INSTRUCTIONS FOR USE

You must follow the test directions carefully to get an accurate result. Call OraSure Technologies at 1-833-601-0127 or visit www.InteliSwab.com to obtain the complete instructions for use. FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.

IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result.
If you do not swab your nose, the device will produce a false negative result.

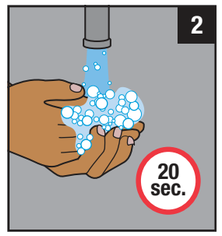
SCAN HERE FOR STEP-BY-STEP VIDEO ▶▶▶

ENGLISH

InteliSwab® COVID-19 RAPID TEST • Rx

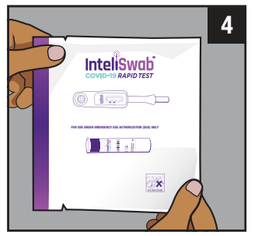
HOW TO USE THE INTELISWAB® COVID-19 RAPID TEST Rx

▶ **YOU WILL NEED A WAY TO TIME THE TEST.**

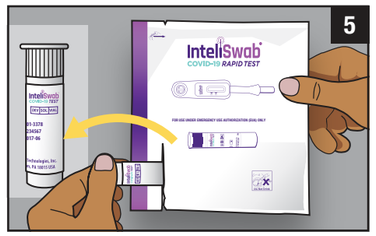


▶ Wash your hands thoroughly with soap and water for **20 seconds before** starting the test.

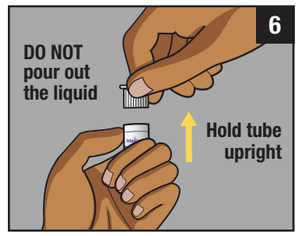
▶ Kit contains: two-part **pouch**, **Instructions for Use** (in English and Spanish), **Positive Result Reference Card** and **test stand**.



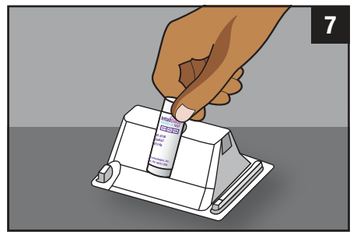
▶ Pick up the two-part **pouch**.



▶ Tear open the pouch containing the **tube** and remove.

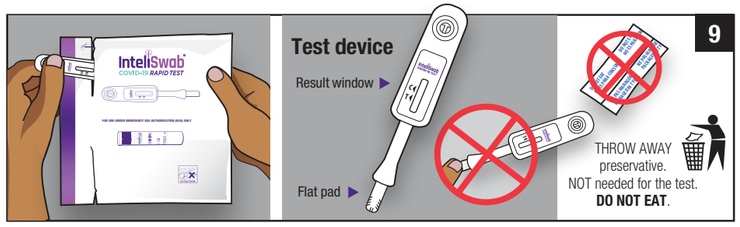


▶ With the tube in an upright position, **GENTLY ROCK THE CAP BACK AND FORTH** to remove it. **DO NOT** twist. **DO NOT** pour out the liquid. **DO NOT** drink.



▶ Slide the tube into the test stand on a **flat sturdy surface. DO NOT** force from the front as splashing may occur. Tube should rest at an angle on the **bottom** of the stand. If the solution spills, you will need a new test.

▶ Blow your nose into a tissue. If assisting someone, instruct them to blow their nose. **DO NOT** use tissue to clear out nasal passage. Discard tissue and wash hands thoroughly. Dry hands before starting the collection.



▶ Tear open the pouch containing the **test device** and remove.

▶ **DO NOT** touch the **flat pad** with your fingers.

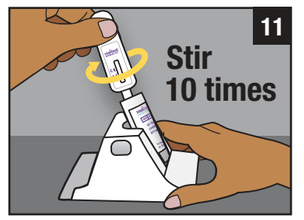
▶ **DO NOT** eat or swallow the preservative.

If the preservative is not present, **DO NOT** use the test.

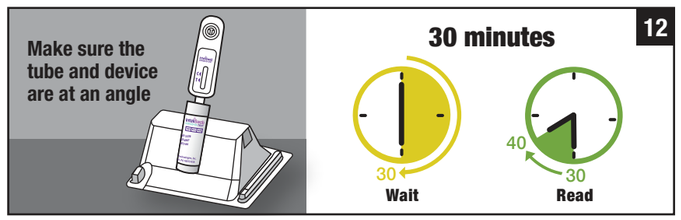
▶ **ADULTS:** Insert flat pad of the device inside the **nostril**. **Circle around the nostril 15 times** while maintaining contact with the **inside wall of the nostril**. **SWAB BOTH NOSTRILS** (Fig. 1 and Fig. 2). If you are conducting a test on a child 15-17 years old or an adult who requires assistance, proceed by swabbing the individual.

CHILDREN (14 AND UNDER): When collecting from a child under the age of 15, slowly **circle the swab in EACH nostril a minimum of 4 times while gently pressing against the inside of the nostril. This should take about 15 seconds**. (Fig. 1 and Fig. 2).

If you DO NOT swab BOTH nostrils 15 times (adult) OR 4 times (child), you may get a false result.



▶ Hold the test stand on a flat surface and insert the flat pad of the device into the tube. Stir **10 times** to mix the sample with the liquid in the tube. Make sure the flat pad is toward the **back** of the tube so it contacts the liquid. Swirling the device **less than** 10 times may cause invalid results.



▶ After mixing, leave the device in the tube. Make sure the flat pad is touching the bottom of the tube and the result window is facing you. Start your timer for **30 minutes**. **DO NOT** remove the device from tube while the test is running. A pink background will pass through the result window as the test is working.

▶ **Read results between 30 and 40 minutes.** To obtain an accurate result, **DO NOT** read **before** 30 minutes or **after** 40 minutes.

Reading before 30 minutes may cause false negative results.

INTERPRETING RESULTS: Read test results in a well-lit area.

Note: The line next to the "C" does not show that an adequate sample has been collected.

POSITIVE RESULT

▶ The test is **POSITIVE** if:
- there is a reddish-purple line next to the "T" and NO reddish-purple line next to the "C"
- there is a reddish-purple line next to the "T" and a reddish-purple line next to the "C", even if the "C" line is faint
- there is a faint reddish-purple line next to the "T" and a reddish-purple line next to the "C"

You need to quarantine so you do not infect others.

As soon as possible . . .

Call your healthcare provider and use InteliSwab® Connect app to report your result. If you have emergency warning signs such as trouble breathing,persistent pain or pressure in the chest, new confusion, inability to wake or stay awake or bluish lips or face, call 911 or go to the closest Emergency Room.

▶ Refer to the **Positive Result Reference Card** provided for more examples of positive test results. This card will help you see how faint the test line can appear.

NEGATIVE RESULT

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

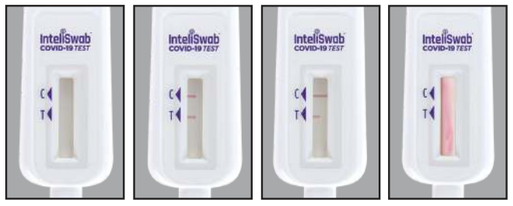
▶ The test is **NEGATIVE** if:
- there is a reddish-purple line next to the "C" and NO reddish-purple line next to the "T"

There must be a line next to the "C" to be able to interpret a negative result.

As soon as possible . . .

Call your healthcare provider and use InteliSwab® Connect app to report your result. If your result is negative but you have signs and symptoms of COVID-19, contact your healthcare provider for additional testing.

INVALID RESULT



▶ The test is not working and should be repeated if:
- no lines are present
- the line next to the "T" or the line next to the "C" is not complete (all the way across the window), or
- a reddish-purple background makes it impossible to read the test after 30 minutes

You will need to obtain another test.

The test did NOT work properly. Call your healthcare provider or the prescribing doctor to receive a new test kit.

NOT SURE OF YOUR RESULT

If you do not know your result or you are unsure of your result, contact OraSure Technologies at **1-833-601-0127** or go to **www.InteliSwab.com**

REPORTING RESULT

Call your healthcare provider and use the InteliSwab® Connect app to report your result. For a list of compatible smartphones and how to download the app visit www.InteliSwab.com/app

DISPOSE

Remove the test device from the tube, put the cap back on the tube and throw away all contents in the normal trash.

⊗ Do NOT Reuse

INTENDED USE

The InteliSwab® COVID-19 Rapid Test Rx is a single-use lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for prescription home use with self-collection (unobserved) of anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 2 years or older who are suspected of COVID-19 infection by their healthcare provider within the first seven (7) days of symptom onset.

The InteliSwab® COVID-19 Rapid Test Rx does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive should self-isolate and seek additional care from their healthcare provider.

Negative results should be treated as presumptive and confirmation with molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Persons 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 report all results obtained with this product to their healthcare provider and the InteliSwab® Connect app. The app will report all test results received 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 HYPERLINK "https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html" Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The InteliSwab® COVID-19 Rapid Test Rx is intended for prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The InteliSwab® COVID-19 Rapid Test Rx is only for use under the Food and Drug Administration's Emergency Use Authorization.

IMPORTANT INFORMATION ABOUT THE INTELISWAB® COVID-19 RAPID TEST Rx

For prescription use only.
For in vitro diagnostic use.

The InteliSwab® COVID-19 Rapid Test Rx is for the detection of the antigen associated with COVID-19, not for any other viruses or pathogens.

Invalid results can occur if the sample and the reagents do not flow up the test device.

The presence of a line next to the "C" does not indicate that an adequate sample was collected during the swabbing of the nostrils.

Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. only).
The InteliSwab® COVID-19 Rapid Test Rx is for use under Emergency Use Authorization (EUA) only.
This product has not been FDA cleared or approved, but has been authorized by FDA under 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 IVDs 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 authorization is terminated or revoked sooner.

IMPORTANT DO'S AND DON'TS

DO:

- Use the InteliSwab® COVID-19 Rapid Test Rx if you have experienced the onset of COVID-19 signs and symptoms within the last 7 days.
- Follow the Instructions for Use (reverse side) to obtain accurate results. Inadequate sampling may result in false results.
- Inspect the divided pouch. If the divided pouch has been damaged, discard the divided pouch and its contents. The results from the InteliSwab® COVID-19 Rapid Test Rx may not be valid if the divided pouch is damaged.
- Use adequate lighting to read a test result.
- Use the test device and tube containing fluid only once and dispose of both properly.
- Wash hands thoroughly prior to testing and after use.
- Call your healthcare provider and use the InteliSwab® Connect app to report your result. For a list of compatible smartphones and how to download the app visit www.InteliSwab.com/app
- Store the InteliSwab® COVID-19 Rapid Test Rx in a dry location between 35°-86°F (2°-30°C). Bring the divided pouch to room temperature (within 59°-104°F, 15°-40°C) before opening.
- Keep out of reach of children.

DO NOT:

- Use the InteliSwab® COVID-19 Rapid Test Rx on children under the age of 2. An adult must perform this test on children between the ages of 2 and 17.
- Use the InteliSwab® COVID-19 Rapid Test Rx beyond the expiration date.
- Use if the packaging has been opened or damaged.
- Open the divided pouch until you are ready to start the test.
- Reuse any test components.

FREQUENTLY ASKED QUESTIONS

What is COVID-19? COVID-19 (coronavirus disease 2019) is a contagious virus that may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in hospitalization or death. The presence of a specific antigen (the SARS-CoV-2 nucleocapsid protein antigen) indicates that an individual is currently infected with COVID-19 (even without the presence of symptoms) and can transmit the virus.

What are common symptoms of COVID-19? Symptoms of COVID-19 may appear 2-14 days after exposure and may include fever, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, or a runny nose, nausea or vomiting and diarrhea. It is also possible for someone infected with COVID-19 to have no symptoms.

What is the difference between a COVID-19 antigen, a molecular and an antibody test, and what kind of test is the InteliSwab® COVID-19 Rapid Test Rx? There are different kinds of tests for diagnosing COVID-19. The InteliSwab® COVID-19 Rapid Test Rx is an antigen test. Antigen tests detect proteins, small parts, from the SARS-CoV-2 virus. Antigen tests are designed to detect virus levels that reflect active infection. Molecular tests (also known as PCR tests) detect genetic material from the virus (RNA). Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

What are the known and potential risks and benefits of this test?
Potential risks include:
Possible discomfort during sample collection.

Possible incorrect results.

Potential benefits include:
The results, along with other information, can help your healthcare provider make informed recommendations about your care.

The results of this test may help limit the spread of COVID-19 to your family and others in your community.

You have the option to refuse this test. However, your doctor has prescribed this test because they believe it could help with your care.

How accurate is the InteliSwab® COVID-19 Rapid Test Rx?
The InteliSwab® COVID-19 Rapid Test Rx is a lateral flow in vitro diagnostic antigen test to detect COVID-19. Antigen tests are designed to detect active infection in individuals. A clinical study was conducted during February and April of 2021 to determine the performance of the InteliSwab® COVID-19 Rapid Test Rx. A total of 146 individuals with signs and symptoms of COVID-19 within the first 7 days of symptom onset were enrolled across 5 different locations in the US. Subjects 18 years or older independently collected the lower nasal sample and completed the home use test. An additional clinical study was conducted during September 2021 in children (ages 2-14). A total of 19 children were enrolled in the study where the parent or care giver collected the anterior nasal sample and performed the test. The InteliSwab® COVID-19 Rapid Test Rx results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 assays to determine test performance. The results from the pediatric study conducted in September 2021 have been combined with the previous study results collected in early 2021. The InteliSwab® COVID-19 Rapid Test Rx correctly identified 85% of the positive samples. Additionally, the InteliSwab® COVID-19 Rapid Test Rx correctly identified 98% of negative samples. For more information about COVID-19 variants detected by InteliSwab®, please visit www.InteliSwab.com/variants

What if you test positive?
A positive result means that it is very likely you have COVID-19 and it is important to report your results to your healthcare provider or the healthcare provider that prescribed the test.

You will be asked to isolate yourself at home to avoid spreading the virus to others.

Follow-up with your health care provider. Your healthcare provider will work with you to determine how best to care for you based on your test results, your medical history and symptoms.

There is a very small chance that this test can give a positive result that is wrong (false positive).

What if you test negative?
A negative result means that the antigens from the virus that causes COVID-19 were not found in your sample.

You may have a different virus or type of infection causing your symptoms.

If you continue to experience symptoms, you should contact your health care provider for another test.

You may have COVID-19 and still get a negative result (false negative) if:

- You didn't perform the test correctly, such as not swabbing correctly or not waiting 30 minutes for test results.
- The level of antigen from the COVID-19 virus was below the test limits.
- You have had signs and symptoms of COVID-19 for more than 7 days. This means you could still possibly have COVID-19 even though the test is negative. Please see your health care provider. Your healthcare provider will consider the test result along with all other aspects of your medical history, including your symptoms and possible COVID-19 exposures to decide how to care for you. It is important for you to work with your healthcare provider to help you understand the next steps you should take. A different type of test might be necessary to determine whether or not you have COVID-19.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

Why do I have a test line and no control line? If you have a test line and no control line, your test is positive. When the level of virus in the sample is high, the line next to the "C" may not be present or may be very faint. The line next to the "C" must be visible to read a negative test result. Please see the other side of this Instructions for Use and the enclosed reference card to help you understand how to interpret test results.

Will this test hurt? No. The nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

Is the solution in the tube harmful?
No. The solution in the tube contains potentially harmful chemicals (Triton X-100 and ProClin 950). The developer solution should only be used as directed; do not ingest; keep out of the reach of children; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: poisonhelp.org or 1-800-222-1222.

Information about Emergency Use Authorizations and COVID-19? For more information on EUAs go here: 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
Visit InteliSwab.com to obtain the complete Instructions for Use.

SWAB
both nostrils

SWIRL
in the tube

SEE
your results

EXPLANATION OF SYMBOLS

LOT Batch Code	Use By
Do Not Reuse	Caution, Consult Accompanying Documents
Temperature Limitation	Manufacturer
REF Catalog Number	Consult Instructions for Use
IVD *In Vitro* Diagnostic Medical Device	

MORE QUESTIONS ABOUT THE INTELISWAB® COVID-19 RAPID TEST Rx?

If you have any questions about the InteliSwab® COVID-19 Rapid Test Rx, please contact our toll-free consumer helpline at 1-833-601-0127 or visit www.InteliSwab.com.

The InteliSwab® COVID-19 Rapid Test Rx Letter of Authorization, authorized Fact Sheet and authorized labeling are available on the FDA website and www.InteliSwab.com.

SCAN HERE FOR STEP-BY-STEP VIDEO:

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