SCoV-2 Ag *Detect*™ Rapid Self-Test

Healthcare Provider Instructions for Use

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

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.

SUMMARY AND EXPLANATION OF THE TEST

SCoV-2 Ag *Detect*™ Rapid Self-Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 Nucleoprotein antigen. The test can be performed using anterior nasal (nares) swab samples collected without transport media, requires no training, and takes less than 25 minutes to obtain results, making it a suitable diagnostic tool for use at home.

PRINCIPLE OF THE TEST

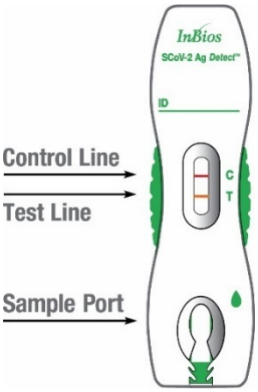
SCoV-2 Ag *Detect*™ Rapid Self-Test is a single-use, qualitative, membrane-based lateral flow immunoassay for detection of SARS-CoV-2 Nucleoprotein antigen. This test may be used with direct nasal swabs respiratory samples collected without transport media.

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 "Reading and Understanding Results" section for additional information regarding results analysis.

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



WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use 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* diagnostic tests 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.
- 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.
- Do not open test in pouch until just before use.
- It is recommended that gloves are used during testing. A face mask should be worn if swabbing someone else. Gloves and face mask are not provided.

- 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.

HAZARDOUS INGREDIENTS

- 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.

Chemical Name (CAS)	Hazard statement(s) (GHS code)	Concentration
IGEPAL® CA-630 (9002-93-1)	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318	≤ 3.0%
ProClin™ 300 (no CAS assigned)	Acute toxicity, Oral (Category 4), H302 Acute toxicity, Inhalation (Category 4), H332 Skin corrosion (Category 1B), H314 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317	≤ 0.05%

STORAGE

The kit is designed to be stored at room temperature (15-30°C or 59-86°F) for the duration of its shelf life. Exposure to temperatures over 30°C or 86°F can impact the performance of the test and should be minimized. The kit should not be frozen or refrigerated. The test cassette should be used immediately after removal from its pouch to minimize exposure to humidity.

KIT CONTENTS

The kit is available under catalog numbers CAGS-1, CAGS-2, CAGS-5, and CAGS-20. All kit components should be stored at 15-30°C or 59-86°F. Kits contain the following components:

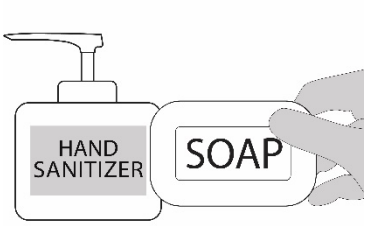
	Catalog: CAGS-1	Catalog: CAGS-2	Catalog: CAGS-5	Catalog: CAGS-20
Single-use test in pouch	One (1)	Two (2)	Five (5)	Twenty (20)
Single-use dropper bottle	One (1)	Two (2)	Five (5)	Twenty (20)
Single-use swab	One (1)	Two (2)	Five (5)	Twenty (20)
SCoV-2 Ag *Detect*™ Rapid Self-Test Instructions (English)	One (1)	One (1)	One (1)	One (1)

MATERIALS NOT PROVIDED

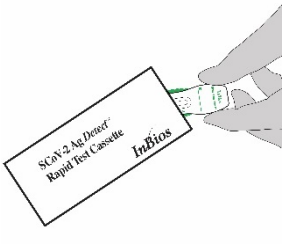
1. Timer (required)
2. Gloves (optional)
3. Face mask (optional)

TEST PROCEDURE: Preparing For The Test

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

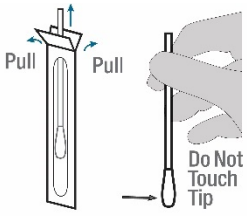


2. Remove one test from the packaging. Place the test on a flat surface, like a counter or tabletop, in an area with good lighting.

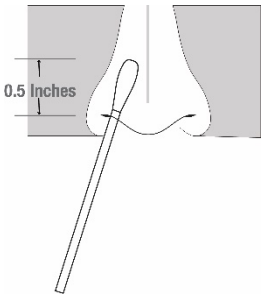


TEST PROCEDURE: Swab Nostrils

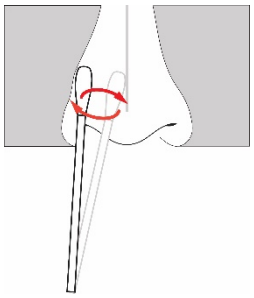
1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand



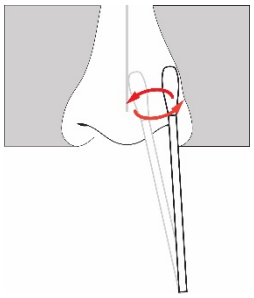
2. Carefully insert the swab at least 0.5 inch (1 cm) inside one nostril.



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



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

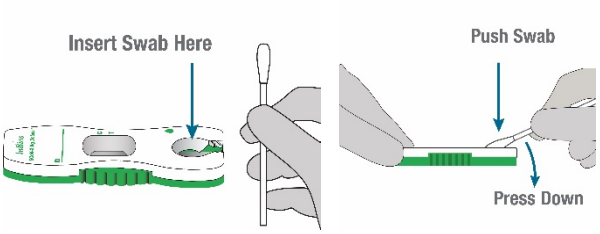


- Only use the swab provided in the kit.
- Improper swabbing may lead to false results.
- Be sure to swab both nostrils with the same swab.
- If swabbing another person, you should wear a face mask.
- The swab may not need to be inserted as far into the nostrils if swabbing a child.
- Test specimens 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.

TEST PROCEDURE: Run The Test

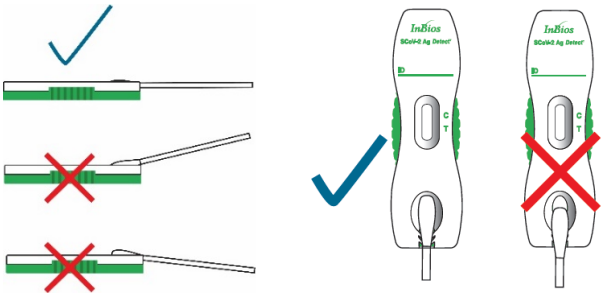
1. Hold the top of the test firmly with one hand and place the swab tip (soft end) into the sample port. Gently push the swab tip into the sample port while pressing the swab handle down. The swab should be firmly in the test.

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

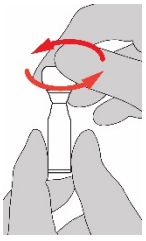


2. The swab should be flat in the test and cover the sample port.

   IMPORTANT! The swab should cover the sample port completely.



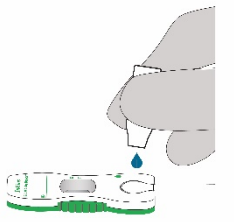
3. Remove top of dropper bottle by twisting the top plastic piece. Do not use mouth or teeth to open bottle.



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.**

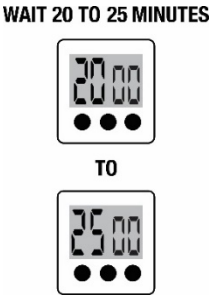
IMPORTANT! Invalid or incorrect results can occur when less than the whole bottle is added to the test. Make sure to add all of the liquid slowly holding the bottle vertically, 0.5 inches above the swab head.

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 (lysis buffer) on top of the swab head in the test cassette.



5. Leave the 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.



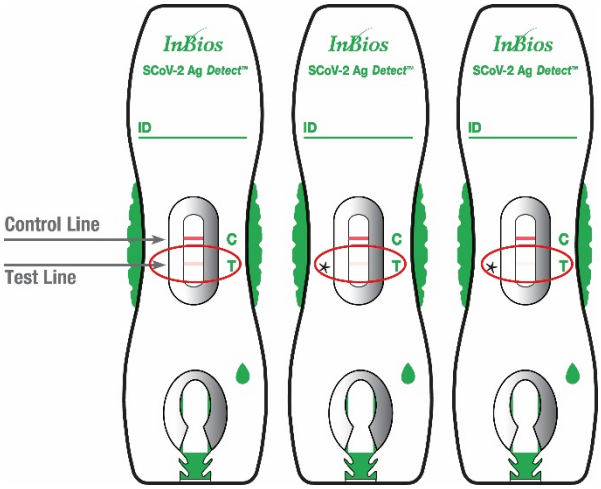
- See the "Reading and Understanding Results" section below for instructions on how to read and understand the SCoV-2 Ag *Detect*™ Rapid Self-Test results.
- Dispose of the test cassette in the trash after reading result.

READING AND UNDERSTANDING RESULTS

The SCoV-2 Ag *Detect*™ Rapid Self-Test should be read between twenty (20) and twenty-five (25) minutes after starting the test. **Do not read results before 20 minutes or after 25 minutes. For best results, read test in a well-lit area.**

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.



What does a positive test result mean?

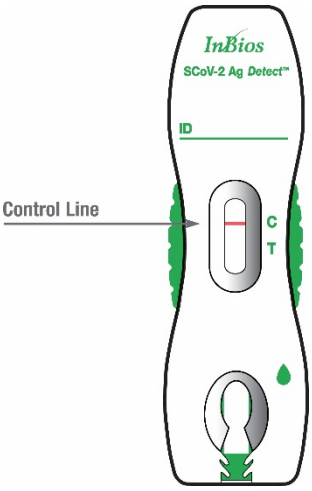
A positive test result means that proteins from the virus that causes COVID-19 were found in your sample. It is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. 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 results, medical history, and symptoms.

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.

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 Information" section below if you test negative and are not experiencing COVID-19 like symptoms. **Negative results do not rule out SARS-CoV-2 infection.**

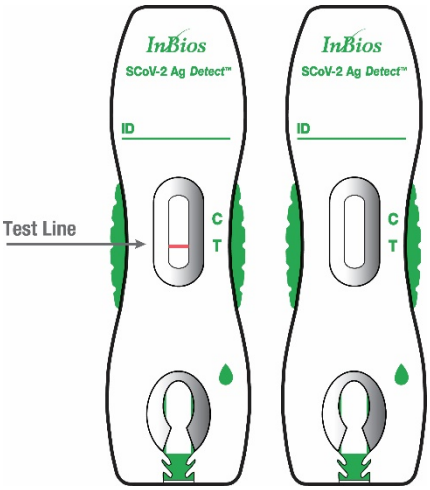
It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. 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.



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

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.



SERIAL TESTING INFORMATION AND LIMIITATIONS

- 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 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 risk for COVID-19.

LIMITATIONS

- There is a higher chance of false negative results with home use 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.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection or other epidemiological reasons to suspect COVID-19, or for serial screening applications tested twice over two or three days with at least 24 hours and no more than 48 hours between tests, and performance may differ in these populations.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in September and October 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.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- False negative test results may occur if a specimen is improperly collected.
- INVALID RESULTS can occur when an insufficient volume of liquid (lysis buffer) from the single-use dropper bottle is added to the test. To ensure delivery of adequate volume, hold the bottle vertically, ~0.5 inch above the swab head, and add all of the liquid slowly. Adding less than the whole bottle 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 the liquid (lysis buffer) on top of the swab head in the 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.
- Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation: Prospective Study

The clinical performance of SCoV-2 Ag *Detect*™ Rapid Self-Test was evaluated in a simulated home environment in the U.S. In the prospective study, subjects presenting with symptoms consistent with possible COVID-19 within 5 days of symptom onset were sequentially enrolled. Subjects had no prior medical or laboratory training, were not regular (i.e., daily) users of self-collection and/or self-testing devices, and received no additional instructions beyond those contained in the kit.

Paired anterior nasal swabs were collected from eligible subjects with one swab collected and tested with the SCoV-2 Ag *Detect*™ Rapid Self-Test by the subject and another swab tested with the comparator assay, an EUA authorized RT-PCR assay.

Positive percent agreement (PPA) and negative percent agreement (NPA) from 257 subjects were evaluated. 95% confidence intervals (95% CI) were calculated by Wilson method. NPA was 100% (95% CI: 98.30% - 100.00%) and the PPA was 85.71% (95% CI: 70.62% - 93.74%) for nasal swab samples collected from symptomatic patients within 5 days post symptom onset (PSO).

	EUA Authorized RT-PCR: Positive	**EUA Authorized RT-PCR: Negative**	**EUA Authorized RT-PCR: Total**
SCoV-2 Ag DetectTM Rapid Self-Test: Positive	30	0	30
SCoV-2 Ag DetectTM Rapid Self-Test: Negative	5	222	227
SCoV-2 Ag DetectTM Rapid Self-Test: Total	35	222	257

PPA: 85.71% (30/35, 95% CI: 70.62% - 93.74%)

NPA: 100.00% (222/222, 95% CI: 98.30% - 100.00%)

Patient Demographics

Age (years)	Total number	Number positive on SCoV-2 Ag *Detect*™ Rapid Self-Test	Prevalence
18-24	37	6	16.22%
25-64	207	22	10.63%
65 and older	13	2	15.38%

Days PSO	**PPA (tally, 95% CI)**	**NPA (tally, 95% CI)**
0	0.00% (0/1, 0.00%-79.35%)	100.00% (9/9, 70.08%-100.00%)
≤1	66.67% (4/6, 30.00%-90.32%)	100.00% (66/66, 94.50%-100.00%)
≤2	82.35% (14/17, 58.97%-93.81%)	100.00% (131/131, 97.15%-100.00%)
≤3	83.33% (25/30, 66.44%-92.66%)	100.00% (185/185, 97.97%-100.00%)
≤4	85.29% (29/34, 69.87%-93.55%)	100.00% (216/216, 98.25%-100.00%)
≤5	85.71% (30/35, 70.62%-93.74%)	100.00% (222/222, 98.30%-100.00%)

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.

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 Self-Test. Limit of detection is 6.3E+03 $TCID_{50}$/mL.

Cross-reactivity
The purpose of this study was to assess whether SCoV-2 Ag *Detect*™ Rapid Self-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 Self-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 Self-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 Self-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 Self-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 any neat or diluted preparations of SARS-CoV-2 virus in nasal swab matrix for the SCoV-2 Ag *Detect*™ Rapid Self-Test, up to a concentration of 2.8E+06 $TCID_{50}$/mL

CONTACT INFORMATION

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).

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