# SCoV-2 Ag Detect™ Rapid Test

***Instructions for Use***

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

## INTENDED USE

The SCoV-2 Ag *Detect*™ Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from 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. 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 SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) 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 patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
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.

The SCoV-2 Ag *Detect*™ Rapid Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The SCoV-2 Ag *Detect*™ Rapid 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.

## SUMMARY AND EXPLANATION OF THE TEST

SCoV-2 Ag *Detect*™ Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 Nucleoprotein antigen. The test can be performed using direct nasal samples collected without transport media, requires minimal training to perform, and takes less than 25 minutes to obtain results, making it a suitable diagnostic tool for use in a point-of-care setting.

## PRINCIPLE OF THE TEST

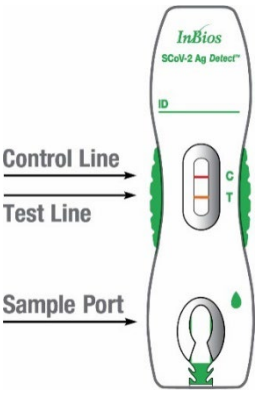
SCoV-2 Ag *Detect*™ Rapid Test is a single-use, qualitative, membrane-based lateral flow immunoassay for detection of SARS-CoV-2 Nucleoprotein antigen. This test may be used with direct nasal swabs respiratory samples collected without transport media.

The rapid test membrane is pre-coated with anti-Nucleoprotein antibodies on the test line region and utilizes a separate control line to assure assay flow and performance. A direct nasal swab specimen is eluted with a proprietary lysis buffer solution directly in the test cassette sample port. Then the eluted sample migrates upward on the membrane to react with the test and control lines.

The viral antigens, if present, bind to the antibody-labeled gold conjugates as the specimen flows upward. Gold conjugates bound to a viral antigen continue to travel upwards and are captured by the test line.

If SARS-CoV-2 Nucleoprotein antigen is present in a patient sample, a red line will appear in the test line region. A red line at the control region should always appear if the assay is performed correctly. The presence of this red control line verifies that proper flow has occurred, and no failure of the gold conjugate has occurred. Refer to the Interpretation of Results section for additional information regarding results analysis.

The entire procedure takes approximately 25 minutes. The layout for the SCoV-2 Ag *Detect*™ Rapid Test is shown below:




## PRECAUTIONS

- For prescription and in vitro diagnostic use only.
- 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 (EUA) for use by laboratories certified under the CLIA that meet the 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.
- 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.
- 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.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Do not use the kit past its expiration date.
- Do not touch the swab tip.
- Use only the provided swabs to collect direct nasal swab specimens. Do not use other swabs.
- Do not store or place the swab in the original paper packaging after specimen collection. If storage is needed, use a sterile plastic tube with cap.
- Do not store swab specimens in viral transport media or use swab specimens stored in viral transport media with this test.
- Do not use excessive force, pressure or bending when collecting the swab samples as this may result in accidental breakage of the swab shaft.
- Once opened, the test cassette should be used within 30 minutes.
- Do not read tests 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.

- Leave test cassette sealed in its foil pouch until just before use. The cassette should be used immediately after removal from its pouch to minimize exposure to humidity. Do not use if pouch is damaged or open.
- The provided polyester spun swabs are for single use only. Do not use if there is an evidence of damage or contamination to the swab.
- INVALID RESULTS can occur when an insufficient volume of Lysis buffer is added to the test. To ensure delivery of adequate volume, hold the bottle vertically, ~0.5 inch above the swab well, and add 8 drops slowly. Adding less than 8 drops may result in inaccurate results.
- Do not directly touch the tip of the Lysis buffer bottle to surfaces to avoid contamination. If bottle tip touches any surface, then it is recommended to discard bottle and use a different bottle provided with this kit.
- **For best results, perform test interpretation in a well-lit area.**
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all samples and kits used as if they contain infectious agents. Follow the standard procedures for proper disposal of used kit components.
- Wear protective clothing, eye protection, and disposable gloves while performing the assay. Wash hands thoroughly when finished.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, and mouth. 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://www.poisonhelp.org or 1-800-222-1222.**

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

## STORAGE

The kit is designed to be stored at room temperature (15-30°C) for the duration of its shelf life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The kit should not be frozen or refrigerated. The test cassette should be used within 30 minutes of removal from its pouch to minimize exposure to humidity.

Human direct nasal swab samples collected *without* viral transport media can be tested with this assay.

- For information on specimen collection for COVID-19, refer to the 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).
- Specimens should not remain at room temperature (15-30°C) longer than 4 hours, or refrigerated (2-8°C) for longer than 4 days prior to testing.
- If samples are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.

## KIT CONTENTS

The kit is available under catalog #COVAG-20 and catalog #COVAG-RC. Kits contain the following components:

| | Catalog #COVAG-20 | Catalog #COVAG-RC |
|---|---|---|
| Single-use test cassettes, individually pouched (store at 15-30°C) | Twenty (20) | Fifty (50) |
| Dropper bottles of Lysis buffer, 6 mL per bottle (store at 15-30°C). | Two (2) | Four (4) |
| Sterile nasal swabs, individually pouched (store at 15-30°C). One of the swabs is intended for use as a negative control. | Twenty (20) | Fifty (50) |
| 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. | One (1) | One (1) |
| Instructions for use for the SCoV-2 Ag *Detect*™ Rapid Test. | One (1) | One (1) |
| Quick Reference Instructions for the SCoV-2 Ag *Detect*™ Rapid Test. | One (1) | One (1) |

## MATERIALS REQUIRED BUT NOT PROVIDED

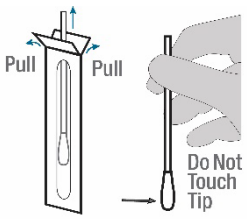
1. Timer
2. Pair of gloves
3. Biohazard container

## TEST PROCEDURE: Sample Collection and Handling

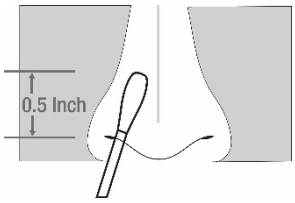
1. Collect the direct anterior nasal swab samples following CDC guidelines: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation for Coronavirus Disease 2019 (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).

2. Wash hands before sample collection. Use appropriate personal protective equipment.

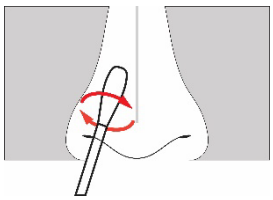

3. Remove the swab from the packaging. Be careful not to touch the swab tip (soft end) with hand. If swab tip touches any surface, then it is recommended to discard swab and use a different swab provided with this kit.



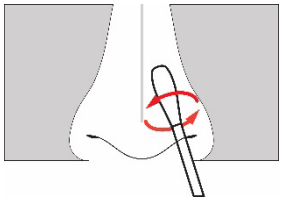

4. Carefully insert the swab at least 1 cm (0.5 inch) inside the nostril.



5. 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.



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



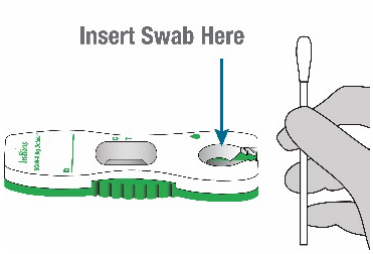
- Only the swab provided in the kit is to be used for nasal swab collection.
- Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Do not return the nasal swab to the original paper packaging. Do not place the swab into transport media.
- If storage is needed for transportation, use a sterile plastic tube with cap without any transport media. Samples are stable for up to 4 hours at room temperature and up to 4 days at 2 -8°C.

## TEST PROCEDURE: Specimen Testing

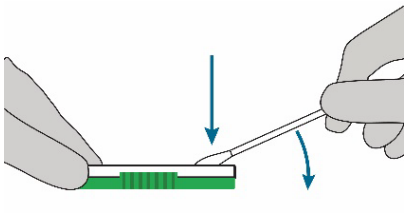
1. For each sample to be tested, remove one test cassette from pouch.
2. Place the cassette horizontally on a flat surface.
3. Write in the specimen ID on the cassette.
4. Use direct anterior nasal swab samples collected following the sample collection steps described in the section above. Test specimens immediately after collection for optimal test performance.


**Important: Check to be sure the cassette is on a flat surface. False negative results can occur if the test cassette is not on a flat surface.**

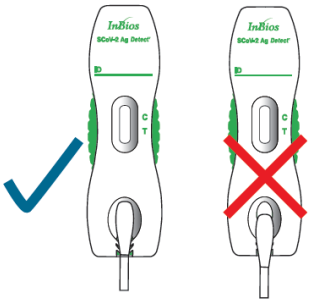
5. Hold the cassette top end firmly with one hand.
6. Place the head of the nasal swab specimen directly into the sample port as shown below. The head of the nasal swab must touch the sample pad at the bottom of the sample port.

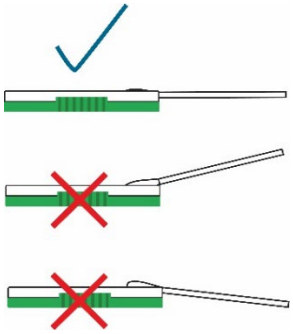


7. While still holding the cassette, firmly push swab into the sample port while pressing the swab shaft downwards. Press the swab until it is secured.



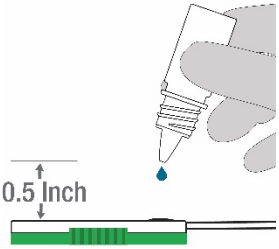
8. The nasal swab should be flat and touching the sample pad.





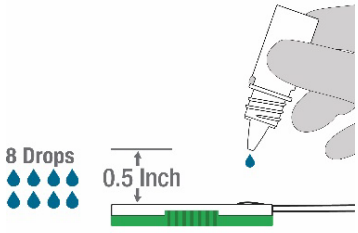
**Important: Check that the swab covers the sample pad completely. Incomplete coverage of the pad may produce a false negative result.**

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



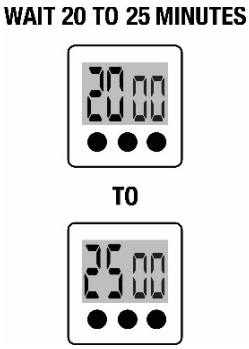

10. **SLOWLY add eight (8) drops of Lysis buffer ON TOP of the swab head. ADD ONE (1) drop at a time. DO NOT touch the tip of the dropper bottle to the swab head while dispensing.**

**Important! Adding less than 8 drops may produce invalid results.**




11. Allow the test cassette to remain undisturbed. Results should be interpreted between twenty (20) and twenty-five (25) minutes after starting the test. Do not interpret results after twenty-five (25) minutes, as they may be inaccurate.

**For best results, perform test interpretation in a well-lit area.**

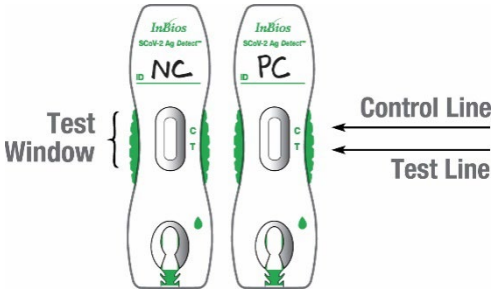


- See the Interpretation of Results section for instructions on how to interpret the SCoV-2 Ag *Detect*™ Rapid Test results.
- Dispose of all tests and swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations.

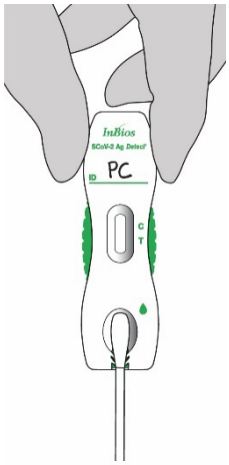
## TEST PROCEDURE: Positive and Negative Control Testing

Run the positive and negative controls once per kit upon kit opening to ensure assay integrity. It is recommended that new users run positive and negative controls prior to testing clinical specimens.

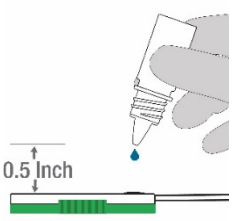
1. Remove two test cassettes from pouches. Place the cassettes horizontally on a flat surface. Write the control name (i.e., positive control or negative control) on the top of each cassette.



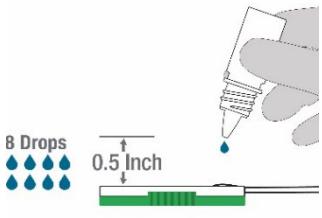

2. Place the Positive Control swab (with SARS-CoV-2 Nucleoprotein antigen dried on the swab) into the sample port of one of the cassettes, following steps 5-8 in the section above.




3. Hold the Lysis buffer bottle vertically ~0.5 inch above the swab head inserted into the sample port as in step 9 above.




4. **SLOWLY add eight drops of Lysis buffer ON TOP of the swab head as in step 10 above. Add ONE DROP at a time. DO NOT touch the tip of the dropper bottle to the swab head while dispensing.**




**Important! Adding less than 8 drops may produce invalid results.**

5. Repeat steps 2-4 with a negative control swab and the other test cassette. Use an unused, sterile swab to perform the negative control testing.
6. Allow the cassettes to remain undisturbed. Results should be interpreted between twenty (20) and twenty-five (25) minutes after starting the test. Do not interpret results after twenty-five (25) minutes, as they may be inaccurate.
7. See the Interpretation of Results section for instructions on how to interpret the SCoV-2 Ag Detect™ Rapid Test results.
8. 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. A 'blue' background color may be present with the Positive Control swab; this is normal and acts as a verification for which swab is the Positive Control.
9. Dispose of all tests and swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations.

## Interpretation of Results

The SCoV-2 Ag *Detect*™ Rapid Test should be interpreted between twenty (20) and twenty-five (25) minutes after starting the test. Do not interpret results after twenty-five (25) minutes because results interpreted after twenty-five (25) minutes may be inaccurate. **For best results, perform test interpretation in a well-lit area.**

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

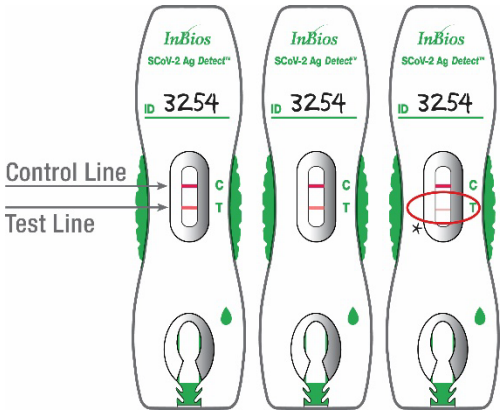
| Status on First Day of Testing | First Result Day 1 | Second Result Day 3 | Third Result Day 5 | Interpretation |
|---|---|---|---|---|
| **With Symptoms** | Positive | N/A | N/A | Positive for COVID-19 |
| **With Symptoms** | Negative | Positive | N/A | Positive for COVID-19 |
| **With Symptoms** | Negative | Negative | N/A | Negative for COVID-19 |
| **Without Symptoms** | Positive | N/A | N/A | Positive for COVID-19 |
| **Without Symptoms** | Negative | Positive | N/A | Positive for COVID-19 |
| **Without Symptoms** | Negative | Negative | Positive | Positive for COVID-19 |
| **Without Symptoms** | 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.

**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.

**Repeat testing does not need to be performed if patients have a positive result at any time.**

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and it is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).



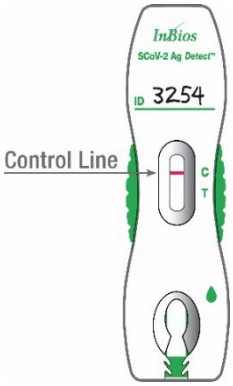

******Observe Test Line Closely!*** A very faint pink test line is still considered a positive result.

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 Test should self-isolate and seek follow up care with their physician or healthcare provider as 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.

**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:**

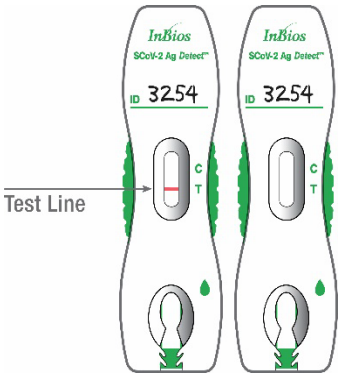
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**




A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be considered presumptive and confirmation with a molecular assay 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. 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.

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




## LIMITATIONS

- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- INVALID RESULTS can occur when an insufficient volume of Lysis buffer is added to the test. To ensure delivery of adequate volume, hold the bottle vertically, ~0.5 inch above the swab well, and add 8 drops slowly. Adding less than 8 drops may result in inaccurate results.
- 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 lysis buffer to the swab head on test cassette.
- False negative results can occur when the swab is not properly inserted into the test cassette. Be careful to ensure the swab is in full contact with the test cassette prior to proceeding with testing.
- False negative results can occur if the cassette is not placed on a flat surface.
- Performance has only been established with human direct anterior nasal swab specimens without viral transport media using the swab provided. Other specimen types have not been evaluated and should not be used with this assay.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- False negative results are more likely after five days or more of symptoms.
- Freezing and thawing of respiratory specimens must be avoided.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 to April 2021. The clinical performance has not been established in 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.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has 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.

## CONDITIONS OF AUTHORIZATION FOR LABORATORY

The SCoV-2 Ag *Detect*™ Rapid Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

However, to assist clinical laboratories using the SCoV-2 Ag *Detect*™ Rapid Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below.

A. Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and InBios International Inc. Technical Support (https://inbios.com/technical-support/) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
G. InBios International Inc. authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1]The letter of authorization refers 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" as "authorized laboratories."

## PERFORMANCE CHARACTERISTICS

**Clinical Performance: Prospective Study**

The clinical performance of SCoV-2 Ag *Detect*™ Rapid Test was evaluated in a multi-site prospective study in the U.S. In the prospective study, patients presenting with symptoms consistent with possible COVID-19 infection within 5 days of symptom onset were sequentially enrolled. A total of three (3) investigational sites encompassing six (6) drive through collection sites participated in the prospective study.

At the POC sites, paired anterior nasal swabs were collected from eligible patients. One nasal swab was tested with the SCoV-2 Ag *Detect*™ Rapid Test immediately after collection (i.e., without placing in VTM). The other nasal swab was tested with the comparator assay, an EUA authorized RT-PCR assay. The anterior nasal swabs were assigned to SCoV-2 Ag *Detect*™ Rapid Test and comparator assay randomly. SCoV-2 Ag *Detect*™ Rapid Test was performed sequentially by

minimally trained operators who are representative of the intended users. Operators only used the Quick Reference Instructions (QRI) for the test without any training provided.

Positive percent agreement (PPA) and negative percent agreement (NPA) from 53 patients enrolled at Site 1, 177 patients enrolled at Site #2 and 73 patients enrolled at Site #3 were evaluated. One specimen was interpreted as invalid on the RT-PCR comparator assay and thus this patient is not included in the analysis. NPA was 100.0% (95% CI: 98.53% - 100.00%) and the PPA was 86.67% (95% CI: 73.82% - 93.74%) for nasal swab samples collected from 302 symptomatic patients within 5 days post symptom onset (PSO).

| | | **EUA Authorized RT-PCR** | **EUA Authorized RT-PCR** | **EUA Authorized RT-PCR** |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **SCoV-2 Ag *Detect*™ Rapid Test** | **Positive** | 39 | 0 | 39 |
| **SCoV-2 Ag *Detect*™ Rapid Test** | **Negative** | 6 | 257 | 263 |
| **SCoV-2 Ag *Detect*™ Rapid Test** | **Total** | 45 | 257 | 302 |

PPA: 86.67% (39/45, 95% CI: 73.82% - 93.74%)
NPA: 100.00% (257/257, 95% CI: 98.53% - 100.00%)

Patient Demographics

| Age (years) | Total number | Number positive on SCoV-2 Ag *Detect*™ Rapid Test | Prevalence |
|---|---|---|---|
| 18-29 | 116 | 13 | 11.21% |
| 30-39 | 98 | 11 | 11.22% |
| 40-72 | 83 | 14 | 16.87% |

| **Days PSO** | **Cumulative RT-PCR Confirmed Positive** | **Cumulative SCoV-2 Ag *Detect*™ Rapid Test Positive** | **PPA (95% Confidence interval)** |
|---|---|---|---|
| 0 | 0 | 0 | NA |
| 1 | 8 | 7 | 87.50% (52.91% - 97.76%) |
| 2 | 14 | 12 | 85.71% (60.06% - 95.99%) |
| 3 | 30 | 26 | 86.67% (70.32% – 94.69%) |
| 4 | 41 | 36 | 87.80% (74.46% – 94.68%) |
| 5 | 45 | 39 | 86.67% (73.82 %– 93.74%) |

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications and performance may differ in these populations.

**Clinical Performance: Prospective Serial Testing Study at National Institutes of Health**
A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of

Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular tests were discordant, a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.
Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 1.
**Table 1. Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.**

| DAYS AFTER FIRST PCR POSITIVE TEST RESULT | ASYMPTOMATIC ON FIRST DAY OF TESTING | ASYMPTOMATIC ON FIRST DAY OF TESTING | ASYMPTOMATIC ON FIRST DAY OF TESTING | SYMPTOMATIC ON FIRST DAY OF TESTING | SYMPTOMATIC ON FIRST DAY OF TESTING | SYMPTOMATIC ON FIRST DAY OF TESTING |
|---|---|---|---|---|---|---|
| | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | Ag Positive / PCR Positive (Antigen Test Performance % PPA) |
| | 1 Test | 2 Tests | 3 Tests | 1 Test | 2 Tests | 3 Tests |
| **0** | 9/97 (9.3%) | 35/89 (39.3%) | 44/78 (56.4%) | 34/57 (59.6%) | 47/51 (92.2%) | 44/47 (93.6%) |
| **2** | 17/34 (50.0%) | 23/34 (67.6%) | 25/32 (78.1%) | 58/62 (93.5%) | 59/60 (98.3%) | 43/43 (100%) |
| **4** | 16/21 (76.2%) | 15/20 (75.0%) | 13/15 (86.7%) | 55/58 (94.8%) | 53/54 (98.1%) | 39/40 (97.5%) |
| **6** | 20/28 (71.4%) | 21/27 (77.8%) | 16/18 (88.9%) | 27/34 (79.4%) | 26/33 (78.8%) | 22/27 (81.5%) |
| **8** | 13/23 (56.5%) | 13/22 (59.1%) | 4/11 (36.4%) | 12/17 (70.6%) | 12/17 (70.6%) | 7/11 (63.6%) |
| **10** | 5/9 (55.6%) | 5/8 (62.5%) | | 4/9 (44.4%) | 3/7 (42.9%) | |

1 Test = one (1) test performance on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performance an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

**Analytical Sensitivity: Limit of Detection (LoD)**
A limit of detection (LoD) study was conducted to determine the lowest concentration of inactivated SARS-CoV-2 virus in nasal swab matrix at which greater than or equal to 95% of all replicates test positive with the SCoV-2 Ag *Detect*™ Rapid Test. Twenty microliters of virus solution were added to each swab sample for testing. Based upon the testing procedure for this study, the LoD is 6.3E+03 $TCID_{50}$/mL, which equates to 125 $TCID_{50}$/swab.

**NIH/RADx Variant Testing**

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the SCoV-2 Ag *Detect*™ Rapid Test detected 100% of live virus Omicron samples at a Ct-value of 23.6 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by the SCoV-2 Ag *Detect*™ Rapid Test in this study.

| Omicron Pool 2 - Live | Average N2 Ct (n=9) | Assay #1 Percent Positive (n=5) | Assay #2 Percent Positive (n=5) | SCoV-2 Ag *Detect*™ Rapid Self-Test Percent Positive (n=5) |
|---|---|---|---|---|
| Dilution 1 | 19.8 | 100 | 100 | 100 |
| Dilution 2 | 20.8 | 100 | 100 | 100 |
| Dilution 3 | 21.5 | 100 | 100 | 100 |
| Dilution 4 | 22.7 | 100 | 100 | 100 |
| Dilution 5 | 23.6 | 100 | 0 | 100 |
| Dilution 6 | 24.0 | 60 | 0 | 0 |
| Dilution 7 | 24.8 | 0 | 0 | 0 |
| Dilution 8 | 25.8 | 0 | 0 | 0 |
| Dilution 9 | 27.4 | 0 | 0 | 0 |
| Dilution 10 | 28.1 | 0 | 0 | 0 |
| Dilution 11 | 29.1 | 0 | 0 | 0 |

**Cross-reactivity**

The purpose of this study was to assess whether SCoV-2 Ag *Detect*™ Rapid Test reacts with related pathogens, high prevalence disease agents, and normal or pathogenic microflora that may be present in clinical nasal swab specimens.

Organisms were evaluated for cross-reactivity by wet testing with the SCoV-2 Ag *Detect*™ Rapid Test. The potential cross-reactive organisms were spiked into pooled, negative nasal swab matrix at 1E+06 CFU/mL for bacteria/fungi and 1E+05 $TCID_{50}$/mL or $CEID_{50}$/mL for viruses. OC43 and parainfluenza virus 4a were tested at lower concentrations (8.9E+04 and 1.6E+04 $TCID_{50}$/mL, respectively) because the commercially supplied stocks were less than 1E+05 $TCID_{50}$/mL. The results of this study are shown in the table below.

Cross-reactivity (analytical specificity) study results

| Specimen Type | Replicate #1 | Replicate #2 | Replicate #3 |
|---|---|---|---|
| Human coronavirus, 229E | Negative | Negative | Negative |
| Human coronavirus, OC43 | Negative | Negative | Negative |
| Human coronavirus, NL63 | Negative | Negative | Negative |
| MERS-coronavirus | Negative | Negative | Negative |
| Adenovirus 21 | Negative | Negative | Negative |
| Human Metapneumovirus (hMPV) | Negative | Negative | Negative |
| Parainfluenza virus 1 | Negative | Negative | Negative |
| Parainfluenza virus 2 | Negative | Negative | Negative |
| Parainfluenza virus 3 | Negative | Negative | Negative |
| Parainfluenza virus 4a | Negative | Negative | Negative |
| Influenza A | Negative | Negative | Negative |
| Influenza B | Negative | Negative | Negative |
| Enterovirus D68 | Negative | Negative | Negative |
| Respiratory syncytial virus (RSV) | Negative | Negative | Negative |
| Rhinovirus | Negative | Negative | Negative |
| *Haemophilus influenzae* | Negative | Negative | Negative |
| *Streptococcus pneumoniae* | Negative | Negative | Negative |
| *Streptococcus pyogenes* | Negative | Negative | Negative |
| *Candida albicans* | Negative | Negative | Negative |
| *Bordetella pertussis* | Negative | Negative | Negative |
| *Mycoplasma pneumoniae* | Negative | Negative | Negative |
| *Chlamydia pneumoniae* | Negative | Negative | Negative |
| *Legionella pneumophila* | Negative | Negative | Negative |
| *Staphylococcus aureus* | Negative | Negative | Negative |
| *Staphylococcus epidermidis* | Negative | Negative | Negative |
| Pooled human nasal wash | Negative | Negative | Negative |

The following pathogens were analyzed *in silico* for sequence homology via NCBI's BLAST, because they were not available for wet testing.

- Human coronavirus HKU1
- SARS-CoV-1
- *Mycobacterium tuberculosis*
- *Pneumocystis jirovecii* (PJP)

The nucleocapsid protein (NP) of human coronavirus HKU1 was determined to have 34% homology with SARS-CoV-2 NP, suggesting a low probability of cross-reactivity. The NP protein of SARS-CoV-1 was determined to have 91% homology with SARS-CoV-2 NP, suggesting cross-reactivity may occur. BLASTs of the *Mycobacterium tubercolosis and Pneumocystis jirovecii* (PJP) proteomes found no homology, indicating a low probability of cross-reactivity.

The SCoV-2 Ag *Detect*™ Rapid Test showed no cross-reactivity against samples spiked with other coronaviruses, other respiratory infections which may present with similar symptoms as SARS-CoV-2, or with pooled human nasal wash. SARS-CoV-1 was predicted to be cross-reactive based on protein sequence homology.

**Endogenous Interfering Substances**

A study to determine the effects of potentially interfering substances on the SCoV-2 Ag *Detect*™ Rapid Test was conducted. The interfering substances were mixed either with negative pooled nasal matrix, or with SARS-CoV-2 in pooled negative nasal matrix to yield a final concentration of SARS-CoV-2 of 1.9E+04 $TCID_{50}$/mL (3x LoD). Each was tested in triplicate. A summary of the results observed is shown below.

Interfering substances study results

| Substance | Tested concentration | Negative sample | Positive sample |
|---|---|---|---|
| Whole Blood | 4% | No interference | No interference |
| Mucin | 0.5% | No interference | No interference |
| Chloraceptic / Cepacol | 1.5 mg/mL | No interference | No interference |
| NeilMed NasoGEL | 5% v/v | No interference | No interference |
| CVS Nasal Drops | 15% v/v | No interference | No interference |
| Afrin | 15% v/v | No interference | No interference |
| Nasal Spray | 15% v/v | No interference | No interference |
| Zicam Cold Remedy | 5% v/v | No interference | No interference |
| Alkalol Homeopathic | 1:10 dilution | No interference | No interference |
| Sore Throat Phenol Spray | 15% v/v | No interference | No interference |
| Tobramycin | 4 µg/mL | No interference | No interference |
| Mupirocin | 10 mg/mL | No interference | No interference |
| Flonase Nasal Spray | 5% v/v | No interference | No interference |
| Tamiflu | 5 mg/mL | No interference | No interference |

No interference was observed with the SCoV-2 Ag *Detect*™ Rapid Test for samples that contained blood components and common nasal treatments, or with pooled human nasal wash.

**High-dose Hook Effect**

Hook effect was not observed for SCoV-2 in nasal swab matrix in any neat or diluted preparation of SCoV-2 virus for the SCoV-2 Ag *Detect*™ Rapid Test, up to a concentration of 2.8E+06 $TCID_{50}$/mL.

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Part Number: 900284-03
Effective Date: XX/XX/2022

REF

COVAG-20, COVAG-RC
Patent is pending.

***Note:*** Paper copies are available upon request through the "Downloads" tab at https://inbios.com/scov-2-ag-detecttm-rapid-test/

EC REP

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www.cepartner4u.com

CE

IVD

# 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 provided in the kit box thoroughly before using Quick Reference Instructions. This is not a complete package insert.

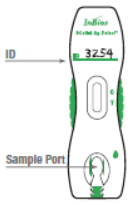
## Kit Materials

| | Catalog #COVAG-20 | Catalog #COVAG-RC |
|---|---|---|
| Single-use test cassettes, individually pouched (store at 15-30°C): | Twenty (20) | Fifty (50) |
| Dropper bottles of Lysis buffer, 6 mL per bottle (store at 15-30°C): | Two (2) | Four (4) |
| Sterile nasal swabs, individually pouched (store at 15-30°C). One of the swabs is intended for use as a negative control: | Twenty (20) | Fifty (50) |
| 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: | One (1) | One (1) |
| Instructions for use for the SCoV-2 Ag Detect™ Rapid Test: | One (1) | One (1) |
| Quick Reference Instructions for the SCoV-2 Ag Detect™ Rapid Test: | One (1) | One (1) |

## 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.

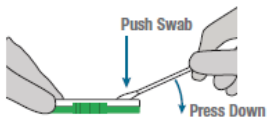
**1.** For each sample to be tested, remove one test cassette from the foil pouches and write the sample identification (sample ID) on the top.



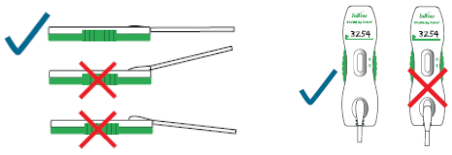

**2.** Collect direct nasal swab samples following the sample collection steps described on the following page.

**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.




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

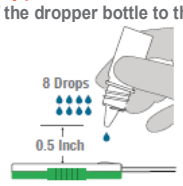


**IMPORTANT!**
Check that the swab covers the sample pad completely.
Incomplete coverage of the pad may produce a false negative result.

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

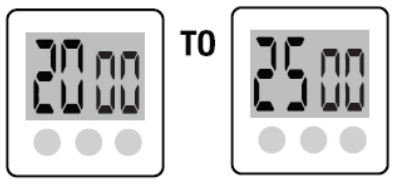
**SLOWLY add eight (8) drops of Lysis buffer ON TOP of the swab head. ADD ONE (1) drop at a time.**

**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.**



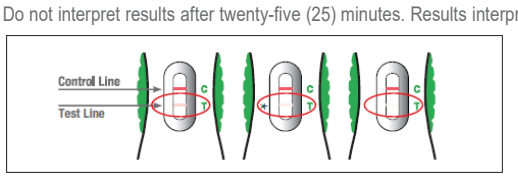

**7.** Allow the test cassette to remain undisturbed. Read the test results after TWENTY (20) to TWENTY-FIVE (25) minutes.

**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.***



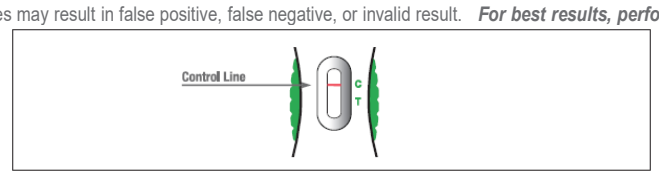

### Positive Result

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 (C) line should be read as positive.**

**Repeat testing does not need to be performed if patients have a positive result at any time**.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).

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 Test should self-isolate and seek follow up care with their physician or healthcare provider as 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.




### Negative Result

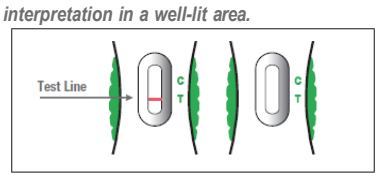
If the control (C) line is visible, but the test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- •Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay 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. 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.




### Invalid Result

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

**Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.**

| 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 |
| With Symptoms | Negative | Positive | N/A | Positive for COVID-19 |
| With Symptoms | Negative | Negative | N/A | Negative for COVID-19 |
| Without Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| Without Symptoms | Negative | Positive | N/A | Positive for COVID-19 |
| Without Symptoms | Negative | Negative | Positive | Positive for COVID-19 |
| Without Symptoms | Negative | Negative | Negative | Negative for COVID-19 |

Results should be considered in the context of an individual's recent exposure exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

Turn over for quality control and sample collection procedures.

## Quality Control

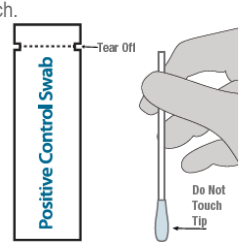
**The positive and negative controls should be run:**

- 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

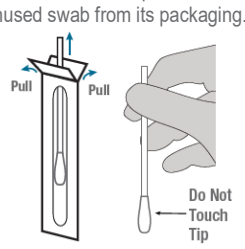
Remove Positive Control swab (with SARS-CoV-2 Nucleoprotein antigen dried on the swab) from its pouch.




**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.

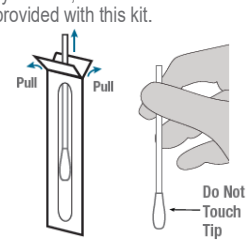
Test unknown specimens as per Test Procedure steps 1-7. If the correct control results are not obtained, do not perform patient tests. Contact Technical Support at 1-866-INBIOS1 or 206-344-5821 during normal business hours before testing patient specimens.

## Sample Collection Procedure

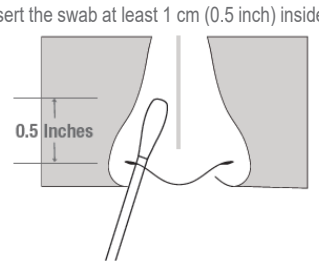
- Collect the direct nasal swab samples following CDC guidelines: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation for Coronavirus Disease 2019 (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).
- Use appropriate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

**1.** Wash hands before sample collection.

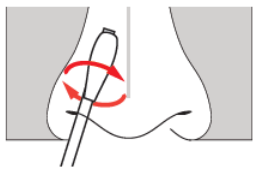

**2.** Remove the swab from the packaging. Be careful not to touch the swab tip (soft end) with hand.
If swab tip touches any surface, then it is recommended to discard swab and use a different swab provided with this kit.



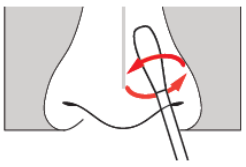

**3.** Carefully insert the swab at least 1 cm (0.5 inch) inside the nostril.




**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, 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, Limitations, Specimen Collection and Handling, and Quality Control.**

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Freezing and thawing of respiratory samples 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 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.

## Intended Use

The SCoV-2 Ag *Detect*™ Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from 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. 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 SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) 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 patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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.

The SCoV-2 Ag *Detect*™ Rapid Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The SCoV-2 Ag *Detect*™ Rapid 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.

## 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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REF

IVD

Part No.: 900296-04

Patent is pending.