InteliSwab™
COVID-19 RAPID TEST • Pro

Rx

Instructions for Use

For Emergency Use Authorization
For *In Vitro* Diagnostic Use

NAME AND INTENDED USE

The InteliSwab™ COVID-19 Rapid Test Pro is a single-use lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 15 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The SARS-CoV-2 nucleocapsid protein is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate that viral antigens have been detected, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not exclude bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

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

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

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

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 for 14 days. 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.

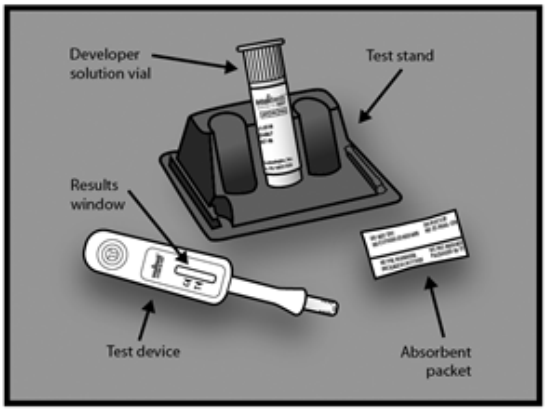
An anterior nasal sample is collected using the flat pad that is integrated into the test device, followed by swirling the test device in the vial of developer solution. The developer solution facilitates the flow of the sample into the device and onto the test strip. As the sample flows through the 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 5 µL 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 AND PRECAUTIONS

- **For prescription use only.**
- **The product has not been FDA cleared or approved; but has been authorized by FDA under EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.**
- **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.**
- **The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19**

under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

- **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.**
- **This test is for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.**
- **Laboratories within the United States and its territories are required to report all results to the appropriate public health agencies.**
- **Do not use test kit if it is past the expiration date.**
- **Follow the Instructions for Use to obtain accurate results. Incorrect sampling may result in false results.**
- **False Negative results can occur if negative results are read before 30 minutes.**
- **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.**

Device Handling Precautions

- **Do not reuse** the Test Device and Developer Solution Vial.
- Inspect the Divided Pouch. If the Divided Pouch has been damaged, discard the Divided Pouch and its contents and select a new Divided Pouch for testing.
- Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
- 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.
- The solution in the tube contains potentially harmful chemicals (Triton X-100 and ProClin 950); however, laboratory studies have shown them to be nontoxic at the levels contained in the solution. The developer solution should only be used as directed; do not ingest; keep out of the reach of children; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

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 this Package Insert). 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 Ora Sure 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.

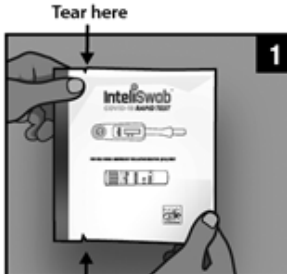
INSTRUCTIONS FOR USE

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.

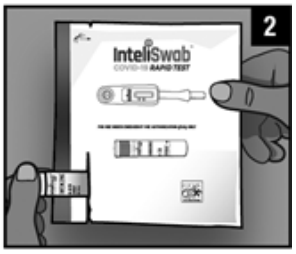
SPECIMEN COLLECTION AND TESTING PROCEDURE

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

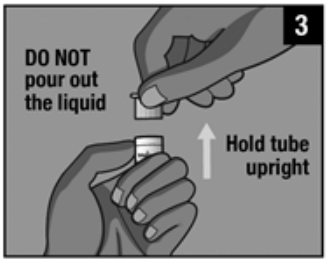


1. Open the two chamber pouch by tearing at the notches on the top of each side of the Pouch (*see picture 1*).

2. Remove the Developer Solution Vial ("Vial") from the Pouch *(see picture 2)*.



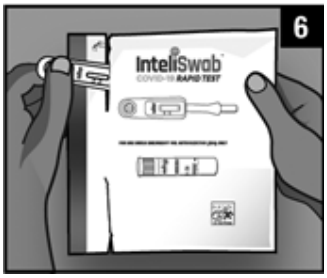
3. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off *(see picture 3)*.



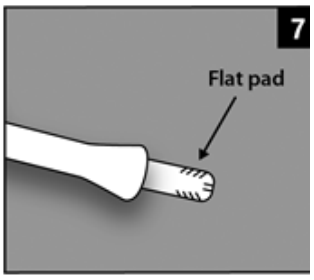
4. Slide the Vial into the top of one of the slots in the Test Stand. **DO NOT** force the Vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the Test Stand (*see picture 4*). If solution spills out of the vial, 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.

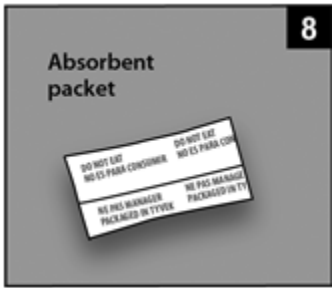
6. Have the individual remove the Device from its Pouch (*see picture 6*).



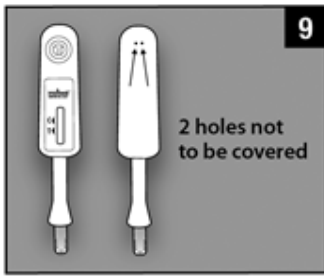
7. **DO NOT** allow the individual to touch the Flat Pad (*see picture 7)*.



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.

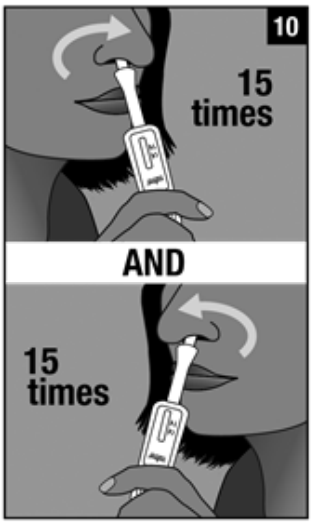


9. **DO NOT** cover the two holes on the back of the Device with labels or other materials. Doing so may cause invalid results (*see picture 9*).

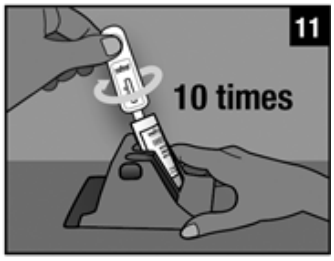


10. Direct the individual to place the Flat Pad of the Device into the nostril, firmly pressing the pad against the nasal wall rotating the pad 15 times. Ensure the individual swabs both nostrils 15 times (*see pictures 10)*. **If you do not swab both nostrils 15 times each, you may get a false result.**

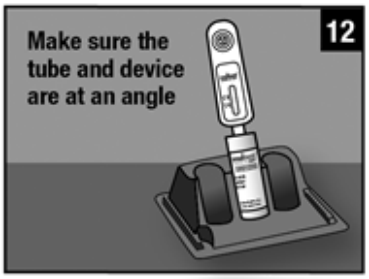
Note: Proceed by swabbing the individual, if they are unable to swab themselves.



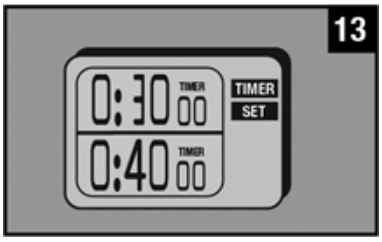
11. Keep the Test Stand on the flat surface, insert the Device into the Vial and swirl the Device 10 times while making sure the Flat Pad is in the solution. Make sure the flat pad is toward the back of the tube so it contacts the liquid. (*see picture 11*). Swirling the device less than 10 times may 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.

NEGATIVE

A test is **Negative** if:

A reddish-purple line appears in the C Zone and NO line appears in the T Zone (*see picture 15*). The line in the C Zone must be present to interpret a negative test result.

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

Negative results do not rule out SARS-CoV-2 infection. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 36 hours between tests. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. 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.

POSITIVE

A test is **Positive** if:

A reddish-purple line appears in the T Zone and there is a line in the C Zone. Lines may vary in intensity. The test is positive regardless of how faint these lines appear (*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*).

A Positive test result is interpreted as nucleocapsid protein antigen was detected in the specimen. The individual is positive for COVID-19. 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** 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. A negative test result may occur if the level of antigen in a sample is below the limit of detection of the test.
2. Weak Positive samples may take longer to develop and can take the entire 30 minutes for a test line to be present. Therefore, all negative test results must be read at least 30 minutes after inserting the device into the developer vial. Negative test results must not be reported prior to reading the device at 30 minutes.
3. Reading any result after 40 minutes may yield inaccurate test results.
4. The control line only indicates that reagents have properly migrated up the test device. In positive patient samples with high levels of virus, the line at the Control (C) Zone may not be present or may be very faint. The control line does not indicate that an adequate human sample was added to the test device.
5. Positive test results do not rule out co-infections with other pathogens.
6. Potential cross reactivity of the InteliSwab™ COVID-19 Rapid Test with COVID-19 vaccines or therapeutics has not been evaluated.
7. False negative results may occur if a specimen is improperly collected or handled.
8. False negative results are more likely after seven days or more of symptoms.
9. Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
10. Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 36 hours between tests has not been determined, a study to support use will be completed.
11. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
12. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in February and April 2021. The clinical performance has not been established in 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.

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 Ora Sure 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. Ora Sure Technologies, Inc., authorized distributor(s) 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. The InteliSwab™ COVID-19 Rapid Test Pro test results were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. The InteliSwab™ COVID-19 Rapid Test Pro when conducted by a lay user correctly identified 84% of positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test Pro correctly identified 98% of negative samples. The COVID-19 infection rate was 35% (51/146) in this study. The performance is shown in the following table.

InteliSwab™ COVID-19 Rapid Test Pro	**Comparator Method**		
	Positive	**Negative**	**Total**
Positive	43	2	45
Negative	8	93	101
Total	51	95	146
Positive Percent Agreement (PPA):	43/51 84%	(95% CI: 71%, 92%)	
Negative Percent Agreement (NPA):	93/95 98%	(95% CI: 93%, 99%)	

Samples Positives by InteliSwab COVID-19 Rapid Test Pro by Age Group			
	Positivity Rate		
Age Group	Number of Specimens	Number of Positives	Positivity Rate
15 to 17	5	4	80%
18 to 23	21	7	33.3%
24 to 64	111	33	29.7%
65+	9	1	11.1%
Total	146	45	30.8%

Samples Positives by InteliSwab COVID-19 Rapid Test Pro by Days Since Symptom Onset	
Days Since Symptom Onset	PPA with 95% CI
0-1	90.9% (10/11) (95% CI:62.3%-98.4%)
0-2	90% (18/20) (95% CI:69.9%-97.2%)
0-3	79.4% (27/34) (95% CI:63.2%-89.7%)
0-4	81.4% (35/43) (95% CI:67.4%-90.3%)
0-5	83.3% (40/48) (95% CI:70.4%-91.3%)
0-6	84% (42/50) (95% CI:71.5%-91.7%)
0-7	84.3% (43/51) (95% CI:72%-91.8%)

ANALYTICAL PERFORMANCE

Limit of Detection (LoD)

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 Pro. 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 Pro LoD was confirmed to be 2.5×10^2 $TCID_{50}$/mL (8.0×10^5 GC/mL). In addition, the LoD of the assay was also determined for the variants in the table below:

Variant	Source/Stock/Strain	$TCID_{50}$/mL
UK Variant: USA/CA_CDC_5574/2020 isolate (B.1.1.7 lineage)	BEI NR-54011	2.8×10^3
South Africa Variant: hCoV-19/South Africa/KRISP-K005325/2020 (B.1.351 lineage)	BEI NR-54009	2.72×10^4
Brazil Variant: hCoV-19/Japan/TY7-503/2021 (P.1 lineage)	BEI NR-54982	5.91×10^4

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 10^5 $TCID_{50}$/mL
	MERS-coronavirus	MRI EMC/2012	2.5 X 10^4 $TCID_{50}$/mL

Potential Cross Reactant		Sources/Strain/ID No.	Concentration Tested
Virus	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
	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 IFU/mL
	Haemophilus influenzae	ATCC 49247	1.0 X 10^7 cfu/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

Usability Study

The usability of the InteliSwab™ COVID-19 Rapid Test Pro and the ability of the packaging and labeling to direct untrained users to perform self-testing was evaluated by observation in the clinical study and an additional usability study. A total of 288 subjects were enrolled in the study and were instructed to self-collect or collect a sample from a child, complete the required procedural steps, and interpret the test results unassisted in a simulated home-setting. The overall success of every task completed by all subjects enrolled was determined by unassisted professional observation. Subjects performed 95% (4423/4636) of steps/tasks correctly.

After the completion of the test, the subject (or Parent/Legal Guardian) completed a test usability and satisfaction questionnaire, 99% of subjects indicated that their overall impression of the test was satisfactory or favorable. 98% of subjects found this test to be easy-to-use across 8 different ease of use survey questions. Additionally, 99% of subjects indicated specifically that it was easy to read and understand the test results.

During the usability study, 1.2% of subjects received an invalid result or did not receive a result when conducting the test.

BIBLIOGRAPHY

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.

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
Rx	Prescription Use		

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

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

Item# 3001-3455– rev. 05/21

QUICK REFERENCE GUIDE

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

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

LEARN MORE

ENGLISH

InteliSwab™ COVID-19 RAPID TEST • Pro

HOW TO USE THE INTELISWAB™ COVID-19 RAPID TEST

1

YOU WILL NEED A WAY TO TIME THE TEST.

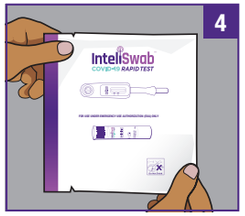
2

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

3

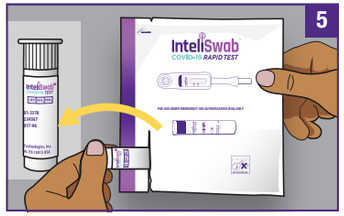
Kit contains: two-part **pouches** (containing 1 developer solution vial, 1 test device and 1 preservative), **test stands, Instructions for Use** and this **Quick Reference Guide.**

4



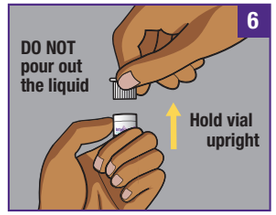
Pick up one of the two-part **pouches**.

5



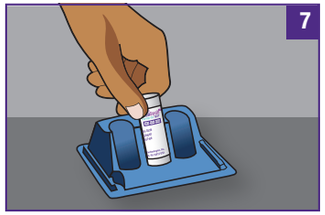
Tear open the pouch containing the vial and remove.

6



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

7

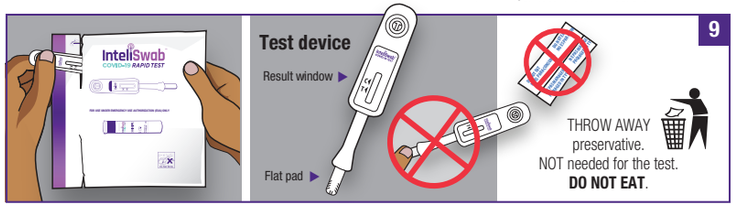


Slide the vial into the test stand on a **flat sturdy surface. DO NOT** force from the front as splashing may occur. Vial should rest at an angle on the **bottom** of the stand. If the solution spills you will need a new test.

8

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

9



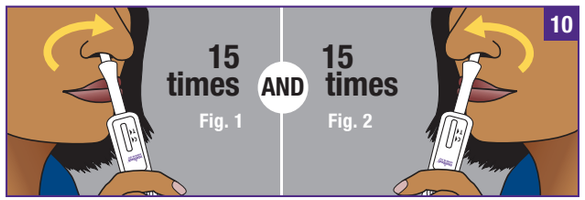
Tear open the pouch containing the **test device** and remove.

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

DO NOT eat or swallow the preservative.

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

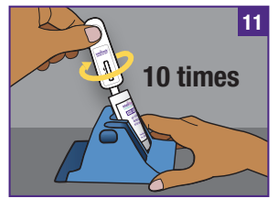
10



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

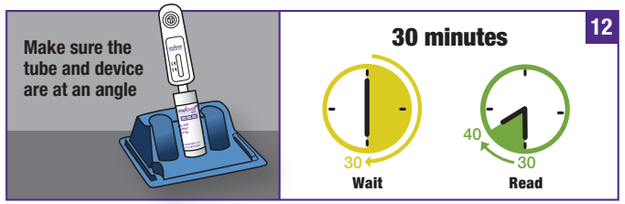
If you do not swab both nostrils 15 times each, you may get a false result.

11



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

12



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

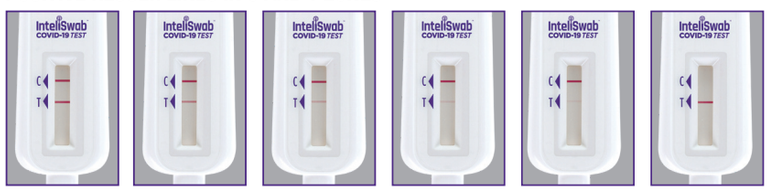
Read results between 30 and 40 minutes. To obtain an accurate result, **DO NOT** read **before** 30 minutes or **after** 40 minutes.

Reading before 30 minutes may cause false negative results.

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

Note: The line next to the "C" does not show that an adequate sample has been collected.

POSITIVE RESULT: LINES IN C AND T ZONES



The test is **POSITIVE** if:

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

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

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

NEGATIVE RESULT: LINE IN C ZONE

READING BEFORE 30 MINUTES MAY CAUSE A FALSE NEGATIVE RESULT.

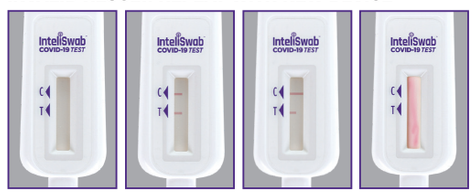
The test is **NEGATIVE** if:

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

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

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

INVALID RESULT: REPEAT WITH NEW DEVICE



The test is not working and should be repeated if:

- no lines are present
- the test line or control line is not complete (all the way across the window), or
- a reddish-purple background makes it impossible to read the test after 30 minutes

You will need to obtain another test.

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

GENERAL TEST CLEAN-UP

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

Do NOT Reuse

INTENDED USE

The InteliSwabCOVID-19 Rapid Test Pro is a single-use lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 15 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

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

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

IMPORTANT DO'S AND DON'TS

DO:

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

DO NOT:

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

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

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

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

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

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

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

FREQUENTLY ASKED QUESTIONS

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

What are common symptoms of COVID-19? Symptoms of COVID-19 may appear 2-14 days after exposure and may include fever, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, or a runny nose, nausea or vomiting and diarrhea. It is also possible for someone infected with COVID-19 to have no symptoms.

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

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

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

Potential risks include:
Possible discomfort during sample collection.

Possible incorrect results.

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

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

How accurate is the InteliSwab™ COVID-19 Rapid Test Pro? The InteliSwab™ COVID-19 Rapid Test Pro is a lateral flow *in vitro* diagnostic antigen test to detect COVID-19. Antigen tests are designed to detect active infection in individuals. A clinical study was conducted during February and April of 2021 to determine the performance of the InteliSwab™ COVID-19 Rapid Test Pro. A total of 146 individuals with signs and symptoms of COVID-19 within the first 7 days of symptom onset were enrolled across 5 different locations in the US. Subjects 18 years or older independently collected the lower nasal sample and completed the home use test. The InteliSwab™ COVID-19 Rapid Test Pro results were compared to highly sensitive molecular FDA Authorized SARS-CoV-2 assays to determine test performance. The InteliSwab™ COVID-19 Rapid Test Pro correctly identified 84% of the positive samples. Additionally, the InteliSwab™ COVID-19 Rapid Test correctly identified 98% of negative samples.

What if the test is positive?
A positive result means that it is very likely the patient has COVID-19. They should isolate yourself at home to avoid spreading the virus to others.

There is a very small chance that this test can give a positive result that is wrong (false positive).

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

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

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

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

Why is there a test line and no control line? If you see a test line and no control line, the test is positive. When the level of virus in the sample is high, the line next to the "C" may not be present or may be very faint. The line next to the "C" must be visible to read a negative test result. Please see the other side of this Quick Reference Guide or the full Instructions for Use to help you understand how to interpret test results.

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

Is the solution in the vial harmful? No. The solution in the vial contains potentially harmful chemicals (Triton X-100 and ProClin 950); however, laboratory studies have shown them to be nontoxic at the levels contained in the solution. The developer solution should only be used as directed; do not ingest; keep out of the reach of children; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222.

SWAB
both nostrils

SWIRL
in the vial

SEE
your results

EXPLANATION OF SYMBOLS

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

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

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

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

LEARN MORE:

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

3001-3538 rev 06/21

BIBLIOGRAPHY

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

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

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Item# 3001-3354 rev. 05/21B

InteliSwab™ 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 InteliSwab™ 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.[1] These Kit Controls do not contain live virus and are formulated with non-infections materials.

NAME AND INTENDED USE

The InteliSwab™ COVID-19 Rapid Test Pro Kit Controls are intended as an external quality control reagents to monitor the performance of the InteliSwab™ COVID-19 Rapid Test Pro with direct anterior nasal samples. For use only with the InteliSwab™ 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 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.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The InteliSwab™ COVID-19 Rapid Test Pro Kit Controls are formulated using a nucleocapsid recombinant antigen in a PBS+1% BSA 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 InteliSwab™ 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 InteliSwab™ COVID-19 Rapid Test Pro.

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MATERIALS PROVIDED

InteliSwab™ 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 1% Bovine Serum Albumin. 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 InteliSwab™ 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 InteliSwab™ 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[2] and Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)[1].**

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 InteliSwab™ COVID-19 Rapid Test Pro.

STORAGE INSTRUCTIONS

Store the InteliSwab™ COVID-19 Rapid Test Pro Kit Controls at 2°-8°C (36°-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°C-8°C (36°-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 InteliSwab™ 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 InteliSwab™ 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 InteliSwab™ COVID-19 Rapid Test Pro Kit Controls are quality control reagents for use only with the InteliSwab™ COVID-19 Rapid Test Pro.

BIBLIOGRAPHY

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

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

For Technical or Customer Service within the United States, phone (800) ORASURE (800-672-7873).
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Item# 3001-3357 rev. 05/21B

InteliSwab™
COVID-19 *RAPID TEST* • Pro

VISUAL REFERENCE PANEL

Item# 3001-3357-70
rev. 05/21B

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.
For *in vitro* Diagnostic Use

All new operators must be able to correctly interpret all devices provided within the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel prior to using the InteliSwab™ COVID-19 Rapid Test Pro.

Failure to read at 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.

These Instructions for Use and the InteliSwab™ 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.

NAME AND INTENDED USE

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is comprised of InteliSwab™ COVID-19 Rapid Test Pro devices that have been designed to represent reading intensities of limit of detection, low positive, and negative test results. The limit of detection test device is indicative of specimens with antigen levels at the limit of detection of the device.

It is the responsibility of each laboratory using the InteliSwab™ COVID-19 Rapid Test Pro to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator's ability to read visual intensities at the Test (T) Zone at all levels including very weak lines representing low antigen levels.

SUMMARY AND EXPLANATION OF THE COVID-19 VISUAL REFERENCE PANEL

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low positive, and negative test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The COVID-19 Limit of Detection Device has a very faint reddish-purple line at the Test (T) Zone. The COVID-19 Low Positive Device has a reddish-purple line at the Test (T) Zone. The COVID-19 Negative Device does not have a line at the Test (T) Zone. All devices have a reddish-purple line at the Control (C) Zone. Refer to Test Result and Interpretation of Test Result section of the InteliSwab™ COVID-19 Rapid Test Pro Instructions for Use on how to interpret the devices.

This panel is to be used to assist new operators with becoming proficient at reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro results at or near the limit of detection of the device. The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro devices. Any line at the Test (T) Zone is considered a positive result regardless of how faint the line appears.

MATERIALS REQUIRED AND PROVIDED in the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel

- Foil Pouch containing three predetermined InteliSwab™ COVID-19 Rapid Test Pro devices representing limit of detection, low positive and negative test results as described below.

  1. COVID-19 Limit of Detection Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured at a predetermined reactivity level to produce a positive test result consistent with the limit of detection of the device.

  2. COVID-19 Low Positive Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured at a predetermined reactivity level to produce a positive test result.

  3. COVID-19 Negative Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured to produce a negative test result.

- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Latex, vinyl, or nitrile disposable gloves

WARNINGS

For *in vitro* Diagnostic Use

- **These Instructions for Use must be read completely before using the product.**
- **Adequate lighting is required for reading and interpreting the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel and the InteliSwab™ COVID-19 Rapid Test Pro.**
- **Follow the Test Result and Interpretation of Test Result section of the InteliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.**
- **The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel when stored protected from light (either pouched or unpouched) is stable through the expiration date printed on the pouch. If not protected from light or stored above indicated temperature, the unpouched device should be discarded after 15 days.**
- **The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro devices. Any line at the Test (T) Zone is considered to be a positive result regardless of how faint the line appears.**
- **All testing MUST be conducted under appropriate biosafety conditions in accordance with CDC guidelines.[1] All study personnel conducting testing MUST read and be familiar with Universal Precautions.[2]**
- **This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA 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.**

PRECAUTIONS

Safety Precautions

- The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel does not contain potentially infectious materials. Hazardous disposal is only required if used in areas containing infectious materials.

- Use of Visual Reference Panels manufactured by any other source will not meet the requirements for an adequate quality assurance program for the InteliSwab™ COVID-19 Rapid Test Pro.

STORAGE INSTRUCTIONS

Store the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel at 15°-30°C (59°-86°F). Do not use the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel pouch only when qualifying new operators in interpreting test results. Reseal and store the devices in their original foil pouch at 15°-30°C (59°-86°F) after use. If not protected from light or stored above the indicated temperatures, the un-pouched device should be discarded after 15 days.

DIRECTIONS FOR USE

Test Procedure

Note: The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the InteliSwab™ COVID-19 Rapid Test Pro occurs.

1. Open the foil pouch containing the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel.
2. Pull out the three devices contained within the foil pouch.
3. Note the date the pouch was opened on the device labels or the pouch label.
4. Follow the Test Result and Interpretation of Test Result section of the InteliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.
5. Store the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel Devices in the original re-sealable foil pouch at 15-30°C (59-86°F).

EXPECTED RESULTS

COVID-19 Limit of Detection Device

The COVID-19 Limit of Detection Device has been manufactured to have a very faint reddish-purple line at the Test (T) Zone. A reddish-purple line should be present in the Result Window in both the Control (C) Zone and the Test (T) Zone. This indicates a weakly positive test result consistent with the limit of detection of the device. The Control (C) Zone and the Test (T) Zone lines will not be the same intensity.

COVID-19 Low Positive Device

The COVID-19 Low Positive Device has been manufactured to have a reddish-purple line at the Test (T) Zone. A reddish-purple line should be present in the Result Window in both the Control (C) Zone and the Test (T) Zone. This indicates a positive test result. The Control (C) Zone and the Test (T) Zone lines will not be the same intensity.

COVID-19 Negative Device

The COVID-19 Negative Device has been manufactured to have a line at the Control (C) Zone. 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.

NOTE: If a new operator is unable to interpret all devices provided as part of the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel, they are not considered to be proficient at reading and interpreting the InteliSwab™ COVID-19 Rapid Test Pro. Failure to read at 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.

LIMITATIONS

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is for use only with the InteliSwab™ COVID-19 Rapid Test Pro.