GenSure™ COVID-19 IgG/IgM Rapid Test

Instructions Manual

For professional use only

Product Name

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

Packing Specifications

Cassette : 1/ bag Kit: 20 / 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) 20 test cassettes; 2) 20 bottles of specimen buffer;
3) 20 disposable blood collecting needles; 4) 20 pipettes;
5) 20 alcohol pad or alcohol swabs (optional).

Storage Conditions And Stability

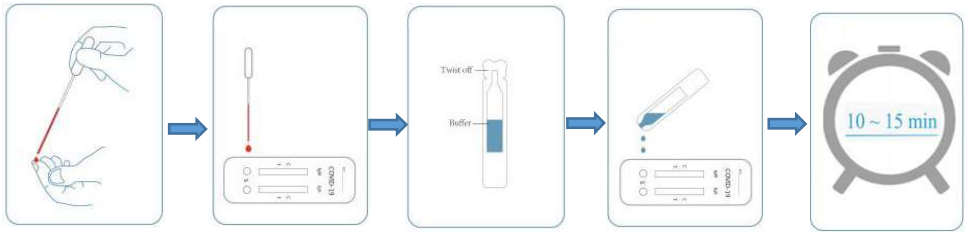
Store at 4-30℃, protected from light, stable for 18 months. See product label for production date and expiration date.

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 after collection as soon as possible, or it must be stored at 2-8℃for 3 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 after collection as soon as possible, or must be stored at 2-8℃ for 3 days. It is not recommended to use samples for more than 3 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

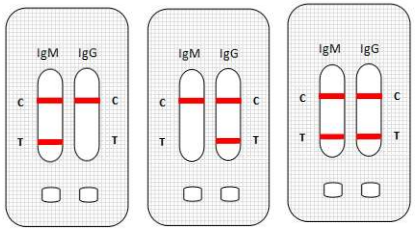
1) Please read the instruction manual carefully before testing.
2) Take out the test cassette, specimen buffer, etc., and use it after returning to room temperature. When everything is ready, tear off the aluminum foil bag, take out the test cassette and place it on the platform. After opening the aluminum foil bag, the test cassette should be used as soon as possible within 1 hour.
3) Add sample:
Aspirate the plasma / serum / whole blood sample with the sample pipette, add 1 drop (approximately 10ul) of sample to each of the two sample wells of the test card, and then tear off the specimen buffer bottle, add 4 drops of specimen buffer to each sample well.
(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

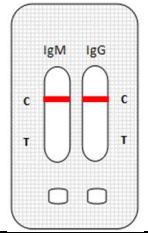
Positive: Two red Control lines and one either test line of the test windows are visible. It indicate the presence of 2019-nCoV IgM and/or IgG antibodies above the detection limit of the reagent in the sample.
Negative: Only the quality control line (C line) has a red line, and the detection line (T 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.

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.
*7) **Note:** If the speicmen is contaminated or abnormal, or the specimen handling method and testing method are not carried out in accordance with the instructions manual, the result will be incorrect, which has nothing to do with product quality.

Clinical Performance

The clinical performance of the GenSure™ COVID-19 IgG/IgM Rapid Test was established with a study using 623 previously collected samples.

		SARS-CoV-2 Molecular		Total
		Positive	Negative	
GenSure™ COVID-19 IgG/IgM Rapid Test	Positive	216	0	216
	Negative	7	400	407
Total		223	400	623
Sensitivity		96.86% (95% CI = 93.66%~98.47%)		
Specificity		100.00% (95% CI = 99.05%~100.00%)		
Total Coincidence Rate		98.88% (95% CI = 97.70%~99.45%)		

The sensitivity of GenSure™ COVID-19 IgG/IgM Rapid Test is 96.86% (95% CI = 93.66%~98.47%), the specificity is 100.00% (95% CI = 99.05%~100.00%), and the total coincidence rate is 98.88% (95% CI = 97.70%~99.45%).

Analytical Performance

1. Cross-Reactivity
Cross reactivity of GenSure™ COVID-19 IgG/IgM Rapid Test was evaluated by testing various material that could cross-react with GenSure™ COVID-19 IgG/IgM Rapid Test. The result showed no cross reactivity.

Influenza A (H1N1, H3N2)	Avian influenza (H5N1, H7N9)	Influenza B (Yamagata, Victoria)
RSV	Rhinovirus	Adenovirus
EBv	Measles virus	HCMV
Rv	Norovirus	Mumps virus
Varicella zoster virus	Mycoplasma pneumoniae	
Human coronavirus (OC43, 229E, NL63)		

2. Class Specificity
Five high-concentration positive plasma samples of patients infected with the novel coronavirus were selected, numbered 01~05, and the above-mentioned positive samples were treated with dithiothreitol (DDT) at a concentration of 0.003mol/L. Use three consecutive batches of product to test the samples before and after treatment respectively, and perform parallel tests for each of the three times according to the operating steps of the instructions, and record the test results. The test results are shown in the table below.

Sample No.	Replicates	Result NO DTT Treatment (IgM/IgG)	Result DTT Treatment (IgM/IgG)	Expected result with DTT treatment (IgM/IgG)
01	1	(3/3) +/+	(3/3) -/+	(3/3) -/+
	2	(3/3) +/+	(3/3) -/+	(3/3) -/+
	3	(3/3) +/+	(3/3) -/+	(3/3) -/+
02	1	(3/3) +/+	(3/3) -/+	(3/3) -/+
	2	(3/3) +/+	(3/3) -/+	(3/3) -/+
	3	(3/3) +/+	(3/3) -/+	(3/3) -/+
03	1	(3/3) +/+	(3/3) -/+	(3/3) -/+
	2	(3/3) +/+	(3/3) -/+	(3/3) -/+
	3	(3/3) +/+	(3/3) -/+	(3/3) -/+
04	1	(3/3) +/+	(3/3) -/+	(3/3) -/+
	2	(3/3) +/+	(3/3) -/+	(3/3) -/+
	3	(3/3) +/+	(3/3) -/+	(3/3) -/+
05	1	(3/3) +/+	(3/3) -/+	(3/3) -/+
	2	(3/3) +/+	(3/3) -/+	(3/3) -/+
	3	(3/3) +/+	(3/3) -/+	(3/3) -/+

The results of the above cross-reaction verification test showed that the high-concentration novel coronavirus IgG antibody did not cross-react with the IgM antibody, and the results were in line with expectations.

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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After-sales service: GenSure Biotech Inc.,
Production address: 3/F, Block 1, Boyun Bldg, No. 9 Fengchan Rd, Economic-Tech Zone, Shijiazhuang, 050000, Hebei, P.R China.
E-mail: info@gensbio.com Web: www.gensbio.com

European Authorized Representative

EC REP QualRep Services B.V.
Address: Utrechtseweg 310 - Bldg B42, NL-6812 AR Arnhem, The Netherlands
E-mail: globalreg@qservegroup.com

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Instructions Manual Revision Date and Version

Revision Date: 2021.03.17 Version No.: 21.06

	Attention, see instruction for use		Use by	REF	Catalog
IVD	For in vitro diagnostic use only	LOT	Lot number	EC REP	European Authorized Representative
	Store at 4-30℃		Manufacturer		Keep dry
	Tests per kit		Do not reuse		Caution