SCoV-2 Ag *Detect*™ Rapid Self-Test Instructions

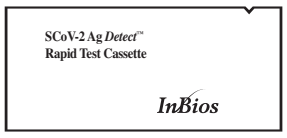
InBios

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)

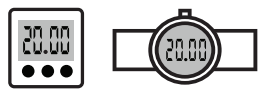


Swab

Single-use dropper bottle

Your bottle may look different than the one shown.

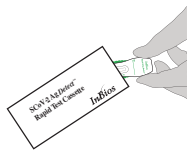
Timing device (not included)

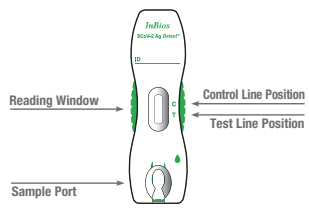


Prepare for the Test

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.

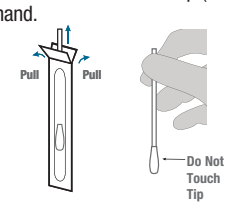




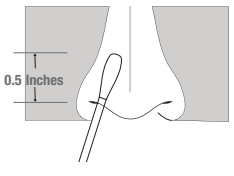
It is recommended that gloves are used during testing. A face mask should be worn if swabbing someone else. Gloves and face mask are not provided.

Step 1: Swab Nostrils

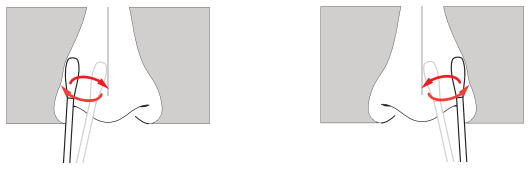
1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand.



2. Carefully insert the swab at least 0.5 inch (1 cm) inside one nostril.



3. Slowly rotate the swab using medium pressure at least four times, rubbing it along the insides of nostril for 15 seconds. The swab tip should be touching the inside wall of the nostril through each rotation. **Using the same swab, repeat sample collection in the other nostril.**

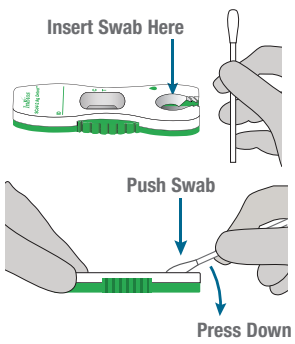


Only use the swab provided in the kit. • Improper swabbing may lead to false results. • Be sure to swab both nostrils with the same swab.

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.

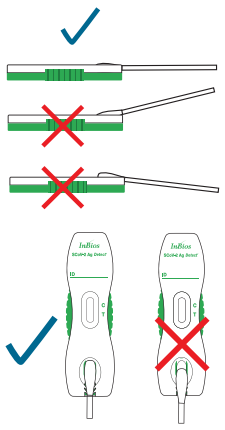
Step 2: Run the Test

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 be firmly in the test.



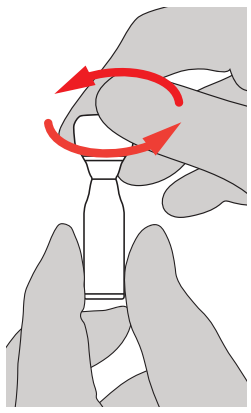
IMPORTANT!
Hold swab close to the tip so it does not break when putting in the test.

2. The swab should be flat in the test and cover the sample port.



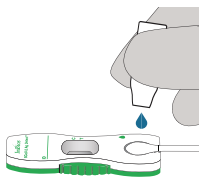
IMPORTANT!
The swab should cover the sample port completely.

3. Remove top of dropper bottle by twisting the top plastic piece. Do not use mouth or teeth to open bottle.



4. Hold the dropper bottle above the swab head. Slowly add all of the liquid on top of the swab head.

Add 1 drop at a time until dropper is empty. Do not add the liquid all at once.

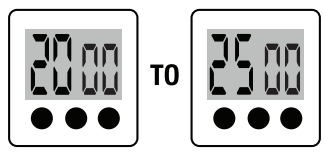


IMPORTANT!
Invalid or incorrect results can occur when less than the whole bottle is added to the test. Make sure to add all of the liquid slowly holding the bottle vertically, 0.5 inches above the swab head.

False negative results can occur when the order of test steps is not correctly followed. Always add the swab to the sample port, and then add the liquid on top of the swab head in the test cassette.

5. Leave test untouched on a flat surface. Check the test results after TWENTY (20) to TWENTY-FIVE (25) minutes.

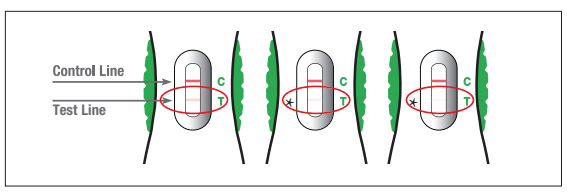
WAIT 20 TO 25 MINUTES



IMPORTANT!
Incorrect results may occur if tests are read before 20 minutes or after 25 minutes.

Step 3: Check Test Results

Positive Result

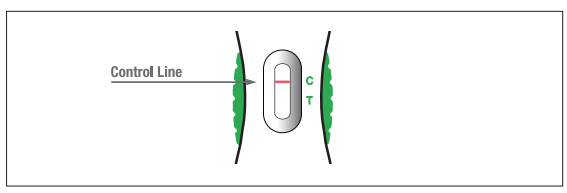


If the control (C) line and the test (T) line are visible, the test is positive. Any faint visible pink test (T) line with the control line (C) should be read as positive.

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



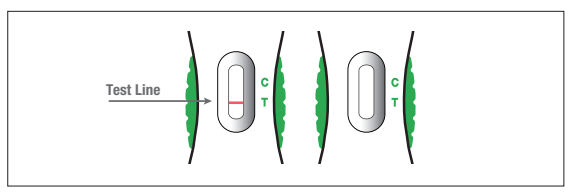
If the control (C) line is visible, but the test (T) line is not visible, the test is negative.

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. 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 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.

Dispose of the test cassette in the trash after reading result.

Turn over for further instructions how to understand your results and determine if repeat testing is necessary.

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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

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.

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

Stability

- The kit should be stored at room temperature (15-30°C or 59-86°F) for the duration of its shelf life.
- Exposure to temperatures over 30°C or 86°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 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 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 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 should be used within 30 minutes.
- Do not read 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 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://poisonhelp.org or 1-800-222-1222.**

Hazardous Ingredients

Chemical Names	GHS Code for each Ingredient	Concentrations
IGEPAL® CA-630	H302, harmful if swallowed H315, causes skin irritation H318, causes serious eye damage	≤3.0%
ProClin™ 300	H302, harmful if swallowed H314, causes severe skin burns and eye damage H317, may cause an allergic skin reaction H318, causes serious eye damage H332, harmful if inhaled	≤0.05%

- 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

- 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.
- 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 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.
- 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 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 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 does not differentiate between SARS-CoV or SARS-CoV-2.

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 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 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, 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 SCoV-2 Ag *Detect*™ Rapid Self-Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The SCoV-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 Result 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 your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

What is the 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 SCoV-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.

How accurate is this test?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at inbios.com/scov-2-ag-detect-self-test/.

What if I have a positive test result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a negative test result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 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 in between tests 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 help you understand the next steps you should take.

What does an invalid test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

Important

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

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Patent Pending
Part No: 900317-04

For questions or to learn more about this product visit www.inbios.com/scov-2-ag-detect-self-test/ or call 866-516-0757 (US Toll Free).

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