunction with nucleic acid or antigen detection in the diagnosis of suspected cases. The results of the kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests. Laboratories conducting laboratory testing for the COVID-19 should meet the requirements of relevant regulations and do a good job in biosafety protection.

【Scope of Application】

The COVID-19 belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the COVID-19 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.

【Principle】

The product adopts antibody capture method and solid phase immunochromatographic method for detection. The sample to be tested (serum/plasma/whole blood) is added to the sample hole and chromatographically. The COVID-19 IgM antibody and IgG antibody in the sample react with the recombinant COVID-19 antigen colloidal gold conjugate to form a colloidal gold-labeled antigen-IgM complex and a colloidal gold-labeled antigen-IgG complex and free colloidal gold labeled chicken IgY. As the sample continues to be chromatographed on the nitrocellulose membrane, it is intercepted by the T-line (detection line) coated with mouse anti-human IgM antibody and formed a colloidal gold-labeled antigen-IgM antibody-coated mouse anti-human IgM antibody immunity complex. There is a red line appears in the T1 line. The uninterrupted colloidal gold immune complex continues to be chromatographed and it is intercepted by the T2 line (detection line) coated with mouse anti-human IgG antibody to form a colloidal gold labeled antigen-IgG antibody-coated with mouse anti-human IgG antibody immunity complex. There is a red line appears in the T2 line. The remaining free colloidal gold labeled chicken IgY continues the chromatography and combines with the rabbit anti-chicken IgY antibody on the C line (quality control line) to form a red line.

【Main Components】

The product consists of test card, instructions for use, sample diluent, alcohol pad, blood lancet and dropper. And in each test card bag, it includes one COVID-19 IgM/IgG antibody detection card and one package of desiccant.

Model	Test card	Instructions for use	Sample diluent	Alcohol pad	Blood lancet	Dropper
1 test/kit	1 test	1	1	1	1	1
5 tests/kit	5 tests	1	5	5	5	5
10 tests/kit	10 tests	1	10	10	10	10
20 tests/kit	20 tests	1	20	20	20	20
25 tests/kit	25 tests	1	25	25	25	25
30 tests/kit	30 tests	1	30	30	30	30
40 tests/kit	40 tests	1	40	40	40	40
50 tests/kit	50 tests	1	50	50	50	50
For each test card bag, it contains one test card and one package of desiccant.						

The test strip is composed of absorbent paper, nitrocellulose membrane, sample pad, colloidal gold marker pad and polyvinyl chloride board. The T1 line (detection line) is coated with mouse anti-human IgM antibody, the T2 line (detection line) is coated with mouse anti-human IgG antibody and the C line (quality control line) is coated with rabbit Anti-chicken IgY antibody. There are recombinant COVID-19 antigen colloidal gold conjugates and colloidal gold labeled chicken IgY.

【Storage Conditions and Shelf Life】

1. The kit should be stored in a dry place at 2-30℃ and the shelf life is 18 months.
2. After the test card is opened (temperature 2-30℃, humidity <65%),the shelf life is 1 hour.
3. See the label for the date of manufacture and expiration date.

【Sample Requirements】

1. The applicable sample types for this kit are serum， plasma and whole blood.
2. The sediment and suspended matter in the sample may affect the test result and should be removed by centrifugation at 3000gX10 min.
3. The severely hemolyzed, lipemic or turbid samples cannot be used for testing.
4. The plasma samples can use heparin sodium or EDTA anticoagulant. After the sample is collected, the test must be completed within the same day. If the test cannot be completed on the same day, please save as follows: The serum and plasma samples can be stored at 2~8℃ for 7 days and at -20℃ for 24 days, the test results will not be affected.
5. The samples and reagents must be fully balanced to room temperature (18~28℃) before testing. The frozen samples should be completely thawed, rewarmed and evenly mixed before use. Avoid repeated freezing and thawing.

【Testing Method】

Step1:If the sample is stored in refrigeration or frozen, the medical staff will take out the sample and the reagents and balance at room temperature (18~28℃) then mix the sample thoroughly after thawing.

Step2: When preparing for the test, the medical staff tear the aluminum foil bag from, take out the test card and place it flat on a table.

Step3: The medical staff pre-marked the sample number on the test card.

Step4: The medical staff use a dropper to draw the serum/plasma sample, first add 1 drop to the sample hole of the card and then drop 3 drops of the sample diluent into the sample hole of the card and start timing.

Step5: Strictly control to observe the test card within 15 minutes after the start of the test to determine the result. It is invalid to observe after 20 minutes.

【The Explanation of the Testing Results】

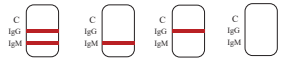
• Negative (-): There is only a red line can be seen with the naked eyes on the quality control line (C line).

• IgM positive & IgG positive: There are three red lines can be seen with the naked eyes on the quality control line and IgM & IgG lines.

• IgM positive & IgG negative: There are two red lines can be seen with the naked eyes on the quality control line and IgM line.

• IgM negative & IgG positive: There are two red lines can be seen with the naked eyes on the quality control line and IgG line.

• Invalid: If there is no red line on the quality control line(C line), no matter whether there is red line appears on the test line (IgM, IgG line) indicates the result is invalid and the test should be retested.



【Limitation of Procedure】

1. The test results of the product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The final diagnosis result should be made by the doctor after comprehensively combining the various test indicators and clinical symptoms. The clinical management of patients should be combined with their symptoms/signs, medical history, other laboratory tests, treatment response and epidemiology. It is recommended to retest the suspicious samples at intervals.
2. The accuracy of the test is affected by the sample collection process. Improper sample collection and storage process will affect the test results. Avoid high temperature and direct sunlight.
3. The kit only provides qualitative detection for the COVID-19 IgM antibody and IgG antibody in the sample and can't be quantitatively detected.
4. The kit is limited by the methodology of the test reagents. The negative result can't rule out the possibility of COVID-19 infection. It is recommended to combine nucleic acid or virus culture and clinical comprehensive judgment.

【Product Performance Index】

1. LoD: The kit tests the LoD reference products of the enterprise. The results of S1 and S2 should be positive for IgG antibody and negative for IgM antibody. The result of S3 should be negative for IgM and IgG antibodies. The results of S4 and S5 should be positive for IgM and negative for IgG. The result of S6 is negative for IgM and IgG.

2. The coincidence rate of negative reference product: The kit tests the negative reference products of the enterprise for 15 times and the results should be negative for IgM and IgG antibodies and the coincidence rate is 100%.

3. The coincidence rate of positive reference product: The kit tests the positive reference products of the enterprise. The results of PC01 to PC05 should be positive for the IgM and IgG antibody and the coincidence rate is 100%. The results of PC06 to PC10 should be negative for the IgG and positive for the IgM antibody and the coincidence rate is 100%. The results of PC11 to PC15 should be positive for the IgG and negative for the IgM antibody and the coincidence rate is 100%.

4. Precision:

4.1 Intra-batch difference: The kit tests the repetitive reference products of the enterprise, The results of S1 and S2 should be positive for IgG antibody and negative for IgM antibody with uniform color. The results of S4 and S5 should be negative for IgG antibody and positive for IgM antibody with uniform color.

4.2 Inter-batch difference: Three batches of kits are used to test the repetitive reference products of the enterprise. The results of S1 and S2 should be positive for the IgG antibody and negative for IgM antibody with uniform color. The results of S4 and S5 should be negative for the IgG antibody and positive for IgM antibody with uniform color.

5. Analysis specificity:

5.1 Cross reaction: The kit has no cross-react with human coronaviruses HKU1, OC43, 229E, H1N1 influenza virus, seasonal H1N1 influenza virus, H3N2, H5N1, H7N9, influenza B Yamagata, Victoria, respiratory syncytial virus, parainfluenza virus, rhinovirus A, B, Group C, Adenovirus 1,2,3,4,5,7,55, Coxsackie virus

5.2 Endogenous interfering substances: Bilirubin ≤0.2g/L, triglyceride ≤10g/L, hemoglobin ≤5g/L, rheumatoid factor ≤500IU/mL, antinuclear antibody titer ≤1:240, anti-mitochondrial antibody titer ≤ 1:160, HAMA≤20ng/mL, total IgG≤50mg/L, total IgM≤5mg/L has no interfere with the test results. The Oseltamivir, levofloxacin, cephaloxone, zanamivir, a-interferon, ribavirin, peramivir, lopinavir, ritonavir, abidol, azithromycin Ropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone therapeutic drugs have no effect on the test results.

5.3 Exogenous interfering substances: The heparin sodium and EDTA anticoagulant have no effect on the detection of the kit.

6. Hook effect: The kit tests samples with a concentration level that exceeds the minimum detection limit of IgG antibodies by more than 1280 folds and the minimum detection limit of IgM antibodies by more than 640 folds will have the hook effect. If there is a high degree of suspicion of being infected with the COVID-19 pneumonia but the antibody test is negative, the sample should be diluted before testing.

【Precautions】

1. Before using this kit, it must read the instructions carefully and strictly control the reaction time. If medical staff do not follow the instructions, they will get inaccurate results.

2. Sample should be tested in a laboratory with certain conditions and all samples and materials in the testing process should be handled in accordance with the operating specifications of the infectious disease laboratory.

3. Beware of the product getting humidity and do not open the aluminum foil bag before it is ready for testing. If the aluminum foil bag is damaged or the test card is damp, it cannot be used.

4. Please use the kit within the shelf life.

5. All reagents and samples should be balanced at room temperature (18 ~ 28 ℃) before use.

6. Do not replace the components in the kit with the components in other kits.

7. The interpretation of inspection methods and results must be carried out in strict accordance with the IFU.

8. The samples and the materials used for testing should be treated as hazardous waste.

【Approval Date and Revision Date of the Instruction for use】

Approval Date: 05/02/2021
Revision Date: 05/02/2021
Date of Issue: 05/02/2021

【Index of CE Symbols】

	Don't use the product when the package is damaged		Please read the instruction book carefully before using
	Please don't reuse it		Validity
4℃ 30℃	Temperature scope within which the product is reserved		Date of manufacture
	Manufacturer	LOT	Batch number
	Avoid overexposure to the sun		Keep dry
IVD	The product is used in vitro, please don't swallow it.		Warning, please refer to the instruction in the annex
EC REP	European union authorization representative	CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC

【Basic information】

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