SCoV-2 Ag *Detect*™ Rapid Test

InBios

Quick Reference Instructions

• **For Emergency Use Authorization (EUA) Only** • **For in vitro Diagnostic (IVD) Use** • **For Prescription Use Only**

Study the Instructions for Use thoroughly before using Quick Reference Instructions. This is not a complete package insert.

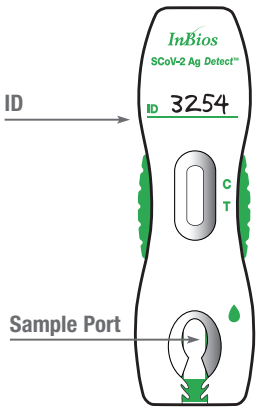
Kit Materials

1. Fifty (50) single-use test cassettes, individually pouched (store at 15-30°C).
2. Four (4) dropper bottles of Lysis buffer, 6 mL per bottle (store at 15-30°C).
3. Fifty (50) sterile nasal swabs, individually pouched (store at 15-30°C). One of the 50 swabs is intended for use as a negative control.
4. Positive Control: swab with SARS-CoV-2 Nucleoprotein antigen dried on the swab. This swab has a blue tint to distinguish it from other swabs in the kit.
5. Instructions for use for SCoV-2 Ag *Detect™* Rapid Test.
6. Quick Reference Instructions for SCoV-2 Ag *Detect™* Rapid Test.

Test Procedure

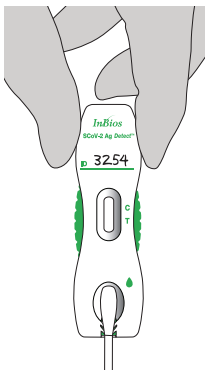
- DO NOT open the foil pouch containing the Test Cassettes until ready to test the sample. Place the Test Cassettes on a clean and flat surface, such as a table top.
- Only perform the test within the recommended temperature, 59-86ºF (15-30ºC) and relative humidity, 20% to 85% non-condensing, may cause erroneous results. Repeat the test if it is performed outside these ranges.
- Use direct nasal swab samples collected following the sample collection steps described in the section below.
- Test specimens immediately after collection for optimal test performance.
- Bring samples to room temperature prior to testing.
- For best results, perform test interpretation in a well-lit area.

1. For each sample to be tested, remove one test cassette from the foil pouches and write the sample identification (sample ID) on the top.

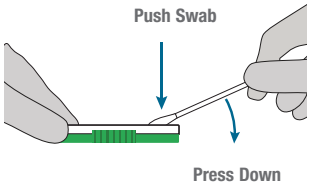


2. Collect direct nasal swab samples following the sample collection steps described in the section below.

3. Hold the cassette top end firmly with one hand. Place the head of the nasal swab specimen directly into the sample port as shown below. The head of the nasal swab must touch the sample pad.



4. While still holding the cassette, **firmly** push swab into the sample port while pressing the swab shaft downwards. Press the swab until it is secured.



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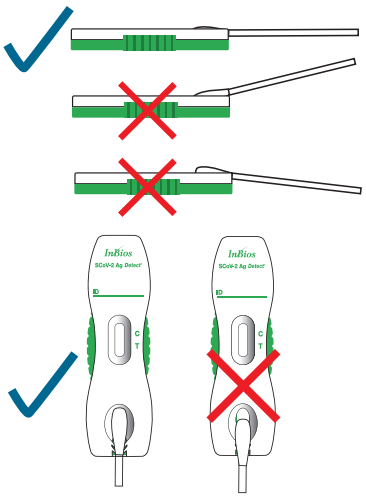
Test Procedure Continued

5. The nasal swab should be flat and touching the sample pad.

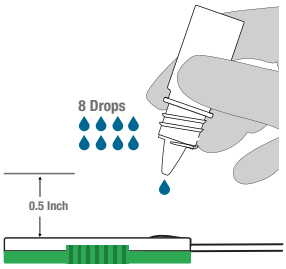


IMPORTANT!
Check that the swab covers the sample pad completely.

Incomplete coverage of the pad may produce a false negative result.

6. Hold the Lysis buffer bottle vertically ~ 0.5 inch above the swab head inserted into the sample port.

SLOWLY add eight (8) drops of Lysis buffer ON TOP of the swab head. ADD ONE (1) drop at a time.

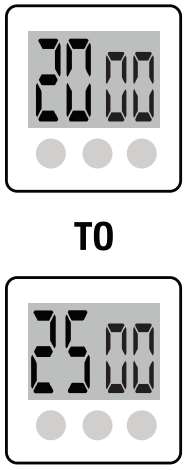


IMPORTANT!
Adding less than 8 drops may produce invalid results.

DO NOT touch the tip of the dropper bottle to the swab head while dispensing.

7. Allow the test cassette to remain undisturbed. Read the test results after TWENTY (20) to TWENTY-FIVE (25) minutes.

WAIT 20 TO 25 MINUTES



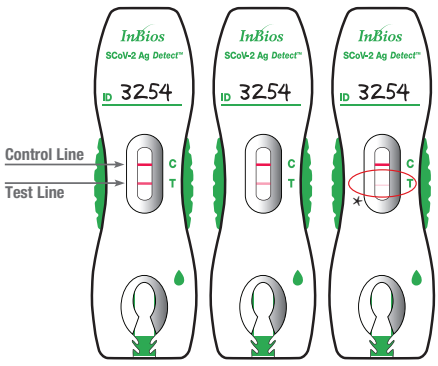
Interpretation of Results

Do not interpret results after twenty-five (25) minutes. Results interpreted after 25 minutes may result in false positive, false negative, or invalid result. ***For best results, perform test interpretation in a well-lit area.***

Positive Result

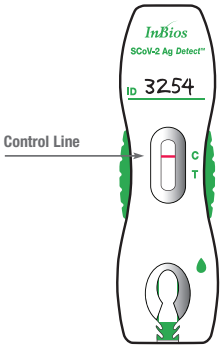
The test detected SARS-CoV-2 Nucleoprotein antigen when a control line ("C") and a test line ("T") appear in the marked areas on the test cassette.

****Observe test line closely!*** A very faint pink test line is still considered a positive result.



Negative Result

The test is negative when only the control line appears on a test cassette. A negative result indicates that the SCoV-2 Ag *Detect™* Rapid Test did not detect SARS-CoV-2 Nucleoprotein antigen.

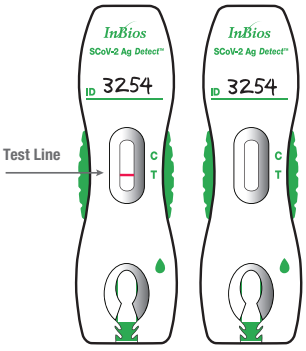


Note: Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Note: For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close contract 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 SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Invalid Result

The test is invalid if no control line appears on the test cassette, regardless of whether a test line is seen. If an invalid result is observed, it is recommended to re-test using a newly collected sample with a new cassette.



Quality Control

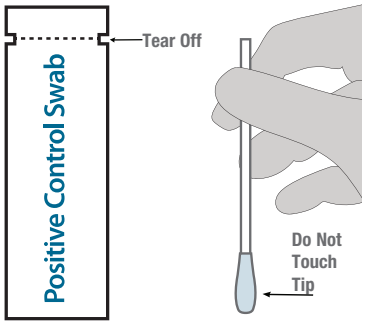
The positive and negative controls should be run:

- Once per kit upon kit opening.
- Once for each new operator.
- As deemed additionally necessary by your internal quality control procedures and in accordance with Local, State and Federal regulations or accreditation requirements.
- Kit includes one set of controls. Additional controls may be purchased separately.

Preparing the positive and negative controls

1. Positive Control

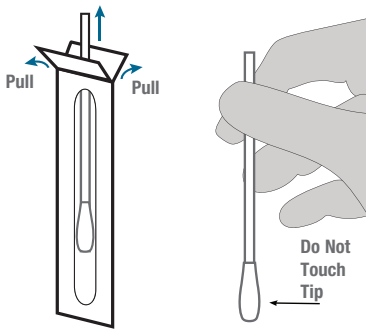
Remove Positive Control swab (with SARS-CoV-2 Nucleoprotein antigen dried on the swab) from its pouch.



Test As Per Test Procedure Steps 3-7

2. Negative control

Use one of the sterile swabs provided with the test kit to perform the negative control testing. Remove an unused swab from its packaging.



Test As Per Test Procedure Steps 3-7

3. Proceed to Test Procedure.

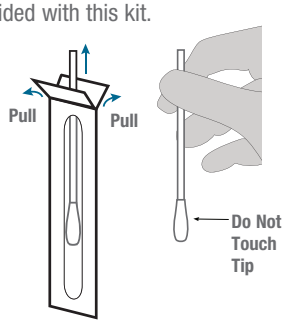
Test unknown specimens as per Test Procedure steps 1-7. If the correct control results are not obtained, do not perform patient tests. Contact Technical Support at 1-866-INBIOS1 or 206-344-5821 during normal business hours before testing patient specimens.

Sample Collection Procedure

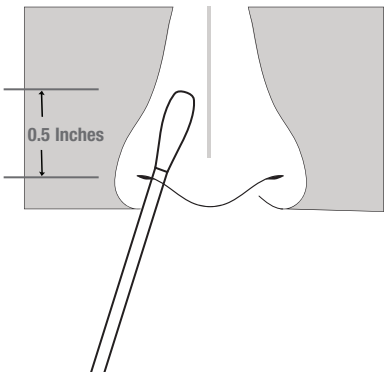
- Collect the direct nasal swab samples following CDC guidelines: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation for Coronavirus Disease 2019 (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).
- Use appropriate personal protective equipment.
- Only the swab provided in the kit is to be used for nasal swab collection.

1. Wash hands before sample collection.

2. Remove the swab from the packaging. Be careful not to touch the swab tip (soft end) with hand. If swab tip touches any surface, then it is recommended to discard swab and use a different swab provided with this kit.



3. Carefully insert the swab **at least** 1 cm (0.5 inch) inside the nostril.



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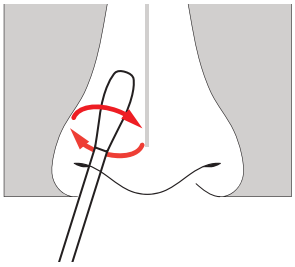
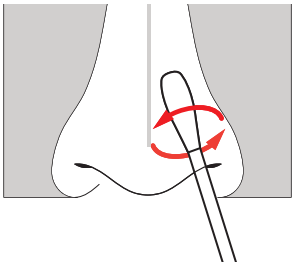
Sample Collection Procedure Continued

4. 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.



5. Using the same swab, repeat sample collection in the other nostril.



6.

- Test specimens immediately after collection for optimal test performance.
- Inadequate specimen collection or improper sample handling/storage/ transport may yield erroneous results.

7.

- Do not return the nasal swab to the original paper packaging.
- If storage is needed for transportation at least four times, use a plastic tube with cap.
- If a delay in testing is expected, store specimens at 2-8°C for up to 4 days.

Limitations

Reference the Instructions for Use for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.

- Failure to follow the test procedure may cause erroneous results or invalidate the test results.
- Freezing and thawing of respiratory specimens must be avoided.
- False negative test results may occur if a specimen is improperly collected, transported, or handled.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, - 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

Intended Use

SCoV-2 Ag *Detect™* Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 Nucleoprotein antigen in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within 5 days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in anterior nasal 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 a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as 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 decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results 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. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Clinical performance may vary depending on the variants circulating at the time of testing. The SCoV-2 Ag *Detect™* Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings. The SCoV-2 Ag *Detect™* Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Assistance

If you have any questions regarding the use of this product or if you want to report a problem with the test, please call InBios International, Inc. Technical Support at 1-866-INBIOS1 or 206-344-5821, or visit inbios.com/technical-support/ to submit your inquiry.

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