ENGLISH

InteliSwab™ COVID-19 RAPID TEST • Pro

QUICK REFERENCE GUIDE

You must follow the test directions carefully to get an accurate result. See the full Instructions for Use for warnings, precautions, limitations and performance characteristics. For Emergency Use Authorization. For *in vitro* diagnostic use. For prescription use only.

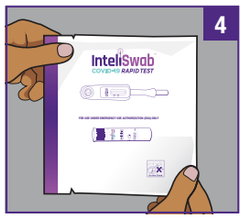
IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the device will produce a false negative result.

HOW TO USE THE INTELISWAB™ COVID-19 RAPID TEST PRO

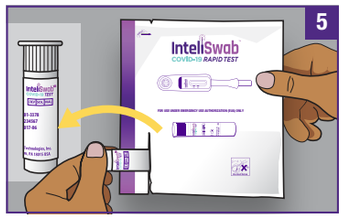
YOU WILL NEED A WAY TO TIME THE TEST.

Wash your hands thoroughly with soap and water for **20 seconds before** starting the test.

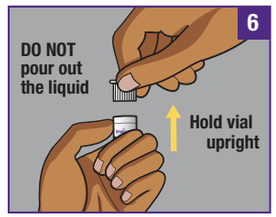
Kit contains: two-part **pouches** (containing 1 developer solution vial, 1 test device and 1 preservative), **test stands, Instructions for Use** and this **Quick Reference Guide.**



Pick up one of the two-part **pouches**.



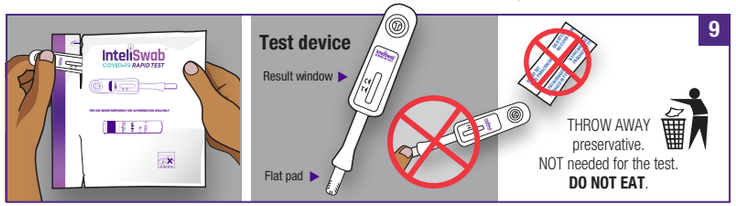
Tear open the pouch containing the vial and remove.



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

Slide the vial into the test stand on a **flat sturdy surface. DO NOT** force from the front as splashing may occur. Vial should rest at an angle on the **bottom** of the stand. If the solution spills, you will need a new test.

Blow your nose into a tissue. If assisting someone, instruct them to blow their nose. **DO NOT** use tissue to clear out nasal passage. Discard tissue and wash hands thoroughly. Dry hands before starting the collection.

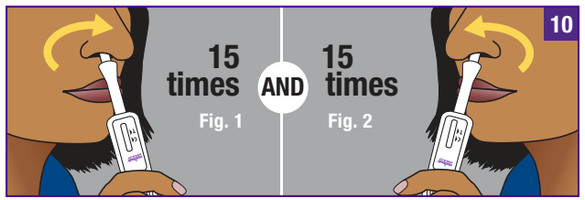


Tear open the pouch containing the **test device** and remove.

DO NOT touch the **flat pad** with your fingers.

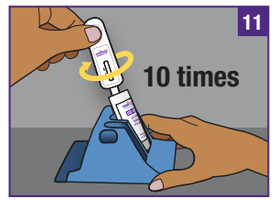
DO NOT eat or swallow the preservative.

If the preservative is not present, **DO NOT** use the test.

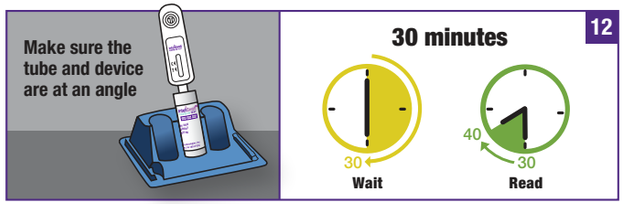


Insert flat pad of the device inside the **nostril**. **Circle around the nostril 15 times** while maintaining contact with the **inside wall of the nostril**. **SWAB BOTH NOSTRILS** (Fig. 1 and Fig. 2). If you are conducting the test on someone who requires assistance, proceed by swabbing the individual.

If you do not swab both nostrils 15 times each, you may get a false result.



Hold the test stand on a flat surface and insert the flat pad of the device into the vial. Stir **10 times** to mix the sample with the liquid in the vial. Make sure the flat pad is toward the **back** of the vial so it contacts the liquid. Swirling the device **less than** 10 times may cause invalid results.



After mixing, leave the device in the vial. Make sure the flat pad is touching the bottom of the vial and the result window is facing you. Start your timer for **30 minutes**. **DO NOT** remove the device from vial while the test is running. A pink background will pass through the result window as the test is working.

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: LINES IN C AND T ZONES

The test is **POSITIVE** if:

- A reddish-purple line appears in the T zone and there is a line in the C zone. Lines may vary in intensity. The test is positive regardless of how faint these lines appear.
- In some cases, the reddish-purple line in the C zone may not be present or may be very faint if there are high levels of virus in the sample.

A positive test result is interpreted as nucleocapsid protein antigen detected in the specimen. The individual is positive for COVID-19.

Line in T zone — The photos show how faint the bottom line may be. These are all positive test results.

NEGATIVE RESULT: LINE IN C ZONE

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

The test is **NEGATIVE** if:

- A reddish-purple line appears in the C zone and NO line appears next to the T zone. The line in the C zone must be present to interpret a negative result.

A negative result is interpreted as nucleocapsid antigen was not detected in the specimen. The individual is presumed negative for COVID-19.

Negative results do NOT rule out SARS-CoV-2 infection. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 36 hours between tests.

INVALID RESULT: REPEAT WITH NEW DEVICE

The test is not working and should be repeated if:

- no lines are present
- the test line or control line is not complete (all the way 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.

If the test did NOT work properly,
Contact OraSure Technologies, Inc. at 1-800-ORASURE (1-800-672-7873)

GENERAL TEST CLEAN-UP

1. Dispose of the used test materials in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
2. Change your gloves between each test to prevent contamination.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

Do NOT Reuse

INTENDED USE

The InteliSwab COVID-19 Rapid Test Pro 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 anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 15 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The InteliSwab COVID-19 Rapid Test Pro does not differentiate between SARS-CoV-1 and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The SARS-CoV-2 nucleocapsid protein is generally detectable in anterior nasal samples during the acute phase of infection. Positive results indicate that viral antigens have been detected, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not exclude bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the HYPERLINK "https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html" Laboratory In Vitro Diagnostics (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The InteliSwab COVID-19 Rapid Test Pro is for use under the Food and Drug Administration's Emergency Use Authorization (EUA) only. The InteliSwab COVID-19 Rapid Test Pro is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in POC settings.

IMPORTANT DO'S AND DON'TS

DO:

- Use the InteliSwab™ COVID-19 Rapid Test Pro 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 two-part pouch. If the two-part pouch has been damaged, discard the two-part pouch and its contents. The results from the InteliSwab™ COVID-19 Rapid Test Pro may not be valid if the two-part pouch is damaged.
- Use adequate lighting to read a test result.
- Use the test device and vial containing fluid only once and dispose of both properly.
- Wash hands thoroughly prior to testing and after use.
- Store the InteliSwab™ COVID-19 Rapid Test Pro in a dry location between 35°-86°F (2°-30°C). Bring the two-part pouch to room temperature (within 59°-104°F, 15°-40°C) before opening.
- Keep out of reach of children.

DO NOT:

- Use the InteliSwab™ COVID-19 Rapid Test Pro on children under the age of 15. An adult must perform this test on children between the ages of 15 and 17.
- Use the InteliSwab™ COVID-19 Rapid Test Pro beyond the expiration date.
- Use if the packaging has been opened or damaged.
- Open the two-part pouch until you are ready to start the test.
- Reuse the test device or vial.

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

For prescription use only.
For *in vitro* diagnostic use.

The InteliSwab™ COVID-19 Rapid Test Pro is for the detection of the antigen associated with COVID-19, not for any other viruses or pathogens.

Invalid results can occur if the sample and the reagents do not flow up the test device. The presence of a line next to the "C" does not indicate that an adequate sample was collected during the swabbing of the nostrils.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, 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 in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

FREQUENTLY ASKED QUESTIONS

What is COVID-19? COVID-19 (coronavirus disease 2019) is a contagious virus that may cause mild to severe respiratory illness, affecting other organs and systems potentially resulting in hospitalization or death. The presence of a specific antigen (the SARS-CoV-2 nucleocapsid protein antigen) indicates that an individual is currently infected with COVID-19 (even without the presence of symptoms) and can transmit the virus.

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

What is the difference between a COVID-19 antigen, a molecular and an antibody test, and what kind of test is the InteliSwab™ COVID-19 Rapid Test Pro? There are different kinds of tests for diagnosing COVID-19. The InteliSwab™ COVID-19 Rapid Test Pro is an antigen test. Antigen tests detect proteins, small parts, from the SARS-CoV-2 virus. Antigen tests are designed to detect virus levels that reflect active infection. Molecular tests (also known as PCR tests) detect genetic material from the virus (RNA). Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection. Antibody tests are not suitable to diagnose an active COVID-19 infection.

What is serial testing? COVID-19 serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

What are the known and potential risks and benefits of this test?

Potential risks include:
Possible discomfort during sample collection.

Possible incorrect results.

Potential benefits include:
The results, along with other information, can help healthcare providers to make informed recommendations about patient care.

The results of this test may help limit the spread of COVID-19 in your community.

How accurate is the InteliSwab™ COVID-19 Rapid Test Pro? The InteliSwab™ COVID-19 Rapid Test Pro is a lateral flow *in vitro* diagnostic antigen test to detect COVID-19. Antigen tests are designed to detect active infection in individuals. A clinical study was conducted during February and April of 2021 to determine the performance of the InteliSwab™ COVID-19 Rapid Test Pro. 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 lower nasal sample and completed the home use test. The InteliSwab™ COVID-19 Rapid Test Pro results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 assays to determine test performance. The InteliSwab™ COVID-19 Rapid Test Pro correctly identified 84% of the positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test correctly identified 98% of negative samples.

What if the test is positive?
A positive result means that it is very likely the patient has COVID-19. They should isolate themselves 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).

What if the test is negative?
Negative results do not rule out SARS-CoV-2 infection. Patients without symptoms that test negative should be tested again with at least 24 hours and no more than 36 hours between tests.

If the second test is negative, the patient is likely not infected with COVID-19.

If the patient has symptoms, they may have a different virus or type of infection. The patient may have COVID-19 and still get a negative result (false negative) if:

- You didn't perform the test correctly, such as not swabbing correctly or not waiting 30 minutes for test results.
- The level of antigen from the COVID-19 virus was below the test limits.
- The patient has signs and symptoms of COVID-19 for more than 7 days. This means they could still possibly have COVID-19 even though the test is negative. The results, along with other information, can help to make informed recommendations about patient care.

Why is there a test line and no control line? If you see a test line and no control line, the 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 of this Quick Reference Guide or the full Instructions for Use to help you understand how to interpret test results.

Will this test hurt? No. The nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable.

Is the solution in the vial harmful? No. The solution in the vial 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 solution. The developer solution should only be used as directed; do not ingest; keep out of the reach of children; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

SWAB
both nostrils

SWIRL
in the vial

SEE
your results

EXPLANATION OF SYMBOLS

LOT Batch Code	Use By
Do Not Reuse	Caution, Consult Accompanying Documents
Temperature Limitation	Manufacturer
REF Catalog Number	Consult Instructions for Use
IVD *In Vitro* Diagnostic Medical Device	EXP Date of Expiration

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

If you have any questions about the InteliSwab™ COVID-19 Rapid Test Pro, please contact our toll-free consumer helpline at 1-800-ORASURE (1-800-672-7873) or visit www.InteliSwab.com.

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

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3001-3538 rev. 06/21