ASSURE-100
Rapid COVID-19 Home Test

For use under Emergency Use Authorization (EUA) only. Carefully read instructions before performing test.
Failure to follow the instructions may result in inaccurate test results.
An anterior nasal swab can be self-collected by an individual age 14 years and older. Children ages 2 to 13 years should be tested by an adult.
In vitro diagnostic use only.

A. 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. Check expiration date on the test cassette pouch.
   - 1 Swab
   - 1 Cassette in Packaging
   - 1 Solution Vial
   - Timer (not included)
3. When you are ready to proceed with the test, open the foil pouch of the cassette. Locate the circular sample well.
   - Result window
   - Do not touch the result window
   - Sample well
   - Note: Testing should commence immediately after opening the sealed pouch.
4. Locate the vial. Open the vial and place on flat surface.

B. COLLECT NASAL SAMPLE
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 1/2-3/4 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.
   - At least 5 big circles.

C. TEST PROCEDURE
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 level surface and CAREFULLY pour ALL of 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.
   - Do NOT pour into the rectangular well.
10. Start your timer for 20 minutes.
   - Read the result 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.

D. TEST INTERPRETATION

<table>
<thead>
<tr>
<th>Status on First Day of Testing</th>
<th>First Result Day 1</th>
<th>Second Result Day 2</th>
<th>Third Result Day 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Negative for COVID-19</td>
<td>Negative for COVID-19</td>
<td>Negative for COVID-19</td>
</tr>
<tr>
<td>Without Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invalid</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
You do not need to perform repeat testing if you have a positive test result at any time. A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely that you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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).

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 you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do 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 your sample. A negative test result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

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 AskMyTestCounts.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.
INTENDED USE
The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow assay 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) swabs from individuals under the age of 14 years.

This test is performed under an Emergency Use Authorization (EUA) and is intended for use when infected with SARS-CoV-2, including in asymptomatic individuals. The test is not intended for use in individuals with symptoms of COVID-19, and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

IF YOU TEST POSITIVE
• If you test positive, then proteins from the virus that causes COVID-19 have been detected in your sample and you likely have COVID-19.

IF YOU TEST NEGATIVE
• If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19. You should continue to follow-up with your healthcare provider.

FOR EMERGENCY USE ONLY
For Use Under an Emergency Use Authorization (EUA) Only.

HOW TO USE THIS TEST
• Serial testing should be performed in all individuals with negative results for the bottom of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

LIMITATIONS
There is a 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 of this false test while performing an EUA at home in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

• If the test is negative, it is possible that you do not have COVID-19, however you should follow-up with a healthcare provider.

• 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 circulating variants but is anticipated to be reflective of the prevalent circulating variants in 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.

• All COVID-19 antigen test negative results are presumptive and confirmation with a laboratory-based assay may be necessary.

• If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

• The test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

• If you have symptoms that may occur if a specimen is incorrectly collected or handled.

STABILITY AND STORAGE
Store the kit at room temperature 65-86°F (18-30°C) and protect from direct sunlight. Do not use past the expiration date. For more information on current expiration dates for at-home OTC COVID-19 diagnostic tests, please visit http://www.fda.gov/covid-tests

Manufactured for Oceanfit Foundry, LLC 11715 Street Mall Honolulu, HI 96816, USA
Made in S. Korea

Date of last revision: 12/22/22
The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow immunoassay intended for the detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swabs from those 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 those 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.

- For EUA only.
- In vitro diagnostic use.
- For use in ages two (2) years and up.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- 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.
- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- This test does NOT determine if you had COVID-19 in the past or if you have immunity.

**Contents:**
- 1 Test Cassette
- 1 Nasal Swab
- 1 Solution Vial
- 1 Instructions for Use
The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow immunosorbent for the detection of nucleocapsid protein antigen from SARS-CoV-2.

**Contents:**
- 1 Instructions for Use
- 2 Solution Vials
- 2 Nasal Swabs
- 2 Test Cassets

**Simple. Fast. Accurate.**

**For Emergency Use Authorization only.**

**For in vitro diagnostic use.**

**For use in ages two (2) years and up.**

**In the USA, this product has not been FDA cleared or approved.**

**For Emergency Use Authorization (EUA) only.**

**This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.**

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**Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing.**

**This test does not determine if you have had COVID-19 in the past or if you have immunity.**

**For up-to-date test kit expiration dating please visit:**

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- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The ASSURE-100 Rapid COVID-19 Home Test has not been evaluated by the CDC, NIAID, or the WHO, and may not be used for diagnostic purposes.
- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing.
- This test does NOT determine if you had COVID-19 in the past or if you have immunity.