2.Cross-Reactivity

Cross reactivity and potential interference of GenSureTM COVID-19 Antigen Rapid Test Kit was evaluated by testing various microorganisms and viruses that could cross-react with GenSureTM COVID-19 Antigen Rapid Test Kit. Each of the microorganisms and viruses were tested in triplicate. The following microorganisms will not cross-react when testing.

Microorganism	Concentration	Cross-Reactivity (Yes/No)
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	No
Avian influenza (H5N1, H7N9)	1.7 x 10^5 $TCID_{50}$/mL	No
Influenza B (Victoria, Yamagata)	2.5 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus	1.0 x 10^5 $TCID_{50}$/mL	No
Respiratory Syncytial Virus	3.8 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.4 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.1 x 10^5 $TCID_{50}$/mL	No
Measles virus	1.0 x 10^6 $TCID_{50}$/mL	No
Human coronavirus (OC43, 229E, NL63)	1.0 x 10^5 $TCID_{50}$/mL	No
MERS coronavirus	1.2 x 10^5 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Chlamydia pneumaniae	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.1 x 10^6 CFU/mL	No
Staphylococcus aureus	5.0×10^6 CFU/mL	No

3.Hook Effect

No high dose hook effect was observed up to 3.6 x 10^5 $TCID_{50}$/mL from SARS-CoV-2 with the GenSureTM COVID-19 Antigen Rapid Test Kit.

Basic Information

Registrant / Manufacturer: GenSure Biotech Inc.
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Tel: 86-311-8993 7995 86-311-8993 7996
After-sales service: GenSure Biotech Inc.
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European Authorized Representative

EC REP OSMUNDA Medical Technology Service GmbH
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CE

Instructions Manual Revision Date and Version

Revision Date: 2021.05.18 Version No.: 21.15

	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
Σ	Tests per kit		Do not reuse		Caution

·For professional use only·

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: 20 / 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 mainmanifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Test 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 specimen 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 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.Material Provided:
(1) 20 test cassettes; (2) 20 specimen processing tubes with extraction buffer; (3) 20 specimen sampling swabs;(4) 1 instructions manual.
2.Material required but not provided: Timer.

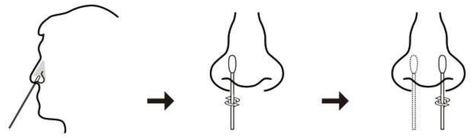
Storage Conditions and Stability

Store at 4-30℃, don't freeze, protected from light, stable for 18 months. See product label for production date and expiration date.

Specimen Requirements

1. The applicable specimen type for this test kit is nasal swab.

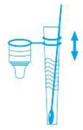
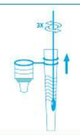
2. The nasal swabs are drawn according to the standard clinical laboratory method: Insert the polypropylene fiber head / synthetic flocking head plastic rod swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab
5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected, thenrepeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities. Withdraw the swab from the nasal cavity.



3. Specimens that can be processed within 24 hours can be stored at 4 ℃; specimens that cannot be processed 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 specimen contamination or growth of bacteria.

Testing Method

Note: Allow the test cassettes, specimen extraction buffers and specimens to equilibrate to room temperature prior to testing.
1.Please read the instruction manual carefully before testing.
2.Specimen solution preparation:

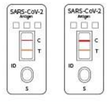
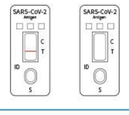
a. Remove and discard the cap from the specimen processing tube. Be careful not to spill the liquid from the tube. 	b. Insert the swab into the processing tube and plunge the swab up and down in the liquid for at least 15 seconds, taking care not to spill the 
c.Remove the swab while pinching wall of the tube with the swab and rotating the swab, to extract the liquid from the swab. 	d.Press the attached tip firmly onto the specimen processing tube containing the processed 

3. Remove the test cassette from the sealed pouch.

4.Specimen adding: Reverse the specimen processing tube, holding the tube upright, transfer 3 drops slowly to the specimen well (S) of the test cassette, then start the timer. Avoid adding bubbles when dripping.

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

Interpretation of Test Results

Positive		**Two lines appear.** One colored line appears at the control region(C), and another colored line appears at the test region (T), irregardless of the intensity of the test line
Negative		One colored line appears at the control region (C), and no line appears at the test region (T).
Invalid		**Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Limitations of Detection Method

1.The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab.
2.A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test or if the specimen 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 specimens, and performance may be different with fresh specimens.
9.If the differentiation of specific SARS viruses and strains is needed, additional testing is required.
10.This device has been evaluated for use with human specimen material only.
11.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

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 specimens and used kit contents.
4.Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient specimens.
5.Do not reuse the used test cassette, specimen 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.If the specimen extraction solution contacts the skin or eye, flush with copious amounts of water.
8.To obtain accurate results, the instructions manual must be followed.
9.Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
10.Speicmen collection and handling procedures require specific training and guidance.
11.When collecting the specimen, use the swab supplied in the kit. Use of alternative swabs may result in false negative results.
12.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 specimens.
13.Testing should be performed in an area with adequate ventilation.
14.Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
15.Wash hands thoroughly after handling.
16.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.
17.The used test cassette should be discarded according to federal, state and local regulations.

Clinical Performance

The clinical performance of the GenSure™ COVID-19 Antigen Rapid Test Kit was established with a study using 548 previously collected swab specimens.

		SARS-CoV-2 Molecular		Total	PPV	NPV
		Positive	Negative			
GenSure™ COVID-19 Antigen Rapid Test Kit	Positive	185	0	185	100%	98.35%
	Negative	6	357	363		
Total		191	357	548		
Sensitivity		96.86% (95% CI= 93.29% ~ 98.84%)				
Specificity		100.00% (95% CI= 98.97% ~ 100.00%)				
Total Coincidence Rate		98.91% (95% CI= 97.63% ~ 99.60%)				

The sensitivity of GenSure™ COVID-19 Antigen Rapid Test Kit is 96.86% (95% CI= 93.29% ~ 98.84%), the specificity is 100.00% (95% CI= 98.97% ~ 100.00%), and the total coincidence rate is 98.91% (95% CI= 97.63% ~ 99.60%).

Analytical Performance

1.Limit of Detection
Take the inactivated novel coronavirus (concentration 3.6×10^5 $TCID_{50}$/mL) and use the extract of the negative nasal swab specimen as the clinical matrix diluent of the virus for serial dilution, and use three batches of kits to test the above specimens. Each batch of the kit was detected 5 tests in parallel. When the virus solution with a concentration of 3.6×10^5 $TCID_{50}$/mL is diluted 7.2×10^3 times (50 $TCID_{50}$/mL) by the negative clinical matrix diluent, the GenSure™ COVID-19 Antigen Rapid Test Kit can detect a positive result. Then use the extract of the negative nasal swab specimen as the clinical matrix diluent of the virus to perform several gradient dilutions of the novel coronavirus inactivated at a dilution factor of 7.2×10^3 times (50 $TCID_{50}$/mL), and test three batches of kits for each concentration. Repeat the test 20 times, with the lowest concentration with 95% positive detection rate as the Limit of Detection. According to the test, the Limit of Detection for this product is 50 $TCID_{50}$/mL.