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.

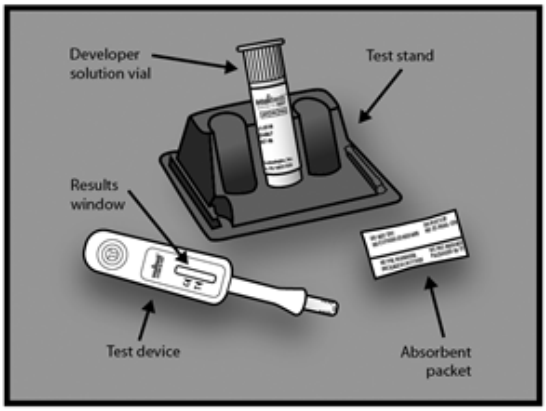
An anterior nasal sample is collected using the flat pad that is integrated into the test device, followed by swirling the test device in the vial of developer solution. The developer solution facilitates the flow of the sample into the device and onto the test strip. As the sample flows through the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

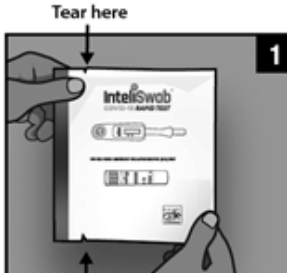
Follow *Safety Precautions* section in these Instructions for Use.

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.

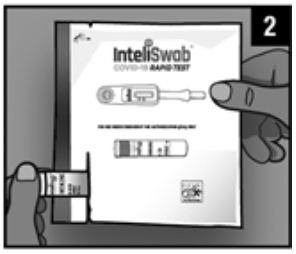
SPECIMEN COLLECTION AND TESTING PROCEDURE

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

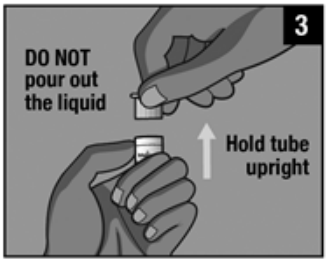
1. Open the two chamber pouch by tearing at the notches on the top of each side of the Pouch (*see picture 1*).



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



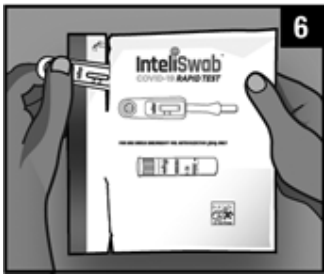
3. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off *(see picture 3*).



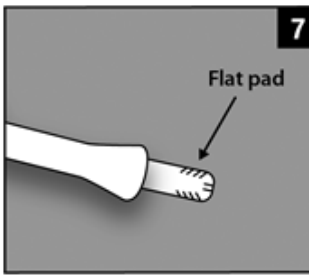
4. Slide the Vial into the top of one of the slots in the Test Stand. **DO NOT** force the Vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the Test Stand (*see picture 4*). If solution spills out of the vial,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

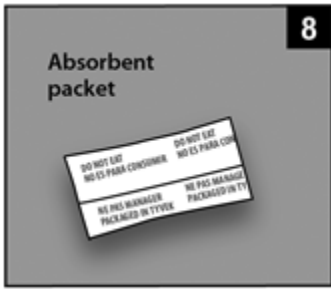
6. Have the individual remove the Device from its Pouch (*see picture 6*).



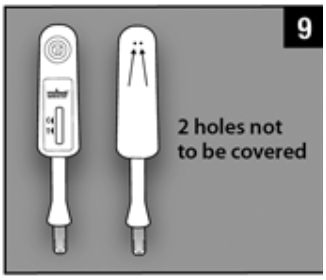
7. **DO NOT** allow the individual to touch the Flat Pad (*see picture 7).*



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.

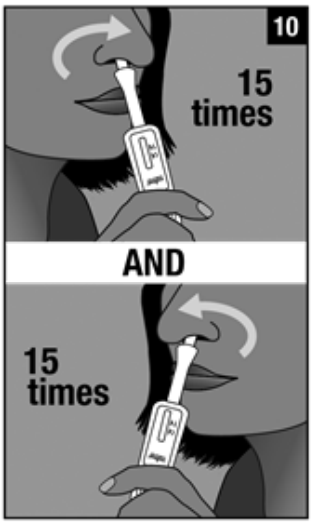


9. **DO NOT** cover the two holes on the back of the Device with labels or other materials. Doing so may cause invalid results (*see picture 9*).

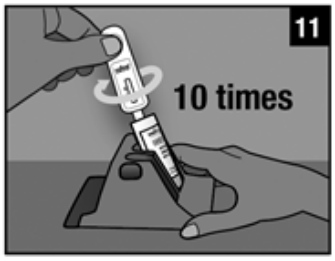


10. Direct the individual to place the Flat Pad of the Device into the nostril, firmly pressing the pad against the nasal wall rotating the pad 15 times. Ensure the individual swabs both nostrils 15 times (*see pictures 10).* **If you do not swab both nostrils 15 times each, you may get a false result.**

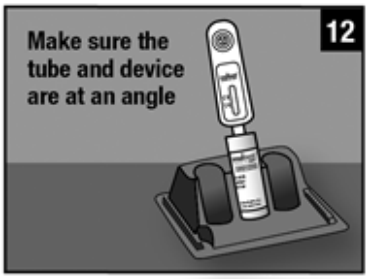
Note: Proceed by swabbing the individual, if they are unable to swab themselves.



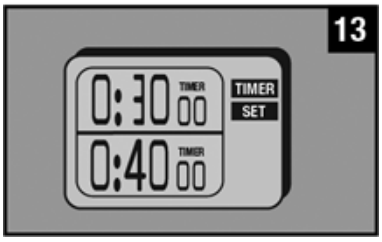
11. Keep the Test Stand on the flat surface, insert the Device into the Vial and swirl the Device 10 times while making sure the Flat Pad is in the solution. Make sure the flat pad is toward the back of the tube so it contacts the liquid. (*see picture 11*). Swirling the device less than 10 times may 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 <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. 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 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., 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 10^3 $TCID_{50}$/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		

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