ASSURE-100

Healthcare Provider Instructions for Use
ASSURE-100 Rapid COVID-19 Home Test
Oceanit Foundry LLC

For use under an Emergency Use Authorization (EUA) only.
For use with anterior nasal swab specimens
For *in vitro* diagnostic (IVD) use only

INTENDED USE
The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

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

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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, and the agent detected may not be the definite cause of disease. Individuals who test positive with the ASSURE-100 Rapid COVID-19 Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 measures such as isolating from others and wearing masks. Negative 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Page 2 of 19 Mapping for SARS-CoV-2 Tests provided by CDC.

The ASSURE-100 Rapid COVID-19 Home Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

The ASSURE-100 Rapid COVID-19 Home 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.

EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

ASSURE-100 Rapid COVID-19 Home 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 Home Test kit contains all components required to carry out an assay test for SARS-CoV-2.

The ASSURE-100 Rapid COVID-19 Home Test 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, placed in a solution vial, mixed, then the solution is poured into the ASSURE-100 device's sample port. A pink/purple 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 pink/purple colored lines. Results should not be read earlier than 20 minutes or after thirty (30) minutes.

MATERIALS PROVIDED

Components	1 Test per Box	2 Tests Per Box	25 Tests Per Box
Test Cassette	1	2	25
Sterile Swab	1	2	25
Solution Vial	1	2	25
Instructions for Use	1	1	1

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or clock

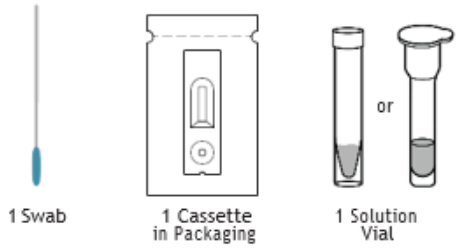
QUALITY CONTROL

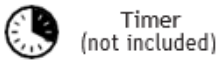
Each ASSURE-100 Rapid COVID-19 Home Test has a built-in internal procedural control. The pink/purple line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct pink/purple Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed.

PREPARE FOR TEST

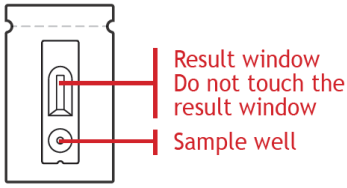
1. Wash or sanitize your hands. Make sure they are dry before starting the test.

2. Check your kit contents. Use only 1 of each of the following for each test.



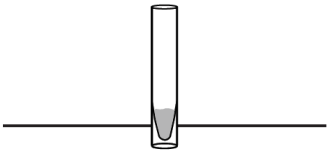


3. When you are ready to proceed with the test, open the foil pouch of the cassette. Locate the circular sample well.



Note: Testing should commence immediately after opening the sealed pouch.

4. Locate the vial. Open the vial and place on flat surface.

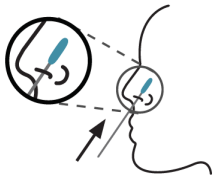


COLLECT NASAL SAMPLE

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling may yield erroneous results. Only the swab provided in the kit is to be used for nasal swab collection.

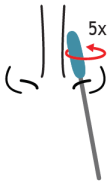
5. Open the swab packaging at the stick end, not the swab end. Do not touch the swab tip.

6. Swab both nostrils as shown.
   Gently insert the entire soft tip of the swab into a nostril (usually ½-¾ of an inch). **You do not need to go deeper**. With young children, the swab may not need to be inserted so far.



Using medium pressure, rub the swab against all of the inside walls of your nostril. Make at least 5 big circles, taking at least 15 seconds per nostril. Do not just spin the swab.

Using the same swab, repeat step 6 in the second nostril.

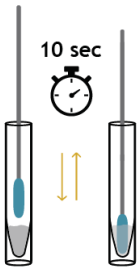


Check: Did you swab both nostrils? A false negative may occur if the nasal swab is not properly collected.

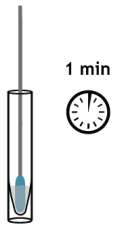
SPECIMEN TRANSPORT AND STORAGE
Do not return the nasal swab to original paper packaging. Samples should be tested immediately after collection. If immediate testing is not possible, swabs should be placed in the solution vial and tested within 20 minutes of collection. If the sample cannot be tested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

7. After swabbing each nostril, immediately place swab into the vial and slowly move up and down for 10 seconds.

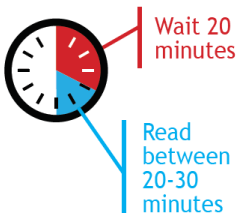


8. Push swab all the way to the bottom of the vial and leave for 1 minute. Following this, dispose of the swab.



9. Place test cassette with the sample well facing up on a flat surface and **CAREFULLY** pour **ALL** the liquid content **GENTLY** into sample well to avoid spilling. It is normal for a minimal amount of the liquid to remain in the bottom of the vial.

10. Start your timer for 20 minutes. Read the results at 20 minutes. Do not read the result before 20 minutes or after 30 minutes.



Note: A false negative or false positive result may occur if the test result is read before 20 minutes or after 30 minutes.

TEST 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	Third Result Day 5	Interpretation
With symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	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/purple 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 Home 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.**
- **Test 2 more times at least 48 hours apart if the individual does not have 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.

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

STORAGE AND STABILITY

Store ASSURE-100 Rapid COVID-19 Home Test in a dry place between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. The test cassette must remain in the sealed foil pouch until use. For up-to-date test kit expiration dating please visit: http://www.fda.gov/covid-tests

WARNINGS 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-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 and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- 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.**

Chemical Name	Harms (GHS) code for each ingredient	Concentration
Triton X-100	Harmful if swallowed (H302) Cause skin irritation (H315) Causes serious eye damage (H318)	1%
Sodium Azide	Harmful if swallowed (H300) Cause skin irritation (H310) Aquatic hazard (H400, H410)	0.09%

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

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2022 and May 2022. 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.

PERFORMANCE CHARACTERISTICS

Limit of Detection

The ASSURE-100 Rapid COVID-19 Home 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 ASSURE-100 Rapid COVID-19 Home 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 Home 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 following table.

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 Home 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 Home 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
Body and Hand Lotion (Suave)	0.5% w/v	No interference observed
Hand Lotion (Equate)	5% w/v	No interference observed
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	No interference observed
Hand Sanitizer 80% ethanol, fast drying	15% v/v	No interference observed
Hand soap liquid gel (Equate)	10% w/v	No interference observed
Hand Sanitizer cream lotion (Gold Bond)	15% v/v	No interference observed
Body Lotion with 1.2% dimethicone (Thera)	0.5% w/v	No interference observed
VicksVapoRub (Camphor, Eucalyptus oil, Menthol)	4.7% w/w	No interference observed
VicksVapoRub (Camphor, Eucalyptus oil, Menthol)	2.6% w/w	No interference observed
VicksVapoRub (Camphor, Eucalyptus oil, Menthol)	1.2% w/w	No interference observed
Surface sanitizer (citric acid)	1% v/v	No interference observed

Flex Studies

A robust use of ASSURE-100 Rapid COVID-19 Home Test was demonstrated by nine (9) flex studies as follows:

1) Temperature and humidity
2) Delay in Sample Testing
3) Delay in Operational Steps/Variable swab mixing
4) Result reading time variability
5) Sample volume variability
6) Disturbance while testing
7) Test device drop
8) Non-level positioning of test device
9) Lighting conditions

Clinical Evaluation

The performance of the ASSURE-100 Rapid COVID-19 Home Test was established in a prospective clinical study conducted between March 2022- May 2022 with 205 subject-collected nasal swabs from patients with COVID-19 symptoms within 8 days of symptoms. Patients were enrolled prospectively at 5 sites in the United States. A high-sensitivity FDA EUA-authorized RT-PCR SARS-CoV-2 assay was used as a comparator method to test anterior nasal swab samples that were collected from each subject by a healthcare professional.

The ASSURE-100 Rapid COVID-19 Home Test results are compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the tables below. When conducted by a lay-user, the ASSURE-100 Rapid COVID-19 Home Test identified 84.7% (95% CI: 73%-92%) of the subjects that were identified as SARS-CoV-2 positive by the comparator assay. Additionally, the ASSURE-100 Rapid COVID-19 Home Test correctly identified 100% (95% CI: 97%-100%) of SARS-CoV-2 negative subjects.

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

ASSURE-100 Rapid COVID-19 Home Test	RT-PCR Method		
	Positive	**Negative**	**Total**
Positive	50	0	50
Negative	9	146	155
Total	**59**	**146**	**205**
Positive Percent Agreement (PPA)	84.7% (95% CI: 73%-92%)		
Negative Percent Agreement (NPA)	100% (95% CI: 97%-100%)		

Table 2: Cumulative PPA results stratified by days of onset up to 7 days of symptoms.

Days Since Symptom Onset	Cumulative Number of Specimens Tested	Cumulative Positive ASSURE-100 Rapid COVID-19 Home Test	Cumulative Positive RT-PCR	Cumulative PPA	% Confidence Interval
0 to 1 day	10	2	2	100%	34%-100%
0 to 2 days	41	8	11	72.7%	43%-90%
0 to 3 days	96	19	25	76%	57%-89%
0 to 4 days	134	31	39	79.5%	64%-89%
0 to 5 days	161	40	48	83.3%	70%-91%
0 to 6 days	188	45	53	84.9%	73%-92%
0 to 7 days	199	50	59	84.7%	73%-92%
Total	**205**	**50**	**59**	84.7%	73%-92%

A total of 205 patients participated in the clinical study. Ages of patients ranged from 7 years to 88 years.

Table 3: Age distribution of patients and specimen positivity.

Age Group	ASSURE-100 Rapid COVID-19 Home Test (N=205)		
	Total	**Total LFA Positive (TP)**	**Prevalence**
2-13 years	2	0	0%
14-24 years	30	8	27%
25-64 years	152	38	25%
≥ 65 years	21	4	19%
Total	205	50	24%

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

USABILITY STUDY

A usability study was conducted to evaluate the ability of representative lay users to follow the instructions steps provided in the ASSURE-100 Rapid COVID-19 Home Test kit instructions under expected use conditions.

Forty-seven (47) representative test kit users (self-testers, caregiver-child pairs) were observed performing the ASSURE-100 Rapid COVID-19 Home Test while following the kit instructions. Participants were observed by the proctor throughout the entire workflow including sample collection, testing, and results interpretation. The proctor filled in a report form based on their observation of the participants. Following completion of the ASSURE-100 Rapid COVID-19 Home Test, the participants were asked to fill in a questionnaire to assess the ease of use of the test, results interpretation and assess their understanding of the consequences if steps were not performed correctly. Results of the usability study were deemed acceptable.

ASSURE-100

TECHNICAL SUPPORT

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

ORDERING AND CONTACT INFORMATION

Oceanit Foundry LLC
Website: assure-test.com
Email: info@assure-test.com

SYMBOLS

	Catalog Number		For *In Vitro Diagnostic* Use
	Lot Number		Number of Tests Provided in Kit Box
	Expiration Date		Manufacturer
	Temperature Limitation		Date of Manufacture
	One Time Use		Consult Instructions for Use

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