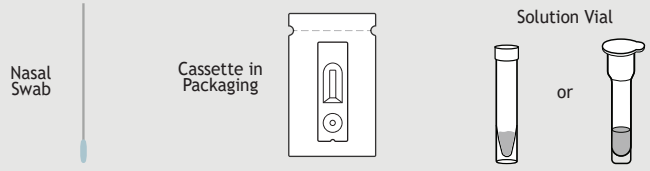
ASSURE-100

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

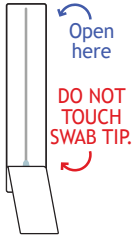
The Assure-100 Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first eight (8) days of symptoms onset when serially tested at least twice over three days with at least 48 hours between tests.

KIT CONTENTS

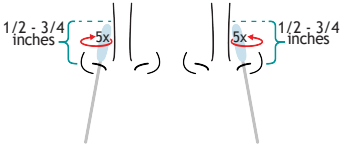


TEST PROCEDURE STEPS

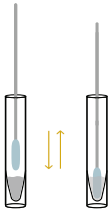
1 **REMOVE** nasal swab from packaging. Do not touch the swab tip.



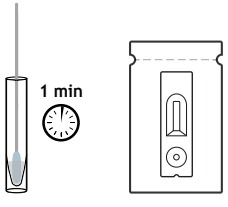
2 **INSERT** entire soft part of the swab into one nostril (½-¾ inches). Rub swab against the inside wall of nostril. Make at least 5 big circles, taking a total of 15 seconds. **Do not just spin the swab.** Repeat in the other nostril.



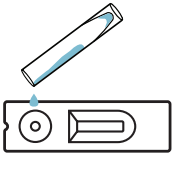
3 After swabbing each nostril, **PLACE** swab into the vial, tip first. **PLUNGE** swab in vial for 10 seconds by rapidly moving swab up and down.



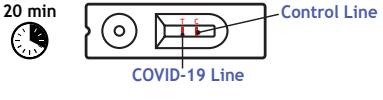
4 **PUSH** swab all the way to the bottom of the vial and leave for one minute. Following this, discard swab and open cassette package.



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

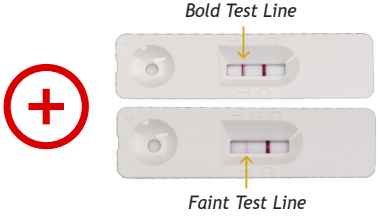
Rapid COVID-19 Test Kit | QUICK REFERENCE INSTRUCTIONS

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

RESULT INTERPRETATION

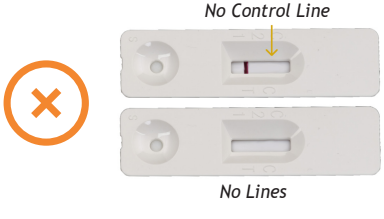
Read the results at 20 minutes.
Do not read the results before 20 minutes or after 30 minutes.
Interpretation before 20 minutes or after 30 minutes may yield false results.

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

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

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 when tested at least twice over three days with at least 48 hours between tests. 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 are 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 Rapid COVID-19 Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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:

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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-19under 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 authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing**.
- Do not use on anyone under 2 years of age.

- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- **Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222**.

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%

- For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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.

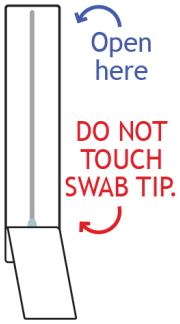
Procedure for Control Swabs

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

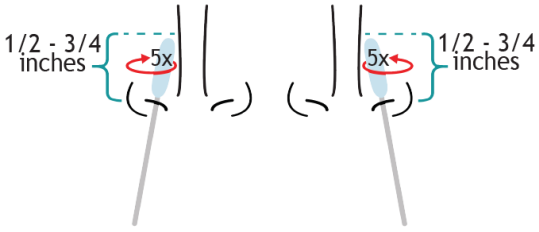
SPECIMEN COLLECTION AND HANDLING
Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling may yield erroneous results. For more information on anterior nasal swab specimen collection, please refer to: Interim Guidelines for Collecting, 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.



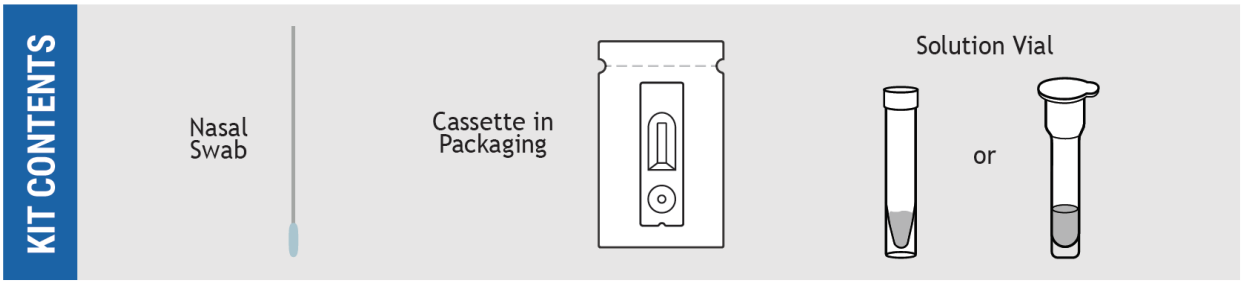
2. Insert entire soft part of the swab into left nostril (½ – ¾ inches). Rub swab against the inside wall of the nostril. Make at least 5 big circles, taking a total of 15 seconds. Do not just spin the swab. Repeat in the other nostril.



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.

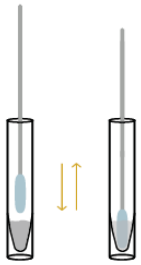
TEST PROCEDURE
Test materials and clinical specimens must be at room temperature before beginning the assay. Use of gloves (not provided) is recommended when conducting testing.

Remove and identify kit components and instructions.

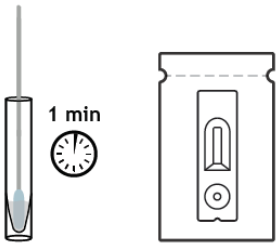


Procedure for Patient Specimens

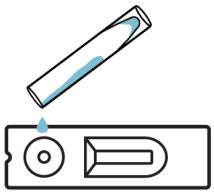
1. After swabbing each nostril, place swab into the vial, tip first. Plunge swab in vial for 10 seconds by rapidly moving swab up and down.



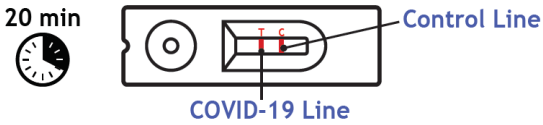
2. Push swab all the way to the bottom of the vial and leave for one minute. Following this, discard swab and open cassette package.



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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Interpretation
With symptoms	Positive	N/A	Positive for COVID-19
	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

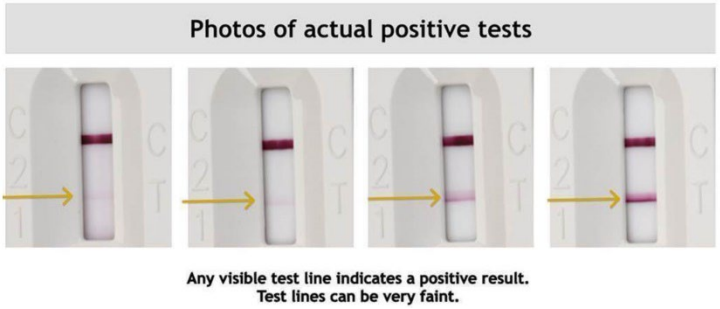
COVID-19 Positive (+):

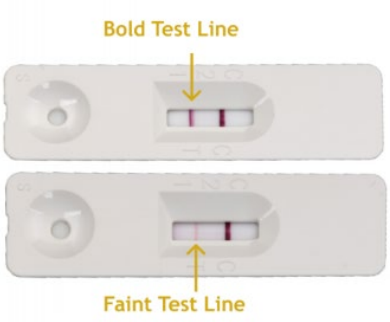
If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink-to-red test (T) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the ASSURE-100 Rapid COVID-19 Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

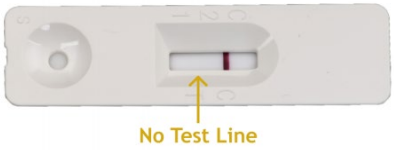




COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

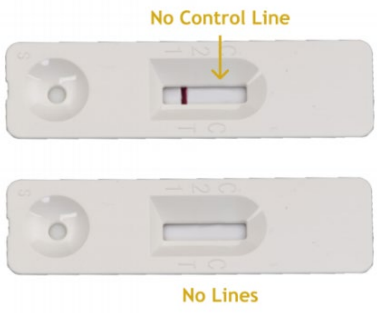


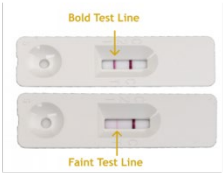
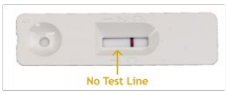
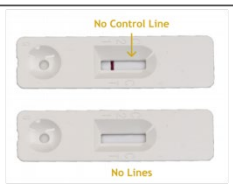
A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.



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

- 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

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.

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)

[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."

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%

Rapid Acceleration of Diagnostics (RADx) Clinical Study

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 4.

Table 4: **Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.**

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97	35/89	44/78	34/57	47/51	44/47
	(9.3%)	(39.3%)	(56.4%)	(59.6%)	(92.2%)	(93.6%)
2	17/34	23/34	25/32	58/62	59/60	43/43
	(50.0%)	(67.6%)	(78.1%)	(93.5%)	(98.3%)	(100%)
4	16/21	15/20	13/15	55/58	53/54	39/40
	(76.2%)	(75.0%)	(86.7%)	(94.8%)	(98.1%)	(97.5%)
6	20/28	21/27	16/18	27/34	26/33	22/27
	(71.4%)	(77.8%)	(88.9%)	(79.4%)	(78.8%)	(81.5%)
8	13/23	13/22	4/11	12/17	12/17	7/11
	(56.5%)	(59.1%)	(36.4%)	(70.6%)	(70.6%)	(63.6%)
10	5/9	5/8		4/9	3/7	
	(55.6%)	(62.5%)		(44.4%)	(42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

OMICRON TESTING

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the ASSURE-100 Rapid COVID-19 Test detected 100% of live virus Omicron samples at a Ct-value of 27.3 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral

concentrations (Ct-values greater than 27.3) were not detected by the ASSURE-100 Rapid COVID-19 Test in this study.

Omicron Pool 1 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	ASSURE-100 Rapid COVID-19 Test Percent Positive (n=5)
Dilution 1	**19.9**	100	100	100
Dilution 2	**21.0**	100	100	100
Dilution 3	**22.3**	100	100	100
Dilution 4	**23.4**	100	100	100
Dilution 5	**25.0**	100	100	100
Dilution 6	**26.6**	100	100	100
Dilution 7	**27.3**	0	100	100
Dilution 8	**28.7**	0	100	0
Dilution 9	**30.1**	0	0	0
Dilution 10	**31.0**	0	0	0
Dilution 11	**32.1**	0	0	0

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. Based upon the testing procedure for this study the LoD equates to 35 $TCID_{50}$/swab.

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 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC-43	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza virus A	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza virus B	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Bacteria	*Bordetella pertussis*	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Chlamydia pneumoniae	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Haemophilus influenzae	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Legionella pneumoniae	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Pseudomonas aeruginosa	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Staphylococcus aureus	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No cross-reactivity	No interference
	Streptococcus pneumoniae	1.0 x 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 or email us at: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

Oceanit Foundry © 2021
828 Fort Street Mall, Ste 600
Honolulu, HI 96813 USA
ASSURE-test.com

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