GenSure™ COVID-19 Antigen Rapid Test Kit
Instructions Manual

Product Name and Catalog No.

Common name: GenSure™ COVID-19 Antigen Rapid Test Kit REF: P2004

Packing Specifications

Cassette:1/ bag, Kit: 1 / box, 5 / box, 10 / box, 20 / box, 25 / box, 40/ box, 50 / box, 100 / box

Expected Usage

The GenSure™ COVID-19 Antigen Rapid Test Kit is a polymer immunochromatographic technology and double antibody sandwich principle that is intended for the qualitative detection of the N protein antigen from SARS-CoV-2 in human nasal swab specimens directly. Testing is limited to laboratories and medical institutions.

Results are for the identification of SARS-CoV-2 N protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The GenSure™ COVID-19 Antigen Rapid Test Kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings.

Summary and Explanation

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 polymer immunochromatographic technology and double antibody sandwich principle were used to detect the novel coronavirus antigen in human nasal swab specimens with the principle of capture method.

During the test, a specimen solution is added to the sample well of the kit. The specimen is first mixed with the colored polymer-labeled novel coronavirus monoclonal antibody 1 on the release pad, and then chromatographed on a nitrocellulose membrane. If the specimen contains novel coronavirus antigens, these antigens will first bind to colored polymer-labeled novel coronavirus monoclonal antibody 1, so that when the mixture is chromatographed on a nitrocellulose membrane, it will be immobilized with the novel coronavirus monoclonal antibody 2. The detection line (T line) was captured to form a colored polymer-labeled novel coronavirus monoclonal antibody1-antigen- novel coronavirus monoclonal antibody 2 immune complex. Therefore, a red line appeared on the T line, which was a positive result. If no novel coronavirus antigen is present in the nasal swab specimens of the subject, a red line will not be formed on the test line (T line), which is a negative result. The quality control line (C line) on the test cassette is coated with goat anti-mouse antibody. Under normal circumstances, a red line should appear on the quality control line(C line) during the test to prove that the test cassette is working properly.

Main Ingredients

1. COVID-19 antigen test cassette; 2. Specimen processing tube; 3. Specimen sampling swabs;
4. Specimen extraction buffer; 5. Dripper.

Storage Conditions and Validity

Store at 4-30℃, don't freeze, protected from light, valid for 12 months. See product label for production date and expiration date.

Sample Requirements

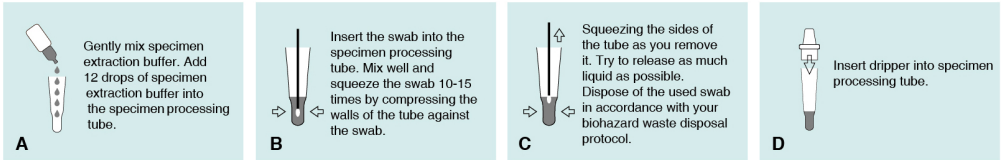
1. The applicable specimen types for this test kit are nasal swab.
2. The nasal swabs are drawn according to the standard clinical laboratory method: Insert the polypropylene fiber head / synthetic flocking head plastic rod swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected, then repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.
3. Specimens that can be detected within 24 hours can be stored at 4 ℃; specimens that cannot be detected within 24 hours should be stored at - 70 ℃ or below (if there is no - 70 ℃ storage condition, they should be temporarily stored in -20 ℃ refrigerator).

Please do not use specimens that have grown bacteria, have been left for too long, or have been repeatedly frozen and thawed to avoid non-specific reactions caused by sample contamination or growth of bacteria

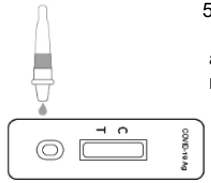
4. The specimen must be returned to room temperature before testing.

Testing Method

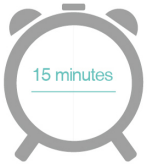
1. Please read the instruction manual carefully before testing.
2. Take out the test cassette, test specimen, etc., and use it after returning to room temperature. When everything is ready, tear off the aluminum foil bag, take out the test cassette and place it on the platform. After opening the aluminum foil bag, the test cassette should be used as soon as possible within 1 hour. The specimen extraction buffer should be capped immediately after opening.
3. Specimen solution preparation:



4. Sample adding: Put the tip of the sample processing tube straight down, then squeeze the wall of the specimen processing tube, so that the specimen drips out from the tube. Add 2 ~ 3 drops of specimen solution to the sample well of the cassette, and wait for the result to appear.

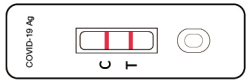


5. Timing observation: judge the result 15 minutes after sample adding, do not observe the result 20 minutes later.

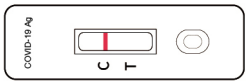


Interpretation of Test Results

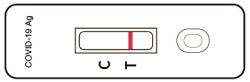
Positive: A red line appears on the quality control line (C line) and the detection line (T line). It indicate the presence of novel coronavirus (SARS-CoV-2) Antigens above the detection limit of the reagent in the sample.
Negative: Only the quality control line (C line) has a red line, and the detection line (T line) has no red line. It means that no novel coronavirus (SRAS-CoV-2) Antigen in the sample or novel coronavirus (SRAS-CoV-2) Antigen 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 cassette is invalid and should be retried.



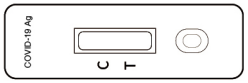
Positive result



Negative result



Invalid result



Invalid result

Limitations of Detection Method

1. The contents of this kit are to be used for the qualitative detection of SARS antigens from nasal swabs.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
3. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
4. Test results must be evaluated in conjunction with other clinical data available to the physician.
5. Positive test results do not rule out co-infections with other pathogens.
6. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
7. Negative results should be treated as presumptive and confirmed with molecular assay, if necessary, for clinical management, including infection control.
8. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
9. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection.
10. If the differentiation of specific SARS viruses and strains is needed, additional testing is required.
11. This device has been evaluated for use with human specimen material only.
12. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
13. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay
14. The validity of the GenSure™ COVID-19 Antigen Rapid Test Kit has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

Product Performance Index

1. Minimum detection limit: Use the company's minimum detection limit reference products S1 to test. the result is positive.
2. Positive reference product compliance rate: Tested with the company's positive reference product, the result is positive.
3. Negative reference product compliance rate: Tested with the company's negative reference product and the result is negative.
4. Repeatability: It is tested with the company's repeatable reference product, the result is positive, and the color is uniform.

Warning and Precautions

1. For in vitro diagnostic use.
2. Do not use the kit contents beyond the expiration date printed on the outside of the box.
3. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
4. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
5. Do not reuse the used test cassette, sample processing tube or swabs, etc.
6. The user should never open the foil pouch of the test cassette exposing it to the ambient environment until the test cassette is ready for immediate use.
7. Discard and do not use any damaged or dropped test cassette or material.
8. If the sample extraction solution contacts the skin or eye, flush with copious amounts of water.
9. To obtain accurate results, the instructions manual must be followed.
10. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
11. Sample collection and handling procedures require specific training and guidance.
12. When collecting the nasal swab sample, use the swab supplied in the kit. Use of alternative swabs may result in false negative results.
13. To obtain accurate results, an opened and exposed test cassette should not be used inside a laminar flow hood or in a heavily ventilated area and do not use visually bloody or overly viscous samples.
14. Testing should be performed in an area with adequate ventilation.
15. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
16. Wash hands thoroughly after handling.
17. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

Clinical Performance

The clinical performance of the GenSure™ COVID-19 Antigen Rapid Test Kit was established with a study using one five hundred and forty-eight (548) previously collected swabs samples.

		SARS-CoV-2 Molecular		Total
		Positive	Negative	
GenSure™ COVID-19 Antigen Rapid Test Kit	Positive	185	0	185
	Negative	6	357	363
Total		191	357	548
Sensitivity		96.86%		
Specificity		100%		
Accuracy		98.91%		

The assay demonstrated acceptable clinical sensitivity (96.86%) when compared to an molecular kit.
The assay also demonstrated excellent clinical specificity (100%) and excellent clinical accuracy (92.7%).
There was no demonstrable cross-reactivity with eighty-nine (98.91) specimens containing seasonal CoVs detected by COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit.

Analytical Performance

1. Limit of Detection
The detection limit of GenSure™ COVID-19 Antigen Rapid Test Kit was 0.1ng/ml.
2. Hook Effect
No high dose hook effect was observed up to 1.0mg/ml of inactivated N protein antigen from SARS-CoV-2 with the GenSure™ COVID-19 Antigen Rapid Test Kit.

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

European Authorized Representative

EC REP OSMUNDA Medical Technology Service GmbH

European Distribution

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Web: www.c19-medi.com
Tel: +49 7161 989620

	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 room temperature		Manufacturer		Keep dry
	Tests per kit		Do not reuse		Caution