InteliSwab® COVID-19 RAPID TEST • Pro

QUICK REFERENCE GUIDE

You must follow the test directions carefully to get an accurate result. See 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

PREPARING FOR THE TEST

KIT CONTENTS:

Pouched devices with a device and a tube, **Test Stands**, **Instructions for Use** and this **Quick Reference Guide**.

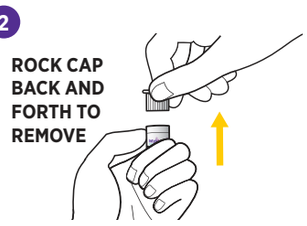
YOU WILL NEED A WAY TO TIME THE TEST

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

1

Pick up one of the two-part pouches. Tear open the pouch containing the **tube** and remove.

2



With the tube 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. Save cap for disposal.

3

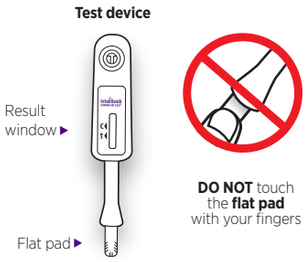
Slide the tube into the test stand on a **flat sturdy surface**. **DO NOT** force from the front as splashing may occur. Tube should rest at an angle on the **bottom** of the stand. If the solution spills, you will need a new test.

4

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.

5

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



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

6

SWAB BOTH NOSTRILS

ADULT: 15 TIMES AND **ADULT: 15 TIMES**

WHEN COLLECTING FROM A CHILD SEE ADDITIONAL INSTRUCTIONS

Fig. 1

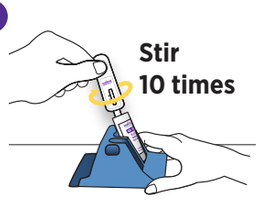
Fig. 2

ADULTS: 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 a test on a child 15-17 years old or an adult who requires assistance, proceed by swabbing the individual.

CHILDREN (14 AND UNDER): When collecting from a child under the age of 15, slowly **circle the swab in EACH nostril a minimum of 4 times while gently pressing against the inside of the nostril**. **This should take about 15 seconds.** (Fig. 1 and Fig. 2).

If you DO NOT swab BOTH nostrils 15 times (adult) OR 4 times (child), you may get a false result.

7



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. Stirring the device **less than** 10 times may cause invalid results.

8

The tube and device will sit at an angle in the test stand

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.

30 minutes

Read results between 30 and 40 minutes. To obtain an accurate result, **DO NOT** read **before** 30 minutes or **after** 40 minutes.

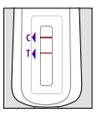
Reading before 30 minutes may cause false negative results.

9

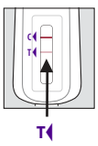
INTERPRETING RESULTS - Read test results in a well-lit area

POSITIVE RESULT COVID-19 DETECTED

The test is **POSITIVE** if:

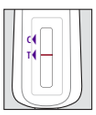


- there is a line next to the "T" and a line next to the "C"



- there is a faint line next to the "T" and a line next to the "C"

Look very closely! Any line next to the "T" means COVID-19 has been detected. The line may be **very faint**.



- there is a line next to the "T" and NO line next to the "C"

Repeat testing does not need to be performed if patients have a positive result at any time.

If the "C" line and the "T" line are visible, the test is positive. Any faint visible "T" line with the "C" line should be read as positive.

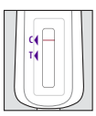
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the InteliSwab® should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

NEGATIVE RESULT COVID-19 NOT DETECTED

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT

There must be a line next to the "C" to be able to interpret negative result.

The test is **NEGATIVE** if:



- there is a reddish-purple line next to the "C" and **NO line next to the "T"**

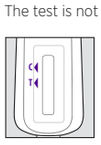
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

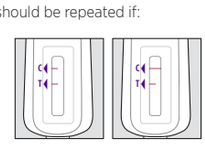
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay 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. 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.

INVALID RESULT

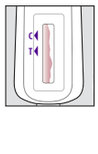
The test is not working and should be repeated if:



- no lines are present



- the line next to the "T" or the line next to the "C" is not complete (all the way across the window)



- a reddish-purple background makes it impossible to read the test after 30 minutes

You will need to re-test with a new test device.

The test did NOT work properly.
Contact OraSure Technologies, Inc. at 1-833-601-0127

HOW TO USE THIS TEST FOR SERIAL (REPEAT) TESTING

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Repeat testing is needed to improve test accuracy. Please follow the table when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

GENERAL TEST CLEANUP

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 (IU)

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 2 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 when tested at least twice over three days with at least 48 hours between tests or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 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.

All 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 measures such as isolating from others and wearing masks. 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.

The InteliSwab® COVID-19 Rapid Test Pro is intended for use by medical professionals or trained operators who are proficient in performing tests in point of care settings. The InteliSwab® COVID-19 Rapid Test Pro is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization (EUA) only. This product has not been FDA cleared or approved.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February through September 2021. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. If you have had symptoms longer than 7 days, you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 18 years and older. Children age 2 to 17 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test swab should be used immediately.
- Do not read test results before 30 minutes or after 40 minutes. Results read before 30 minutes or after 40 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin and eyes. Do not ingest any kit components. The solution in the tube contains potentially harmful chemicals (see table below).

Chemical Name	GHS Code for each Ingredient	Concentrations
Triton X-100	H302, harmful if swallowed H315, skin irritation H318, serious eye damage H400, short-term (acute) aquatic hazard H410, long-term (chronic) aquatic hazard	0.2%
ProClin 950	H302, harmful if swallowed H332, harmful if inhaled H314, causes severe skin burns and eye damage H317, may cause an allergic skin reaction H335, respiratory irritation H410, long-term (chronic) aquatic hazard	0.1%

If the solution contacts the skin or eyes, flush with copious amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222**.

- For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

FREQUENTLY ASKED QUESTIONS

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

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect results (see Warnings and Interpreting Results sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization

What is the difference between a COVID-19 antigen test and a molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the InteliSwab® COVID-19 Rapid Test Pro, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

What if you test positive?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should selfisolate from others and contact a healthcare provider for medical advice about your positive result.

What if you test negative?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV- 2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an invalid test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new test device should be used to collect a new nasal specimen and you should test again.

Why do I have a test line and no control line?

If you have a test line and 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.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

How accurate is the InteliSwab® COVID-19 Rapid Test Pro?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.inteliswab.com.

EXPLANATION OF SYMBOLS

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

MORE QUESTIONS ABOUT THE INTELISWAB® COVID-19 RAPID TEST PRO?
Contact our toll-free consumer helpline at 1-833-601-0127 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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