ASSURE-100

Instructions for Use: ASSURE-100 Rapid COVID-19 Test Kit
Oceanit Foundry LLC

For use under an Emergency Use Authorization (EUA) only.
For use with nasal swab specimens.
For *in vitro* diagnostic (IVD) use only
Rx only
This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA)

INTENDED USE

The ASSURE-100 Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen from direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first eight (8) days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The ASSURE-100 Rapid COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab 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 patient 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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive, and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection 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 ASSURE-100 Rapid COVID-19 Test is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings.

The ASSURE-100 COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

SARS-CoV-2, also known as the COVID-19 virus, was first identified in December 2019. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the ß genus. The virus can cause mild to severe respiratory illness and has spread globally, including in the United States. Symptoms include fever, cough, shortness of breath, and others.

ASSURE-100 Rapid COVID-19 Test is a fast lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from anterior nasal swab specimens. Each ASSURE-100 Rapid COVID-19 Test kit contains all components required to carry out an assay test for SARS-CoV-2.

PRINCIPLES OF THE PROCEDURE

The ASSURE-100 Rapid COVID-19 Assay is an immunochromatographic membrane assay that uses highly sensitive, custom-engineered molecules to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other regents/pads to construct a test strip. This test strip and a well to hold the swab specimen solution are located within a plastic test cassette.

To perform the test, an anterior nasal swab specimen is collected from the patient's nostrils, the sample is placed and mixed in a collection vial containing sample diluent, and then is poured into the ASSURE-100 device's sample port. A pink-to-red test line and control line will appear on the test strip if SARS-CoV-2 antigen is detected. Test results are interpreted visually at twenty (20) minutes based on the presence or absence of visually detectable red colored lines. Results should not be read earlier than 20 minutes or after thirty (30) minutes.

REAGENTS AND MATERIALS

Materials Provided

Nasal Swabs (30): Individually wrapped sterile foam swabs
Solution vials (32): Plastic vials containing solution to be used for test
Cassettes (32): Plastic cassette containing test strip, individually packaged in foil
Positive control swab (1): Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
Negative control swab (1): Individually wrapped sterile foam swab
Product Insert (1)
Procedure Card (1)

Materials Recommended but not Provided

Clock, timer or stopwatch
Personal Protective equipment (e.g., gloves)

Warning and Precautions:

- For in vitro diagnostic use
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Federal Law restricts this device to sale by or on the order of a license practitioner (U.S. only).

- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
- Immediately use after opening the test device in the pouch. Tests should be used no more than one hour after opening the pouch.
- In order to obtain accurate results, the test must follow the instructions on this package insert.
- Do not use kits past its expiration date.
- Do not mix components from different kit lots.
- Do not reuse the used cassette.
- Inadequate or inappropriate sample collection, storage, and transport may yield false tests results.
- Do no store specimens in viral transport media for specimen storage.
- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
- Solutions used to make the positive control swab are non-infectious. However, patients' samples, controls, and cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water. For additional information on reagents please refer to Safety Data Sheet (SDS) located at https://assure-test.com/assure-100-sds/.
- Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
- Swabs in the kit are approved for use with ASSURE-100 Rapid COVID-19 test. Do not use other swabs.
- Do not store the swab after specimen collection in the original paper packaging, if storage is needed use buffer vial.

Hazardous ingredients for the Reagent Solution		
Chemical Name/Concentration	**Harms (GHS) code for each ingredient**	**Concentration**
Triton X-100	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2) H315 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	1%
Sodium Azide	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity – repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.09%

STORAGE AND STABILITY
Store kit(s) at room temperature (15-30°C). Ensure all test components are at room temperature before use. The ASSURE-100 Rapid COVID-19 Test is stable until the expiration date marked on the outer packaging and containers.

QUALITY CONTROL
ASSURE-100 Rapid COVID-19 Test has built-in procedural controls. For quality control, it is suggested that you record these controls for each test run.

Procedural Control:
The pink-to-purple line at the "Control" positions is an internal procedural control. If the test flows and the reagents work, this line will always appear.

External Positive and Negative Controls:
Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ASSURE-100 Rapid COVID-19 Test kits contain a Positive Control Swab and an extra sterile swab to serve as the Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new lot received per the Procedure for Control Swabs below.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Oceanit Foundries Technical Support (US +1 855 929 6011/info@assure-test.com) before testing patient specimens.

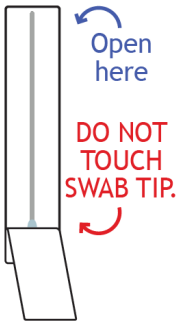
Procedure for Control Swabs

1. Remove control swab from labeled packaging.
2. Follow steps 1-4 of the Test Procedure for Patient Specimens.

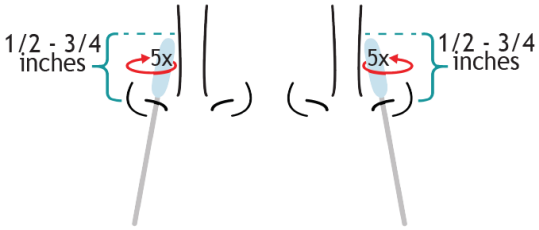
SPECIMEN COLLECTION AND HANDLING
Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling may yield erroneous results. For more information on anterior nasal swab specimen collection, please refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at:
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Anterior Nasal Swab
Only the swab provided in the kit is to be used for anterior nasal swab collection.

1. Remove anterior nasal swab from packaging. Do not touch the swab tip.



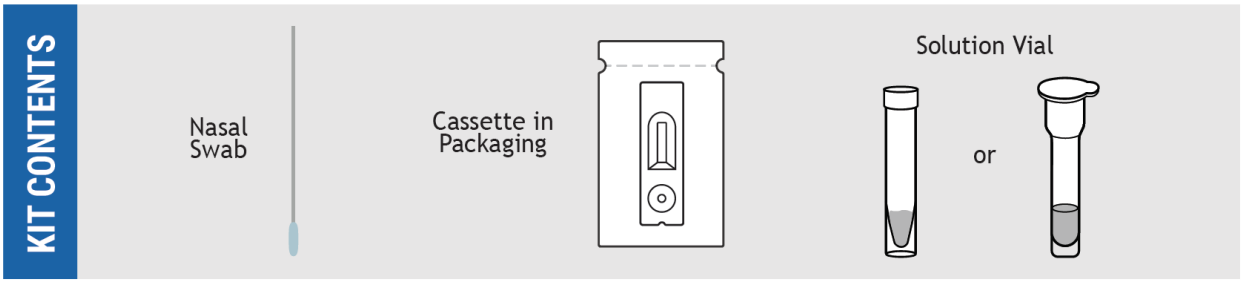
2. Insert entire soft part of the swab into left nostril (½ – ¾ inches). Rub swab against the inside wall of the nostril. Make at least 5 big circles, taking a total of 15 seconds. Do not just spin the swab. Repeat in the other nostril.



SPECIMEN TRANSPORT AND STORAGE
Do not return the nasal swab to original paper packaging. Samples should be tested immediately after collection. If immediate testing is not possible, swabs should be placed in the solution vial and tested within 20 minutes of collection. If the sample cannot be tested within 20 minutes of collection, it should be discarded and another sample should be taken at least 15 minutes after the initial sample was taken.

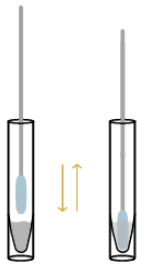
TEST PROCEDURE
Test materials and clinical specimens must be at room temperature before beginning the assay. Use of gloves (not provided) is recommended when conducting testing.

Remove and identify kit components and instructions.

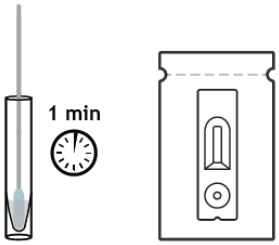


Procedure for Patient Specimens

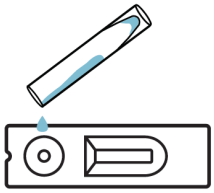
1. After swabbing each nostril, place swab into the vial, tip first. Plunge swab in vial for 10 seconds by rapidly moving swab up and down.



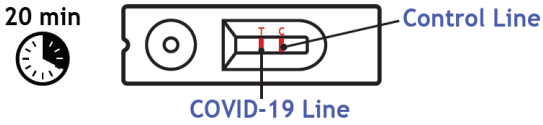
2. Push swab all the way to the bottom of the vial and leave for one minute. Following this, discard swab and open cassette package.



3. Place test cassette flat on a level surface and pour **ALL** of the liquid content gently into the cassette well. It is normal for a minimal amount of the liquid to remain in the bottom of the vial.



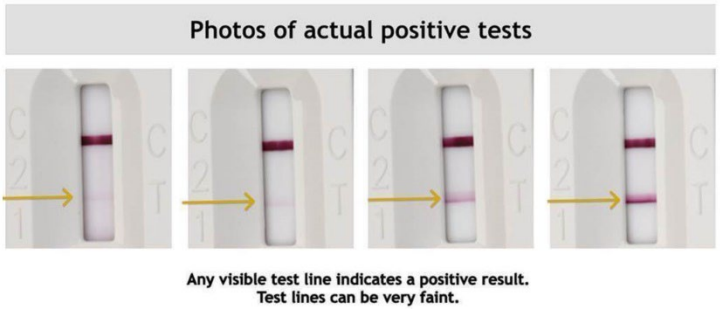
4. Wait 20 minutes. See results interpretation section. Results should not be read earlier than 20 minutes or after 30 minutes.

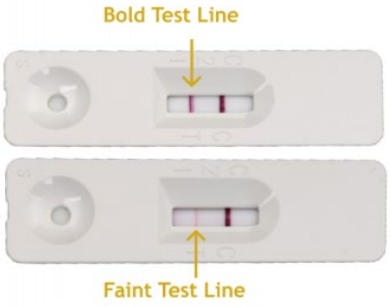


RESULT INTERPRETATION

Positive Result:

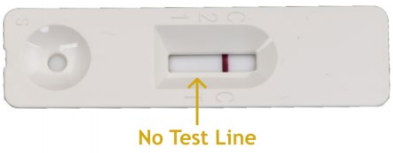
Results are read at 20 minutes. Positive results may appear as bold or as faint as shown in the examples below. The appearance of ANY shade of pink-to-red test line AND the appearance of a pink-to-red control line indicates a positive result for the presence of SARS-CoV-2 antigen. Do not read the test less than 20 minutes or more than 30 minutes after transferring solution into cassette. A positive result does not rule out co-infections with other pathogens. If the control line does not appear, the test is invalid and the results should NOT be interpreted. Please re-test the patient with a new test.





Negative Result:

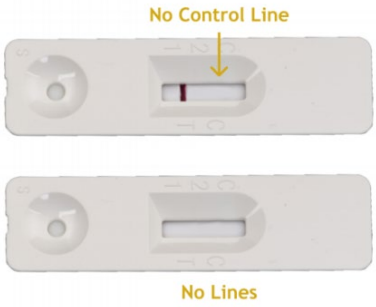
Results are read at 20 minutes. Negative results will show ONLY a control line. A negative result means that SARS-CoV-2 antigen was not detected. Do not read the test less than 20 minutes or more than 30 minutes after transferring solution into cassette.



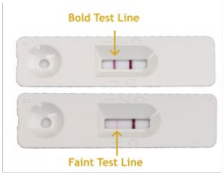
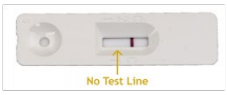
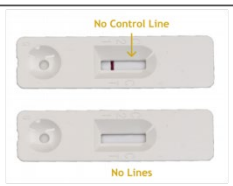
A negative does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. If a control line does not appear, the test is invalid and the results should NOT be interpreted. Please re-test the patient with a new test.

Invalid Result:

If at 20 minutes, the pink-to-red control line does not appear, even if any shade of pink-to-red Test line appears, the results are invalid.



An invalid test means this test was unable to determine whether patient has COVID-19 or not. These results should not be further interpreted and a new test is needed to get a valid result.

Positive	The appearance of ANY shade of pink-to-ted test line AND the appearance of a pink-to-red control line indicates a positive result for the presence of SARS-CoV-2 antigen.	
Negative	Negative results will show ONLY a control line. A negative result means that SARS-CoV-2 antigen was not detected.	
Invalid	If at 20 minutes, the pink-to-red control line does not appear, even if any shade of pink-to-red test line appears, the results are invalid.	

LIMITATIONS

- This test is not for use in at-home settings.
- The test is intended for direct specimens only. Viral Transport Media (VTM) should not be used with this test as it may cause false results.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from anterior nares nasal swab specimens only.
- 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 improperly.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Failure to follow the test procedure and interpretation of results may adversely affect test performance and/or invalidate the test results.
- The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Positive test results do not rule out co-infections with other pathogens. Positive and negative predictive values are dependent on COVID-19 prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.
- False negative results may occur if the test result is read before the 20 minutes or after the 30 minutes.
- The ASSURE-100 Rapid COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV2.
- The ASSURE-100 Rapid COVID-19 Test has been evaluated using only human anterior nasal specimens.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2021 and October 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing

may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time

CONDITIONS OF AUTHORIZATION FOR THE LABORATORIES

The ASSURE-100 Rapid COVID-19 Assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories using the ASSURE-100 Rapid COVID-19 Assay, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use the product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and Oceanit Foundries (via email: info@assure-test.com, or via phone by contacting Oceanit Foundries Technical Service at 1-808-500-7574) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Oceanit Foundries, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation." as "authorized laboratories."

CLINICAL PERFORMANCE

The performance of ASSURE-100 Rapid COVID-19 Test was established in a prospective clinical study conducted between September 2021- October 2021 with 153 nasal swabs collected by a healthcare professional from symptomatic patients suspected of COVID-19 within 8 days of symptoms. Patients were enrolled prospectively at four sites by a total of eight operators. The ASSURE-100 Rapid COVID-19 Test results are compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the tables below.

Table 1: Performance of ASSURE-100 Rapid COVID-19 Test in subjects within 8 days of symptoms.

ASSURE-100 Rapid COVID-19 Test	RT-PCR method		
	Positive	Negative	Total
Positive	31	0	31
Negative	4	117	121
Total	35	117	152*
Positive Percent Agreement (PPA)	89% (95% CI: 74% - 95%)		
Negative Percent Agreement (NPA)	100% (95% CI: 97%-100%)		

*1 sample generated an invalid ASSURE-100 Rapid COVID-19 Test result (0.6% invalid rate)

Table 2: Cumulative PPA results stratified by days of onset up to 8 days of symptoms.

Days Since Symptom Onset	# Specimens Tested	# Cumulative Positive ASSURE-100 Rapid COVID-19 Antigen Test	Cumulative Positive RT-PCR	Cumulative PPA
0 to 1 day	37	1	2	50%
0 to 2 days	68	4	5	80%
0 to 3 days	98	9	11	82%
0 to 4 days	118	15	18	83%
0 to 5 days	130	22	25	88%
0 to 6 days	137	23	26	88%
0 to 7 days	142	25	28	89%
0 to 8 days	153	31	35	89%
Total	**153**	**31**	**35**	**89%**

Patient Demographics

A total of 158 patients participated in the clinical study. Ages of patients from 2 years to 92 years. Age distribution and the positive results broken down by age of the patients are shown below.

Table 3: Age distribution of patients and specimen positivity.

Age Group	ASSURE-100 COVID-19 Antigen Test (N=158)		
	Total	Total Positive	Prevalence
2-13 years	7	1	14%
14-24 years	21	1	5%
25-64 years	105	26	25%
≥ 65 years	20	3	15%
Total	153	31	20%

ANALYTICAL PERFORMANCE

Limit of Detection

The ASSURE-100 Rapid COVID-19 test limit of detection (LoD) was determined by evaluating different concentrations of chemically inactivated SARS-CoV-2 virus. Negative nasal swab samples were eluted in saline (0.9% NaCl). Inactivated SARS-CoV-2 virus was diluted in this negative clinical nasal matrix pool at various titers to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 50µL of each virus dilution onto the swab. The contrived nasal swab samples were tested according to the test procedure.

The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The LoD of the ASSURE-100 Rapid COVID-19 Test in natural nasal swab matrix was confirmed as 700 $TCID_{50}$/mL.

Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity and potential interference of ASSURE-100 Rapid COVID-19 Test was evaluated by testing commensal and pathogenic microorganisms that may exist within the nasal cavity (11 bacteria, 16 viruses, 1 yeast and pooled human nasal wash). Each of the organisms were tested in triplicate in the absence or presence of chemically inactivated SARS-CoV-2 virus (2,100 $TCID_{50}$/mL). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross Reactant		Test Concentration	Cross-Reactivity Results	Interference Results
Virus	Enterovirus	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human Adenovirus	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC-43	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza virus A	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza virus B	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human respiratory syncytial virus	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Rhinovirus	1.0×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Bacteria	*Bordetella pertussis*	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Chlamydia pneumoniae	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Haemophilus influenzae	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Legionella pneumoniae	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Pseudomonas aeruginosa	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Staphylococcus aureus	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Staphylococcus epidermidis	1.0×10^6 CFU/mL	No cross-reactivity	No interference
	Streptococcus pneumoniae	1.0×10^6 CFU/mL	No cross-reactivity	No interference

	Streptococcus pyogenes	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Streptococcus salivarius	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
Yeast	*Candida albicans*	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference

The Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of nucleocapsid protein sequence homology between SARS-CoV-2 and organisms not available for wet testing.

- No protein sequence homology was found between *M. tuberculosis*, however, cross-reactivity cannot be ruled out.
- For *P. jirovecii* no protein sequence homology was found, however, cross-reactivity cannot be ruled out.
- The human coronavirus HKU1 nucleocapsid protein was found to have 36.7% homology across 82% of the sequence. Thus, cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and SARS-CoV is high, at 90.5% across 100% of the sequence, therefore cross-reactivity is likely.
- The homology between SARS-CoV-2 nucleocapsid protein and MERS-CoV is relatively low, at 48.5% over 91% of the sequence, however, cross-reactivity cannot be ruled out.

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 6.3 x10^6 $TCID_{50}$/mL of chemically inactivated SARS-CoV-2 virus with the ASSURE-100 Rapid COVID-19 Test.

Endogenous Interfering Substances

Substances naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity, were evaluated for interference with the ASSURE-100 Rapid COVID-19 Test at the concentrations listed below in the presence of chemically inactivated SARS-CoV-2 at a low concentration. None were found to affect test performance.

Substance	Concentration	Interference Results
Whole Blood (Sheep)	4%	No interference observed
Mucin (Bovine)	0.5%	No interference observed
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No interference observed
Naso GEL (NeilMed)	5% v/v	No interference observed
CVS Nasal Drops (Phenylephrine)	15% v/v	No interference observed
Afrin (Oxymetazoline)	15% v/v	No interference observed
CVS Nasal Spray (Cromolyn)	15% v/v	No interference observed
Zicam	5% v/v	No interference observed
Homeopathic (Alkalol)	1:10 dilution	No interference observed
Sore Throat Phenol Spray	15% v/v	No interference observed
Tobramycin	4 µg/mL	No interference observed
Mupirocin	10 mg/mL	No interference observed
Fluticasone Propionate	5% v/v	No interference observed
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No interference observed

CUSTOMER HELPLINE

If you have any questions about the ASSURE-100 Rapid COVID-19 Test or your test result, please contact our Customer Helpline +1 855 929 6011
info@assure-test.com

SYMBOLS

	This symbol indicates that the product has a temperature limitation.
	This symbol indicates the total number of tests provided in the kit box.
	This symbol indicates that the product is for single use only. It is not to be re-used.
	For *In Vitro* Diagnostic Use.
	This symbol indicates that you should consult the instructions for use.
	For Prescription Use Only.
	This symbol indicates the product's catalog number.
	This symbol indicates the name and location of the product manufacturer.

ORDERING AND CONTACT INFORMATION

Reorder Numbers:
828-100: ASSURE-100 Rapid COVID-19 Test Kit
US +1 855 929 6011

Technical Support Advice:
US +1 855 929 6011
info@assure-test.com

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ASSURE-test.com

Date of last revision: 5/04/2022

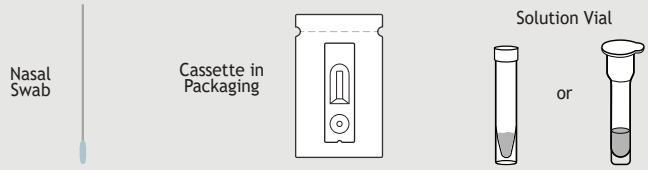
ASSURE-100

Rapid COVID-19 Test Kit | QUICK REFERENCE INSTRUCTIONS

- For Use Under an Emergency Use Authorization (EUA) Only.
- For in vitro diagnostic use.
- For prescription use only.
- For use with kit provided anterior nasal swabs only.

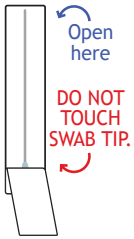
The Assure-100 Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first eight (8) days of symptoms onset.

KIT CONTENTS

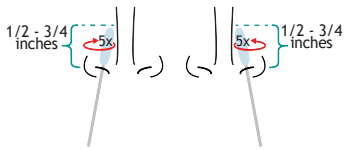


TEST PROCEDURE STEPS

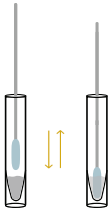
1 **REMOVE** nasal swab from packaging. Do not touch the swab tip.



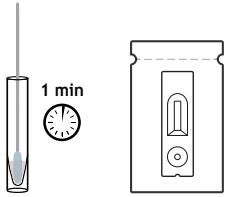
2 **INSERT** entire soft part of the swab into one nostril (½-¾ inches). Rub swab against the inside wall of nostril. Make at least 5 big circles, taking a total of 15 seconds. **Do not just spin the swab.** Repeat in the other nostril.



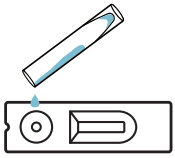
3 After swabbing each nostril, **PLACE** swab into the vial, tip first. **PLUNGE** swab in vial for 10 seconds by rapidly moving swab up and down.



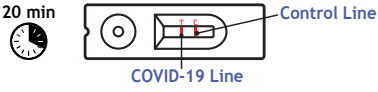
4 **PUSH** swab all the way to the bottom of the vial and leave for one minute. Following this, discard swab and open cassette package.



5 Place test cassette flat on a level surface and **POUR** all liquid content gently into the cassette well. It is normal for some of the liquid to remain in the bottom of the vial.



6 **WAIT** 20 minutes. Results interpretation continued on other side.



See Back

ASSURE-100

Rapid COVID-19 Test Kit | QUICK REFERENCE INSTRUCTIONS

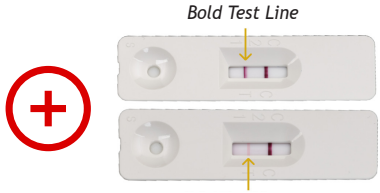
Refer to the Instructions for Use for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test. Positive test results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as SARS-CoV.

ASSURE support line: Further information can be obtained by contacting info@assure-test.com or by calling +1.855.929.6011

RESULT INTERPRETATION

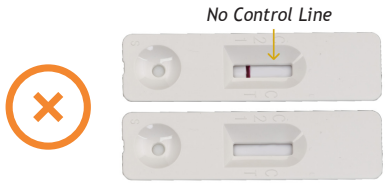
Read the results at 20 minutes.
Do not read the results before 20 minutes or after 30 minutes.
Interpretation before 20 minutes or after 30 minutes may yield false results.

Positive results may appear as bold or as faint as shown in the examples below. The appearance of ANY shade of pink-to-red test line AND the appearance of a pink-to-red control line indicates a positive result for the presence of SARS-CoV-2 antigen. A positive result does not rule out co-infections with other pathogens.



Negative results will show ONLY a control line. A negative result means that SARS-CoV-2 antigen was not detected. A negative does 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 treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Invalid results when no control line is present. Invalid tests should be repeated using a new specimen and new test cartridge.



PROCEDURE FOR CONTROL SWABS

1. Remove control swabs from labeled packaging.
2. Follow steps 3-6 of the Test Procedure steps.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate complexity, high complexity, or waived tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.