

One by Prism

112 Church Street
Elkin, NC 28621
Phone: (877) 200-8968
Email: Ecommerce@onebyprism.com



PLEASE READ THIS COVID-19 TEST KIT NOTICE CAREFULLY BEFORE PURCHASING ANY TEST KITS (DEFINED BELOW). THE TEST KITS HAVE BEEN AUTHORIZED BY THE FDA UNDER AN EMERGENCY USE AUTHORIZATION (THE “EUA”). THE EUA AND THIS NOTICE CONTAINS VERY IMPORTANT INFORMATION ABOUT CUSTOMER’S OBLIGATIONS, INCLUDING WITH RESPECT TO THE CLINICAL ADMINISTRATION OF THE TEST KITS.

Information Relating to the Test Kits and Conditions of Use

- a. The IntelliSwab™ COVID-19 Rapid Test (“Test Kits”), manufactured by OraSure Technologies, Inc. are indicated for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests. These Test Kits are authorized for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals 15 years or older.
- b. A copy of the EUA for the Test Kits is attached hereto as **Exhibit A**.
- c. The Test Kits have not been FDA cleared or approved. The Test Kits have been authorized by the FDA under an EUA for non-prescription home use.
- d. Emergency use of these Test Kits 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The Test Kits have been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- e. Please notify ONE by Prism of any complaints about the Test Kits via telephone at (877) 200-8968.
- f. Please note that you are obligated to use each Test Kit that you purchase solely in compliance with the conditions of the EUA and emergency authorization or clearance associated with such Test Kit.
- g. Please keep all records associated with the Test Kits, if required by the EUA until otherwise notified by the FDA.
- h. Please review the “IntelliSwab™ COVID-19 Rapid Test Instructions for Use,” the “IntelliSwab™ COVID-19 Rapid Test Positive Test Results Additional Reference Images,” the Fact Sheet for Individuals, the Fact Sheet for Healthcare Professionals, and the IntelliSwab COVID-19 Rapid Test box label, which are available on the ONE by Prism website, onebyprism.com
- i. By purchasing the Test Kits, you agree to look solely to OraSure Technologies, Inc. for any claims related to defect or breach of warranty. ONE by Prism shall have no obligation or liability to take back or replace any Test Kits. **The Test Kits are not returnable and purchase orders are non-cancellable.**
- j. If you would like a hard copy of the EUA for the Test Kits or related documentation, please email a request to Ecommerce@onebyprism.com. In the request please include Your Name, the Name of the Lab, Your Customer Account Number, Full mailing address, Contact to address the mailing to, and Contact phone number.

EXHIBIT A

Emergency Use Authorization

(Starts on Following Page)



June 4, 2021

Tiffany Miller
VP Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Device: IntelliSwab COVID-19 Rapid Test
EUA Number: EUA210378
Company: OraSure Technologies, Inc.
Indication: Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older.

Dear Ms. Miller:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared 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 subject to the terms of any authorization issued under Section 564(a) of the Act.³

¹ For ease of reference, this letter will use the term “you” and related terms to refer to OraSure Technologies, Inc.

² For ease of reference, this letter will use the term “your product” to refer to the IntelliSwab COVID-19 Rapid Test used for the indication identified above.

³ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the “InteliSwab COVID-19 Rapid Test Healthcare Provider Instructions for Use” (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁴

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product 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 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older. Your product does not differentiate between SARS-CoV-1 and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease.

⁴ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

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

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

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Your product is performed using anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older. First, the individual sets the Test Stand on a sturdy surface, before opening the test kit pouch. The cap is then removed from the Developer Solution Vial which is then inserted into the Test Stand. After the individual blows their nose the Flat Pad of the Test Device is inserted into one nostril and rotated 15 times before repeating in the second nostril. The Test Device is then insert in the Developer Solution Vial, swirled and then left for 30 minutes. Test results are interpreted visually after 30 minutes based on the presence or absence of visually detectable reddish-purple colored lines. Upon completion of the test and result interpretation the user should share their results with their healthcare provider.

The InteliSwab COVID-19 Rapid Test includes the following materials or other authorized materials: Test Stand and two Divided Pouches each containing one Test Device, Absorbent Packet, and Developer Solution Vial and instructions.

Your product includes an internal control test line that must generate the expected result for a test to be considered valid, as outlined in the “InteliSwab COVID-19 Rapid Test Healthcare Provider Instructions for Use”, the “InteliSwab COVID-19 Rapid Test Positive Test Results Additional Reference Images” and the “InteliSwab COVID-19 Rapid Test Instructions for Use.”

The labeling entitled “InteliSwab COVID-19 Rapid Test Healthcare Provider Instructions for

Use”, the “InteliSwab COVID-19 Rapid Test Positive Test Results Additional Reference Images” the InteliSwab COVID-19 Rapid Test “Instructions for Use” and the “InteliSwab COVID-19 Rapid Test” box label (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Professionals: OraSure Technologies, Inc. - InteliSwab COVID-19 Rapid Test Positive Test
- Fact Sheet for Individuals⁵: OraSure Technologies, Inc. - InteliSwab COVID-19 Rapid Test Positive Test

The above described product, with the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS’s determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS’s corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

⁵ Note that the information typically found in a Fact Sheet for Individuals is contained in the “InteliSwab COVID-19 Rapid Test Instructions for Use.” In addition, a separate Fact Sheet for Individuals will also be made available on your website.

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

OraSure Technologies, Inc. (You) and Authorized Distributor(s)⁶

- A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) must make available the IntelliSwab COVID-19 Rapid Test “Instructions for Use” and “InteliSwab COVID-19 Rapid Test Positive Test Results Additional Reference Images” for your product in the shipped kit using the “InteliSwab COVID-19 Rapid Test” box label and make these two documents and the “Fact Sheet for Individuals” electronically available on your website.
- C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.
- D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor’s offices, etc.) to which your product is distributed and the number of tests distributed to each location.
- F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any

⁶ “Authorized Distributor(s)” are identified by you, OraSure Technologies, Inc., in your EUA submission as an entity allowed to distribute your product.

such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAREporting@fda.hhs.gov).

- G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.
- H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

OraSure Technologies, Inc. (You)

- I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
 - J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.
 - K. You must make the authorized “InteliSwab COVID-19 Rapid Test Healthcare Provider Instructions for Use” and the “Fact Sheet for Healthcare Professionals” electronically available on your website. Additionally, you must provide the opportunity to request a copy of the “InteliSwab COVID-19 Rapid Test Healthcare Provider Instructions for Use” and “Fact Sheet for Healthcare Professionals” in paper form, and after such request, promptly provide the requested labeling at no additional cost.
 - L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
 - M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
 - N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.
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- O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.
- P. You must evaluate the analytical limit of detection and assess traceability⁷ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You must develop a mobile phone application or website to further facilitate results reporting by the individual using your product, and submit to FDA such application or website within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.
- R. You must further evaluate your product in an FDA agreed upon post authorization analytical bridging study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.
- S. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- T. You must further evaluate the clinical performance of your product in pediatric individuals <15 years of age, an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- U. You must complete the agreed upon real-time stability study for your product and

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

- V. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.
- W. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.
- X. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
 - This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
 - This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure

EXHIBIT B

Fact Sheets for Healthcare Providers

(Starts on Following Page)

FACT SHEET FOR HEALTHCARE PROFESSIONALS

OraSure Technologies, Inc.
InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the InteliSwab™ COVID-19 Rapid Test.

The InteliSwab™ COVID-19 Rapid Test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older.

All individuals who use this assay are required to receive and should carefully review the InteliSwab™ COVID-19 Rapid Test Instructions for Use before they use the test.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “Where can I go for updates and more information?” section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in “Where can I go for updates and more information?” section at the end of this document) or your local jurisdictions website for the most up to date information.

This test is for use at home with self-collected anterior nasal samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for Healthcare Professionals* (see links provided in “Where can I go for updates and more information?” section).

- The InteliSwab™ COVID-19 Rapid Test can be used to test individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 36 hours between tests.
- The InteliSwab™ COVID-19 Rapid Test is for non-prescription home use with self-collected anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older.

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that nucleocapsid antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. COVID-19 test results should always be considered in the context of clinical observations and epidemiological data such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

FACT SHEET FOR HEALTHCARE PROFESSIONALS

OraSure Technologies, Inc.
InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

The InteliSwab™ COVID-19 Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that nucleocapsid antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing

with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance) (see links provided in "*Where can I go for updates and more information?*" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 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.

What do I need to know about Serial Testing in Asymptomatic Individuals?

In asymptomatic patients, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates

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FACT SHEET FOR HEALTHCARE PROFESSIONALS

OraSure Technologies, Inc.
InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

that SARS-CoV-2 antigen is present, but does not rule out coinfection with other pathogens.

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, 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. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "Where can I go for updates and more information?" section).

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

<https://www.fda.gov/medicaldevices/device-advice->

[comprehensive-regulatoryassistance/medical-device-databases](https://www.fda.gov/medicaldevices/device-advice-comprehensive-regulatoryassistance/medical-device-databases). A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization>.

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Information for Laboratories:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Isolation Precautions in Healthcare Settings:

<https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to fact sheet for individuals and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

OraSure Technologies, Inc.:

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

EXHIBIT C

Fact Sheets for Patients

(Starts on Following Page)

FACT SHEET FOR INDIVIDUALS

OraSure Technologies, Inc.

InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

You are provided this Fact Sheet because you obtained the InteliSwab™ COVID-19 Rapid Test for testing yourself or dependants for the proteins from the virus that causes COVID-19. The intended use of this test is for testing twice over three days with at least 36 hours between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

What is the InteliSwab™ COVID-19 Rapid Test?

The InteliSwab™ COVID-19 Rapid Test is a type of test called an antigen test. Antigen tests are designed to

detect proteins from the virus that causes COVID-19 respiratory specimens, for example in anterior nasal swab specimens. The InteliSwab™ COVID-19 Rapid Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms tested twice over three days with at least 36 hours between tests.

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

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the InteliSwab™ COVID-19 Rapid Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on the test result along with other factors of your medical history, and your symptoms.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR INDIVIDUALS

OraSure Technologies, Inc.

InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than seven days may be more likely to be negative compared to a molecular assay.

If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 infection than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

It is important that you work with your healthcare provider to help you understand the next steps you should take

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect

genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is three full days of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved). Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation.

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf>

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR INDIVIDUALS

OraSure Technologies, Inc.

InteliSwab™ COVID-19 Rapid Test

June 4, 2021

Coronavirus
Disease 2019
(COVID-19)

This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:









<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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	<i>In Vitro</i> 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



OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015 USA
(800) ORASURE (1-800-672-7873)
(610) 882-1820
www.OraSure.com


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 IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel

- Foil Pouch containing three predetermined IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel and the IntelliSwab™ COVID-19 Rapid Test Pro.**
- **Follow the Test Result and Interpretation of Test Result section of the IntelliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.**
- **The IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro.

STORAGE INSTRUCTIONS

Store the IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel at 15°-30°C (59°-86°F). Do not use the IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the IntelliSwab™ COVID-19 Rapid Test Pro occurs.

1. Open the foil pouch containing the IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.
5. Store the IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel, they are not considered to be proficient at reading and interpreting the IntelliSwab™ 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 IntelliSwab™ COVID-19 Rapid Test Pro and may result in false negative results.

LIMITATIONS

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