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

The SCoV-2 Ag *Detect*™ Rapid Self-Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the SCoV-2 Ag *Detect*™ Rapid Self-Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Page 2 of 19 Mapping for SARS-CoV-2 Tests provided by CDC.

The SCoV-2 Ag *Detect*™ Rapid Self-Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The SCoV-2 Ag *Detect*™ Rapid Self-Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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

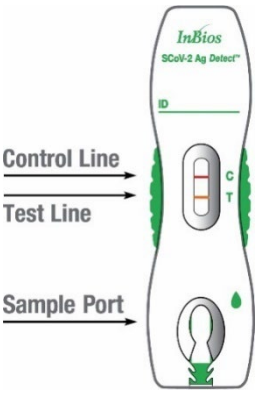
SCoV-2 Ag *Detect*™ Rapid Self-Test is a single-use, qualitative, membrane-based lateral flow immunoassay for detection of SARS-CoV-2 Nucleoprotein antigen. This test may be used with direct nasal swabs respiratory samples collected without transport media.

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

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit components or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test cassette should be used within 30 minutes.
- 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.

- **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.
- 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

HAZARDOUS INGREDIENTS

- **Keep testing kit and components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

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

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 within 30 minutes of removal from its pouch to minimize exposure to humidity. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests.

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:

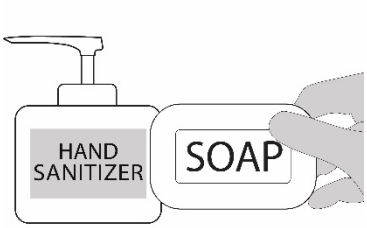
	Catalog: CAGS-1	Catalog: CAGS-2	Catalog: CAGS-5	Catalog: CAGS-20
Single-use test in pouch	One (1)	Two (2)	Five (5)	Twenty (20)
Single-use dropper bottle	One (1)	Two (2)	Five (5)	Twenty (20)
Single-use swab	One (1)	Two (2)	Five (5)	Twenty (20)
SCoV-2 Ag *Detect*™ Rapid Self-Test Instructions (English)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

MATERIALS NOT PROVIDED

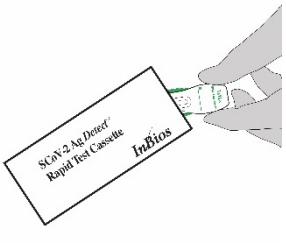
1. Timer (required)
2. Gloves (optional)
3. Face mask (optional)

TEST PROCEDURE: Preparing for the Test

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

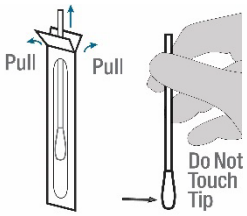


2. Remove one test from the packaging. Place the test on a flat surface, like a counter or tabletop, in an area with good lighting.

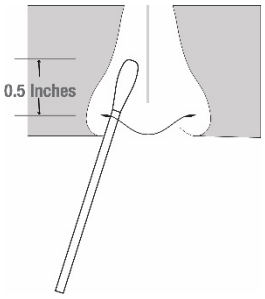


TEST PROCEDURE: Swab Nostrils

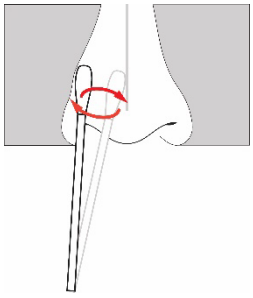
1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand



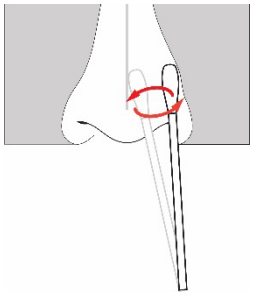
2. Carefully insert the swab at least 0.5 inch (1 cm) inside one nostril.



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.

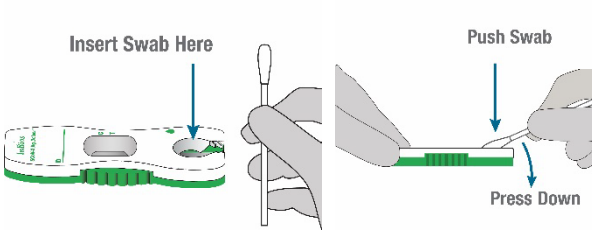


- Only use the swab provided in the kit.
- Improper swabbing may lead to false results.
- Be sure to swab both nostrils with the same swab.
- If swabbing another person, you should wear a face mask.
- The swab may not need to be inserted as far into the nostrils if swabbing a child.
- Test specimens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

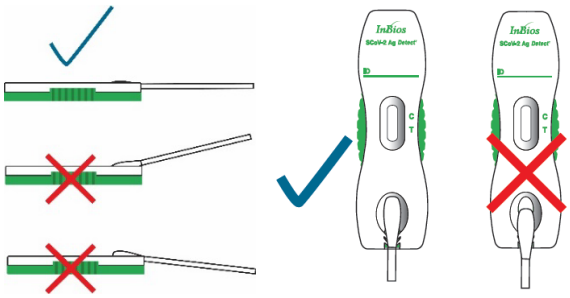
1. Hold the top of the test firmly with one hand and place the swab tip (soft end) into the sample port. Gently push the swab tip into the sample port while pressing the swab handle down. The swab should be firmly in the test.

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

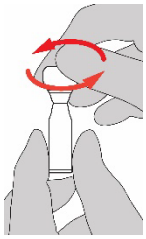


2. The swab should be flat in the test and cover the sample port.

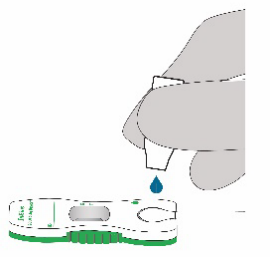
   IMPORTANT! The swab should cover the sample port completely.



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



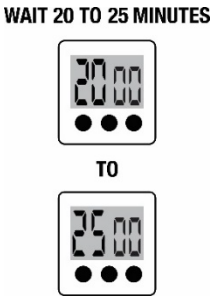
4. Hold the dropper bottle above the swab head. Slowly add all of the liquid on top of the swab head. **Add 1 drop at a time until dropper is empty. Do not add the liquid all at once.**



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.**

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

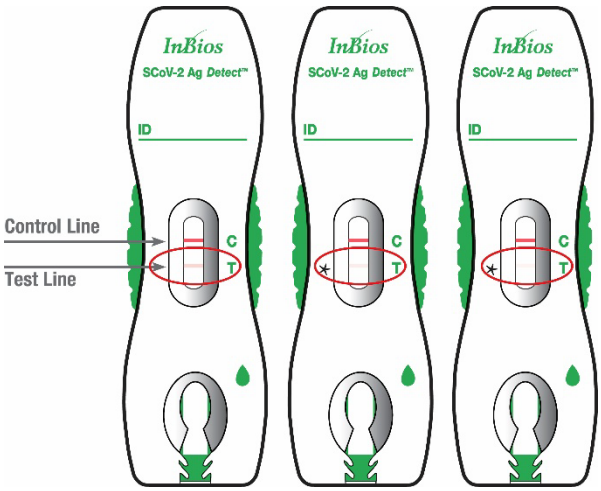
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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 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.



****Look at test line closely!*** A very light pink test line is still considered a positive result.

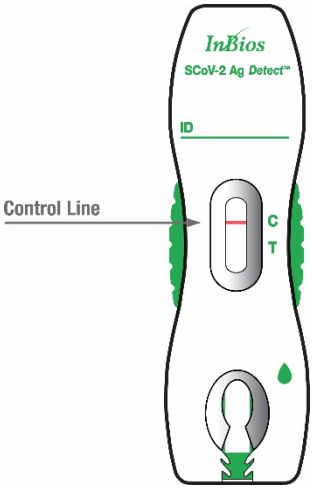
Negative Result: If the control (C) line is visible, but the test (T) line is not visible, the test is negative.

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

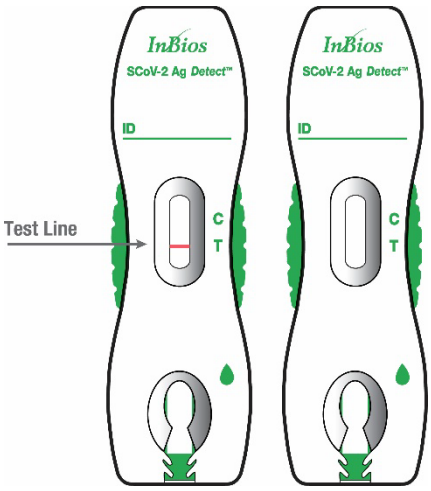
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

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 diseases 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.



LIMITATIONS

- 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.
- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2021 and October 2021. The clinical performance has not been established 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 detects both viable (live) and nonviable 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.

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 *Detect*™ Rapid Self-Test	**Positive**	30	0	30
SCoV-2 Ag *Detect*™ Rapid Self-Test	**Negative**	5	222	227
SCoV-2 Ag *Detect*™ 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.

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 USA-WA1/2020 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. 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 Self-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 Self-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 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 1-866-516-0757 (US toll-free).

InBios International, Inc.
307 Westlake Ave N, Suite 300
Seattle, WA 98109 USA
1-866-516-0757 (Toll-free USA)
+1-206-344-5821 (International)
www.inbios.com

Part Number: 900318-04
Effective Date: XX/XX/2022

REF CAGS-1, CAGS-2, CAGS-5, CAGS-20

Patent is pending.

Note: Paper copies are available upon request through www.inbios.com/covid-19 free of charge.