HOW TO USE THE INTELSWAB™ COVID-19 RAPID TEST

1. Unpack the InteliSwab COVID-19 Rapid Test Kit.
2. Wash your hands thoroughly with soap and water for 20 seconds before starting the test.
3. Open the swab device and remove the test card.
4. Pick up the two-part pouch.
5. Tear open the pouch containing the tube and remove.
6. With the tube in a standing position, GENTLY ROCK THE CAP BACK AND FORTH 10 times. DO NOT pour out the liquid. DO NOT shake.
7. Slide the tube into the test stand on a flat sturdy surface. 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 pink background will clear out nasal passage. Discard tissue and wash hands thoroughly. Dry hands before starting the collection.
8. 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 black lips or face, call 911 or go to the closest Emergency Room.
   The test did NOT work properly. Contact OraSure Technologies, Inc. at 1-833-601-0127

TESTING:

1. IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result.
2. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again in 24 to 48 hours. If both your first and second test results are negative, you may not have COVID-19.
3. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again in 24 to 48 hours. If both your first and second test results are negative, you may not have COVID-19.
4. Read test results in a well-lit area.
5. Read test results between 30 and 40 minutes.
6. Do NOT touch the flat pad with your fingers.

POSITIVE RESULT

1. 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 need to self-isolate so you do not infect others.
   - You may need additional testing, depending on your personal health history and other factors.
   - Call your healthcare provider.
   - Make sure the device and tube are at an angle.
   - Send the device and tube to InteliSwab Connect app to report your result.
   - If you do not know your result or you are unsure of your result, contact OraSure Technologies at 1-833-601-0127.
   - Throwing away the test in an area with a trash can will help you see how faint the test line can appear.
   - Refer to the Positive Result Reference Card provided for more examples of positive test results.

INVALID RESULT

1. The test is INVALID if:
   - Swirling 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 pink background will clear out nasal passage.
   - Do NOT pour out the liquid.
   - DO NOT eat or swallow the preservative.
   - Refer to the Negative Result Reference Card for an example of an invalid result.
   - The test did NOT work properly. Contact OraSure Technologies, Inc. at 1-833-601-0127

NEGATIVE RESULT

1. 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 is a faint reddish-purple line next to the “C” or the line next to “C” is not complete (all the way across the window), or
   - reddish-purple background makes it impossible to read the test after 30 minutes.
   - You will need to obtain another test.
   - The test did NOT work properly. Contact OraSure Technologies, Inc. at 1-833-601-0127

Next Steps . . .

1. Call your healthcare provider and use InteliSwab Connect app to report your result.

NOT SURE OF YOUR RESULT

1. If you do not receive your result or you are unsure of your result, contact OraSure Technologies at 1-833-601-0127 or go to www.InteliSwab.com

REPORTING RESULT

1. 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

1. 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.

INTERPRETING RESULTS:

1. Interpreting Results:
   - HOW TO USE THE INTELISWAB™ COVID-19 RAPID TEST
   - 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.

2. Reading before 30 minutes or 40 minutes.
3. Reading before 30 minutes may cause false negative results.

NOTICE: The test device and tube are intended to be used by the test subject. The manufacturer of this test is not responsible for the accuracy of the test if the test subject does not follow the directions provided in the test kit.

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ENGLISH
INTENDED USE

The InteliSwab™ COVID-19 Rapid Test is a lateral flow immunosorbent assay (ISA) with the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (naso) swab samples from individuals aged 2 years or older who are suspected of COVID-19 by the presence of symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal swab samples from individuals aged 2 years or older who are suspected of COVID-19 by the presence of symptoms of COVID-19 within the first 7 days of symptom onset.

The InteliSwab™ COVID-19 Rapid Test is for use under Emergency Use Authorization (EUA) only. This test has been authorized by FDA under EUA. This product has been authorized solely for the detection of proteins from SARS-CoV-2, not for other viruses or organisms.

The use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and for diagnosis of COVID-19 under Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(b)(2)), unless the declaration of authorization is terminated or revoked sooner.

DO:

- Use the InteliSwab™ COVID-19 Rapid Test for COVID-19 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. 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.
- Call your healthcare provider and use the InteliSwab Connect app to report your result. For a list of compatible smartphones and to download the app visit www.InteliSwab.com/app
- 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 59°-104°F, 15°-40°C) before opening.
- Keep out of reach of children.

IMPORTANT INFORMATION ABOUT THE INTELISWAB™ COVID-19 COVID-19 RAPID TEST

The InteliSwab™ COVID-19 Rapid Test is for the identification of the antigen associated with SARS-CoV-2 in nasal samples. Positive results indicate the presence of SARS-CoV-2 virus. Antigen tests are designed to detect active infection, which may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in death or severe outcomes, if a person is exposed to SARS-CoV-2.

The presence of a line next to the “C” indicates SARS-CoV-2 antigen was detected in the sample. The presence of a line next to the “T” indicates SARS-CoV-2 antigen was not detected in the sample.

The InteliSwab™ COVID-19 Rapid Test is a lateral flow in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 viral particles using LAMP. The InteliSwab™ COVID-19 Rapid Test is for use under Emergency Use Authorization (EUA) only. This test has been authorized by FDA under EUA. This product has been authorized solely for the detection of proteins from SARS-CoV-2, not for other viruses or organisms.

The use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and for diagnosis of COVID-19 under Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(b)(2)), unless the declaration of authorization is terminated or revoked sooner.

FREQUENTLY ASKED QUESTIONS

1. What is COVID-19?
COVID-19 (coronavirus disease 2019) is a contagious virus that can cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in death or severe outcomes, if a person is exposed to SARS-CoV-2.

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 or difficulty breathing, fatigue, weakness, new loss of taste or smell, sore throat, congestion, or a runny nose, nausea or body aches, headache, loss of taste or smell, muscle or body aches, headache, loss of taste or smell, or vomiting and diarrhea. It is also possible for someone infected with COVID-19 to have no symptoms.

3. What is the difference between an antigen test and a molecular test?
There are different kinds of tests used to identify the presence of COVID-19. The InteliSwab™ COVID-19 Rapid Test is an antigen test. These tests are used to identify the presence of SARS-CoV-2 virus. Antigen tests are designed to detect active infection, which may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in death or severe outcomes, if a person is exposed to SARS-CoV-2.

4. What is molecular testing?
Molecular testing is used to detect SARS-CoV-2 virus RNA. These tests are designed to detect active infection, which may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in death or severe outcomes, if a person is exposed to SARS-CoV-2.

5. What is serial testing?
Serial testing is performed by testing twice over three days with at least 24 hours (and up to 48 hours) between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

6. What is the level of antigen from the COVID-19 virus in the sample?
In the case of COVID-19, the level of antigen from the COVID-19 virus in the sample can be lower in some samples compared to highly sensitive molecular FDA Authorized SARS-CoV-2 tests.

7. What is the level of antigen from SARS-CoV-2 and its prevalence, which change over time?
The level of antigen from the COVID-19 virus in the sample can be lower in some samples compared to highly sensitive molecular FDA Authorized SARS-CoV-2 tests.

8. What are the known and potential risks and benefits of this test?
Potential benefits include:
- Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- This test may help limit the spread of COVID-19 to your family and others in your community.

How accurate is the InteliSwab™ COVID-19 Rapid Test?
The InteliSwab™ COVID-19 Rapid Test is a lateral flow in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 viral particles using LAMP.

9. What are the known and potential benefits of this test?
This test is intended for non-prescription self-use and/or as applicable for an adult-collected nasal swab sample from individuals aged 2 years or older, with or without symptoms or other diagnostic information is necessary to differentiate between SARS-CoV-1 and SARS-CoV-2.

10. What are the known and potential risks of this test?
Possible incorrect results.

11. What is the known and potential complications of this test?
Possible discomfort during sample collection.

12. What is the known and potential discomfort during sample collection?
Possible discomfort during sample collection.

13. What are the known and potential complications of this test?
Possible incorrect results.

14. What are the known and potential risks of this test?
Possible discomfort during sample collection.

15. What are the known and potential complications of this test?
Possible incorrect results.

16. What are the known and potential risks of this test?
Possible discomfort during sample collection.

17. What are the known and potential complications of this test?
Possible incorrect results.

18. What are the known and potential risks of this test?
Possible discomfort during sample collection.

19. What are the known and potential complications of this test?
Possible incorrect results.

20. What are the known and potential risks of this test?
Possible discomfort during sample collection.

21. What are the known and potential complications of this test?
Possible incorrect results.

22. What are the known and potential risks of this test?
Possible discomfort during sample collection.

23. What are the known and potential complications of this test?
Possible incorrect results.

Please refer to the Letter of Authorization for SARS-CoV-2 tests provided by Test Code Mapping for SARS-CoV-2 Tests provided by OraSure Technologies, Inc.

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 1-833-601-0207 or visit www.InteliSwab.com

The InteliSwab™ COVID-19 Rapid Test Letter of Authorization, authorized Fact Sheets and authorized labels are available on the FDA website and www.InteliSwab.com

See your results

Scan here for step-by-step video:

Scan here for step-by-step video:

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www.OraSure.com
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WHY CHOOSE THE INTELISWAB™ COVID-19 RAPID TEST?

If you test negative:
- If you test negative, you likely do not have COVID-19. If you do not have symptoms and you receive a negative result, you are likely not infected with COVID-19.
- If you have symptoms, you may have a different virus or type of infection.

If you have COVID-19 and still get a negative result:
- Possible incorrect results.
- Possible discomfort during sample collection.

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 1-833-601-0207 or visit www.InteliSwab.com

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Scan here for step-by-step video:

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About the InteliSwab™ COVID-19 Rapid Test

The InteliSwab™ COVID-19 Rapid Test is intended for use under the Food and Drug Administration’s Emergency Use Authorization.
IntelliSwab COVID-19 RAPID TEST

SIMPLE & CONVENIENT TESTING
No assembly required — ready to use
No waiting for mail or lab processing

RESULTS IN MINUTES

HOME TEST

SIMPLY SWAB, SWIRL AND SEE
SMART SCIENCE MADE SIMPLE™

GENTLE SHALLOW NASAL SWAB

ANYTIME, ANYWHERE

INSTRUCTIONS DE USE EN ESPAÑOL
Instrucciones de uso en español.

The IntelliSwab™ COVID-19 Rapid Test detects active infection in individuals 2 years and older with symptoms within the first 7 days of onset or in individuals without symptoms when tested twice with at least 24 hours but no more than 48 hours between tests. See instructions for use for full intended use.

QUICK AND EASY RESULTS
• Use at home or anywhere there is a flat surface
• No professional supervision or video consultation required
• No phone or other equipment needed to interpret results

CONTENTS
• One (1) pouch with
  • Single-use test device
  • Tube with developer fluid
  • Instructions for Use in English and Spanish
  • Positive Result Reference Card
  • Test stand

You will need a way to time the test for 30 minutes (e.g., watch, clock or cellphone). To report results to public health, visit www.IntelliSwab.com/app for compatible smartphones and download information.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial capacity testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

Store the IntelliSwab™ COVID-19 Rapid Test in a dry location between 15°C–30°C (59°F–86°F).

QUESTION? Go to www.IntelliSwab.com or call 1-833-601-6257

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