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

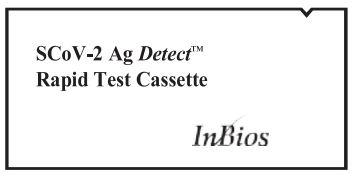
InBios

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

Carefully read these instructions before starting the test.

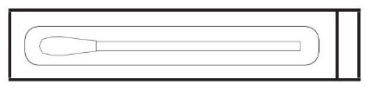
Materials Needed for Testing

1. Test in pouch (Do not open until use)

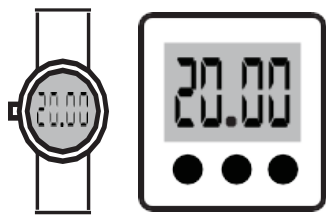


2. Single use dropper bottle

3. Swab



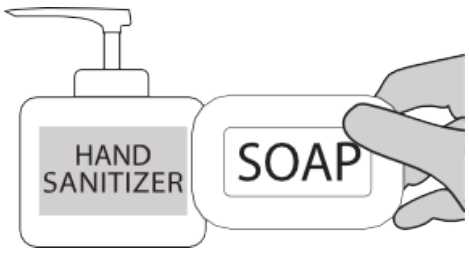
4. Timing device (not included)



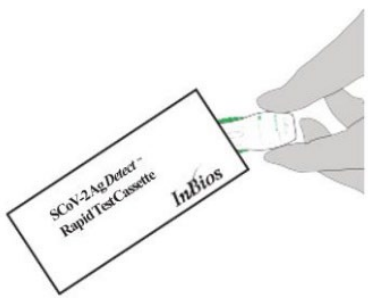
It is recommended that gloves are used during testing. A face mask should be worn if swabbing someone else. Gloves and a face mask are not provided.

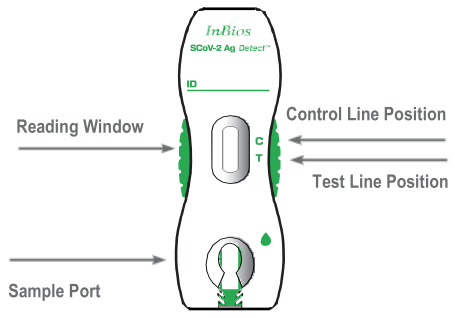
Prepare for the Test

1. Wash hands or use hand sanitizer before starting the test.



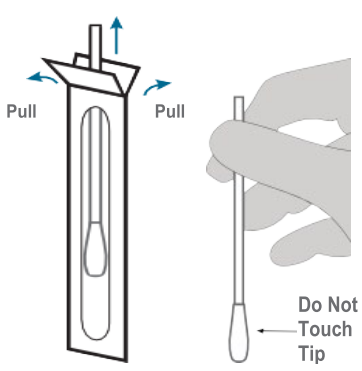
2. Remove one test from the packaging. Place the test on a flat surface, like a counter or tabletop, in an area with good lighting.



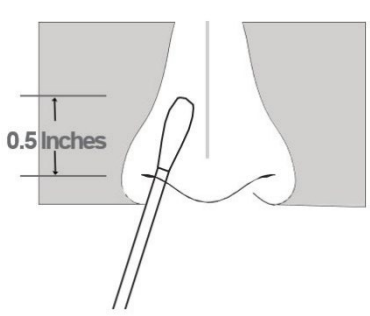


Step 1: Swab Nostrils

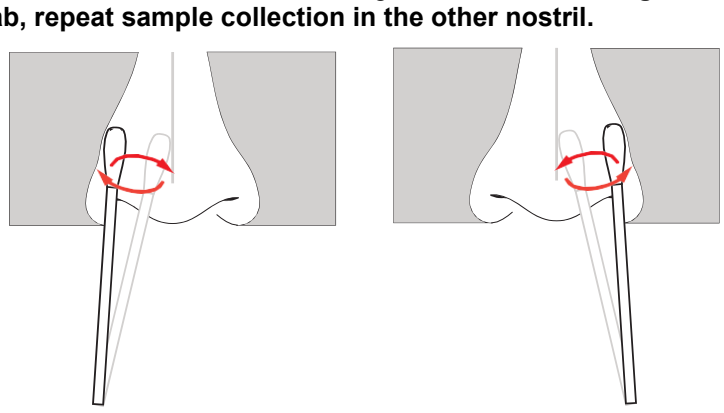
1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand.



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



3. Slowly rotate the swab using medium pressure at least four times, rubbing 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.**

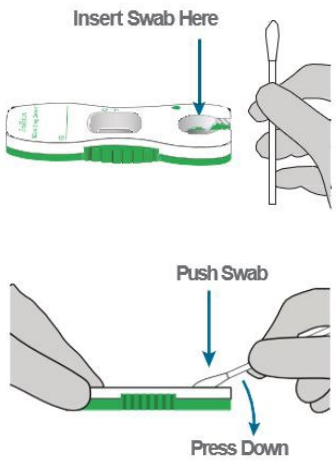


Only use the swab provided in the kit. • Improper swabbing may lead to false results. • Be sure to swab both nostrils with the same swab.

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

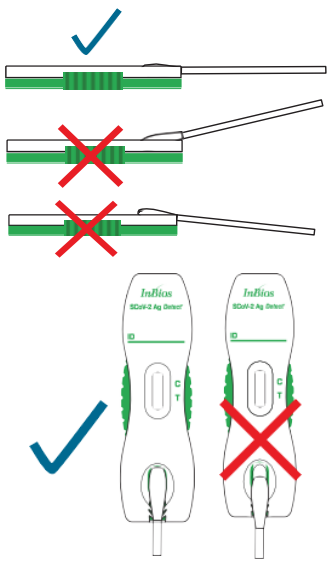
1. Hold the top of the test firmly with one hand and place the swab tip (soft end) into the sample port. Gently push the swab tip into the sample port while pressing the swab handle down. The swab should be firmly in the test.



IMPORTANT!

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

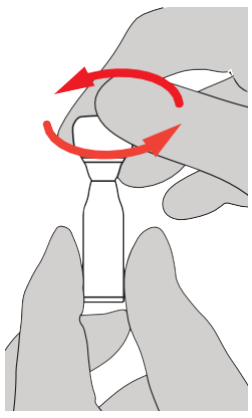
2. The swab should be flat in the test and cover the sample port.



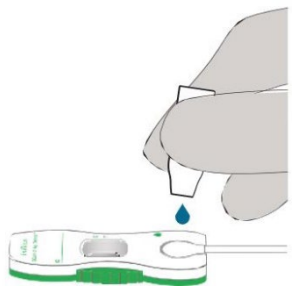
IMPORTANT!

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.



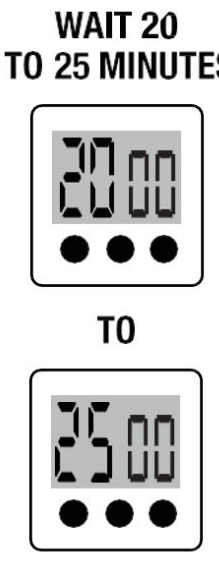
4. Hold the dropper bottle above the swab head. Slowly add all of the liquid on top of the swab head. **Add 1 drop at a time until dropper is empty. Do not add the liquid all at once.**



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



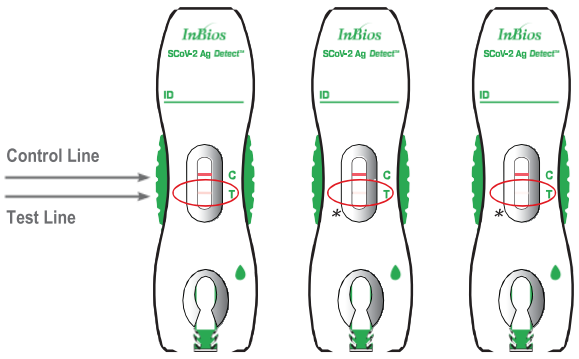
IMPORTANT!

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

Turn over for instructions how to read and understand the results.

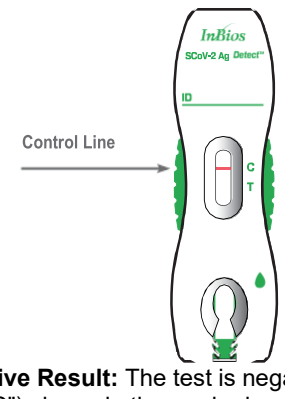
Step 3: Check Test Results

Positive Results



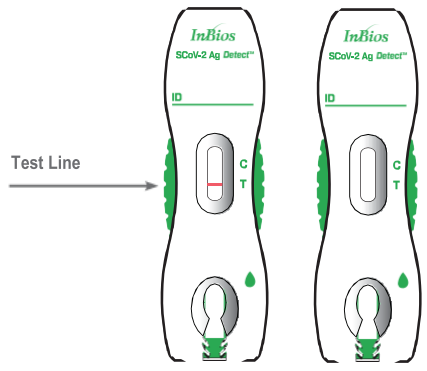
Positive Result: The test is positive if a control line (“C”) and test line (“T”) both show in the marked areas on the test. This means that COVID-19 antigen was detected. ***Look at test line closely!*** A very light pink test line is still considered a positive result.

Negative Result



Negative Result: The test is negative if a control line (“C”) shows in the marked area of the test but no test line (“T”) shows. This means that COVID-19 antigen was not detected.

Invalid Results



Invalid Result: The Test is invalid if no control line shows on the test, even if a test line (“T”) does show up.

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

Understanding Your Results

What does a positive test result mean?

A positive test result means that proteins from the virus that causes COVID-19 were found in your sample. It is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give you a positive test result that is wrong (false positive). If you test positive with the SCoV-2 Ag *Detect* ™ Rapid Self-Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

What does a negative test result mean?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. Read the serial testing section below if you test negative and are not experiencing COVID-19 like symptoms. **Negative results do not rule out SARS-CoV-2 infection.**

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

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?

If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 the test should be run again, using a new test and dropper bottle.

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

Warnings and Precautions

- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- Children 13 years old or younger should not swab themselves and should instead be swabbed by an adult.
- Failure to follow the test procedure may cause incorrect results.
- Do not use a test kit that is expired.
- Test components are single-use. Do not re-use.
- Collecting sample: Test your swab sample immediately for best test performance. Handle swab gently to avoid breaking. Do not touch swab tip during testing.
- The control line may show up within a few minutes of starting the test. It may take up to 20 minutes for a test line to show up.
- False negative test results may occur if a specimen is improperly collected or handled.
- 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.
- For best results, read test in a well-lit area.

Serial Testing Information and Limitations

- If you have symptoms of COVID-19 that started within the last five days, you can use a single test.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing. For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.

Intended Use

SCoV-2 Ag *Detect*™ Rapid Self-Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 Nucleoprotein antigen. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first five days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first five days of symptom onset. This test is also 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, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The SCoV-2 Ag *Detect*™ Rapid Self-Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs 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. The agent detected may not be the definite 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.

Negative results should be treated as presumptive, 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 an individual’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary for patient management.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

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

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 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 person aged 2 years or older. The SCoV-2 Ag Detect™ Rapid Self-Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

Frequently Asked Questions

Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the known and potential risks and benefits of this test?
Potential risks include:
- Possible discomfort during sample collection
- Possible incorrect test results (see Understanding Your Test Results section)

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is Serial Testing?
Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing twice over three days) is more likely to detect COVID-19, especially when you do not have any symptoms.

What is the difference between an antigen and molecular test?
An antigen test, such as the SCoV-2 Ag *Detect*™ Rapid Self-Test, detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory- based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

How accurate is this test?
In a clinical evaluation where results from the SCoV-2 Ag *Detect*™ Rapid Self-Test were compared to an FDA EUA authorized molecular SARS-CoV-2 test, the SCoV-2 Ag *Detect*™ Rapid Self-Test correctly identified 85.7% of positive specimens and 100% of negative specimens. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Where can I find information about Emergency Use Authorizations (EUAs) and COVID-19?
- For more information on EUAs, please visit: 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

For Emergency Use Authorization (EUA) Only

- 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.

Hazardous Ingredients

Chemical Name (CAS)	Hazard statement(s) (GHS code)	Concentration
IGEPAL® CA-630 (9002-93-1)	Acute toxicity, Oral (H302) Skin irritation (H315) Serious eye damage (H318)	≤3.0%
ProClin™ 300 (no CAS assigned)	Acute toxicity, Oral (H302) Acute toxicity, Inhalation (H332) Skin corrosion (H314) Serious eye damage (H318) Skin sensitization (H317)	≤0.05%

- Keep test kit out of reach of children.
- Do not drink liquid in dropper bottle.
- Do not let dropper bottle liquid enter your eyes or touch your skin, as discomfort and irritation may occur.
- If dropper bottle liquid gets in your eyes, rinse carefully with clean water for several minutes. If wearing contact lenses, remove immediately if able, continue rinsing, and seek medical help
- Users should consider eye protection.
- If dropper bottle liquid gets on your skin, wash area immediately with a lot of soap and clean water to rinse liquid from skin.

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Patent Pending
Part No:900317-02

For questions or to learn more about this product visit www.inbios.com/covid-19 or call 206-344-5821 or 866-462-4671 (US Toll Free).