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.

READ BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

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

INTERPRETING RESULTS:
HOW TO USE THE INTELISWAB COVID-19 RAPID TEST Rx

1. Wash your hands thoroughly with soap and water for 20 seconds before starting the test.
2. Place the pouch inside the InteliSwab test stand.
3. Insert the flat pad of the device inside the tube. Stir 10 times to mix the sample with the liquid in the tube. Make sure the flat pad is touching the bottom of the tube.
4. 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 touching the bottom of the tube.
5. With the tube in an upright position, gently rock the cap back and forth to remove the liquid and do NOT tilt.
6. Hold the tube upright.
7. Set the timer for 30 minutes.
8. After 30 minutes, check the tube for a reddish-purple background. A pink background will pass through the result window.
9. If you have emergency warning signs such as trouble breathing, persistent pain or pressure in the chest, new confusion, trouble waking or stay awake or bluish lips or face, call 911 or go to the closest Emergency Room.
10. As soon as possible...
   Call your healthcare provider and use the InteliSwab® Connect app to report your result.
   If you have emergency warning signs, contact the prescribing doctor to receive medical treatment.
   If your result is negative but you have signs and symptoms of COVID-19, contact your healthcare provider for additional testing.

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

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

YOU WILL NEED A WAY TO TIME THE TEST.

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.

READ BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

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

INTERPRETING RESULTS:
HOW TO USE THE INTELISWAB COVID-19 RAPID TEST Rx

1. Wash your hands thoroughly with soap and water for 20 seconds before starting the test.
2. Place the pouch inside the InteliSwab test stand.
3. Insert the flat pad of the device inside the tube. Stir 10 times to mix the sample with the liquid in the tube. Make sure the flat pad is touching the bottom of the tube.
4. 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 touching the bottom of the tube.
5. With the tube in an upright position, gently rock the cap back and forth to remove the liquid and do NOT tilt.
6. Hold the tube upright.
7. Set the timer for 30 minutes.
8. After 30 minutes, check the tube for a reddish-purple background. A pink background will pass through the result window.
9. If you have emergency warning signs such as trouble breathing, persistent pain or pressure in the chest, new confusion, trouble waking or stay awake or bluish lips or face, call 911 or go to the closest Emergency Room.
10. As soon as possible...
   Call your healthcare provider and use the InteliSwab® Connect app to report your result.
   If you have emergency warning signs, contact the prescribing doctor to receive medical treatment.
   If your result is negative but you have signs and symptoms of COVID-19, contact your healthcare provider for additional testing.

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

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

YOU WILL NEED A WAY TO TIME THE TEST.
**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 signs and symptoms in 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 tubing container fluidly 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 smart phones 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) to achieve the best results. Bring the divided pouch to room temperature (within 59°-104°F, 15°-40°C) before opening.
- Keep out of reach of children.

**FREQUENTLY ASKED QUESTIONS**

**What is COVID-19?**

COVID-19, which stands for coronavirus disease 2019, is a contagious disease caused by the SARS-CoV-2 virus, a novel coronavirus that can cause a wide range of symptoms, including fever, cough, and shortness of breath. It is transmitted through respiratory droplets, and symptoms typically occur between 2-14 days after exposure. Antigen tests are designed to detect active infection in individuals who are actively shedding the virus. The test 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 with the within the first 7 days of symptoms onset were enrolled across 11 different locations in the U.S. Subjects 18 years or older individuals collected the lower nasal sample and completed the home use test. An additional 100 asymptomatic individuals 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 were compared to a commercially available molecular FDA Authorized SARS-CoV-2 assay to determine test performance. The results from the pediatric study conducted in September 2021 have been combined with the previous studies conducted in February and April 2021. The InteliSwab® COVID-19 Rapid Test Rx correctly identified 85% of the test samples. For more information about COVID-19 variants detected check our variants page at www.InteliSwab.com/variants

**What if you test positive?**

A positive result means that it is very likely you have COVID-19. You should share your results with your healthcare provider or the healthcare professional 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 to best 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). There is a very small chance that this test can give a negative result that is wrong (false negative). There is a very small chance that this test can give a positive result that is wrong (false positive). There is a very small chance that this test can give a negative result that is wrong (false negative).

**What if you test negative?**

A negative result means that the antigen from the test 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 consult your healthcare provider for another test. You may have COVID-19 and still get a negative result (false negative). You did not perform the test correctly, such as not swabbing correctly or not waiting 30 minutes. The level of antigen from the COVID-19 virus was below the limit test. You have had signs and symptoms of COVID-19 for more than 5 days. This means you could still possibly have COVID-19 even though the test is negative. Please see your healthcare provider. Your healthcare provider will consider the test result along with all other aspects of your medical history, including your symptoms and your situation of exposure to others, 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 performance 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 in the virus sample is high, the line next to the “C” and the line next to the “T” will 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 the test result.

**Will this test hurt?** No! The nasal swab is not sharp and it should not hurt. Sometimes the swab may cause a little discomfort, but when you feel pain, stop the test and seek advice from a healthcare provider.

**Is the solution in the tube harmful?** No. The solution will not harm your skin or mucous membranes. It is not potentially harmful chemicals (Triton X-100 and ProClin 300). 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 skin or eyes, wash with大量的 amounts of water. If irritation persists, seek medical advice: posthelp.org or 1-800-222-1222.

**Information about Emergency Use Authorizations and COVID-19?** For more information on EUAs go to www.cdc.gov/coronavirus. 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 skin or eyes, wash with大量 amounts of water. If irritation persists, seek medical advice: posthelp.org or 1-800-222-1222.

**Information about Emergency Use Authorizations and COVID-19?** For more information on EUAs go to www.cdc.gov/coronavirus. 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 skin or eyes, wash with大量 amounts of water. If irritation persists, seek medical advice: posthelp.org or 1-800-222-1222.

**Scan here for step-by-step video:**

OnaSure Technologies, Inc. 220 East First Street, Bethlehem, PA 18015 USA 610-867-5500 www.OnaSure.com © 2021 OnaSure Technologies, Inc. 5010-5349 rev. 05/22

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

**MOORE 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 help line at 1-833-601-0127 or visit www.InteliSwab.com.