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/**
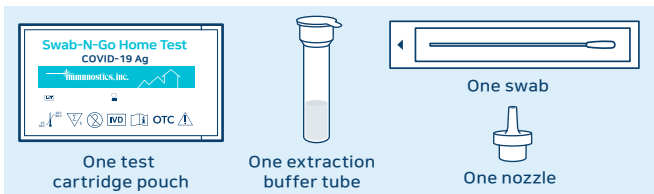
Step-by-step instructions

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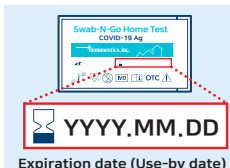
  - Wash your hands or use hand sanitizer.
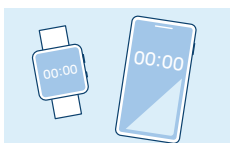 - Make sure your hands are dry before you start testing.

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

One swab
One test cartridge pouch
One extraction buffer tube
One nozzle

Note: Do not open individual components until instructed to do so.
- Check items for damage.

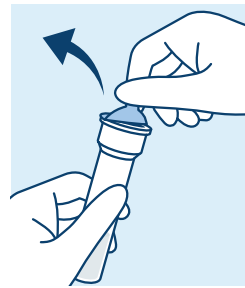Expiration date (Use-by date)
YYYY.MM.DD

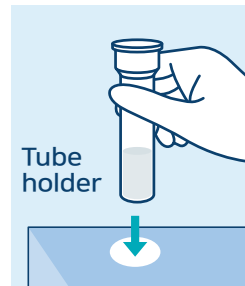- Check the expiration date (Use-by date) on the cartridge pouch.

- Have a watch or timer ready (not included in the kit).
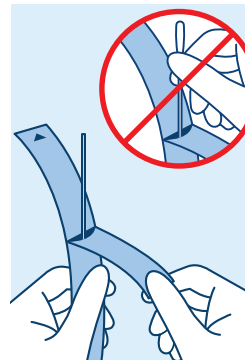
2 Open the extraction buffer tube

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

Tube holder

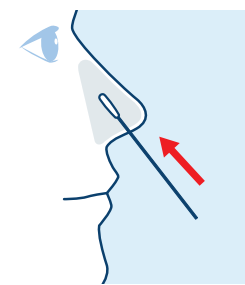- Put the unsealed tube in the tube holder provided in the box.

3 Remove the swab from its wrapper

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

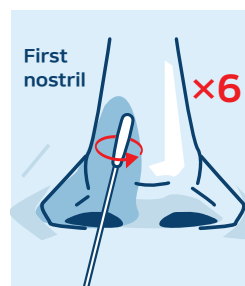- Remove the swab from its wrapper. Do not touch the tip of the swab.

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.

First nostril ×6

- Firmly and **slowly swab** in a complete circle against the inside of the nostril **at least 6 times**.
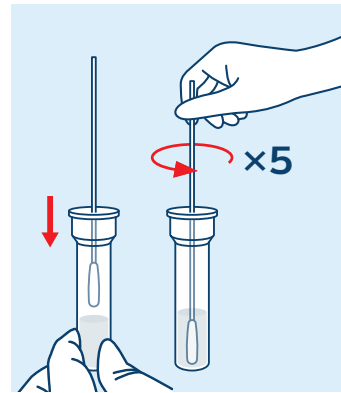
Second nostril ×6

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

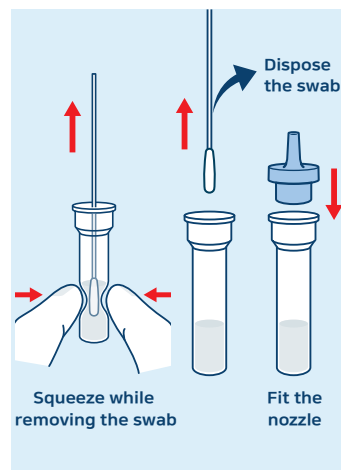 **Note:** Failure to swab properly may cause false negative results.

Same swab

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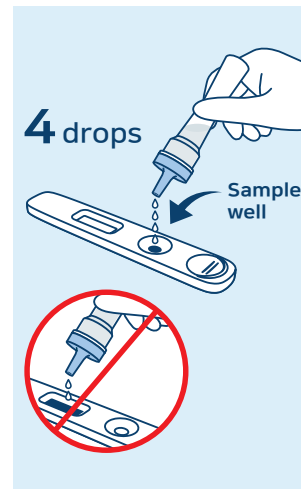
  WARNING: False results may occur if the swab is swirled less than 5 times.

×5

Dispose the swab

- 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.

Squeeze while removing the swab
Fit the nozzle

6 Add sample to the test cartridge

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

4 drops
Sample well

- 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.

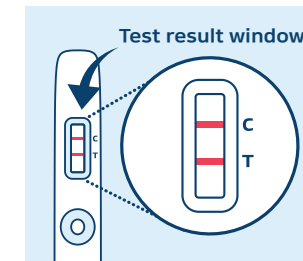 Do not add the sample to the 'test result window' of the test cartridge.

7 Wait 15 minutes

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.

Test result window

- 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.

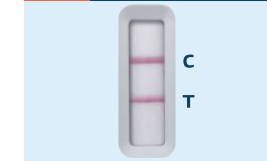#### 9 Interpret the test result

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.
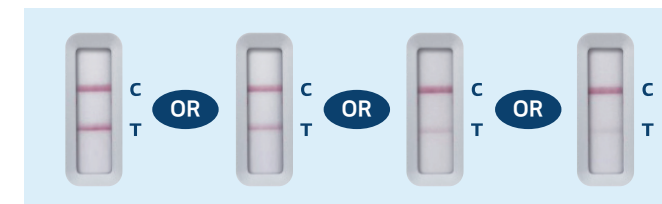
9-A Positive result

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.
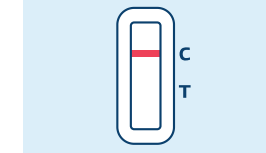**You do not need to perform repeat testing if you have a positive result at any time.**

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

C OR C OR C OR C

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).

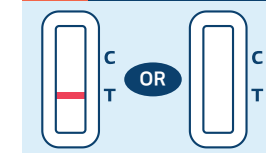##### 9-B Negative result

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.
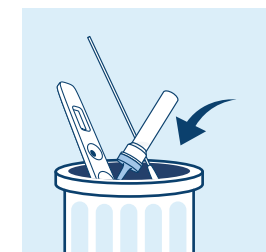
9-C Invalid result

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

C OR C

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.