Swab-N-Go Home Test COVID-19 Ag is for in vitro diagnostic use only under the Food and Drug Administration’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 an in vitro diagnostic test intended for the qualitative detection of nucleic acid fragments from the virus that causes COVID-19.

This test is authorized for non-prescription use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older. This test is for healthcare providers to test asymptomatic individuals who are otherwise healthy and do not have symptoms of COVID-19. This test is not intended for individuals to test themselves. This test is not authorized for use in emergency settings.

**Warnings, Precautions, and Safety Information**

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- The Swab-N-Go Home Test COVID-19 Ag is only for in vitro diagnostic use and has not been cleared or approved by the FDA. It is a device specifically designed to detect SARS-CoV-2, and not for any other viruses or pathogens.
- The emergency use of this test is only authorized under FDA’s statutory authority when there are compelling circumstances justifying the authorization of emergency use of a test in a diagnostic setting (Section 351(i)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(1), unless the declaration in termination or authorization is revoked sooner).

**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, individuals tested at least two more times after initial negative results, and with initial negative results, should be tested again after all 48 hours, and if the 2nd test is also negative, a 3rd test.
- 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, under the Food and Drug Administration’s Emergency Use Authorization, this product has been FDA cleared or approved.

**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. The clinical sensitivity of the test may not be as high as laboratory tests and will vary depending on the clinical setting.
- The performance of this test was 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 or is intended to be reflected in the epidemiological variation and the efficacy of the spread of COVID-19. The test performance of the test may vary depending on the variants circulating, including newly emerging variants 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 test results are negative, a 3rd test may be necessary. You should follow-up with a healthcare provider.
- If the test is used for antigen tests contained the virus that causes COVID-19 have been found in the sample and you likely have COVID-19. These test results are considered positive. Because there can be very few users, conditions affecting their vision such as: color blindness, glaucoma, or color blindness are encouraged to seek follow-up with their ophthalmologist or healthcare provider as additional light source, or another person).
- Do not use this test as the only guide to manage your illness. Consult your healthcare provider for medical advice about your result.
- 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 to perform it, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.fda.gov/covid-tests.
- A positive result means that it is likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-report your result to your family and others in your community. The results of this test may help limit the potential spread of COVID-19.
- A negative result means that it is unlikely you have COVID-19 because proteins from the virus that causes COVID-19 were not found in your sample. You should continue to have symptoms of COVID-19, and your first test is negative, you should test again in at least 48 hours before you can complete another molecular test. If you do not have symptoms and receive a negative result, you should test again in at least 48 hours. For individuals without symptoms and want to complete a total of three tests, if you have a negative result, it does not rule out SARS-CoV-2 infection. There are other tests you can use. It is important that you work with your healthcare provider to help you understand the next steps you should take.

**What is 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 sample should be used to collect a new nasal sample and you should test again with a new test.

**How accurate is the test?**

The most up-to-date information on COVID-19 is available at the CDC general webpage: https://www.cdc.gov/covid-19/in.html. In addition, please also contact your healthcare provider with any questions/concerns.
1. Gather and check your supplies:
   - Make sure you have enough time to complete the entire test process. It takes approximately 30 minutes once you begin.
   - Do not perform the test in conditions outside of recommended process. It takes approximately 20 minutes once you begin.

2. Open the extraction buffer tube:
   - Open the extraction buffer tube by removing its fail seal.

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 ⅛ to ¼ of an inch into your nostril.
   - Note: For children, extreme depth of insertion into the nostril may be less than ⅛ to ¼ inch.
   - For very young children and some patients, you may need another person to hold their head while swabbing.

5. Transfer swab to the extraction buffer tube:
   - Remove the swab 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 not swirled at least 5 times.

6. Add sample to the test cartridge:
   - Note: Swabs should not be tested immediately after processing in the extraction tube.
   - Remove the test cartridge from its package and place it on a flat, clean, and dry surface.
   - Gently 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 a drop of the sample is added to the sample well.
   - Do not add the same swab to another 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.
   - Dispose of the swabs, test result may be false negative or invalid.

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.
   - Pat for red lines in the 'C' and 'T' in the test result window to read your result.

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

10. Dispose of used test kit materials:
   - After interpreting the test results, dispose of all used test kit materials.
**Swab-N-Go Home Test COVID-19 Ag cartridge box**

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**For Emergency Use Authorization (EUA) only**

**For in vitro diagnostic use**

Immunostics, Inc.

Distributed by

Boditech Med Inc.

Manufactured by

Using the RAPIDCHECK mobile application:
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.
4. Scan QR code with phone camera to download the App.

Visit www.immunostics.com/app-1 for a list of compatible smartphone OS systems.

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.

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**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.**

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

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

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