INSTRUCTIONS FOR USE
You must follow the test directions carefully to get an accurate result. Call OraSure Technologies at 1-800-orasure (1-800-627-7873) or visit 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 INTELIISWAB™ COVID-19 RAPID TEST Rx

1. YOU WILL NEED A WAY TO TIME THE TEST.
2. Wash your hands thoroughly with soap and water for 20 seconds before starting the test.
4. Pick up the two-part pouch.
5. Tear open the pouch containing the test device and remove.
6. Hold tube upright.
7. With the tube in an upright position, gently rock the cap back and forth to remove. DO NOT twist. DO NOT pour out the liquid. DO NOT flick.
8. Slide the tube into the test stand on a flat sturdy surface. DO NOT force from the front or 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.
9. 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 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.
10. 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. Shaking the device less than 10 times may cause invalid results.
11. 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.
12. 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”.

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

INVALID RESULT
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 1-866-601-0127 or go to www.InteliSwab.com.

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.

You will need a way to time the test.

Test device
Result window
Flat pad

Flat pad
Fig. 1
Fig. 2

60 sec

Hold tube upright

T
C

Do NOT touch the flat pad with your fingers.

Do NOT open or swallow the preservative.

If the preservative is not present, Do NOT use the test.

Pour out the liquid.

The test is POSITIVE if:

As soon as possible . . .

Call your healthcare provider or the prescribing doctor 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.

As soon as possible . . .

Call your healthcare provider or the prescribing doctor 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 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.

You will need to obtain another test.

You will need another test.

Reading before 30 minutes may cause a false negative result.

Reading before 30 minutes may cause a false negative result.

Testing before 30 minutes may cause a false negative result.

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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 by the FDA under an Emergency Use Authorization.

DO:
- Use the InteliSwab™ COVID-19 Rapid Test Rx if you have experienced the onset of specific 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.
- Report all test results (whether positive or negative) to your healthcare provider or prescribing doctor.
- Store the InteliSwab™ COVID-19 Rapid Test Rx in a dry location between 31°F (0°C) and 104°F (40°C) before opening.
- Keep out of reach of children.

DON'Ts:
- Use the InteliSwab™ COVID-19 Rapid Test Rx on children under the age of 15.
- Use the InteliSwab™ COVID-19 Rapid Test Rx under the order of a licensed practitioner (U.S. only).
- Use the test device and tube containing fluid more than once or on different individuals.
- Use Authorizations and Rx Letter of Authorization, authorized by the FDA, are available on the FDA website and at www.InteliSwab.com.

FREQUENTLY ASKED QUESTIONS

1. What is COVID-19? COVID-19 is caused by a virus that may cause mild to severe disease, affecting other systems and potentially resulting in hospitalization or death. The presence of specific COVID-19 signs and symptoms (e.g., fever, cough, or shortness of breath) indicates that an individual is currently infected with COVID-19. Negative test results do not rule out COVID-19 and should not be used as evidence to exclude COVID-19 infection in a person who tests positive. Negative test results should be treated as presumptive or negative; further testing is necessary to determine infection status. Positive results do not rule out other infections and some COVID-19 infections with other viruses and the antigen detected may not be definitive. A test with positive results should be performed on an additional sample.

2. 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, vomiting or diarrhea. It is also possible for someone infected with COVID-19 to have no symptoms.

3. What is the difference between an COVID-19 antigen, PCR, 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 viruses in a sample, but it is common for a test to detect COVID-19 even if you have not been infected with COVID-19. A negative result means that it is very likely you have COVID-19.

4. Will this test hurt? No. The nasal swab from the test device should not hurt. Sometimes the swab can feel slightly uncomfortable if you feel pain, but it is comfortable and safe. Please see your test results and advice on how to understand test results.

5. Is the solution in the tube harmful? No. The solution in the tube contains an antiseptic solution (95% ethanol and 1% hydrogen peroxide) and water. It contains potentially harmful chemicals (Triton X-100 and ProClin 950); however, laboratory studies have shown them to be nontoxic at the levels contained in the test. The InteliSwab™ COVID-19 Rapid Test Rx is only for use under the Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

6. HOW DO YOU KNOW IF YOU HAVE COVID-19? A positive result means that it is very likely you have COVID-19 and is necessary to determine infection status. Positive results do not rule out other infections and some COVID-19 infections with other viruses and the antigen detected may not be definitive. A test with positive results should be performed on an additional sample. Positive results should be treated as presumptive or positive; further testing is necessary to determine infection status. Positive results do not rule out other infections and some COVID-19 infections with other viruses and the antigen detected may not be definitive. A test with positive results should be performed on an additional sample.

7. How accurate is the InteliSwab™ COVID-19 Rapid Test Rx? The InteliSwab™ COVID-19 Rapid Test Rx is a qualitative, lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2. The test measures the presence of SARS-CoV-2 nucleocapsid protein antigen. The test is a qualitative one and has been tested to determine 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 U.S. Subjects 18 or older independently collected the lower nasal sample and completed the home use test. The InteliSwab™ COVID-19 Rapid Test Rx results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 tests designed to determine test performance. The InteliSwab™ COVID-19 Rapid Test Rx correctly identified 84% of the positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test Rx correctly identified 98% of negative samples.

8. What if you test positive? You may have COVID-19 and should still get a negative test result. Please see the other side for instructions on how to interpret your test result and advice on how to understand test results.

9. Why do you have a test line and no control line? If you have a test line but 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 for instructions on how to interpret your test result and advice on how to understand test results.

10. How long is the test line visible? You can give a positive result that is wrong (false positive). There are several ways that this test can give a positive result that is false (false positive).

11. What if you test negative? 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 result is negative (false negative). Your healthcare provider should be able to give you the result and further advise you on whether you need to get tested again. The test may be necessary to determine whether or not you have COVID-19.

12. What are the risks and benefits of this test? There are risks and benefits of this test.

13. Are the lab results available? 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.

14. Why do I have a test line and an antibody test? It is possible for you to have antibodies, but not to be infected with COVID-19. A different type of test might be necessary to determine whether or not you have COVID-19.

15. Why do I have a test line and no signs or symptoms of COVID-19? If 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 result is negative (false negative). Your healthcare provider should be able to give you the result and further advise you on whether you need to get tested again. The test may be necessary to determine whether or not you have COVID-19.
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.

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