

## Healthcare Provider Instructions for Use

### **For Emergency Use Authorization For *In Vitro* Diagnostic Use**

#### **INTENDED USE (IU)**

The IntelliSwab® 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 IntelliSwab® 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 IntelliSwab® 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 IntelliSwab® 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.

#### **SUMMARY AND EXPLANATION OF THE TEST**

COVID-19 (coronavirus disease 2019) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first identified in December 2019 in Wuhan, Hubei, China. Due to the increased number of reported cases in nearly 170 countries, the World Health Organization (WHO) publicly recognized this as a pandemic on 11MAR20. The President of the United States declared the COVID-19 outbreak a national emergency on 13MAR20. Patient's symptoms are similar to influenza with transmission via respiratory droplets from coughing and sneezing. COVID-19 can cause respiratory symptoms, fever, cough, shortness of breath, and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, organ failure in several organs, acute kidney injury, heart problems, blood clots, additional viral and bacterial infections and even death. SARS-CoV-2 is considered contagious whether COVID-19 disease is symptomatic or asymptomatic and patients should self-isolate. The presence of SARS-CoV-2 nucleocapsid protein antigen indicates that the individual is currently infected and capable of transmitting the virus.

The IntelliSwab® COVID-19 Rapid Test Pro uses a sandwich capture lateral flow immunoassay to detect SARS-CoV-2 nucleocapsid protein antigen. SARS-CoV-2 nucleocapsid protein antigen is captured and visualized by colloidal gold labeled with SARS-CoV-2 antibodies generating a visible line in the test zone for a positive sample.

## PRINCIPLES OF THE TEST

The IntelliSwab® COVID-19 Rapid Test Pro is a manually performed, visually read immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen using a proprietary integrated collection swab to directly collect samples from the anterior nasal cavity. The IntelliSwab® COVID-19 Rapid Test Pro is comprised of both a single-use test device and a vial containing a pre-measured amount of a buffered developer solution. The test consists of a sealed pouch with two separate compartments for each component. The IntelliSwab® COVID-19 Rapid Test Pro utilizes a proprietary lateral flow immunoassay procedure.

The assay test strip, which can be viewed through the test device result window, is comprised of a series of components: the blocker pad, the conjugate pad, the nitrocellulose membrane, and finally the absorbent pad. The performance of the assay occurs by hydration and transport of reagents and specimen as they interact across the strip via chromatographic lateral flow.

An anterior nasal sample is collected using the flat pad that is integrated into the test device, followed by swirling the test device in the vial of developer solution. The developer solution facilitates the flow of the sample into the device and onto the test strip. As the sample flows through the device, it rehydrates the reagents on the blocker pad, which contains biotinylated anti-SARS-CoV-2 antibodies. The sample then re-hydrates the gold colorimetric reagent, which contains anti-SARS-CoV-2 antibodies. If the sample contains SARS-CoV-2 nucleocapsid protein antigen, it will react with the anti-SARS-CoV-2 antibodies in the blocker pad and conjugate pad and forms a sandwich complex that migrates up the test strip. As the complex continues to migrate up the test strip it encounters the Test (T) Zone and will react with the streptavidin immobilized on the nitrocellulose, a reddish-purple line will appear, qualitatively indicating the presence of SARS-CoV-2 nucleocapsid antigen in the sample. The intensity of the line color is not directly proportional to the amount of antigen present in the sample. If the sample does not contain SARS-CoV-2 nucleocapsid protein antigen, the sandwich complex will not form and the reagents will flow past the Test (T) Zone.

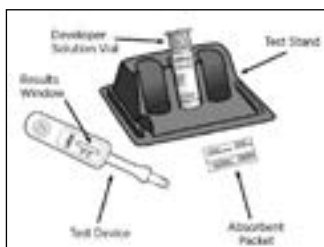
Further up the test strip, the sample will encounter the Control (C) Zone. This is a built-in procedural control which serves to demonstrate that the fluid migrated through the test device. For negative results and most positive results a line will form at the Control (C) Zone. In some cases when viral levels are high, the line at the Control Zone may be very faint or may not be present.

Results are interpreted between 30 and 40 minutes after inserting the device into the Developer Vial. Do not read negative results before 30 minutes as it may result in false negative results. Do not read any result after 40 minutes as it may result in inaccurate results.

## MATERIALS PROVIDED

**IntelliSwab® COVID-19 Rapid Test Pro Kits are available in the following packaging configurations:**

Components of Kit Catalog Number	25 Count Kit 1001-0614	100 Count Kit 1001-0615
Divided Pouch, Each containing: Test Device (1) Absorbent Packet (1) Developer Solution Vial (1) (each vial contains 0.75 mL of a buffered saline solution with an antimicrobial agent)	25	100
Test Stands	5	10
Instructions for Use	1	1
Quick Reference Guide	1	1



## MATERIALS NOT PROVIDED BUT REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

### IntelliSwab® COVID-19 Rapid Test Pro Kit Controls (Catalog #: 1001-0613)

IntelliSwab® COVID-19 Positive Control (1 vial, blue cap, 0.25 mL)

IntelliSwab® COVID-19 Negative Control (1 vial, white cap, 0.25 mL)

Loops (package of 5µL loops)

Instructions for use for IntelliSwab® COVID-19 Rapid Test Pro Kit Controls

### IntelliSwab® COVID-19 Rapid Test Pro Visual Reference Panel (Catalog #: 1001-0599)

IntelliSwab® COVID-19 Limit of Detection (1 device)

IntelliSwab® COVID-19 Low Positive (1 device)

IntelliSwab® COVID-19 Negative (1 device)

Instructions for Use for IntelliSwab® COVID-19 Rapid Test Pro Visual Reference Panel

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 to 40 minutes

Biohazard waste container

## WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- For prescription use only.
- Read all instruction carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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.
- 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.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. only).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Test devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions<sup>1</sup> when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE)<sup>2</sup> and gloves when running the test and handling a patient's test device. Change gloves 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 test kit if it is past the expiration date.
- Do not touch the swab tip.
- Once opened, the test swab should be used immediately.
- Follow these Instructions for Use to obtain accurate results. Incorrect sampling may result in false results.
- Do not read the 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 reagent solution contains potentially harmful chemicals (see table below). If the solution contacts your skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice: <https://www.poissonhelp.org> or 1-800-222-1222.

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%

- Invalid results can occur if the swab is not stirred at least 10 times.
- If any of the solution in the Developer Vial spills, it may cause invalid results. You need to repeat testing with a new test.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health agencies.
- For more information on EUAs please visit: <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](http://www.cdc.gov/COVID19)

1. CDC. Universal Precautions For Prevention Of Transmission Of Human Immunodeficiency Virus, Hepatitis B Virus, And Other Bloodborne Pathogens In Health-Care Settings. MMWR 1988; 37(24):377-388.

2. CDC. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. [cdc.gov](http://cdc.gov).

## Device Handling Precautions

- Inspect the Divided Pouch. If the Divided Pouch has been damaged or open, discard the Divided Pouch and its contents and select a new Divided Pouch for testing.
- If the Test Device is not immediately inserted into the Developer Solution after sample collection, remove the absorbent packet from the Divided Pouch and place the Test Device into the Divided Pouch for transport or until the device can be inserted into the Developer Solution. The Test Device must be inserted into the Developer Solution within 30 minutes of collection.
- Adequate lighting is required to read a test result.

## STORAGE INSTRUCTIONS

Store unused IntelliSwab® COVID-19 Rapid Test Pro kits unopened at 2° - 30°C (35° - 86°F). Do not open the Divided Pouch until you are ready to perform the test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15° - 40°C, 59° - 104°F) before opening.

## QUALITY CONTROL PROCEDURES

### Built-in Control Features

The IntelliSwab® COVID-19 Rapid Test Pro for anterior nasal specimens has a built-in procedural control that demonstrates the assay components have migrated adequately through the device. For negative tests, a reddish-purple line in the Control (C) Zone of the Result Window indicates that the fluid migrated appropriately through the Test Device. The line in the Control (C) Zone does not determine if a human sample has been added or if there is an adequate sample. For most positive tests, a reddish-purple line will appear in the Control (C) Zone and the Test (T) Zone; however, in cases where the viral load in the sample is very high, the line in the Control (C) Zone may not be present or may be very faint. (Refer to Test Result and Interpretation of Test Result section in these Instructions for Use).

### External Quality Control

IntelliSwab® COVID-19 Rapid Test Pro Kit Controls are for use with the IntelliSwab® COVID-19 Rapid Test Pro. The IntelliSwab® COVID-19 Rapid Test Kit Pro Controls are specifically formulated and manufactured to ensure performance of the test and are used to verify an operator's ability to properly perform the test and interpret the results. The COVID-19 Positive Control will produce a positive test result and has been manufactured to produce a faint line in the Test (T) Zone. The COVID-19 Negative Control will produce a negative test result (Refer to Test Result and Interpretation of Test Result section in these Instructions for Use). Use of Kit Control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the IntelliSwab® COVID-19 Rapid Test Pro. If external controls do not produce expected results, testing of individuals should not be performed. Contact OraSure Technologies' Customer Care if the IntelliSwab® COVID-19 Rapid Test Kit Control reagents do not produce the expected results.

### Run the External Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (36°-86°F), and
- At periodic intervals as dictated by the user facility country, state or local regulations and policies.

### Test Procedures for External Controls

Refer to the IntelliSwab® COVID-19 Rapid Test Pro Kit Control Instructions for Use for full instruction on the use of these reagents. It is the responsibility of each laboratory using the IntelliSwab® COVID-19 Rapid Test Pro to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### Qualification for New Operators

The IntelliSwab® COVID-19 Visual Reference Panel is available separately for use with the IntelliSwab® COVID-19 Rapid Test Pro. The IntelliSwab® COVID-19 Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low positive and negative test result. New operators must be able to correctly interpret all test results in the IntelliSwab® COVID-19 Visual Reference Panel prior to using the IntelliSwab® COVID-19 Rapid Test Pro to test patient samples. Failure to read low intensities can result in the inability to detect specimens near the limit of detection of the IntelliSwab® COVID-19 Rapid Test Pro and may result in false negative results.

## INSTRUCTIONS FOR USE

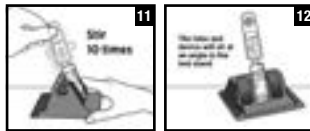
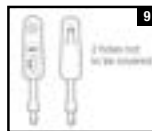
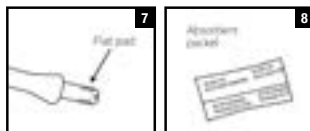
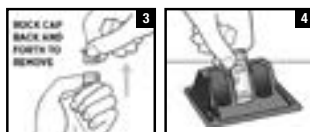
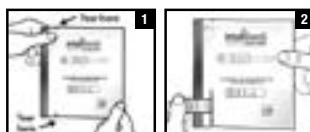
Follow *Safety Precautions* section in these Instructions for Use.

Gather all the materials you will need. Allow the IntelliSwab® COVID-19 Rapid Test Pro to come to operating temperature (15° - 40°C, 59° - 104°F) before use. Refer to the External Quality Control section in these Instructions for Use to determine when the IntelliSwab® COVID-19 Rapid Test Kit Pro Controls should be run.

## SPECIMEN COLLECTION AND TEST PROCEDURE

Set the Test Stand at your workspace. Make sure the Test Stand is on a sturdy surface. Use only the Test Stand provided.

1. Open the two chamber pouch by tearing at the notches on the top of each side of the Pouch (*see picture 1*).
2. Remove the Developer Solution Vial ("Vial") from the Pouch (*see picture 2*).
3. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off (*see picture 3*).
4. Slide the Vial into the top of one of the slots in the Test Stand. **DO NOT** force the Vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the Test Stand (*see picture 4*). If solution spills out of the vial, you will need to obtain a new test.
5. Instruct the individual to blow their nose into a tissue. **DO NOT** have them clean out their nose with the tissue (*see picture 5*). Have the individual discard the tissue and wash or sanitize their hands.
6. Remove the Device from its Pouch (*see picture 6*).
7. **DO NOT** touch the Flat Pad (*see picture 7*).
8. Check to make sure that an Absorbent Packet is included with the Device (*see picture 8*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
9. **DO NOT** cover the two holes on the back of the Device with labels or other materials. Doing so may cause invalid results (*see picture 9*).
10. **ADULTS:** Direct the individual to insert the 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** (*see picture 10*). If you are conducting a test on a child 15-17 years old or an adult who requires assistance, proceed by swabbing the individual.
11. **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.
12. **If you DO NOT swab BOTH nostrils 15 times (adult) OR 4 times (CHILD), you may get a false result.**
13. Keep the Test Stand on the flat surface, insert the Device into the Vial and swirl the Device 10 times while making sure the Flat Pad is in the solution. Make sure the flat pad is toward the back of the tube so it contacts the liquid. (*see picture 11*). Swirling the device less than 10 times may cause invalid results.
14. Leave Device in the Vial making sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing you (*see picture 12*). Make sure the tube and device are at an angle.
15. Start timing the test (*see picture 13*) by setting the timer for 30 minutes. **DO NOT** remove the Device from the Vial while the test is running.
16. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (*see picture 14*).



## TEST RESULT AND INTERPRETATION OF TEST RESULT

Interpret results between 30 and 40 minutes. Do not read negative results before 30 minutes as it may result in false negative results. Do not read any result after 40 minutes as it may yield inaccurate results.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

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.

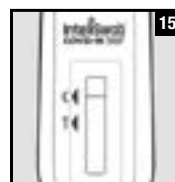
### COVID-19 NEGATIVE (-)

A test is **Negative** if:

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative (see picture 15).

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

- Test the individual again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow-up testing for SARS-CoV-2 with molecular test or testing for other respiratory disease should be considered.

All negative results should be treated as presumptive and confirmation testing with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with 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.

## COVID-19 POSITIVE (+)

A test is **Positive** if:

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible reddish-purple test (T) line with the control line (C) should be read as positive (see pictures 16 and 17).

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 (see picture 18).

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

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).

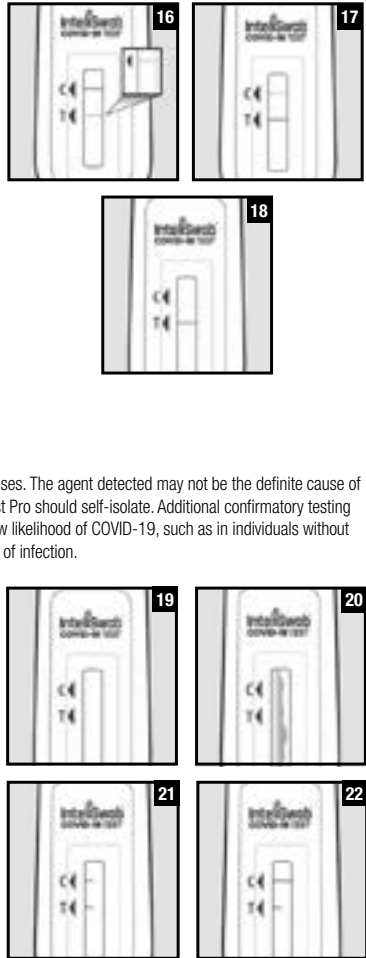
Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the IntelliSwab® COVID-19 Rapid Test Pro should self-isolate. Additional confirmatory testing with a molecular test 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.

## INVALID

A test is **Invalid** and requires re-testing with a new test device if any of the following occurs:

- **NO** lines appear on the device (see picture 19), or
- a reddish-purple background in the Result Window makes it difficult to read the result after 30 minutes (see picture 20), or
- any partial line on one side of the C or T Zones (see pictures 21 and 22)

An **Invalid** test result means that there was a problem running the test. **An Invalid result cannot be interpreted. An invalid test result needs to be repeated with a fresh sample and a new test device. Please contact OraSure Technologies' Customer Care (1-800-ORASURE) if you are unable to obtain a valid test result upon repeat testing.**



## 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.

## LIMITATIONS OF THE TEST

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 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.
2. 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.
3. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
4. If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
5. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
6. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
7. Incorrect test results may occur if a specimen is incorrectly collected or handled.
8. This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

## CONDITIONS OF AUTHORIZATION FOR LABORATORY

The IntelliSwab® COVID-19 Rapid Test Pro Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the IntelliSwab® COVID-19 Rapid Test Pro ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- A. Authorized laboratories\* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.
- D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and OraSure Technologies, Inc. (via email: [customer@orasure.com](mailto:customer@orasure.com)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling.
- G. OraSure Technologies, Inc. and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

\*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC) i.e. in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

## PERFORMANCE CHARACTERISTICS

### CLINICAL PERFORMANCE

A clinical study to evaluate the performance of the IntelliSwab® COVID-19 Rapid Test Pro was conducted during February and April of 2021 in five (5) geographically diverse sites across the US. A total of 146 individuals with signs and symptoms of COVID-19 within the first seven (7) days of symptom onset completed the study and obtained a valid result. Subjects eighteen (18) years and older independently collected an anterior nasal sample, conducted the test, interpreted and reported their self-test result. The parents of subjects fifteen (15) to seventeen (17) years of age collected the anterior nasal sample, conducted the test, interpreted and recorded the test result for the child. An additional clinical study was conducted during September 2021 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 IntelliSwab® COVID-19 Rapid Test Pro test results were compared to highly sensitive molecular FDA EUA SARS-CoV-2 assays to determine test performance. The results from the pediatric study conducted in September 2021 have been combined with the previous study results collected in early 2021. The IntelliSwab® COVID-19 Rapid Test Pro when conducted by a lay user correctly identified 85% of positive samples. Additionally, the IntelliSwab® COVID-19 Rapid Test Pro correctly identified 98% of negative samples. The COVID-19 infection rate was 37% (61/165) in this study. The performance is shown in the following table.



InteliSwab® COVID-19 Rapid Test Pro	Comparator Method		
	Positive	Negative	Total
Positive	52	2	54
Negative	9	102	111
<b>Total</b>	61	104	165
Positive Percent Agreement (PPA):	52/61	85%	(95% CI: 74%, 92%)
Negative Percent Agreement (NPA):	102/104	98%	(95% CI: 93%, 100%)

Days of COVID-19 Symptoms	RT-PCR Positives	InteliSwab® COVID-19 Rapid Antigen Positives
0-1	14	13
2	11	10
3	17	11
4	11	10
5	5	5
6	2	2
7	1	1
<b>Total</b>	61	52

Age Group	RT-PCR Positives	InteliSwab® COVID-19 Rapid Antigen Positives
2-13	10	9
14-23	10	9
24-64	39	33
65+	2	1
<b>Total</b>	61	52

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36-48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

Days After First PCR Positive Test Result	Asymptomatic on First Day of Testing			Symptomatic on First Day of Testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later, and the final test performed 48 hours after the second test.

## ANALYTICAL PERFORMANCE

### Limit of Detection (LoD)

To determine the LoD, 50 µL of sample was spiked onto the collection pad. A preliminary LoD was determined by evaluating different concentrations of a SARS-CoV-2 live virus stock (USA\_WA1/2020) diluted in nasal matrix. Contrived samples were randomized, and operators were blinded to the sample identities for testing on the IntelliSwab® COVID-19 Rapid Test. The LoD was confirmed as the lowest concentration of SARS-CoV-2 that was detected ≥95% of the time (i.e., concentration where 19 out of 20 test results were positive). The IntelliSwab® COVID-19 Rapid Test LoD was confirmed to be  $2.5 \times 10^2$  TCID<sub>50</sub>/mL ( $8.0 \times 10^5$  GC/mL). Based upon the testing procedure for this study the LoD of  $2.5 \times 10^2$  TCID<sub>50</sub>/mL equates to 12.5 TCID<sub>50</sub>/swab.

### NIH/RADx Variant Testing

The performance of this test in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institute of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimen used to prepare this dilution series prepared and tested by RADx in May 2022 to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an authorized EUA authorized RT-PCR method, the IntelliSwab® COVID-19 Rapid Test detected 100% of live virus Omicron samples at Ct-value of 24.5. Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 25.6) were not detected by the IntelliSwab® COVID-19 Rapid Test in this study.

Omicron Pool 1 Live Omicron Clinical Samples (BA.2)	Average Ct-N2 (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	IntelliSwab® COVID-19 Rapid Test Percent Positive (n=5)
Dilution 1	19.4	100	100	100
Dilution 2	20.6	100	100	100
Dilution 3	21.6	100	100	100
Dilution 4	22.4	100	100	100
Dilution 5	23.3	100	100	100
Dilution 6	24.5	0	100	100
Dilution 7	25.6	0	100	0
Dilution 8	26.5	0	0	0
Dilution 9	27.7	0	0	0
Dilution 10	28.5	0	0	0
Dilution 11	29.4	0	0	0
Dilution 12	30.3	0	0	0

### Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-Reactivity and Microbial Interference studies were conducted to determine if other respiratory pathogens that could be present in a nasal sample could cause a false-positive test result, or interfere with a true positive result. A panel of sixteen (16) viruses, ten (10) bacteria, three (3) fungi, and pooled human nasal wash was evaluated in this study. No cross-reactivity or interference was seen with the following microorganisms when tested at the concentrations listed in the table below with the exception of SARS-CoV, which resulted in positive test results due to the high homology between SARS-CoV and SARS-CoV-2 nucleocapsid proteins.

Potential Cross Reactant		Source/Strain/ID No.	Concentration Tested
Virus	Adenovirus 1	ATCC VR-1	$1.43 \times 10^5$ TCID <sub>50</sub> /mL
	Human metapneumovirus (hMPV)	Zeptomatrix 0810157CF	$1.43 \times 10^5$ TCID <sub>50</sub> /mL
	Rhinovirus	ATCC VR-1601	$4.45 \times 10^5$ TCID <sub>50</sub> /mL
	Enterovirus 68	ATCC VR-1826	$8.0 \times 10^5$ TCID <sub>50</sub> /mL
	Human Coronavirus OC43	Zeptomatrix 0810024CF	$1.43 \times 10^6$ TCID <sub>50</sub> /mL
	Human Coronavirus 229E	ATCC VR-740	$1.43 \times 10^6$ TCID <sub>50</sub> /mL
	Human Coronavirus NL63	BEI Resources	$1.43 \times 10^5$ TCID <sub>50</sub> /mL
	SARS-coronavirus	MRI Urbani	$7.9 \times 10^3$ TCID <sub>50</sub> /mL
	MERS-coronavirus	MRI EMC/2012	$2.5 \times 10^4$ TCID <sub>50</sub> /mL
	Parainfluenza virus 1	ATCC VR-94	$1.43 \times 10^6$ TCID <sub>50</sub> /mL
	Parainfluenza virus 2	ATCC VR-92	$1.43 \times 10^6$ TCID <sub>50</sub> /mL
	Parainfluenza virus 3	ATCC VR-93	$1.43 \times 10^6$ TCID <sub>50</sub> /mL
	Parainfluenza virus 4b <sup>a</sup>	Zeptomatrix 0810060BCF	$8.5 \times 10^4$ TCID <sub>50</sub> /mL

Potential Cross Reactant		Source/Strain/ID No.	Concentration Tested
Virus	Parainfluenza virus 4b <sup>b</sup>	ATCC VR-1377	8.0 X 10 <sup>4</sup> TCID <sub>50</sub> /mL
	Influenza A	ATCC VR-1894	1.43 X 10 <sup>5</sup> CEID <sub>50</sub> /mL
	Influenza B	ATCC VR-1931	1.43 X 10 <sup>5</sup> TCID <sub>50</sub> /mL
	Respiratory syncytial virus	ATCC VR-26	4.0 X 10 <sup>6</sup> PFU/mL
Bacteria	<i>Bordetella pertussis</i>	ATCC 9797	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Chlamydia pneumoniae</i>	ATCC VR-2282	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Haemophilus influenzae</i>	ATCC 49247	1.0 X 10 <sup>7</sup> IFU/mL
	<i>Legionella pneumoniae</i>	Zeptomatrix 801645	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Streptococcus pneumoniae</i>	ATCC 49319	4.48 X 10 <sup>5</sup> cfu/mL
	<i>Streptococcus pyogenes</i>	ATCC 19615	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Mycoplasma pneumoniae</i>	ATCC 15531-TTR	1.0 X 10 <sup>5</sup> cfu/mL
	<i>Staphylococcus aureus</i>	ATCC 12600	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Staphylococcus epidermidis</i>	ATCC 14990	1.0 X 10 <sup>6</sup> cfu/mL
	<i>Mycobacterium tuberculosis</i>	Zeptomatrix 801660	1.0 X 10 <sup>6</sup> cfu/mL
Fungi	<i>Candida albicans</i>	ATCC 14503	5.0 X 10 <sup>6</sup> cfu/mL
	<i>Pneumocystis carinii</i>	ATCC PRA-159	1.0 X 10 <sup>6</sup> nuclei/mL
	<i>P. jirovecii</i> - <i>S. cerevisiae</i> recombinant	Zeptomatrix 801698	1.0 X 10 <sup>6</sup> cfu/mL
	Pooled Human Nasal Wash	Lee Biosolutions 991-26	N/A

<sup>a</sup> Used for Exclusivity Testing

<sup>b</sup> Used for Microbial Interference

Cross reactivity in samples containing HKU1 coronavirus could not be conclusively ruled out through in silico comparison of the HKU1 and the SARS-CoV-2 nucleocapsid protein amino acid sequence. Additionally, the SARS-CoV-2 Nucleocapsid protein sequence was BLAST aligned on the NIH NCBI database to the entire set of proteins encoded by *P. jirovecii*. No significant identity was found as a result of this search and thus no interference is expected with the IntelliSwab® COVID-19 Rapid Test Pro, however, cross-reactivity cannot be ruled out.

## High Dose Hook Effect










Potential hook effect in the IntelliSwab® COVID-19 Rapid Test Pro was assessed by loading 50 µL of neat virus stock directly onto the center of the flat pad of test device in triplicate, resulting in a test concentration of  $1.0 \times 10^5$  TCID<sub>50</sub>/mL. No hook effect was seen with the USA-WA1/2020 SARS-CoV-2 isolate.

## Endogenous Interfering Substances

A study was conducted to determine if any substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity listed in the table interfere in the performance of the IntelliSwab® COVID-19 Rapid Test Pro. In addition to the materials that are found in the nasal cavity, substances that are commonly found on the hands were also tested. Test performance was evaluated in the absence and presence of SARS-CoV-2 (3x LoD). None of the substances listed in the tables below interfered with the performance of the IntelliSwab® COVID-19 Rapid Test Pro.

Substance	Source/Item #	Concentration
Human Whole Blood (EDTA tube)	American Blood Bank	4%
Mucin (porcin stomach, type II)	Sigma M2378	0.5%
Chloraseptic (Menthol/Benzocaine)	Chloraseptic Max	1.5 mg/mL
Naso GEL (NeillMed)	NeillMed	5% v/v
Nasal Drops (Phenylephrine)	CVS Health	15% v/v
Nasal Spray (Oxymetazoline)	CVS Health	15% v/v
Nasal Spray (Cromolyn)	Nasal Crom	15% v/v
Zicam	Zicam	5% v/v
Homeopathic (Alkalol)	Alkalol	10% v/v
Sore Throat Phenol Spray	Chloraseptic	15% v/v
Tobramycin	Sigma T4014	4 µg/mL
Mupirocin	Sigma M7694	10 mg/mL
Tamiflu (Oseltamivir Phosphate)	Acros 461170050	5 mg/mL
Fluticasone Propionate	CVS Health	5% v/v
Biotin	Sigma B4501	3.5 µg/mL

Substance Used	Source/Brand	Amount used
Disinfectant Wipes (Alkyl (C14 (50%), C12 (40%), C16 (10%) Dimethyl Benzyl Ammonium Chloride, 0.26%)	Lysol	1 wipe
Bleach Wipes (0.525% bleach)	Hype-wipe	1 wipe
Hand Sanitizer Gel (70% ethyl alcohol)	CVS	1.038 g
Hand Lotion	Corn Huskers	0.991 g
Hand Lotion with Aloe	Gold Bond Healing	1.013 g
Hand Lotion with Coconut Oil, Cocoa Butter, and African Shea Butter	Gold Bond Ultimate Healing	1.067 g
Hand Soap	Softsoap Fresh Breeze	1.055 g

EXPLANATION OF SYMBOLS	
 Batch Code	 <i>In Vitro</i> Diagnostic Medical Device
 Catalog Number	 Manufacturer
 Caution, Consult Accompanying Documents	 Part Number
 Use By	 Temperature Limitation
 Prescription Use	

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**OraSure Technologies, Inc.**

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For Technical or Customer Service phone  
(800) ORASURE (800-672-7873).






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<sup>®</sup> COVID-19 RAPID TEST PRO

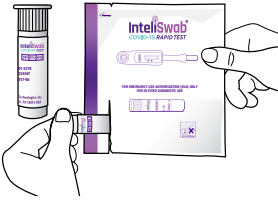
**PREPARING FOR THE TEST**

**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**



**ROCK CAP BACK AND FORTH TO REMOVE**


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.


**Test device**



Result window ▶

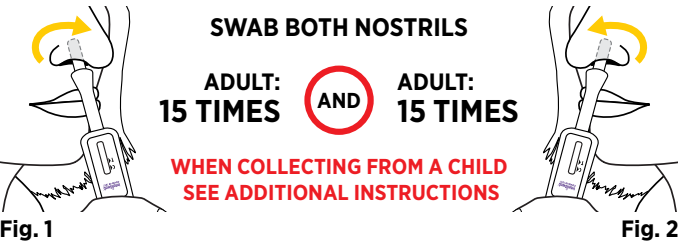
Flat pad ▶

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



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

**6**



**SWAB BOTH NOSTRILS**

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

**WHEN COLLECTING FROM A CHILD SEE ADDITIONAL INSTRUCTIONS**

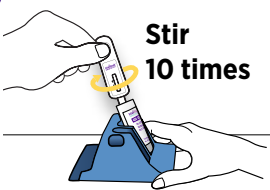
**Fig. 1** **Fig. 2**

**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**



**Stir 10 times**

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**

**30 minutes**

**Wait**

**Read**

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.

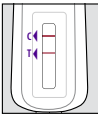
**Reading before 30 minutes may cause false negative results.**

**9**

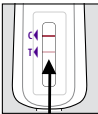
**INTERPRETING RESULTS - Read test results in a well-lit area**

**POSITIVE RESULT COVID-19 DETECTED**

The test is **POSITIVE** if:



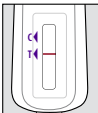
• there is a line next to the "T" and a line next to the "C"



• 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**.

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.



• 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.**

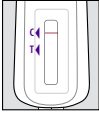
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. 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<sup>®</sup> 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"

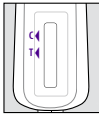
**To increase the chance that the negative result for COVID-19 is accurate, you should:**

- 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.

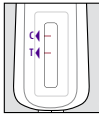
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results 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**

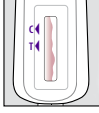
The test is not working and should be repeated if:



• 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** Item #3001-3538-70 Rev. 01/23

INTENDED USE (IU)

The IntelliSwab® 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 IntelliSwab® 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 IntelliSwab® 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 IntelliSwab® 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.poissonhelp.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](http://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 IntelliSwab® 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 self-isolate 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 IntelliSwab® 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](http://www.inteliswab.com).

EXPLANATION OF SYMBOLS

 Batch Code	 Use By
 Do Not Reuse	 Caution, Consult Accompanying Documents
 Temperature Limitation	 Manufacturer
 Catalog Number	 Consult Instructions for Use
 <i>In Vitro</i> 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](http://www.InteliSwab.com).









The IntelliSwab® COVID-19 Rapid Test Pro Letter of Authorization, authorized Fact Sheets and authorized labeling are available on the FDA website and [www.InteliSwab.com](http://www.InteliSwab.com).

OraSure Technologies, Inc.  
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(610) 882-1820  
[www.OraSure.com](http://www.OraSure.com)

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1. CDC. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. cdc.gov.
2. CDC. Universal Precautions For Prevention Of Transmission Of Human Immunodeficiency Virus, Hepatitis B Virus, And Other Bloodborne Pathogens In Health-Care Settings. MMWR 1988; 37(24):377-388.

### EXPLANATION OF SYMBOLS

 Batch Code	 In Vitro Diagnostic Medical Device
 Catalog Number	 Manufacturer
 Caution, Consult Accompanying Documents	 Temperature Limitation
 Part Number	 Use By

For Technical or Customer Service within the United States, phone (800) ORASURE (800-672-7873).  
For customers outside the United States, phone +(001) 610 882 1820 or go to [www.OraSure.com](http://www.OraSure.com)



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Item# 3001-3354 rev. 05/22

# IntelliSwab<sup>®</sup>

## COVID-19 RAPID TEST • Pro

**KIT CONTROLS**

**FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.**

**For *in vitro* Diagnostic Use**

**These Instructions for Use and the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro Instructions for Use must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result. Before proceeding with testing, all operators MUST read and become familiar with Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.' These Kit Controls do not contain live virus and are formulated with non-infections materials.**

### NAME AND INTENDED USE

The IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro Kit Controls are intended as an external quality control reagents to monitor the performance of the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro with direct anterior nasal samples. For use only with the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro.

### Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (35°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies.

It is the responsibility of each laboratory using the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro Kit Controls are formulated using a nucleocapsid recombinant antigen in a buffered solution. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The COVID-19 Positive Control will produce a reddish-purple line at the Test (T) Zone. The COVID-19 Negative Control will generate a negative test result (no line at the T Zone). Both controls will produce a reddish-purple line in the Control (C) Zone. Refer to *Test Result and Interpretation of Test Result* section of the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro Instructions for Use. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro.

Item# 3001-3354-70  
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## MATERIALS PROVIDED

### IntelliSwab® COVID-19 Rapid Test Pro Kit Controls

Each Kit Control box contains an IFU and two vials (one COVID-19 Positive Control and one COVID-19 Negative Control) as described below:

#### COVID-19 Positive Control

One blue-capped vial containing 0.25 mL of SARS-CoV-2 nucleocapsid recombinant antigen diluted in Phosphate-Buffered Saline with EDTA and Goat Serum. Preservative: 2-methyl-4-isothiazolin-3-one.

#### COVID-19 Negative Control

One white-capped vial containing 0.25 mL of Phosphate-Buffered Saline with 1% Bovine Serum Albumin. Preservative: 2-methyl-4-isothiazolin-3-one.

Specimen Collection Loops

## MATERIALS REQUIRED AND PROVIDED in the IntelliSwab® COVID-19 Rapid Test Pro Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial  
Test Stands  
Instructions for Use

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 minutes  
Latex, vinyl, or nitrile disposable gloves  
Biohazard waste container

## WARNINGS

### For *in vitro* Diagnostic Use

- These Instructions for Use must be read completely before using the product.
- Follow the instructions carefully when performing the IntelliSwab® COVID-19 Rapid Test Pro. Failure to do so may cause an inaccurate test result.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; for use by laboratories certified under CLIA 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.
- 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. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner
- Before proceeding with testing, all study personnel MUST read and be familiar with Universal Precautions<sup>2</sup> and Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)<sup>1</sup>.

## PRECAUTIONS

### Safety Precautions

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the IntelliSwab® COVID-19 Rapid Test Pro.

## STORAGE INSTRUCTIONS

Store the IntelliSwab® COVID-19 Rapid Test Pro Kit Controls at 2°-8°C (35°-46°F). Do not use the Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°-8°C (35°-46°F) after use. Once opened, Kit Controls should be discarded after one week.

## DIRECTIONS FOR USE

### General Test Preparation

Perform procedures according to the *General Test Preparation* section of the IntelliSwab® COVID-19 Rapid Test Pro IFU.

## TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used loop in a waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Vial containing the specimen. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer Vial.**
5. Leave the Test Device in the Developer Solution Vial and start a timer. Do not remove the Test Device from the vial until you have read the results. Read the results in a fully lighted area after 30 minutes, but no more than 40 minutes. Read the results as described in the *Test Result and Interpretation of Test Result* section of the IntelliSwab® COVID-19 Rapid Test Pro Kit IFU.
6. Dispose of the used test materials in a waste container.

## EXPECTED RESULTS

### COVID-19 Negative Control

The COVID-19 Negative Control will produce a Negative test result. A single line should be present in the Result Window in the Control (C) Zone and NO line should be present in the Test (T) Zone. This indicates a Negative test result.

### COVID-19 Positive Control

The COVID-19 Positive Control will produce a Positive test result and has been manufactured to produce a very faint line at the Test (T) Zone. Two lines should be present in the Result Window. A line in the Control (C) Zone and a line in the Test (T) Zone should be present. This indicates a Positive test result. The lines will not necessarily be the same intensity.

**NOTE: If the test result for either the COVID-19 Negative Control or the COVID-19 Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen.** Contact OraSure Technologies' Customer Care if the Kit Control reagents do not produce the expected result.

## LIMITATIONS

The IntelliSwab® COVID-19 Rapid Test Pro Kit Controls are quality control reagents for use only with the IntelliSwab® COVID-19 Rapid Test Pro.