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.IntelliSwab.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.

INSTRUCTIONS FOR USE

1. Tear open the pouch containing the test device and remove.

2. Pick up the two-part pouch.

3. Hold the tube stand on a flat surface and insert the flat pad of the device into the tube. Stir 10 times while maintaining contact with the liquid in the tube. Make sure the flat pad is toward the back of the tube so it contacts the liquid. Stirring the device less than 10 times may cause invalid results.

4. After mixing, leave the device in the tube. Make sure the line next to the “C” or the line next to the “T” is not complete (all the way across the line). You need to self-test so you do not infect others. You may need additional testing, depending on your personal health history and other factors.

5. DO NOT pour out the liquid.

6. With the tube in an upright position, gently rock the cap back and forth to remove it. DO NOT pour out the liquid. DO NOT drink.

7. Make sure the tube and device are at an angle.

8. Pour out the liquid.

9. Insert flat pad of the device into 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).

10. After rocking, 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 the tube while the test is running. A faint background will pass through the result window as the test is working. Reading before 30 minutes or after 40 minutes may cause false negative results.

11. After 30 minutes, read the result. The test is working and should be repeated if:
   - 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.

12. You will need to obtain another test.

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.IntelliSwab.com

DISPOSAL
Remove the test device from the tube, put the cap back on the tube and throw away in normal trash. If you have a 2-pack test kit, KEEP THE TEST STAND AND INSTRUCTIONS FOR COMPLETING ADDITIONAL TEST PROVIDED IN THE KIT. Once all devices have been used for testing, throw away all contents.

Do NOT Reuse

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Do NOT Reuse
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. 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 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.
- Report all test results (positive or negative) to your healthcare provider.
- Store the InteliSwab® COVID-19 Rapid Test in a dry location between 35°-86°F (2°C-30°C). Bring the divided pouch to room temperature (within 55°F-104°F, 15°C-40°C) before opening.
- Keep out of reach of children.

IMPORTANT INFORMATION ABOUT THE INTELSWAB® COVID-19 RAPID TEST

For consumer over-the-counter use.

The InteliSwab® COVID-19 Rapid Test is for home-use in the diagnosis of SARS-CoV-2 infection for people aged 15 years or older who are suspected of having COVID-19, not for any other viruses or pathogens.

This test has been authorized by FDA under EUA. This test has not been FDA cleared or approved. This test has been authorized under the Emergency Use Authorization of the US Food and Drug Administration’s Emergency Use Authorization.

The InteliSwab® COVID-19 Rapid Test is for use under the Emergency Use Authorization of the US Food and Drug Administration. 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 the product 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.

The InteliSwab® COVID-19 Rapid Test is a lateral flow assay. The test is intended for use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older who are suspected of having COVID-19, not for any other viruses or pathogens.

What is serial testing? COVID-19 serial testing is a testing strategy where individuals test themselves multiple times for COVID-19 on a routine basis, such as three times per week. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

What if you test negative? People who test negative should continue taking precautions such as wearing masks and social distancing. If you are more than 48 hours after your negative result, then you are likely not infected with COVID-19. If you have symptoms, you may have a different virus or type of infection. You may have COVID-19 and still get a negative test result. See your health care provider.

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The InteliSwab® COVID-19 Rapid Test results are not intended to be used for surveillance testing. The InteliSwab® COVID-19 Rapid Test results may not be valid if the divided pouch is damaged.

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