INSTRUCTIONS FOR USE

You must follow the test directions carefully to get an accurate result. Call OraSure Technologies at 1-833-601-0127 or 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.

SCAN HERE FOR STEP-BY-STEP VIDEO ▸ ▸ ▸

ENGLISH

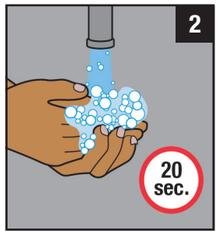
InteliSwab™ COVID-19 RAPID TEST

HOW TO USE THE INTELISWAB™ COVID-19 RAPID TEST

1

▸ **YOU WILL NEED A WAY TO TIME THE TEST.**

2

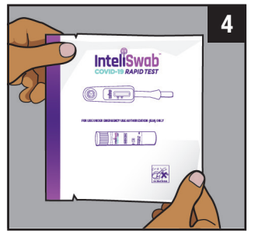


▸ Wash your hands thoroughly with soap and water for **20 seconds before** starting the test.

3

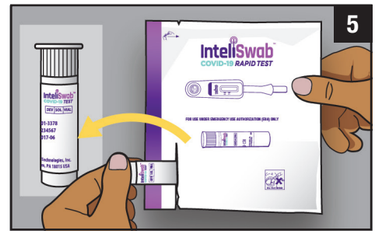
▸ Kit Contains: **pouched device(s)** with a device and a tube, **Instructions for Use** (in English and Spanish), **Positive Result Reference Card** and **test stand.**

4



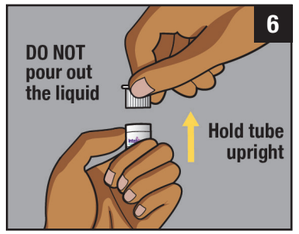
▸ Pick up the two-part **pouch**.

5



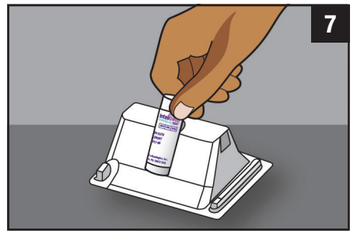
▸ Tear open the pouch containing the **tube** and remove.

6



▸ 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.

7

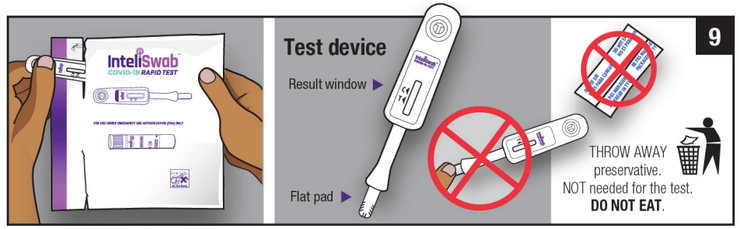


▸ Slide the tube into the test stand on a **flat sturdy surface**. **DO NOT** force from the front as splashing may occur. Tube should rest at an angle on the **bottom** of the stand. If the solution spills, you will need a new test.

8

▸ 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.

9



▸ 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.

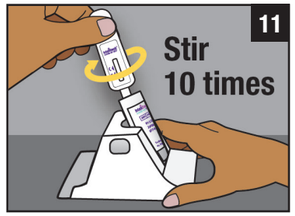
10

▸ **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).

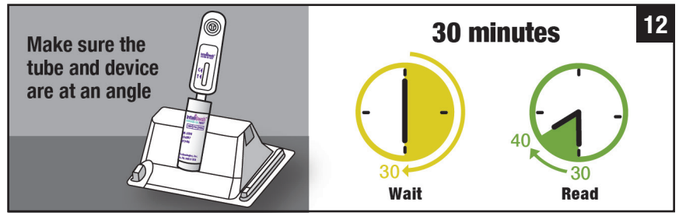
If you DO NOT swab BOTH nostrils 15 times (adult) OR 4 times (child), you may get a false result.

11



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

12



▸ 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.

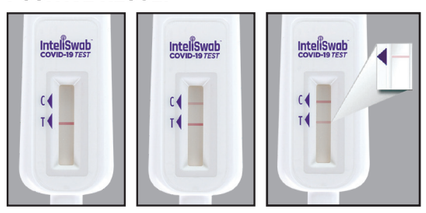
▸ **Read results between 30 and 40 minutes.** To obtain an accurate result, **DO NOT** read **before** 30 minutes or **after** 40 minutes.

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"

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.

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

→ **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.

NEGATIVE RESULT

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

▸ 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.

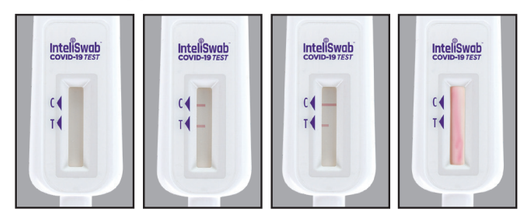
If you have COVID-19 symptoms and your test result is negative, you likely do not have COVID-19.

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.

→ **Next Steps . . .**

Call your healthcare provider and use InteliSwab Connect app 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.

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), or
- a 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

NOT SURE OF YOUR RESULT

If you do not know 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/app

DISPOSE

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.

Do NOT Reuse

Item #3001-3570-70
rev. 01/22

INTENDED USE

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 direct anterior nasal (nares) swab samples from individuals aged 18 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 adult-collected 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 (nares) swab samples from individuals aged 18 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The InteliSwab™ COVID-19 Rapid Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is 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 bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the InteliSwab™ COVID-19 Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management.

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 COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their healthcare provider.

Individuals should report all results obtained with this product to their healthcare provider and the InteliSwab™ Connect app. The app will report all test results received from individuals who use the authorized product to relevant 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.

The InteliSwab COVID-19 Rapid Test is intended for non-prescription self-use and/or as applicable for an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The InteliSwab COVID-19 Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

IMPORTANT DO'S AND DON'TS

DO:

- Use the InteliSwab™ COVID-19 Rapid Test 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 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 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.

DO NOT:

- DO NOT USE the InteliSwab™ COVID-19 Rapid Test on children under the age of 2. An adult must perform this test on children between the ages of 2 and 17.
- DO NOT USE the InteliSwab™ COVID-19 Rapid Test beyond the expiration date.
- DO NOT USE if the packaging has been opened or damaged.
- DO NOT OPEN the divided pouch until you are ready to start the test.
- DO NOT REUSE the test device or tube.

IMPORTANT INFORMATION ABOUT THE INTELISWAB™ COVID-19 RAPID TEST

For consumer over-the-counter use.

The InteliSwab™ COVID-19 Rapid Test 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.

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, 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)(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.

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 test and a molecular test? There are different kinds of tests for diagnosing COVID-19. The InteliSwabTM COVID-19 Rapid Test 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). Antigen tests are less sensitive than molecular tests. If you have symptoms and your test is negative, 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 this test will give you a negative result when you have COVID-19.

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.

Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. If you do not have symptoms, testing should be performed at least twice over three days, 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 required for individuals with COVID-19 like symptoms that are within 7 days of symptom onset.

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 your healthcare provider make informed recommendations about your care.

The results of 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 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. 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. An additional clinical study was conducted during September in children (ages 2-14). A total of 19 children were enrolled in the study where the parent or caregiver collected the anterior nasal sample and performed the test. The InteliSwab™ COVID-19 Rapid Test results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 assays to determine test performance. The InteliSwab™ COVID-19 Rapid Test correctly identified 85% of the positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test correctly identified 98% of negative samples. For more information about COVID-19 variants detected by InteliSwab, please visit www.InteliSwab.com/variants

What if you test positive?
A positive result means that it is very likely you have COVID-19 and it is important to report your results to 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).

Information about Emergency Use Authorizations and COVID-19? For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Visit InteliSwab.com to obtain the complete Instructions for Use and Fact Sheets.

What if you test negative?
If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19.

If you have symptoms, you may have a different virus or type of infection.

You 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.
- 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 is negative. Please see your health care 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 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.

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. Please see the other side of this Instructions for Use and the enclosed reference card 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. If you feel pain, please stop the test and seek advice from a healthcare provider.

Is the solution in the tube harmful?
No. The solution in the tube contains potentially harmful chemicals (Triton X-100 and ProClin 950). 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: poisonhelp.org or 1-800-222-1222.

SWAB
both nostrils

SWIRL
in the tube

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?

If you have any questions about the InteliSwab™ COVID-19 Rapid Test, please contact our toll-free consumer helpline at 1-833-601-0127 or visit www.InteliSwab.com.

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

SCAN HERE FOR STEP-BY-STEP VIDEO:

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015 USA
(610) 882-1820
www.OraSure.com

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3001-3570 rev. 01/22

InteliSwab™ COVID-19 RAPID TEST

1 TEST

1 TEST

InteliSwab™
COVID-19 RAPID TEST

Swab both nostrils

Swirl in the tube

See your results

HOME TEST

RESULTS IN MINUTES

InteliSwab™ COVID-19 RAPID TEST

SIMPLE & CONVENIENT TESTING

No assembly required — ready to use

No waiting for mail or lab processing

SIMPLY SWAB, SWIRL AND SEE

SMART SCIENCE MADE SIMPLE™

ANYTIME, ANYWHERE

LEARN MORE

GENTLE SHALLOW NASAL SWAB

The InteliSwab™ COVID-19 Rapid Test is for use under the Food and Drug Administration's Emergency Use Authorization only. 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. 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.

REF

LOT

YYYY-MM-DD
XXXXXX
XXXXXX

PO

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OraSure Technologies, Inc.
220 East First Street, Bethlehem, PA 18015 USA
(+1) 610-882-1820 www.OraSure.com

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InteliSwab™ COVID-19 RAPID TEST

Instrucciones de use en español ubicadas dentro de la caja.

The InteliSwab™ 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 (a watch, clock or cellphone). To report results to public health, visit www.InteliSwab.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 (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 InteliSwab™ COVID-19 Rapid Test in a dry location between 35°-86°F (2°-30°C).

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

IVD 86°F 35°F

Item #3001-3630-70
rev. 01/22

InteliSwab™ COVID-19 RAPID TEST

2 TESTS

Swab both nostrils

Swirl in the tube

See your results

InteliSwab™
COVID-19 *RAPID TEST*

HOME TEST

RESULTS IN MINUTES

InteliSwab™ COVID-19 *RAPID TEST*

SIMPLE & CONVENIENT TESTING

No assembly required — ready to use

No waiting for mail or lab processing

SIMPLY SWAB, SWIRL AND SEE

SMART SCIENCE MADE SIMPLE™

ANYTIME, ANYWHERE

LEARN MORE

GENTLE SHALLOW NASAL SWAB

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REF

LOT

YYYY-MM-DD
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XXXXXX
P0

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InteliSwab™ COVID-19 *RAPID TEST*

Instrucciones de use en español ubicadas dentro de la caja.

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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

- Two (2) pouches, each 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). To report results to public health, visit www.InteliSwab.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 (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 InteliSwab™ COVID-19 Rapid Test in a dry location between 35°-86°F (2°-30°C).

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

IVD 86°F 35°F

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