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.

HOW TO USE THE INTE LISWAB™ COVID-19 RAPID TEST Rx

1. Wash your hands thoroughly with soap and water for 20 seconds before starting the test.
2. DO NOT touch the flat pad with your fingers.
3. Tear open the pouch containing the test device and remove.
4. DO NOT touch the flat pad with your fingers.
5. Place the test device in the result window.
6. Hold the test device on a flat surface, circle around the nostril 15 times (adult) OR 4 times (child), if you are conducting a test on a child 15-17 years old or an adult who requires assistance, proceed by swabbing the individual.
7. 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”.
   - The test is not working and should be repeated if:
     - No lines are present.
     - The test is not working and should be repeated if:
       - No lines are present.
       - If you do not swab both nostrils 15 times (adult) OR 4 times (child), you may get a false result.

8. Unfold the flat pad and place 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.
9. Remove the flat pad of the device inside the tube. Make sure the flat pad is toward the bottom of the tube so it contacts the liquid. Swabbing the device less than 15 times may cause invalid results.
10. After mixing, leave the device in the tube. Record the time you started the collection.

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 blue lips or face, call 911 or go to the closest Emergency Room.

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.

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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.
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 of SARS-CoV-2 in nasopharyngeal specimens from individuals aged 2 years or older who are suspected of COVID-19 infection. For prescription use only. For in vitro diagnostic use. 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 the Director of the FDA under 42 U.S.C. § 2419. This product has been authorized only for the detection of proteins from SARS-CoV-2, not 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 for use of the above emergency use of IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(2)(A) of the Federal Food, Drug and Cosmetic Act; 21 U.S.C. § 360b. The emergency use authorization is terminated or revoked sooner.

**IMPORTANT INFORMATION ABOUT THE INTELISWAB COVID-19 RAPID TEST RX**

**DO:**
- Use the InteliSwab™ COVID-19 Rapid Test Rx if you have experienced the onset of COVID-19 symptoms and want to know if you have COVID-19 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 test device and tube containing the fluid only 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/Connect.
- 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 (59°-104°F, 15°-40°C) before opening.
- Keep out of reach of children.

**FREQUENTLY ASKED QUESTIONS**

**What is COVID-19?**
- COVID-19 (coronavirus disease 2019) is a contagious virus that may cause mild to severe respiratory illness. Some people who are infected with COVID-19 may develop severe illness.\

**What is SARS-CoV-2?**
- SARS-CoV-2 is the specific strain of Coronavirus that causes COVID-19.

**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 designed to detect active infection in individuals suspected of COVID-19. The 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 test use were enrolled across 5 different locations in the US. Subjects 18 years or older independently collected the lower nasal swab and completed the home use test. The clinical study was conducted during September 2021 in children (ages 2-17). A total of 16 children were enrolled in the study where the parent or caregiver collected the anterior nasal swab and performed the test. The InteliSwab™ COVID-19 Rapid Test Rx was validated using highly sensitive molecular FDA Authorized SARS-CoV-2 reagents to determine test performance. The results from the pediatric study conducted in September 2021 have been combined with the previous study results conducted in February and April 2021 and the InteliSwab™ COVID-19 Rapid Test Rx correctly identified 85% of the positive 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. It is recommended you contact your healthcare provider or the healthcare provider you prescribe 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.

**What if you test negative?**
- A negative result may mean that you do not have COVID-19. However, it is possible you could have COVID-19 and test negative. There is a small chance that this test can give a positive result that is actually false positive.

**What are the potential risks and benefits of this test?**
- There are no known risks associated with this test.

**Why do I have a different virus or type in your sample?**
- You may have a different virus or type in your sample.

**DO NOT:**
- Use the InteliSwab™ COVID-19 Rapid Test Rx if you have experienced the onset of COVID-19 symptoms and want to know if you have COVID-19 within the last 7 days.
- Use the InteliSwab™ COVID-19 Rapid Test Rx on children under the age of 2.
- 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.
- If the packaging has been opened or damaged.
- Open the divided pouch until you are ready to start the test.
- Reuse any test components.

**How can I interpret my test results?**
- If you test positive, you may be infected with COVID-19 if you have since been exposed to SARS-CoV-2 and have symptoms. If you test negative, you may not be infected with COVID-19 if you have not been recently exposed to SARS-CoV-2. This means you could still have COVID-19 if you test negative. Please see your healthcare provider.

**What are the known and potential risks associated with this test?**
- This product does not contain a DNA or RNA polymerase. Although the manufacturer has determined that the contents of the test do not contain a DNA or RNA polymerase, the manufacturer has not determined if the product is safe or effective for use in humans.

**How to use this test and tube properly?**
- Wash hands thoroughly prior to testing and after use.
- 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 test device and tube containing the fluid only and dispose of both properly.
- Keep out of reach of children.

**More questions about the InteliSwab™ COVID-19 RAPID TEST RX?**
- For more information on EUAs and EUA Letter of Authorization, authorized Fact Sheet and authorized labeling are available on the FDA website and www.InteliSwab.com.
This card provides additional examples of what a positive result could look like. Use the Instructions for Use included in the box to complete your test. Upon completion, if you think you have a positive result but are unsure, please compare your test to the images below.

**EXAMPLES OF POSITIVE TEST RESULTS**

These photos show how faint the line next to the “T” may be. These are all positive test results. In some cases, the line next to the “C” may be very faint.

Look very closely!
The bottom line may be **very faint**.

Any line next to the “T” means you may have COVID-19, even if the line is very faint.

**THE TEST RESULT IS ALSO POSITIVE IF:**

There is a line next to the “T” and NO line next to the “C”

If your test does not look like any of these, see Instructions for Use for more examples of test results. Be sure to follow all instructions.

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; and, 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.

Para obtener información en español, vea el reverso. 3001-3576-70 rev. 06/21