精硕生物
GENSURE

GenSure™ COVID-19 IgG/IgM Rapid Test

Instructions Manual

For medical institutions use only

Product Name

Common name: GenSure™ COVID-19 IgG/IgM Rapid Test
REF: P2002

Packing Specifications

Card : 1/ bag, 1 / box, 10 / box, 15/ box, 20 / box, 25 / box, 40 / box, 50 / box.

Expected Usage

This product is used for the qualitative testing of novel coronavirus (2019-nCoV) IgM and IgG antibodies in human serum, plasma or whole blood in vitro, and can be used for clinical auxiliary diagnosis of novel coronavirus (2019-nCoV) infection.

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 the 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.

Inspection Principle

The microsphere immunochromatographic technology was used to detect the novel coronavirus (2019-nCoV) IgG/IgM antibody in human serum / plasma / whole blood with the principle of capture method.

During the test, a blood sample is added to the sample well of the kit. The sample is first mixed with the microsphere-labeled antigen on the release pad, and then chromatography on a nitrocellulose membrane. If the sample contains novel coronavirus (2019-nCoV) IgG/IgM antibodies, these antibodies will first bind to microsphere-labeled (2019-nCoV) antigen, so that when the mixture is chromatographied on a nitrocellulose membrane, it will be captured by the detection line (T line) immobilized with anti-human IgG/IgM antibody to form a sandwich microsphere labeled immune complex. Therefore, a red line appeared on the T line, which is a positive result. If no novel coronavirus (2019-nCoV) IgM/IgG antibody is present in the blood of the subject, a red line will not be formed on the test line (T line), which is a negative result. Under normal circumstances, a red line should appear on the quality control line(C line) during the test to prove that the test card is working properly.

Main Ingredients

1) COVID-19 IgG/IgM test card;
2) one bottle of specimen buffer per test;
3) one disposable blood collecting needle per test;
4) one dripper per test;
5) one alcohol pad per test.

Storage Conditions And Validity

Store at 4-30℃, protected from light, valid for 18 months. See product label for production date and expiration date.

Sample Requirements

1) The applicable sample type for this test kit is serum / plasma / whole blood(including peripheral blood).
2) The whole blood is drawn according to the standard clinical laboratory method, and serum or plasma is separated, and hemolysis should be avoided as much as possible during processing.
3) Plasma samples can be collected using EDTA or heparin anticoagulant blood vessels. The samples should be tested as soon as possible after collection to avoid leaving them for a long time at room temperature. Serum or plasma samples should be tested within 4 hours as soon as possible, or it must be stored at 2-8℃for 7 days. If longer storage is required, it should be stored at -20℃(-70℃if possible). It is not recommended to use severe hemolytic samples. Whole blood samples should be tested within 4 hours as soon as possible, or must be stored at 2-8℃ for 7 days. It is not recommended to use samples for more than 7 days.
4) The sample must be returned to room temperature before testing. The frozen samples need to be completely melted, rewarmed and mixed before use. They should be slowly returned to room temperature and stirred. When the particles in the sample are clearly visible, the precipitate should be removed by centrifugation before testing. Avoid repeated freezing and thawing.

Testing Method

1) Please read the instruction manual carefully before testing.
2) Take out the test card, test sample and control, etc., and use it after returning to room temperature. When everything is ready, tear off the aluminum foil bag, take out the test card and place it on the platform. After opening the aluminum foil bag, the test card should be used as soon as possible within 1 hour.
3) Add sample:

a. Use the dripper to suck the plasma/serum/whole blood sample. Due to capillary action, the dripper will automatically suck the sample until the sample is filled with the capillary;

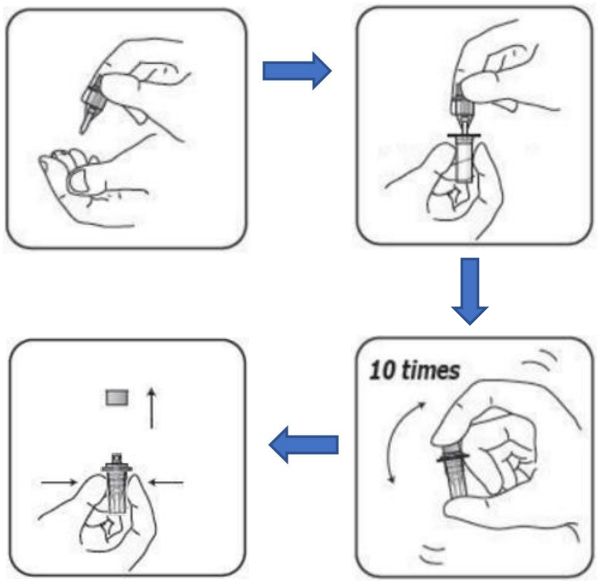
b. Insert the end of the dripper capillary into the tube containing the sample diluent;

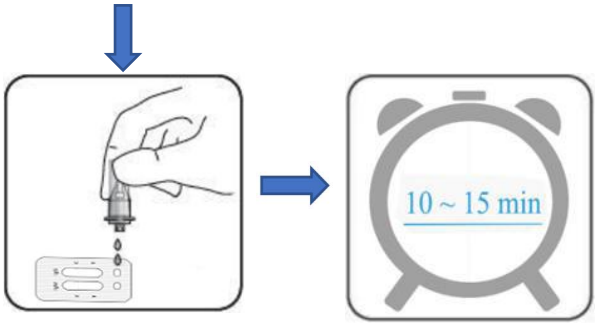
c. Shake the tube up and down to mix the sample and diluent thoroughly;

d. Pull out the cap on the other end of the dripper;

e. Add 3 drops (about 100ul) of the mixed solution to each of the two sample wells of the card.

(4) Observe the results within 10-15 minutes after the sample is added, do not observe the result after 15 minutes.





Interpretation of test results

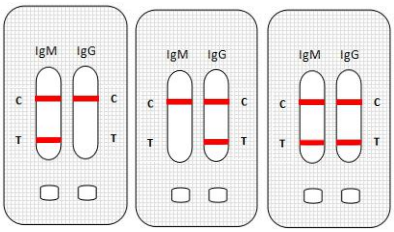
Positive: Two red Control lines and one either test line of the test windows are visible. It indicate the presence of 2019-nCoV IgM and/or IgG antibodies above the detection limit of the reagent in the sample.

Negative: Only the quality control line (C line) has a red line, and the detection line (T line) has no red line. It means that no novel coronavirus (2019-nCoV) IgG/IgM antibody in the sample or novel coronavirus (2019-nCoV) IgG/IgM antibody level is below the detection level.

Invalid: No red line appears on the quality control line (C line), indicating failure. It may be due to improper operation or test card is invalid and should be retried.

Note: The intensity of the red color in the test line region (T) will vary depending on the concentration of COVID-19 IgG/IgM antibodies present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

Interpretation of results



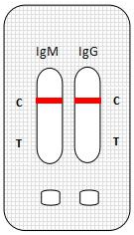
（1） （2） （3）

Positive：

(1) IgM is positive and IgG is negative: it is suggested that the patient may be in the period of new infection;

(2) IgM is negative and IgG is positive: it may be in the late stage of infection or previous infection;

(3) IgM is positive and IgG is positive: it may be in the duration of infection.



Negative：

No IgM and / or IgG antibodies were detected, suggesting that no infection has occurred, or that the infection has not elicited an immune response.

Invalid：

Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test card. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations Of Detection Methods

1. This product is a qualitative in vitro diagnostic reagent for auxiliary diagnosis.
2. This reagent is only used for the qualitative detection of IgG/IgM antibodies present in human blood samples.
3. The positive result only indicates that the 2019-nCoV IgG/IgM antibody may be present, and it cannot be used as the sole judgment criterion for the 2019-nCoV virus infection. The diagnosis should be based on the latest version of the *Diagnosis and Treatment Program for novel coronavirus Pneumonia Infection*.
4. Negative results cannot completely rule out the possibility of 2019-nCoV virus infection. It may be that the IgG/IgM antibody level is too low to be detected by this kit.
5. Inconsistent or erroneous results may occur due to improper technical or procedure procedures, contaminated samples, hemolysis, or the presence of drugs that interfere with the test.
6. The kit is only used as a supplement detection indicator for suspected cases with negative PCR of novel cornavirus or used in conjunction with PCR in the diagnosis of suspected cases.It cannot be used as a basis for the diagnosis and exclusion of pneumonia infected with a novel coronavirus and is not suitable for screening in the general population.

Product Performance Index

1. Minimum detection limit: Using the company's minimum detection limit reference products L1, L2, and L3 to validate, the results of positve controls L1 and L2 are confirmed to be positive and the detection of negative control L3 is confirmed to be negative.
2. Positive reference compliance rate: Tested with the company's positive reference, the result is positive.
3. Negative reference compliance rate: Tested with the company's negative reference and the result is negative.
4. Repeatability: It is tested with the company's repeatable reference, the result is positive, and the color is uniform.

Precautions

1) This product is for in vitro testing only.
2) If the sample is suspected to be contaminated, re-sampling should be performed.
3) Do not use expired kits.
4) All samples shall be treated as infectious materials during the test.
5) When testing samples, wear protective clothing such as lab coats, disposable gloves, and goggles.
6) For medical institutions use only.

Basic Information

Registrant / Manufacturer: GenSure Biotech Inc.,
Registered address: B1-78, Rizhongtian Science and Technology Park, No.585 Tianshan Street, Shijiazhuang High-tech Zone, 050000, Hebei, P.R.China

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