Immunostics, Inc.

Swab-N-Go Home Test
COVID-19 Ag
Instructions for Use

Document No.: INS-SH-US
Revision Date: July, 2023 (Rev.01)

Swab-N-go Home Test COVID-19 Ag is for in vitro diagnostic use only under the FDA's Emergency Use Authorization. This product has not been FDA cleared or approved.

Please read all the instructions before performing the test.
For use with anterior nasal swab specimens.

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.

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.

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 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 contents or packaging is damaged.
- Test components are 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/covid-tests
- 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 20 minutes. Results read before 15 minutes or after 20 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 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

- 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 to 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 you 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 a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have 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.
- 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.

Frequently Asked Questions (FAQ)

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Swab-N-Go Home Test COVID-19 Ag, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How accurate is the test?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.fda.gov/covid-tests.

What if I have a positive test result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a negative test result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an invalid test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

Important

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the CDC general webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

Symbol glossary

(Explanation of symbols used in Immunostics' device labeling)

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

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Immunostics, Inc.

Swab-N-Go Home Test
COVID-19 Ag

This product has not been FDA-cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).

Please read all the instructions before performing the test.
For use with anterior nasal swab specimens.
For *In Vitro* Diagnostic (IVD) Use Only.

Please note:

1) This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use this test result as the only guide to manage your illness.
2) This product has been authorized for the detection of proteins from SARS-CoV-2 and, not for any other virus or pathogens.
3) 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.5C § 360bbb-3(b)1), unless the declaration is terminated, or authorization is revoked sooner.

RAPIDCHECK mobile application

The RAPIDCHECK app allows you to save your 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 your test.
- Visually read and interpret your test result.
- Report your test result(s) at MakeMyTestCount.Org as directed by the app. Alternatively, for digital instructions go to https://immunostics.safekey.tools/

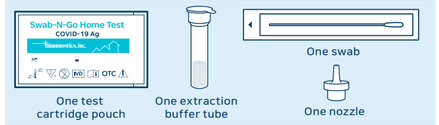
Step-by-step instructions

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.

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



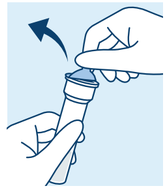
Note: Do not open individual components until instructed to do so.

- Check items for damage.

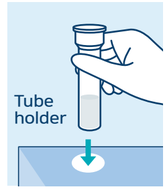
- Check the expiration date (Use-by date) on the cartridge pouch.

- Have a watch or timer ready (not included in the kit).

2 Open the extraction buffer tube



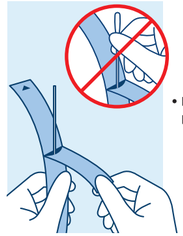
- Open the extraction buffer tube by removing its foil seal.



- Put the unsealed tube in the tube holder provided in the box.

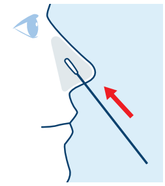
3 Remove the swab from its wrapper

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



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

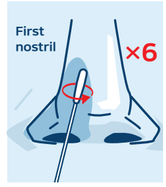
4 Swab both nostrils using the same swab



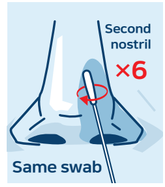
- Gently insert the entire absorbent **tip** of the swab **no more than ½ to ¾ of an inch** into your nostril.

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**.

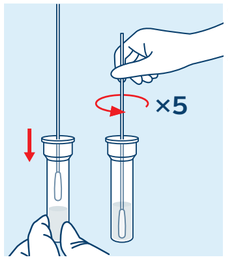


- Repeat the same sample collection procedure for the other nostril using the same swab.

Note: Failure to swab properly may cause false negative results.

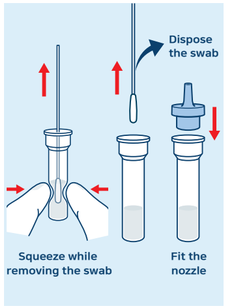
5 Transfer swab to the extraction buffer tube

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.**

WARNING: False results may occur if the swab is swirled less than 5 times.



- 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 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.

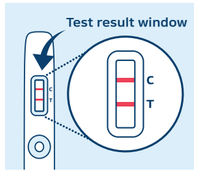
Do not add the sample to the 'test result window' of the test cartridge.

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.

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.

9 Interpret the test result

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

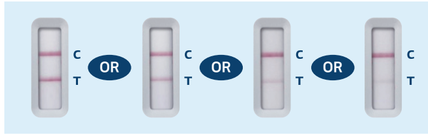
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

- **Test result may be positive, negative, or invalid.**

9-A Positive result

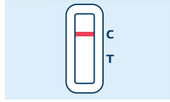
COVID-19 Positive (+)
If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red test (T) line with the control line (C) should be read as positive.
You do not need to perform repeat testing if you have a positive result at any time.

Note: Test result is positive even if the line next to "T" is faint.



A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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).

9-B Negative result



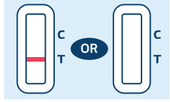
COVID-19 Negative (-)
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

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 your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

9-C Invalid result



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

Next steps:

- If the test result is invalid, you need to retest with a new test kit after collecting a fresh sample.
- If the test result is still invalid upon retesting, contact Immunostics Inc. at 1-732-918-0770.

Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions

10 Dispose of used test kit materials

After interpreting the test results, dispose of all used test kit materials.

Document No.: INS-SH-US
Revision Date: July, 2023 (Rev.01)

Swab-N-Go Home Test COVID-19 Ag cartridge box

PS-1830 Rev01 06/30/2023

immunostics, inc.

Swab-N-Go Home Test

COVID-19 Ag

PS-1830 Rev01 06/30/2023

Scan QR code with phone camera to download the App.
For a list of compatible smartphone OS systems, visit www.immunostics.com/app-1

Using the RAPIDCHECK mobile application:
(You may also use the printed instructions included in the box.)
Please follow the in-app self-paced, step-by-step instructions.

1. Download and open the App.
2. Answer a few questions in the App.
3. Follow step-by-step instructions for performing your test.
4. Visually read and interpret your test result.
5. Report your test result.

Required for using the mobile application: Access to smartphone, internet,and email account.

immunostics, inc.

UDI (01)08061330808491(17)240815(10)SHSEA03

LOT SHSEA03 2024.08.15

For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests

- Do not use on anyone under 2 years of age.
- For ages 2 to 13 years, anterior nares specimens must be collected by an adult.

In the USA, this product has not been FDA-cleared or approved; but has been authorized by FDA under an EUA. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro 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.

8 806133 080849

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www.immunostics.com

For Emergency Use Authorization (EUA) only
For in vitro diagnostic use

For symbol glossary, refer to the printed instructions included in the box.

PS-1830 Rev01 06/05/2023

immunostics, inc.

Swab-N-Go Home Test

COVID-19 Ag

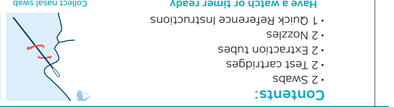
Open Here

OTC 2 TESTS

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

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

Have a watch or timer ready (not included in the kit)



Test result in 15 MIN

For in vitro diagnostic use

- This box contains two tests and a Quick Reference Instructions (QRI).
- If you have symptoms of COVID-19, you will need to use the test at least twice over three days with at least 48 hours between tests.
- If you do not have any symptoms of COVID-19, you will need to use the test at least three times over five days, with at least 48 hours between tests.
- Purchase additional tests to perform further serial (repeat) testing.
- This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

Swab-N-Go Home Test COVID-19 Ag offers rapid, easy-to-interpret results at home with a simple procedure without any training.

For Emergency Use Authorization (EUA) only

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COVID-19 Ag

OTC 2 TESTS

Swab-N-Go Home Test COVID-19 Ag offers rapid, easy-to-interpret results at home with a simple procedure without any training.

- This box contains two tests and a Quick Reference Instructions (QRI).