COVI-GO™ SARS-CoV-2 Ag Self-Test

HEALTHCARE PROVIDER INSTRUCTIONS FOR USE

For Emergency Use Authorization (EUA) only.

***In vitro* diagnostic use only.**

For use with anterior nasal swab specimens.

INTENDED USE

The COVI-Go™ SARS-CoV-2 Ag 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 years 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 COVI-Go SARS-CoV-2 Ag Self-Test does not differentiate between SARS-CoV or SARSCoV-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 COVI-Go SARS-CoV-2 Ag 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 Mapping for SARS-CoV-2 Tests provided by CDC.

The COVI-Go SARS-CoV-2 Ag 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 COVI-Go SARS-CoV-2 Ag 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

- COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2.
- Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020.
- Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death.
- The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.
- The COVI-Go SARS-CoV-2 Ag Self-Test is a single-use rapid chromatographic immunoassay. It qualitatively detects SARS-CoV-2 antigens in direct human anterior nasal (nares) swab samples only.
- SARS-CoV-2 specific antibodies and a control antibody (anti rabbit IgG) are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip housed in a completely contained plastic testing device.
- During the test, the nasal swab is submerged into the extraction buffer to extract the virus and expose the nucleocapsid protein. The user then vigorously rotates the test from side to side to aid in extracting the sample from the swab. After two minutes of elapsed time, the patient inverts the test device by rotating it upside down to start the development stage. This allows the extracted sample and solution to fall via gravity to the bottom of the test where it is absorbed by the lateral flow test strip.
- In development stage of the test, the extracted sample and liquid, moves through the absorbent membranes of the lateral flow test strip to the detection zone where the result is visible. This process takes 20 minutes. The presence of any pink/red Test Line (denoted as "T" on the clear plastic housing) is considered POSITIVE for SARS-CoV-2, whereas the absence of a Test Line is considered NEGATIVE for SARS-CoV-2. A pink/red Control Line (denoted as "C" on the clear plastic housing) verifies that the liquid and reagents have moved past the test line, ensuring a valid result. In the absence of a Control Line, the result is considered INVALID.

PRODUCT DESCRIPTION

The COVI-Go SARS-CoV-2 Ag Self-Test requires the following components for use.

KIT COMPONENT	QUANTITY			
	1 PACK	2 PACK	4 PACK	100 PACK
COVI-GO™ TEST DEVICE	1 EACH / BOX	2 EACH / BOX	4 EACH / BOX	100 EACH/BOX
COVI-GO™ STERILIZED SWAB ASSEMBLY	1 EACH / BOX	2 EACH / BOX	4 EACH / BOX	100 EACH/BOX
INDIVIDUAL IFU	1 EACH / BOX	1 EACH / BOX	1 EACH / BOX	1 EACH/BOX

Materials required but not provided: Timer

QUALITY CONTROL

The COVI-Go SARS-CoV-2 Ag Self-Test features a procedural internal control that is built into the "control line (c)" of the device and is used to ensure that the applied specimen has migrated up through the test strip. It is coated with goat anti-rabbit IgG and a red-colored line should appear after sample was added.

STORAGE AND HANDLING

- Test kits must be stored at 2–30 °C (35.6–86 °F) until use.
- Test kits must be stored out of reach of children. Discard any expired test kits in household waste.
- Do not reuse test components.
- Do not open the test kit until you are ready to test.

WARNINGS, PRECAUTIONS AND SAFETY

- 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 five 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 3 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 contents 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 card should be used within 15 minutes.
- False results may occur if not tested at room temperature and in areas with high humidity.
- **Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit 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**.

Hazardous ingredients:

Chemical Name /CAS	**GHS Code for applicable ingredient**	**Concentration (%)**
Sodium Azide Cas-No: 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.05% in final solution

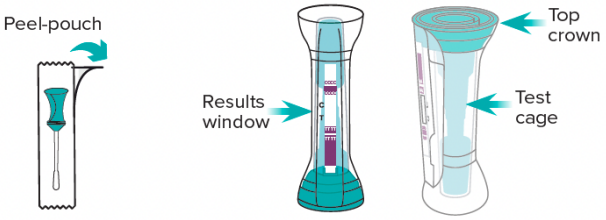
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency- use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between August 2022 – November 2022. The clinical performance has not been established for 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.
- 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.

PREPARE THE TEST

KIT CONTENTS



1 Sterile flocked nasal swab in a peel-pouch

1 Single-use, disposable test device in a notched foil pouch

Needed but not provided: clock or timer

STORAGE AND HANDLING

- Test kits must be stored at 35.6–86°F (2–30°C) until use.
- Test kits must be stored out of reach of children. Discard any expired test kits in household waste.
- Do not reuse test components.
- Do not open the test kit until you are ready to test.

HOW TO USE THIS TEST

- **Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.**
- **If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.**

A. PREPARING FOR THE TEST

1. Read all the instructions before you start the test.
2. Check the test's expiration date . Do not use an expired test.
3. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.

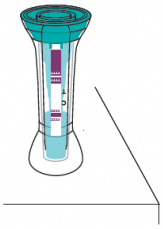
4. Use a flat, level surface, (such as a table or countertop) for testing.
5. Use a timer during the test.
6. Make sure you have all the test components before you begin.
7. Bring test kit to room temperature (59-86°F /15-30°C)
8. Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

TAKE THE TEST

B. TAKING THE SAMPLE AND RUNNING THE TEST

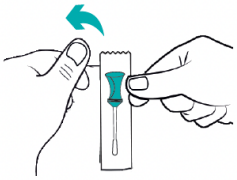
1 Peel open the notched foil pouch to unwrap the test device. Ensure that the test device is intact and that there are no green beads in the desiccant package (orange beads are expected). **Do not use test if green beads are present.**

Place the test device on a **flat surface** with the top crown at the top.



2 Blow your nose. If you are testing someone else, have them blow their nose.

3 Peel open the pouch to unwrap the swab. Make sure you hold the swab by the swab handle. **Do not touch the swab tip.**



4 Gently insert the entire absorbent tip of the swab into the nostril no more than ½ to ¾ inch. There is no need to go deeper.

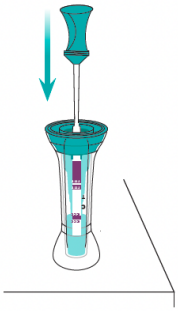
Slowly rotate the swab in a circular motion **5 times** by firmly pressing against the inside walls of the nostril for **5 seconds**.

Repeat in the other nostril using the same swab.

Instructions for swabbing children: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to hold the child's head while swabbing.

Warning: Do not just spin the swab. Inaccurate test results may occur if the nasal swab specimen is not properly collected.

5 While the test is still on the flat surface, insert the swab into the test at the top crown, pushing the swab all the way down into the **center of the test cage.** You will hear a "click".



Continue pushing the swab all the way through until the swab handle is flush with the top of the device and you hear a second "click".

STOP

Make sure the top of the swab handle is pushed as far into the test as possible by firmly pressing the handle in with your thumb or an additional hand.

Do not proceed until you have confirmed that the swab handle is fully inserted.

6 Vigorously swing the test side to side for **4 seconds.**

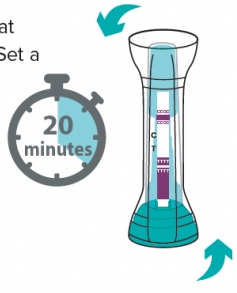
Do not attempt to shake up and down as this may cause incorrect results.

7 Set a timer for **2 minutes**. Allow the test to stand upright with the top crown up.

8 Turn the test upside down so that the top crown is at the bottom. Set a timer for **20 minutes**.

Do not lay the test on its side.

Warning: Do not read the result before 20 minutes or after 30 minutes.



INTERPRET THE RESULTS

Test Interpretation

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

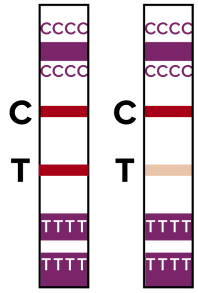
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Reading the Test Results

WARNING: Do not read the result before 20 minutes or after 30 minutes. Inaccurate test interpretations may occur.

Look at the result window and locate the letters C and T on the side of the window.
A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

COVID-19 Positive (+)



If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint red/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 COVI-Go™ SARS-CoV-2 Ag Self-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.

COVID-19 Negative (-)

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

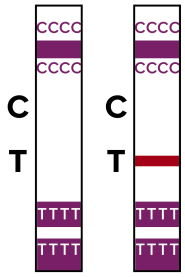
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **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



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

CLINICAL PERFORMANCE

A clinical study to evaluate the performance of the COVI-Go SARS-CoV-2 Ag Self-Test was conducted during August and November 2022 in Five (5) geographically separate sites across the US. A total of 461 individuals with signs and symptoms of COVID-19 within the first five (5) days of symptom onset completed the study and obtained a valid result. Subjects fourteen (14) years and older independently collected an anterior nasal sample, conducted the test, interpreted, and reported the result. The parents of subjects two (2) to thirteen (13) years of age collected the anterior nasal sample or allowed the child to self-collect, conducted the test, interpreted, and recorded the test result for the child. The COVI-Go SARS-CoV-2 Ag Self-Test results were compared to a highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assay to determine test performance.

The study included a total of 50 evaluable positive samples and 411 evaluable negative samples (defined as positive or negative according to comparator assay(s)). Analysis of the CT values of the comparator RT-PCR assay(s) confirmed that 15 (30%) of study subjects that were positive according to comparator assay(s) had low viral loads (high Ct values). This may be associated with the Omicron variant since the low positive percentage in this study is higher than that observed in prior clinical studies for previously authorized COVID-19 rapid antigen tests.

Antigen test performance decreases as the percent of low positives increases since the molecular comparator method is more sensitive than the candidate antigen test. Therefore, to be consistent with previous studies, the analysis for the primary performance calculation was conducted to reflect study populations with low positives ranging from 10 to 20% (controlled analysis). Multiple Percent Positive Agreements (PPAs) were calculated for the positive sample's cohort when different proportions of low positive samples were included and are shown in the table below. At 10% low positives, the PPA was 84.62% and the NPA was 98.5% with 95% confidence interval bounds of 70.27%- 92.75% for PPA and 96.9% to 99.3% for NPA respectively. This was the basis of the authorization. At 20% low positives, the PPA was 75.00% with 95% confidence interval bounds of 60.56% - 85.43%. When all study participants are included, the PPA is 68.00% and the NPA is 98.5% with the 95% confidence interval bounds of 54.19% to 79.24% for the PPA and 96.9% to 99.3% for the NPA, respectively.

Controlled Analysis of COVI-Go SARS-CoV-2 Ag Self-Test low positive results vs molecular comparator results

Measure	Overall Trial	10% Low Positive	12.5% Low Positive	15% Low Positive	17.5% Low Positive	20% Low Positive
High Positive Samples	35	35	35	35	35	35
Low Positive Samples	15	4	6	7	8	9
Total Comparator Positive for PPA Calculation	50	39	41	42	43	44
Total Test Positives for PPA Calculation	34	33	33	33	33	33
Positive Percent Agreement (PPA)	68.00%	84.62%	80.49%	78.57%	76.74%	75.00%
95% CI (XX% - XX%)	54.19% - 79.24%	70.27% - 92.75%	65.99% - 89.77%	64.06% - 88.29%	62.26% - 86.85%	60.56% - 85.43%
NPA (%) = 98.5% (405/411) 95% CI (XX%-XX%) = 96.9% - 99.3%						

Days of COVID-19 Symptoms	Number of Specimens Tested	Candidate Positives, n (%)	Comparator Positives, n (%)	PPA (%), 95% CI, by Comparator*
Day 0	21	0	1 (4.76%)	0/1, 0.00% (20.7% - 100%)
Day 1	97	7* (7.22%)	9 (9.28%)	5/9, 55.6% (26.7% - 81.1%)
Day 2	147	16* (10.9%)	18 (12.2%)	12/18, 66.7% (43.7% - 83.7%)
Day 3	117	9 (7.69%)	11 (9.40%)	9/11, 81.8% (52.3% - 94.9%)
Day 4	73	7 (9.59%)	10 (13.7%)	7/10, 70.0% (39.7% - 89.2%)
Day 5	6	1 (16.7%)	1 (16.7%)	1/1, 100% (20.7% - 100%)
All	461	40 (8.68%)	50 (10.8%)	34/50, 68.0% (54.2% - 79.2%)

*Two (2) false positives were observed on day 1, and four (4) false positives were observed on day 2.

Clinical Performance: Prospective Serial Testing Study at National Institutes of Health

Age Group	Number of Subject Samples tested	Investigational Positive	Comparator Positive	% Positivity Rate (for comparator), 95% CI*
<14 years of age	62	2	5	1/5, 20.0% (37.6% - 96.4%)
14 - 23 years of age	108	2	2	2/2, 100% (34.2% - 100%)
24 - 64 years of age	265	27	34	22/34, 64.7% (47.9% - 78.5%)
≥65 years of age	26	9	9	9/9, 100% (70.1% - 100%)
Total	461	40	50	34/50, 68.0% (54.2% - 79.2%)

*PPA calculation is performed using Comparator Positives as a denominator, therefore the number of investigational positives included in this calculation is a subset of what is included in the table.

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 test 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 the table below.
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			SYMPTOMATIC ON FIRST DAY OF TESTING		
	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 performed 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 performed 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 PERFORMANCE

Limit of Detection (LOD)
The preliminary Limit of Detection (LoD) of the COVI-Go SARS-CoV-2 Ag Self-Test was determined with samples spiked with gamma irradiated SARS-CoV-2 (USA-WA1/2020) into pooled negative nasal wash (PNW). 185µL of the spiked sample preparation was pipetted onto a swab and subsequently added to the COVI-Go SARS-CoV-2 Ag Self-Test device. Tenfold dilution series were performed and tested. This was followed by additional two-fold dilutions of the lowest positive tenfold dilution concentration. The preliminary LoD was confirmed by running twenty (20) replicates of the preliminary LoD concentration and found to be 1.4×10^4 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of $1.4x10^4$ $TCID_{50}$/mL equates to $2.59x10^3$ $TCID_{50}$/swab.

The performance of this test 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 COVI-Go SARS-CoV-2 Ag Self-Test detected 100% of live virus Omicron samples at a Ct-value of 24.5 (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 24.5) were not detected by the COVI-Go SARS-CoV-2 Ag Self-Test in this study.

Omicron Pool 1 – Live Omicron clinical samples	Average N2 Ct (n=6)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	COVI-Go SARS-CoV-2 Ag Self-Test Percent Positive (n=5)
Dilution 1	22.7	100	100	100
Dilution 2	23.3	100	100	100
Dilution 3	24.5	100	100	100
Dilution 4	25.7	0	100	0
Dilution 5	26.8	0	0	0
Dilution 6	28.3	0	0	0

Cross-Reactivity (Analytical Specificity) And Microbial Interference

Cross reactivity and microbial interference studies were conducted to determine if other respiratory pathogens/flora that could be present in a direct nasal swab sample could cause a false-positive test result or interfere with a true positive result. A panel of sixteen (16) viruses, ten (10) bacteria, two (2) fungi, and pooled nasal wash was used for these studies. Final target organism 1.43×10^5 $TCID_{50}$/mL, 1.0×10^5 PFU/mL, or 1.43×10^5 $CEID_{50}$/mL for viruses, and $1.0x10^6$ CFU/mL for bacteria and fungi. When the target concentration was not achievable due to the titer of the stockculture, the highest concentration possible was tested without dilution. For organisms for which a specific titter was not provided, it was assumed the stock concentration was 104. Dilutions for cross reactivity testing were made in pooled negative nasal matrix (PNM). Each cross-reacting organism was tested in replicates of three (3). For microbial interference testing, the 2X organism solution was further mixed 1:1 with PNM spiked with gamma irradiated SARS-CoV-2 at 6X LoD to achieve final concentrations of 1X target organism and 3X LoD SARS-CoV-2 (1xLoD 1.4×10^4 $TCID_{50}$/mL). Microbial interference was tested for each organism in triplicate. False positive results were observed during cross reactivity testing only for SARS-CoV Urbani when tested at 1.58×10^4 $TCID_{50}$/mL. A titration of SARS-CoV was performed to find the concentration at which cross reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 1.58×10^2 $TCID_{50}$/mL.

Organism	Concentration Tested	Cross Reactivity Result	Interference Result
Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Human coronavirus OC43	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Human coronavirus NL63	1.17×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
SARS-coronavirus	1.58×10^3 $TCID_{50}$/mL	Reactive	No Interference
MERS-coronavirus	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Adenovirus	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Human metapneumovirus4 Type B2	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Parainfluenza virus 1	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Parainfluenza virus 3	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Parainfluenza virus 4b	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Influenza A	1.43×10^5 $CEID_{50}$/mL	No Cross Reactivity	No Interference
Influenza B	1.43×10^5 $CEID_{50}$/mL	No Cross Reactivity	No Interference
Enterovirus 68	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Respiratory syncytial virus	1×10^5 PFU/mL	No Cross Reactivity	No Interference
Rhinovirus	1.43×10^5 $TCID_{50}$/mL	No Cross Reactivity	No Interference
Haemophilus influenzae	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Streptococcus pneumonia	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Streptococcus pyogenes	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Candida albicans	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Bordetella pertussis	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Mycoplasma pneumonia	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Chlamydia pneumoniae	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Legionella pneumophila	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Mycobacterium tuberculosis	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Staphylococcus aureus subsp. Aureus	1×10^6 CFU/mL	No Cross Reactivity	No Interference
Staphylococcus epidermidis	9.3×10^5 CFU/mL	No Cross Reactivity	No Interference
Pooled Negative Matrix	NA	No Cross Reactivity	No Interference

Summary of In-silico analysis

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1 and Pneumocystis jirovecii and SARS-CoV-1.

- SARS-CoV2 nucleocapsid protein accession number YP_009724397.2 was searched using BLASTp for similarity with Human coronavirus HKU1 (taxid:290028) and found that closest match with Human Coronavirus HKU1 nucleocapsid protein shows 37% identity. Despite there being little homology observed, the cross-reactivity of the test against Mycobacterium tuberculosis cannot be ruled out.
- SARS-CoV2 nucleocapsid protein accession number YP_009724397.2 was searched using BLASTp for similarity with Pneumocystis jirovecii (taxid:42068) and no significant similarity found. Despite there being little homology observed, the cross-reactivity of the test against Mycobacterium tuberculosis cannot be ruled out.

Endogenous Interfering Substances

Interfering substances testing was performed using a panel of fourteen (15) endogenous and exogenous substances tested at concentrations recommended by the FDA.1 The substances tested are listed in the table below. To evaluate the potential for a given substance to cause a false-positive test result, the substance was first diluted in PNM to twice (2X) the final target concentration, then further mixed 1:1 with PNM to achieve the final (1X) target substance concentration. To determine if any of the potential interfering substances in the test panel could interfere with the detection of a true positive test result, a 2X substance solution was further mixed 1:1 with PNM spiked with SARS-CoV-2 at 6X LoD to achieve final concentrations of 1X target substance and 3X LoD SARS-CoV-2 (1xLoD 1.4×10^4 $TCID_{50}$/mL). Each interfering substance sample was tested in triplicate. Test results are summarized in the table below. At the concentrations tested none of the substances caused a false-positive test result in un-spiked samples or interfered with the detection of a true positive test result in 3X LoD spiked samples.

Sample ID	Test Concentration	Result
Human Whole Blood (EDTA tube)	4% v/v	No Interference
Mucin (porcine stomach, type II)	0.5%	No Interference
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No Interference
Naso GEL (NeilMed)	5% v/v	No Interference
Nasal Drops (Phenylephrine)	15% v/v	No Interference
Nasal Spray (Oxymetazoline)	15% v/v	No Interference
Nasal Spray (Cromolyn)	15% v/v	No Interference
Zicam	5% v/v	No Interference
Homeopathic (Alkalol)	10% v/v	No Interference
Sore Throat Phenol Spray	15% v/v	No Interference
Tobramycin	4 µg/mL	No Interference
Mupirocin	10 mg/mL	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Interference
Fluticasone Propionate	5% v/v	No Interference
Disinfecting Wipes	5% v/v	No Interference
Hand Soap	5% v/v	No Interference

Hand Sanitizer	5% v/v	No Interference
Daily Moisturizing Lotion	5% v/v	No Interference
Healing Hand Lotion	5% v/v	No Interference
Radiance Renewal (Hand Lotion)	5% v/v	No Interference
Biotin	3500 ng/mL	No Interference

Statement on biotin interference:
The COVI-Go SARS-CoV-2 Ag Self-Test uses Biotin reagents. To test for interference, concentrations of biotin up to 3500ng/mL were added to a representative nasal matrix (pooled nasal wash) in the presence and absence of Irradiated SARS-CoV-2 virus at 3x LoD. No false negatives or false positives were observed.

HIGH DOSE HOOK EFFECT

To verify that false negative results do not occur when tested with very high concentrations of virus, devices were tested with undiluted virus in triplicate. Gamma irradiated SARS-CoV-2 was tested at 2.8 × 106 TCID50/mL. As shown in the table below, all three replicates produced positive results.

High Dose Hook Effect

Concentration (TCID50/mL)	Result
2.8E+06	Positive

USABILITY STUDY

The usability of the COVI-Go™ SARS-CoV-2 Ag Self-Test by patients (or parents of patients) was evaluated by observation in an additional clinical usability study. A total of 117 subjects were enrolled in the study and were instructed to self-collect or collect a sample from a child, run the test per the quick reference guide and interpret the test results unassisted in a simulated home-setting. The overall success of every task completed by all subjects enrolled was determined by unassisted observation. Subjects performed 95.5% (1453/1521) of essential steps/tasks correctly. After the result was reported to the observer, the patient (or parent of patient) completed a test usability and satisfaction questionnaire, in which 97% of subjects indicated that the instructions were clear and easy to follow. Furthermore, the patients (or parent of patient) reported an average “clear and easy to follow” rating of 93% (109/117) for collecting the sample, applying the sample to the device and seeing the test results. In conclusion the subject questionnaire results show good understanding by all patients (or parents of patients) of the instructions, device use, and test results interpretation.

FLEX STUDY

The robustness of the COVI-Go™ SARS-CoV-2 Ag Self-Test was demonstrated by seven (7) Flex studies: mixing of sample, delay in result reading, high temperature and humidity, low temperature and humidity, impact of light sources, non-level surface during test run, and disturbance during analysis.

TECHNICAL SUPPORT

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SYMBOLS

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests		Catalogue number
	In vitro diagnostic medical device		Use-by date
	Consult instructions for use		Batch code
	Store between 2-30°C / 36-86°F		Do not reuse

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