InteliSwab®
COVID-19 *RAPID TEST* • Pro

Healthcare Provider Instructions for Use

For Emergency Use Authorization
For *In Vitro* Diagnostic Use

INTENDED USE (IU)

The InteliSwab® COVID-19 Rapid Test Pro is a single-use lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 2 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The InteliSwab® COVID-19 Rapid Test Pro does not differentiate between SARS-CoV-1 and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen.

The SARS-CoV-2 nucleocapsid protein is generally detectable in anterior nasal samples during the acute phase of infection. Positive results indicate that viral antigens have been detected, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not exclude bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

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

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 InteliSwab® 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 InteliSwab® 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 InteliSwab® 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 InteliSwab® 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.

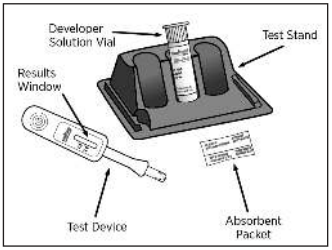
Further up the test strip, the sample will encounter the Control (C) Zone. This is a built-in procedural control which serves to demonstrate that the fluid migrated through the test device. For negative results and most positive results a line will form at the Control (C) Zone. In some cases when viral 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

InteliSwab® 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

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

InteliSwab® COVID-19 Positive Control (1 vial, blue cap, 0.25 mL)
InteliSwab® COVID-19 Negative Control (1 vial, white cap, 0.25 mL)
Loops (package of 5µL loops)
Instructions for use for InteliSwab® COVID-19 Rapid Test Pro Kit Controls

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

InteliSwab® COVID-19 Limit of Detection (1 device)
InteliSwab® COVID-19 Low Positive (1 device)
InteliSwab® COVID-19 Negative (1 device)
Instructions for Use for InteliSwab® 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[1] when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE)[2] 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.poisonhelp.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-regualtory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: 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.

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 InteliSwab® 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 InteliSwab® 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

InteliSwab® COVID-19 Rapid Test Pro Kit Controls are for use with the InteliSwab® COVID-19 Rapid Test Pro. The InteliSwab® 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 InteliSwab® 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 InteliSwab® 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 2º-30ºC (36º-86ºF), 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 InteliSwab® 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 InteliSwab® 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 InteliSwab® COVID-19 Visual Reference Panel is available separately for use with the InteliSwab® COVID-19 Rapid Test Pro. The InteliSwab® 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 InteliSwab® COVID-19 Visual Reference Panel prior to using the InteliSwab® 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 InteliSwab® 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 InteliSwab® 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 InteliSwab® COVID-19 Rapid Test Kit Pro Controls should be run.

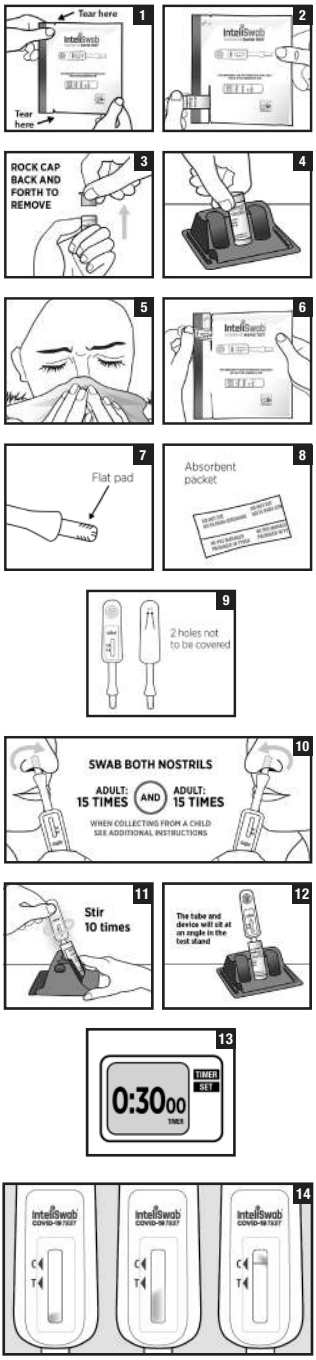
SPECIMEN COLLECTION AND TEST PROCEDURE

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.

    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**.

    If you DO NOT swab BOTH nostrils 15 times (adult) OR 4 times (CHILD), you may get a false result.
11. 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.
12. 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.
13. 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.
14. 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.

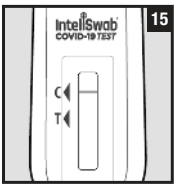
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19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



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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.

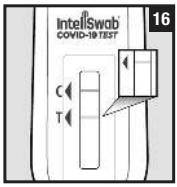
All negative results should be treated as presumptive and confirmation testing with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence 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

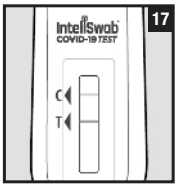
COVID-19 POSITIVE (+)

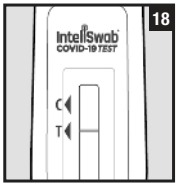
A test is **Positive** if:

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).

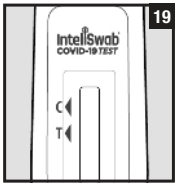
Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the InteliSwab® COVID-19 Rapid Test Pro should self-isolate. Additional confirmatory testing with a molecular test for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

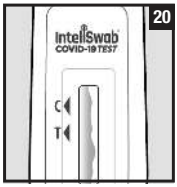
INVALID

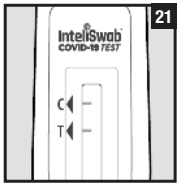
A test is **Invalid** and requires re-testing with a new test device if any of the following occurs:

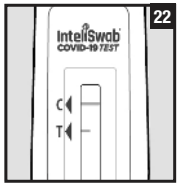
- **NO** lines appear on the device *(see picture 19)*, or
- a reddish-purple background in the Result Window makes it difficult to read the result after 30 minutes *(see picture 20)*, or
- any partial line on one side of the C or T Zones (*see pictures 21 and 22)*

An **Invalid** test result means that there was a problem running the test. **An Invalid result <u>cannot be interpreted</u>. 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 InteliSwab® 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 InteliSwab® 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: customercare@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 InteliSwab® 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 InteliSwab® 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 InteliSwab® COVID-19 Rapid Test Pro when conducted by a lay user correctly identified 85% of positive samples. Additionally, the InteliSwab® 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
Total	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
Total	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
Total	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 InteliSwab® 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 InteliSwab® COVID-19 Rapid Test LoD was confirmed to be 2.5 x 10^2 $TCID_{50}$/mL (8.0 X 10^5 GC/mL). Based upon the testing procedure for this study the LoD of 2.5 x 102 $TCID_{50}$/mL equates to 12.5 $TCID_{50}$/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 InteliSwab® 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 InteliSwab® 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)	InteliSwab® 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 X 10^5 $TCID_{50}$/mL
	Human metapneumovirus (hMPV)	Zeptometrix 0810157CF	1.43 X 10^5 $TCID_{50}$/mL
	Rhinovirus	ATCC VR-1601	4.45 X 10^5 $TCID_{50}$/mL
	Enterovirus 68	ATCC VR-1826	8.0 X 10^5 $TCID_{50}$/mL
	Human Coronavirus OC43	Zeptometirx 0810024CF	1.43 X 10^5 $TCID_{50}$/mL
	Human Coronavirus 229E	ATCC VR-740	1.43 X 10^5 $TCID_{50}$/mL
	Human Coronavirus NL63	BEI Resources	1.43 X 10^5 $TCID_{50}$/mL
	SARS-coronavirus	MRI Urbani	7.9 X 10^3 $TCID_{50}$/mL
	MERS-coronavirus	MRI EMC/2012	2.5 X 10^4 $TCID_{50}$/mL
	Parainfluenza virus 1	ATCC VR-94	1.43 X 10^5 $TCID_{50}$/mL
	Parainfluenza virus 2	ATCC VR-92	1.43 X 10^5 $TCID_{50}$/mL
	Parainfluenza virus 3	ATCC VR-93	1.43 X 10^5 $TCID_{50}$/mL
	Parainfluenza virus 4b[a]	Zeptometrix 0810060BCF	8.5 X 10^4 $TCID_{50}$/mL

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

[a] Used for Exclusivity Testing

[b] 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 InteliSwab® COVID-19 Rapid Test Pro, however, cross-reactivity cannot be ruled out.

High Dose Hook Effect

Potential hook effect in the InteliSwab® 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 1.0×10^5 $TCID_{50}$/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 InteliSwab® 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 presences of SARS-CoV-2 (3x LoD). None of the substances listed in the tables below interfered with the performance of the InteliSwab® 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 (NeilMed)	NeilMed	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

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number		Manufacturer
	Caution, Consult Accompanying Documents	PN	Part Number
	Use By		Temperature Limitation
	Prescription Use		

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OraSure Technologies, Inc.

220 East First Street,
Bethlehem, PA 18015 USA
(800) ORASURE (800-672-7873)
(610) 882-1820
www.OraSure.com
www.OraSure.com / www.InteliSwab.com

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

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