INSTRUCTIONS FOR USE
You must follow the test directions carefully to get an accurate result. Call OraSure Technologies at 1-833-601-0127 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 INTELI SWAB® COVID-19 RAPID TEST

1. Test device
2. Recall window
3. Flat pad
4. Pick up the two-part pouch
5. Tear open the pouch containing the tube and remove
6. Hold tube upright
7. With the tube in alignment position, GENTLY ROCK THE CAP BACK AND FORTH to mix the sample with the liquid
8. DO NOT pour out the liquid. DO NOT shake the tube
9. Slide the tube into the test stand on a flat sturdy surface. DO NOT force from the front as splashing may occur. Tube should rest at an angle on the bottom of the stand. The result window is facing you. Start your timer for 30 minutes
10. The result window should display the test result. A pink background will cause invalid results
11. After mixing, leave the device in the tube. Stir 10 times
12. DO NOT touch the flat pad

THROW AWAY: results for the test. DO NOT eat or swallow the pouch

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.

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.

POSITIVE RESULT

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 bluish lips or face, call 911 or go to the closest Emergency Room

INVALID RESULT

The test is not working and should be repeated if:
• 4 lines are present
• No line next to the “T” or 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

DO NOT Read

NOT SURE OF YOUR RESULT

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

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

DISPOSE

Remove the test device from the tube, put the cap back on the tube and dispose away in normal trash. If you have a pulse oximeter, 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

Next Steps . . .

If your result is negative but you have signs and symptoms of COVID-19, contact your healthcare provider for additional testing.

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NEGA

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

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The InteliSwab® COVID-19 Rapid Test is a lateral flow immunoassay with an integrated swab, intended for 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 (nasal) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 2 years or older in communities with 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 not been FDA cleared or approved. This test has been authorized by FDA under EUA. This product has been authorized only for the detection of proteins from SARS-CoV-2, and 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 IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(2) 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 does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results for the identification of SARS-CoV-2 nucleocapsid protein antigen are generally detectable in anterior nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out the possible presence of other agents and the agent detected may not be the cause of disease. All individuals who test positive with the InteliSwab® COVID-19 Test should self-isolate and seek follow-up care with their healthcare provider, if additional testing is necessary. There are no specific symptoms that can give a positive result that is wrong (false positive).

What is the difference between the InteliSwab® COVID-19 Rapid Test and a molecular test? There are different kinds of tests that are being performed for COVID-19. The InteliSwab® COVID-19 Rapid Test is an antigen test. Antigen tests detect proteins, small parts, from the virus (SARS-CoV-2 virus). Antigen tests are designed to detect the specific antigen associated with SARS-CoV-2, the virus that causes COVID-19, in individuals who may be symptomatic but not testing positive with a molecular test. Molecular tests (also known as PCR tests) detect genetic material from the virus, and results with these tests are less sensitive than molecular tests. If you have symptoms that persist more than 24 hours, you should discuss with your healthcare provider if additional testing is necessary. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance that a negative result will give you a negative result when you have COVID-19.

What is serial testing? COVID-19 serial testing is done by taking the same test multiple times for COVID-19 on a routine basis, such as every 7-10 days or every day by testing more frequently, you may detect COVID-19 more quickly, the spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19. However, serial testing may not give you any symptoms if you do not have symptoms, testing should be provided at least twice over a three-month period with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing. Serial testing is not recommended for individuals with COVID-19 who are between 7 days of symptom onset.

What are common symptoms of COVID-19? Some individuals may appear 2-14 days after exposure and may include: cough; fever or chills; fatigue; muscle or body aches; headache; loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting and diarrhea. It is also possible for some people infected with COVID-19 to have no symptoms.

How accurate is the InteliSwab® COVID-19 Rapid Test? The InteliSwab® COVID-19 Rapid Test is a lateral flow in vivo diagnostic test to detect COVID-19. Antigen tests are designed to detect active infection or declare a negative result. If you test positive, you may be infected with COVID-19. If you test negative, you may not be infected with COVID-19. However, it may be possible that you have COVID-19 but you test negative. This is called a "false negative" result.

What is your test line and no control line? If you have a test line and no control line, you should discuss with your healthcare provider if additional testing is necessary. This result indicates that you may have COVID-19 but you test negative. This is called a "false negative" result.

If you do not have symptoms, testing should be performed on a routine basis, such as every 7-10 days or every day by testing more frequently, you may detect COVID-19 more quickly, the spread of infection.

Is the solution in the tube harmful? No. The solution in the tube contains potentially corrosive substances that can irritate the skin and eyes. If you get the solution in your eyes, flush with copious amounts of water. If irritation persists, seek medical advice from your healthcare provider.


The level of antigen from the COVID-19 virus was below the test limits. You may have had symptoms and signs of COVID-19 for more than 7 days. This means you should 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 possible COVID-19 exposures to decide how to care for you. 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.

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 all circulating SARS-CoV-2 variants based on the type and location of the clinical evaluation. Performance at the time of testing may vary depending on the variations circulating, including with their pharmaceutical ingredients, and may be affected by other factors. If you test positive, you should discuss with your healthcare provider if additional testing is necessary.

For more information on COVID-19 visit www.InteliSwab.com/variants

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If you test positive, you may have COVID-19 and it is important to contact 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 give a positive result that is wrong (false positive).

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What is the known and potential risks and benefits of this test? Possible benefits include: Possible discomfort during sample collection. Possible incorrect results. Potential benefits include: The results, along with other information, can help your healthcare provider make informed recommendations about your care. The accuracy of this test may help limit the spread of COVID-19 to your family and others in your community.

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Swirl in the tube

SIMPLY SWAB, SWIRL AND SEE

LEARN MORE

GENTLE SHALLOW NASAL SWAB

HOME TEST

RESULTS IN MINUTES

SMART SCIENCE MADE SIMPLE™

ANYTIME, ANYWHERE

The IntelliSwab™ COVID-19 Rapid Test detects active infection in individuals 15 years and older with symptoms within the first 7 days of onset in individuals without symptoms when tested twice within 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 (a watch, clock or cellphone).

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 (repeat) 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 35°-86°F (2°-30°C).

QUESTIONS? Go to www.IntelliSwab.com or call 1-833-601-0127

Item #3001-3630-70
rev. 10/21
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QUICK AND EASY RESULTS
- Use at home or anywhere there is a flat surface
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