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 INTELLISWAB™ COVID-19 RAPID TEST

1. Test device
   - Peel open the pouch containing the test device and remove.
   - DO NOT touch the flat pad with your fingers.
   - DO NOT put or swallow the preservative. If the preservative is not present, DO NOT use the test.

2. Read result window
   - Insert the 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 the test on someone who requires assistance, proceed by swabbing the individual. If you do not swab both nostrils 15 times each, you may get a false result.

3. Test stand
   - 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 fluid in the tube. Make sure the flat pad is toward the back of the tube so it contacts the liquid. Swabbing the device less than 10 times may cause invalid results.

4. Hold tube upright
   - 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.

5. 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.

6. 30 minutes

8. Next Steps
   - Call your healthcare provider to report your result.
   - Call your healthcare provider to report your result.

9. 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 must have a line next to the “T” or the line next to the “C” must be faint as you do not infect others. You may need additional testing, depending on your personal health history and other factors.

10. As soon as possible...
    - Call your healthcare provider to report your result.
    - If your 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.

11. INVALID RESULT
    - The test is NOT working and should be repeated if:
      - The lines are present.
      - The line next to the “T” or the line next to the “C” is not complete (the line 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.

12. 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.

LEARN MORE

INTERPRETING RESULTS:

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."
  - There is a faint reddish-purple line next to the "T" and a reddish-purple line next to the "C."

- You must have a line next to the "T" or the line next to the "C" to be able to interpret a positive result.
- If your first test result is negative, you should test again in 24 to 36 hours. If both your first and second tests are negative, you may have COVID-19.

NEGATIVE RESULT
- The test is NEGATIVE if:
  - There is no red line next to the "C." and NO red line next to the "T."
  - There is a faint red line next to the "C." and NO red line next to the "T."

- You do NOT need to instruct them to blow their nose.

- If both your first and second tests are negative, you may have COVID-19.

Next Steps...
- Call your healthcare provider to report your result.
- Call your healthcare provider to report your result.

DISPOSE
Remove the test device from the tube, put the cap back on the tube and throw away in normal trash. Keep the test stand and instructions for completing additional tests provided in the kit. Once all devices have been used for testing, throw away all contents.

Do NOT Reuse
**IMPORTANT INFORMATION**

**INTENDED USE**

The InteliSwab™ COVID-19 Rapid Test 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 in individuals with or without symptoms or other epidemiological reasons to test for COVID-19 when tested twice over two or three days with at least 24 hours but not more than 48 hours between tests. This test is authorized for non-prescription use with self-collected anterior nasal samples from individuals 18 years or older in a non-laboratory setting. The InteliSwab™ COVID-19 Rapid Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen and should be generally detectable in anterior nasal samples during the acute phase of infection. Positive results do not indicate the presence of vital antigens, but clinical correlation with past medical 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 definitive cause of disease. Individuals who test positive on the InteliSwab™ COVID-19 Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with molecular assay, if necessary, for management of clinical care.

Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions.

For serial testing programs, additional confirmatory antibody testing and/or diagnostics are recommended to determine SARS-CoV-2 infection status. The test results do not help determine the spread of COVID-19 to your family and other community.

**DO:**

- Use the InteliSwab™ COVID-19 Rapid Test for testing for COVID-19 infection
- Follow the Instructions for Use (reverse side) to obtain accurate results. Inaccurate 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 may not be valid if the divided pouch is damaged.
- Use adequate lighting to read a test result.
- Use the device and tube containing fluid only once and dispose of both properly.
- Wash hands thoroughly prior to testing and after use.
- Report all test results (whether positive or negative) to your healthcare provider.
- Store the InteliSwab™ COVID-19 Rapid Test in a dry location between 35°-86°F (2°-30°C).
- Bring the divided pouch to room temperature (within 35°F-104°F; 1°-40°C) before opening.
- Keep out of reach of children.

**DON’T:**

- Do NOT use the InteliSwab™ COVID-19 Rapid Test if the packaging has been opened or damaged.
- Do NOT use the InteliSwab™ COVID-19 Rapid Test beyond the expiration date.
- Do NOT use the packaging has been opened or damaged.
- Do NOT use the InteliSwab™ COVID-19 Rapid Test if the packaging has been opened or damaged.
- Do NOT reuse the device or tube.

**WHAT IS COVID-19?**

COVID-19 is a contagious virus that may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in hospitalization or death. The pathogen of a specific antigen (the SARS-CoV-2 nucleocapsid protein antigen) that is generally present in respiratory samples from individuals with signs and symptoms of COVID-19 infection, such as in individuals with known exposures to COVID-19 or with suspected COVID-19. Antigen tests are intended to detect SARS-CoV-2 infection, not to diagnose SARS-CoV-2 or determine the level of the viral load in an individual. The InteliSwab™ COVID-19 Rapid Test is an antigen test. Antigen tests are generally used to test for SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions.

**WHAT IS THE INTELISWAB™ COVID-19 RAPID TEST?**

The InteliSwab™ COVID-19 Rapid Test is a lateral flow immunoassay designed to detect the SARS-CoV-2 nucleocapsid protein antigen from SARS-CoV-2. A clinical study was conducted during February and April of 2021 to determine the performance of the InteliSwab™ COVID-19 Rapid Test. 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 nasal swab sample using the InteliSwab™ COVID-19 Rapid Test. Results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 assays to determine test performance. The InteliSwab™ COVID-19 Rapid Test correctly identified 84% of the positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test correctly identified 98% of negative samples.

**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. You should isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can miss a result that is wrong (false negative). If you have symptoms, you may have a different virus or type of infection. You should seek advice from a healthcare provider.

**WHAT IS THE ROLE OF ANTI-RIBONUCLEASE (REVERSE TRANSCRIPTASE) PCR TESTS?**

Rapid tests will not perform as well as laboratory-based PCR tests. Laboratory studies have shown them to be most accurate at the levels contained in the test. The developer solution should only be used as directed; do not ingest, leap out of the test device, or group with eyes and skin. If the solution contacts the skin, eye, flush with copious amounts of water if irritation persists. For medical advice: https://www.poisonguide.com/contact-us or 1-800-222-1222.

**WHAT DO YOU DO NEXT?**

If your test is negative, if you have no symptoms, you may continue your daily routine. If you have symptoms, you may have a different virus or type of infection. You should seek advice from a healthcare provider.

For more information about the developers of the InteliSwab™ COVID-19 Rapid Test, please visit www.InteliSwab.com. If you have any questions about the InteliSwab™ COVID-19 Rapid Test, please contact our toll-free consumer helpline at 1-833-601-0127 or visit www.InteliSwab.com.

**MORE QUESTIONS ABOUT THE INTELISWAB™ COVID-19 RAPID TEST?**

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

**LEARN MORE:**