SCoV-2 Ag Detect™ Rapid Self-Test Instructions

For Emergency Use Authorization (EUA) only. In vitro diagnostic use only.

Carefully read these instructions before starting the test.

### Materials Needed for Testing
- Test in pouch (Do not open until use)
- Swab
- Single-use dropper bottle
- Timing device (not included)

### Prepare for the test

1. Wash hands or use hand sanitizer before starting the test.
2. Remove one test from the packaging. Place the test on a flat surface, like a counter or tabletop, in an area with good lighting.

### Step 1: Swab Nostrils

1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand.

Only use the swab provided in the kit. * Improper swabbing may lead to false results. * Be sure to swab both nostrils with the same swab.

If swabbing another person, you should wear a face mask. • The swab may not need to be inserted as far into the nostrils if swabbing a child.

### Step 2: Run the Test

1. Hold the top of the test firmly with one hand and place the swab tip (soft end) into the sample port. Gently push the swab tip into the sample port while pressing the swab handle down. The swab should not break when putting in the test.

### Step 3: Check Test Results

#### Positive Result

If the control (C) line and the test (T) line are visible, the test is positive. Any faint visible pink 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 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 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).

#### Negative Result

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 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. This 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 healthcare provider.

#### Invalid Result

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

### Important Notes

- It is recommended that gloves are used during testing. A face mask should be worn if swabbing someone else. Gloves and face mask are not provided.
- A positive test result means that the virus that causes COVID-19 was detected in your sample. You do not need to perform repeat testing if you have a positive result at any time.
- Any faint visible pink test (T) line with the control line (C) should be read as positive.
- If the control (C) line and the test (T) line are visible, the test is positive. Any faint visible pink 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 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 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).
How to Use This Test

- Serial testing should be performed in all individuals with negative results; 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 negative but 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 your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Test Interpretation

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

Stability

- The kit should be stored at room temperature (15°C-30°C or 59°F-86°F) for the duration of its shelf life.
- Exposure to temperatures over 30°C or 90°F can impact the performance of the test and should be minimized.
- The kit should not be frozen or refrigerated.
- For more information on expiration dating for COVID-19 antigen tests, please refer to https://www.fda.gov/covid-19.

Warnings and Precautions

- Read all instructions carefully prior to 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 for the detection of SARS-CoV-2 RNA for any other uses will be in the future.
- The performance of the test is only authorized for the determination of the coronavirus that currently exist and it’s not already the criteria that are not validated.
- 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(h)(1), unless the declaration to termination is authorized or revoked sooner.
- Serial testing should be performed in individuals with negative results at least twice over three days (with at least 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 had symptoms longer than 5 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 supervised by a legal guardian who understands how to perform the test.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or face-covering when collecting a specimen from a child or another individual.
- Do not use any of the kit's contents or packaging to damage.
- Test components are single-use. Do not reuse.
- Do not use test past its expiration date.
- Do not touch the swab tip.
- Once opened, the test should be used within 30 minutes.
- Do not heat test results before 20 minutes or after 25 minutes. Results read before 20 minutes or after 25 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not reuse 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 infection persists, seek medical advice. https://1hospa.org or 1-800-222-1222.

Hazardous Ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>GHS Code for each Ingredient</th>
<th>Concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGEPAL® CA-630</td>
<td>H332, harmful if inhaled</td>
<td>≤0.2%</td>
</tr>
<tr>
<td></td>
<td>H315, causes skin irritation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H318, causes serious eye damage</td>
<td></td>
</tr>
<tr>
<td>ProClin™ 300</td>
<td>H332, harmful if inhaled</td>
<td>≤0.05%</td>
</tr>
<tr>
<td></td>
<td>H314, causes severe skin and eye damage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H317, may cause an allergic skin reaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H318, causes serious eye damage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H312, harmful if swallowed</td>
<td></td>
</tr>
</tbody>
</table>

- For more information on EUA, please visit: https://www.fda.gov/emergency-preparedness-response-website/pandemic/after-market-safety-FEUAs.html
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Limitations

- 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. Most tests have a false negative rate less than 1% in individuals with COVID-19 as compared to a molecular test performed on samples with low viral load.
- 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 for all circulating variants but it is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance of the test 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 molecular 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.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have 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.

Intended Use

The SCoV-2 Ag Detect™ Rapid Self-Test is a lateral flow immunoassay device 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 or older and adult collected anterior nasal (nase) swabs samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 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 SCoV-2 Ag Detect™ Rapid Self-Test is not differentiable between SARS-CoV-2 and SARS-CoV-1.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient symptoms 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 definitive cause of disease. Individuals who test positive with the SCoV-2 Ag Detect™ Rapid Self-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 is 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 LCDN and SNOMED codes, as defined by the Laboratory Laboratory and Diagnosis System (LODS) Test Code Page 2 of 19 Mapping for SARS-CoV-2 Tests provided by CDC.

The SCoV-2 Ag Detect™ Rapid Self-Test is intended for nonprescription use and/or as an auxiliary, for an adult to use testing another aged 2 years or older in a non-laboratory setting. The SC0V-2 Ag Detect™ Rapid Self-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.

Frequently Asked Questions

What are the known and potential risks and benefits of the test?

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Risks; Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about care.
- The results of this test can help limit the potential spread of COVID-19 to your family and others in your community.
- For more information on EUA, go here: https://www.fda.gov/emergency-preparedness-response-terrorism/sars-cov-2-detection-research.

What is a positive test result?

Positive test result. The test indicates the presence of COVID-19, confirming that you likely have COVID-19.

What if I have a negative test result?

Negative test result. The test indicates that you do not likely have COVID-19. You may be negative for 48 hours since antigen tests are not as sensitive as molecular tests; if you do not have symptoms and received a negative result, you should test at least two more times with 48 hours between each test, for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to understand the next steps you should take.

What does an invalid test result mean?

Invalid test result. The test was not done correctly or you have COVID-19 in your nose. You may need to purchase additional tests to perform this serial (repeat) testing.

What is the potential difference between an antigen and molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19: Molecular tests detect genetic material from the virus. Antigen tests, such as the SC0V-2 Ag Detect™ Rapid Self-Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

What is 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.

What is the current epidemiological context of an individual’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Please notify your healthcare provider of positive or negative results from the SCoV-2 Ag Detect™ Rapid Self-Test.