For Emergency Use Authorization (EUA) Only
For use with anterior nasal swab specimens
For in vitro diagnostic use

Swab-N-Go HomeTest
COVID-19 Ag

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

HEALTHCARE PROVIDER INSTRUCTIONS FOR USE

July 2023 Rev. 00
Immunostics Inc.

1. INTENDED USE

The Swab-N-Go Home Test COVID-19 Ag is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2.

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 two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 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 Swab-N-Go Home Test COVID-19 Ag does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine 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 Swab-N-Go Home Test COVID-19 Ag 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 health 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 the CDC.

The Swab-N-Go Home Test COVID-19 Ag is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged two years or older in a non-laboratory setting.

The Swab-N-Go Home Test COVID-19 Ag 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.

2. 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 Swab-N-Go Home Test COVID-19 Ag is a rapid, qualitative immunochromatographic immunoassay for the detection of the antigens from SARS-CoV-2 in direct anterior nares (nasal) swab specimens.

The Swab-N-Go Home Test COVID-19 Ag Kit is comprised of a Test Cartridge, Extraction Tube, Nozzle, and Nasal Swab (sample collection device).

Individual's nasal swab specimen is processed in the extraction buffer dispensed in a prefilled unitized tube. The extraction buffer breaks down the mucus in the specimen thereby exposing viral antigens and enhancing their detection by the test cartridge.

Extracted swab sample is manually added to the sample well of the test cartridge to initiate the test. When the extracted swab sample migrates through the test strip of the test cartridge, SARS-CoV-2 viral antigens bind to the mouse monoclonal Anti-SARS-CoV2-latex conjugate in the conjugate pad forming an antigen-antibody complex which is then captured by the mouse monoclonal Anti-SARS-CoV-2 Antibody present at the test line(T) on the nitrocellulose membrane as the sample migrates through the test strip.

Furthermore, as the sample migrates through the test strip, chicken IgY- latex conjugate present in the test strip is captured by the mouse monoclonal anti-chicken IgY antibody present at the control line (C) on the nitrocellulose membrane.

Test result is interpreted visually at 15 minutes after addition of the extracted swab sample to the sample well of the test cartridge by following due test procedure. The presence of two red-colored lines; one in the control line region "C" and other in the test line region "T" of the test cartridge indicates positive test result.

The presence of one red colored line only in the control line region "C" indicates negative test result. No appearance of a colored line in the control region "C" indicates an invalid test result.

The red-colored line appearing in the control region "C" has been designed as the built-in/ internal procedural control of Swab-N-Go Home Test COVID-19 Ag.

Swab-N-Go Home Test COVID-19 Ag result should be read and interpreted after 15 minutes but before 30 minutes after addition of the extracted swab sample to the 'sample well' of the test cartridge. Refer to "7. TEST INTERPRETATION" section.

3. KIT CONTENTS

The Swab-N-Go Home Test COVID-19 Ag is offered in a 2 test/kit size. Each kit .contains:

- 2 Swabs
- 2 Test cartridges
- 2 Extraction tubes
- 2 Nozzles
- 1 Quick Reference Instructions

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Watch or Timer
- RAPIDCHECK mobile application and compatible smartphone (optional)
  (**Compatible smart phones:** iPhones (iOS 14.2 or later), and Android Phones (Android 10 or later). For a list of compatible smartphone OS systems, visit www.immunostics.com/app-1)

5. QUALITY CONTROL

Each Swab-N-Go Home Test COVID-19 Ag cartridge has a built-in internal procedural control. The red line appearing at the "C" position is an internal procedural control. This procedural Control Line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. A distinct red Control Line should always appear regardless of the presence of antigen in the sample if the test has been performed correctly. If the Control Line does not appear within 15 minutes of applying sample to the test cartridge, the test result is invalid, and a new test should be performed.

6. TEST PROCEDURES

Note: The user may also use RAPIDCHECK mobile application for procedural instructions.

The RAPIDCHECK app allows the user to save Swab-N-Go Home Test COVID-19 Ag results and report the test result(s) at MakeMyTestCount.org.

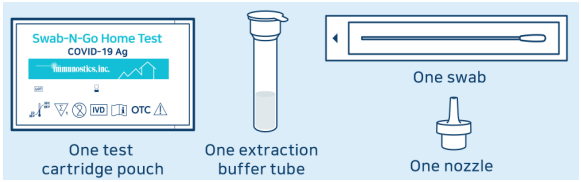
Compatible smart phones: iPhones (iOS 14.2 or later), and Android Phones (Android 10 or later). For a list of compatible smartphone OS systems, visit www.immunostics.com/app-1.

- Download the app by scanning the QR code.
- Open the App.
- Answer a few questions in the App.
- Follow step-by-step instructions for performing the test.
- Visually read and interpret the test result.
- Report the test result(s) at MakeMyTestCount.Org as directed by the app.
- Alternatively, for digital instructions go to https://immunostics.safekey.tools/.

6.1. Gather and check your supplies.

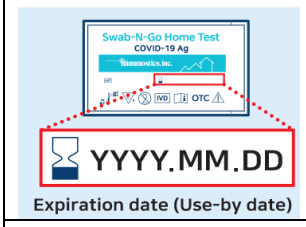
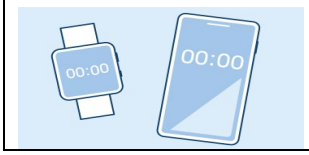
- Make sure you have enough time to complete the entire test process. It takes approximately 20 minutes once you begin.
- Do not perform the test in conditions outside of recommended room temperatures (15– 30°C /59–86°F).

- Wash your hands or use hand sanitizer.
- Make sure your hands are dry before you start testing.

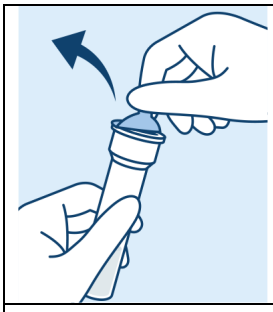
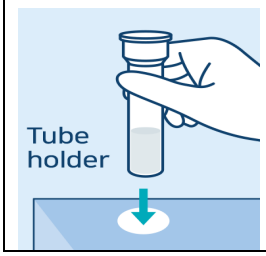


Note: Do not open individual components until instructed to do so.

- Open the kit and remove one each of the following items.
- Check items for damage.

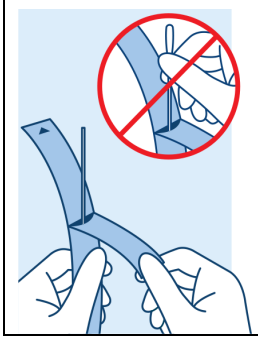
	• Check the expiration date (Use-by date) on the cartridge pouch. • For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests
	• Have a watch or timer ready (not included in the kit).

6.2. Open the extraction buffer tube.

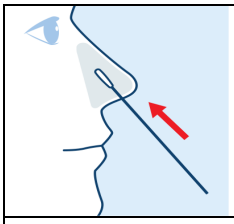
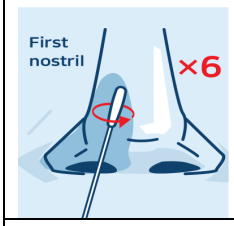
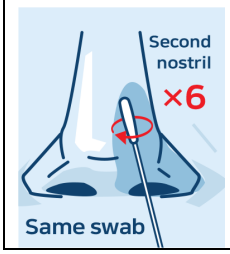
	• Open the extraction buffer tube by removing its foil seal.
	• Put the unsealed tube in the tube holder provided in the box.

6.3. Remove the swab from its wrapper.

Note: If you are swabbing others, please wear a face mask.

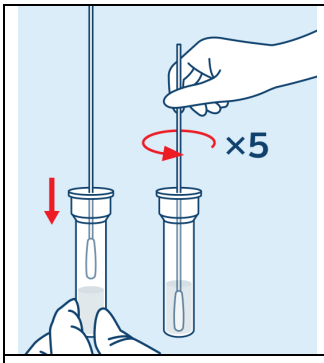
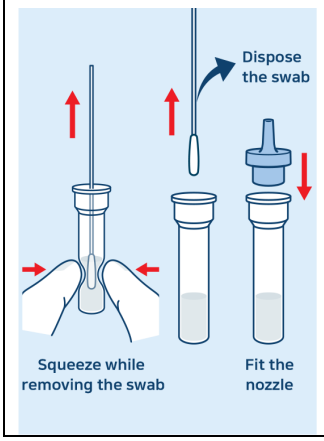
	• Remove the swab from its wrapper. Do not touch the tip of the swab.

6.4. Swab both nostrils using the same swab.

	• Gently insert the entire absorbent tip of the swab no more than ½ to ¾ of an inch into your nostril. Note: For children, maximum depth of insertion into the nostril may be less than ½ to ¾ inch. For very young children and some patients, you may need another person to hold their heads while swabbing.
	• Firmly and slowly swab in a complete circle against the inside of the nostril at least 6 times.
	• Repeat the same sample collection procedure for the other nostril using the same swab. Note: Failure to swab properly may cause false negative results.

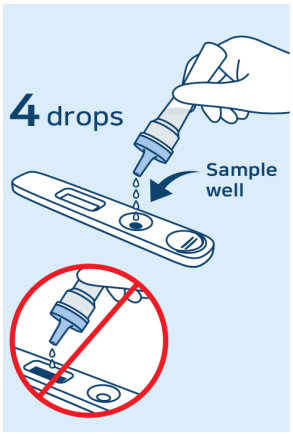
6.5. Transfer swab to the extraction buffer tube

Note: Transfer the swab to the extraction tube immediately after collecting the nasal sample.

	• Remove the tube from the tube holder. • Immediately place the swab into the extraction tube. • Swirl the swab 5 times in the tube liquid, while making sure the swab tip remains completely immersed in the liquid.
	• Remove the swab while squeezing the sides of the tube to press out as much liquid as possible from the swab. Note: If you do not squeeze the swab, test result may be false negative. • Dispose of swab in a trash bin. • Snap-fit the nozzle onto the extraction tube.

6.6. Add sample to the test cartridge.

Note: Swab samples should be tested immediately after processing in the extraction tube.

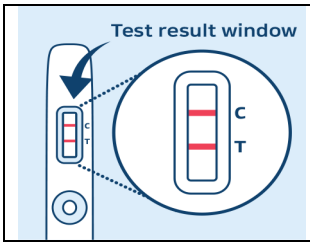
	• Remove the test cartridge from its pouch and place it on a flat, clean, and dry surface. • Slowly squeeze 4 drops of the sample into the sample well of the test cartridge. Note: Test result may be false negative or invalid if less than 4 drops of the sample are added to the sample well. Do not add the sample to the test result window of the test cartridge.

6.7. Wait 15 minutes.

	• Start a timer for 15 minutes immediately after adding the sample to the test cartridge. • Leave the test cartridge on a flat surface until the timer goes off. • Read test result immediately when timer goes off.

6.8. Read the test result.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

	• Read the test result in a well-lit area. • Look for red lines in the area next to the 'C' and 'T' in the test result window to read your result.

7. TEST INTERPRETATION

The test result should be read and interpreted between 15-30 minutes after the sample has been added to the test cartridge. Reading and interpretation of the results after 30 minutes may yield inaccurate results. There is a higher chance of false negative results with antigen test than with laboratory-based molecular tests due to the sensitivity of the test technology. Therefore, repeat (serial) testing for negative results should be performed as indicated below.

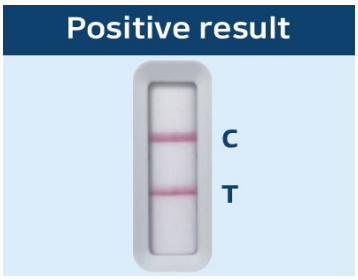
Serial Testing Results Interpretation

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

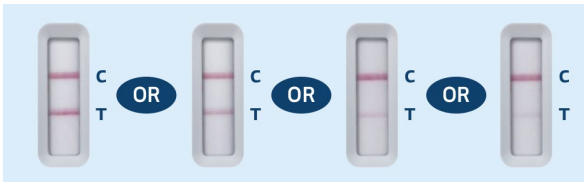
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19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

COVID-19 Positive (+)



Note: Test result is positive even if the line next to 'T' is faint.

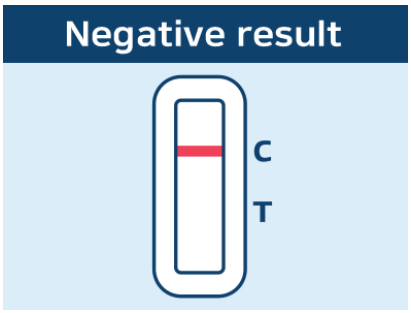


COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red 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 Swab-N-Go Home Test COVID-19 Ag 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 (-)

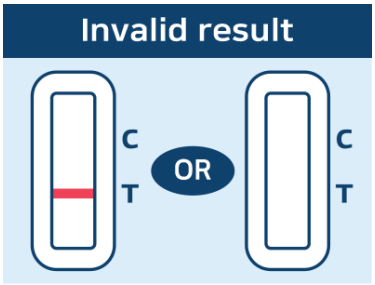


COVID-19 Negative (-)

- 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 you have symptoms on the first day of testing.**
  - **Test 2 more times at least 48 hours apart if you do 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 individual's sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests.
- If the test is negative but COVID-19-like symptoms (e.g., fever, cough, and/or shortness of breath) continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
- All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid result

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

8. STORAGE AND STABILITY

Store the Swab-N-Go Home Test COVID-19 Ag kit between 2-30°C (36-86°F). Ensure that all kit components are at room temperature before use. Kit components are stable until the expiration date printed on the outer packaging. Do not use any kit component beyond the expiration date. The test cartridge must remain in the sealed foil pouch until use. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

9. WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- 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 for longer than 7 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 aged 14 years and older. Children aged 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 contents or packaging is damaged.
- Test components are for single use. Do not re-use.

- Do not use kit past its expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit "At-Home OTC COVID-19 Diagnostic Tests": https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Do not touch the swab tip.
- Once opened, the test cartridge should be used within 15 minutes.
- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 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.**

Chemical Name	GHS Code	Concentration
Sodium azide	H300, Fatal if swallowed	0.05%
	H310, Fatal in contact with skin	
	H400, Very toxic to aquatic life	
	H410, Very toxic to aquatic life with long lasting effects	

- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

10. LIMITATIONS

- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2022 and August 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.
- 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 with a healthcare provider 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.

- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision such as far sightedness, glaucoma, or color blindness are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- 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.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Extract the swab in the extraction buffer tube right after collecting the nasal swab sample.
- Swab samples should be tested immediately after extraction in the extraction tube. If immediate testing is not possible, the nozzle-fitted extraction tube may be stored for up to 1 hour at room temperature around 15–30 °C (59–86 °F). Do not freeze the extracted sample.

11.PERFORMANCE CHARACTERISTICS

11.1. Limit of Detection (Analytical Sensitivity):

A Limit of Detection (LoD) study was performed to determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all replicates test positive (true positive) with the Swab-N-Go Home Test COVID-19 Ag.

The LoD of the Swab-N-Go Home Test COVID-19 Ag was determined by testing serial dilutions of heat-inactivated SARS-CoV-2 virus spiked into pooled human normal nasal fluid from healthy donors which was confirmed SARS CoV-2 negative by an FDA-authorized RT-PCR test.

Replicate test samples were prepared by pipetting out 50 µL of the spiked sample preparation onto the swabs that were then processed per the Instructions for Use (IFU).

The lowest concentration at which all 5 of 5 replicates tested positive was 4.44 $x10^2$ $TCID_{50}$/mL which was chosen as the tentative LoD for the confirmation study.

LoD was confirmed by testing 20 replicates with at least 95% detection. Final LoD of the test was determined to be 4.44 x 10^2 $TCID_{50}$/mL which equates to 22.2 $TCID_{50}$/swab, as this is the lowest concentration of SARS CoV-2 resulting in at least 19 out of 20 replicates that produced a positive result.

11.2. Cross-reactivity (analytical specificity) and microbial interference*:*

Cross-reactivity and microbial interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen from the nasal cavity.

The final concentrations that were tested, were >10^6 CFU/mL for bacteria and > 10^5 pfu/mL or $TCID_{50}$/mL for viruses.

Each organism was wet-tested in both the absence and presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate at 3 × LoD =13.3 x 10^3 $TCID_{50}$/mL concentration) for evaluating cross-reactivity and microbial interference respectively. All test samples were prepared in the negative clinical matrix and were tested in triplicate.

Neither cross reactivity nor interference was observed for any of the microorganisms at the concentrations tested as shown in the following table.

Cross-reactivity and microbial interference testing of the Swab-N-Go Home Test COVID-19 Ag			
Microorganisms tested	**Concentration tested**	**Cross-reactivity**	**No interference**
Human coronavirus 229E	6.3 x 10^5 $TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	1.9 x 10^6 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	1 x 10^5 $TCID_{50}$/mL	0/3	3/3
MERS-coronavirus	5.2 x 10^5 $TCID_{50}$/mL	0/3	3/3
Adenovirus Type 1	2.0 x 10^{10} $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus	1 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 1	2.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 2	7.5 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 3	2.28 x 10^6 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 4A	1.78 x 10^5 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus Type 4B	1 x 10^5 $TCID_{50}$/mL	0/3	3/3
Influenza A virus H3N2	7.0 x 10^5 PFU/mL	0/3	3/3
Influenza B virus B/Lee/40	3.8 x 10^5 PFU/mL	0/3	3/3
Respiratory syncytial virus A	4.25 x 10^5 PFU/mL	0/3	3/3
Human Enterovirus A	2.25 x 10^6 PFU/mL	0/3	3/3
Human Rhinovirus B	3 x 10^8 PFU/mL	0/3	3/3
Haemophilus influenzae	3 x 10^8 CFU /mL	0/3	3/3
Streptococcus pneumoniae	3 x 10^8 CFU /mL	0/3	3/3
Streptococcus pyogenes	3 x 10^8 CFU /mL	0/3	3/3
Staphylococcus aureus	3 x 10^8 CFU /mL	0/3	3/3
Staphylococcus epidermidis	3 x 10^8 CFU /mL	0/3	3/3
Bordetella pertusis	3.21 x 10^9 CFU /mL	0/3	3/3
Mycoplasma pneumoniae	2.81 x 10^7 CFU/mL	0/3	3/3
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	0/3	3/3
Legionella pneumophila	8 x 10^6 CFU /mL	0/3	3/3
Candida albicans	3 x 10^8 CFU mL	0/3	3/3
Normal respiratory microbial flora	Pooled human nasal wash	0/3	*Not applicable*

In-silico analyses were performed to estimate the likelihood of cross-reactivity with Human Coronavirus HKU1, *Pneumocystis jirovecii* and *Mycobacterium tuberculosis* by determining the degree of protein sequence homology between the SARS-CoV-2 nucleocapsid protein antigen and these microorganisms.

In-silico analysis for evaluating cross reactivity with Human coronavirus HKU1 was performed using the Basic Local Alignment Search Tool (BLAST) to assess the degree of protein sequence homology and was conducted using the NCBI database with BLASTP program. Based on the protein BLAST sequence alignment, homology was found to be relatively low (36.7% across 82% of sequences), but cross-reactivity cannot be ruled out.

In-silico analysis for evaluating cross reactivity with *Pneumocystis jirovecii* was carried out using Pneumocystis jirovecii protein sequences (taxID 42068) available from GenBank and aligned with the SARS-CoV-2 nucleocapsid protein sequences using BLASTP with parameters set to find significant homologous sequences. No significant homology was observed regarding SARS-CoV-2 nucleocapsid protein. Therefore, it is concluded that there is a very low probability of cross-reactivity with *Pneumocystis jirovecii*, however, cross-reactivity cannot be ruled out.

Similarly, *in-silico* analysis for evaluating cross reactivity with *Mycobacterium tuberculosis* was carried out using *Mycobacterium tuberculosis* protein sequences (taxID 77643) available from GenBank and aligned with the SARS-CoV-2 nucleocapsid protein sequences using BLASTP with parameters set to find significant homologous sequences. No significant homology was observed regarding SARS-CoV-2 nucleocapsid protein. Therefore, it is concluded that there is a very low probability of cross-reactivity with *Mycobacterium tuberculosis*, however, cross-reactivity cannot be ruled out.

11.3. Endogenous and exogenous substances interference:

This study was performed to evaluate interference from 19 potentially interfering substances (including over-the-counter medications and common house-hold items) that might be present in the respiratory tract or artificially introduced onto the nasal swab in the home environment.

Each potential interferent was tested in the presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate at 3 × LoD =13.3 x 10^3 $TCID_{50}$/mL concentration). All test samples were prepared in the negative clinical matrix and were tested in triplicate.

None of endogenous or exogenous substances that were tested, was found to interfere with the Swab-N-Go Home Test COVID-19 Ag at concentrations shown in the following table.

Endogenous and exogenous substances interference testing of Swab-N-Go Home Test COVID-19 Ag			
Potential endogenous and exogenous interferents that were tested	**Concentration tested**	**Cross-reactivity**	**No Interference**
Human whole blood	4%	0/3	3/3
Mucin (Porcine)	0.5%	0/3	3/3
Chloraseptic Menthol-Beozocaine throat lozenges	1.5 mg/mL	0/3	3/3
Naso GEL® (NeilMed)	5 % v/v	0/3	3/3
CVS Phenylephrine Nasal Drops	15 % v/v	0/3	3/3
Afrin Oxymetazoline Nasal Spray	15 % v/v	0/3	3/3
CVS Cromolyn Nasal Spray	15 % v/v	0/3	3/3
Zicam® Intense SINUS RELIEF	5 % v/v	0/3	3/3
Zicam® Nasal Allclear	5 % v/v	0/3	3/3
Aklalol®	1:10 dilution	0/3	3/3
Sore Throat Phenol Spray	15% v/v	0/3	3/3
Tobramycin	4 µg/mL	0/3	3/3
Mupirocin nasal ointment	10 mg/mL	0/3	3/3
Fluticasone propionate	5% v/v	0/3	3/3
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	0/3	3/3
Mouth wash (Ethyl alcohol)	5% v/v	0/3	3/3
Bleach (Sodium Hypochlorite)	1% v/v	0/3	3/3
Dish washing Liquid	1% v/v	0/3	3/3
Laundry Detergent	1% v/v	0/3	3/3

11.4. High-dose hook effect:

A high-dose hook effect study was performed to demonstrate that the Swab-N-Go Home Test COVID-19 Ag does not yield false negative results when very high levels of SARS CoV-2 antigens are present in a tested specimen.

No high-dose hook effect was observed when concentrations up to 2.23×10^5 $TCID_{50}$/mL of the heat-inactivated SARS-CoV-2 stock virus (SARS-CoV-2 isolate) were tested with the Swab-N-Go Home Test COVID-19 Ag.

11.5. Flex Studies:

The robustness of the Swab-N-Go Home Test COVID-19 Ag was demonstrated by following Flex studies:

- Effect of operating temperature and humidity extremes
- Effect of swab mixing variability
- Effect of swab expression variability
- Effect of delayed extraction of nasal swabs after sample collection
- Effect of delay in testing the nasal swabs after extraction
- Effect of sample volume variation
- Effect of delay in reading test result
- Effect of wrong placement of samples
- Effect of non-level surface
- Effect of Disturbance During Analysis
- Effect of buffer volume variation

12. CLINICAL PERFORMANCE

The clinical performance of the Swab-N-Go Home Test COVID-19 Ag was evaluated at the hands of intended users in a two-phase prospective, all-comer's study at six clinical sites in the United States that were representative of OTC/home-use settings.

Patients or legal guardians of patients above 2 years of age presenting symptoms suspicious of COVID-19 visiting the study sites seeking testing, were approached to participate in the study. Additionally, subjects that were symptomatic who had come in close-contact with individuals who tested positive for COVID-19 but they themselves were not aware of their infected status, were also invited to participate in the study.

Participants aged 14 years or older followed the Quick Reference Instructions provided in the Swab-N-Go Home Test COVID-19 Ag kit to self-collect an anterior nares (nasal) swab sample and performed the test using the test kit. Participants younger than 14 years of age were swabbed and tested by an adult participant (e.g., parent or legal guardian).

Another anterior nares (nasal) swab sample was also taken from each study participant by a healthcare professional for comparative testing on a high-sensitivity, FDA EUA-authorized RT-PCR method as the comparator.

The study evaluated Swab-N-Go Home Test COVID-19 Ag performance in total 308 subjects showing symptoms associated with COVID-19.

The Swab-N-Go Home Test COVID-19 Ag correctly identified 55 out of 63 SARS-CoV-2-positive individuals, and all of the 245 SARS-CoV-2-negative individuals. The agreement between the RT-PCR comparator and the Swab-N-Go Home Test COVID-19 Ag has been calculated and summarized in the following table.

Performance summary of Swab-N-Go Home Test COVID-19 Ag against an authorized RT-PCR comparator method			
Swab-N-Go Home Test COVID-19 Ag	**Comparator Method**		
	Positive	**Negative**	**Total**
Positive	55	0	55
Negative	8	245	253
Total	63	245	308
PPA	87.3% (95% CI: 76.9% - 93.4%)		
NPA	100.0% (95% CI: 98.5% - 100.0%)		

The performance of the Swab-N-Go Home Test COVID-19 Ag relative to subject demographics such as patient age is shown in the following table.

Performance of the Swab-N-Go Home Test COVID-19 Ag stratified by age groups				
Age in years	**Number of study subjects enrolled**	**Comparator Positive**	**Prevalence**	**Swab-N-Go Home Test COVID-19 Ag Positive**
2 to 13	**43**	**14**	**32.56 %**	**14**
14 to 24	**33**	**9**	**23.08 %**	**6**
25 to 64	**199**	**35**	**17.59 %**	**31**
65+	**27**	**5**	**18.52 %**	**4**
Total	**308**	**63**	**20.45 %**	**55**

The performance of the Swab-N-Go Home Test COVID-19 Ag relative to days post-onset of symptoms is shown in the following table.

Days post symptom-onset	Number of study subjects enrolled	Total number of samples at each day post symptom-onset	Cumulative Swab-N-Go Home Test COVID-19 Ag Positive	Positive percent agreement (PPA %)
0	**15**	**1**	**1**	**100.0 %**
1	**38**	**4**	**3**	**75.0 %**
2	**64**	**7**	**6**	**85.7 %**
3	**70**	**15**	**12**	**80.0 %**
4	**48**	**10**	**10**	**100.0 %**
5	**43**	**13**	**11**	**84.6 %**
6	**16**	**6**	**6**	**100.0 %**
7	**14**	**7**	**6**	**85.7 %**
Total	**308**	**63**	**55**	**87.30 %**

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 RTPCR, 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 following table.

Table: 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 Test	3 Test	1 Test	2 Test	3 Test
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 (100.0%)
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 on 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.

13. TECHNICAL SUPPORT

For questions, or to report a problem, please call 1-800-722-7505 (Toll Free) or 1-732-918-0770

14. SYMBOLS AND ABBREVIATIONS

The following symbols appear in the Swab-N-Go Home Test COVID-19 Ag Test product labeling:

	Manufacturer
	Temperature limit
	Date of manufacture
	Consult instructions for use
	*In vitro* diagnostic medical device
	Use-by date
	Do not re-use
	Catalogue number
	Caution
	Contains sufficient for <n> tests
	Batch code

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