HENRY SCHEIN®

COVID-19 TEST KIT
CUSTOMER NOTICE

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 *InteliSwab COVID-19 Rapid Test Pro* ("Test Kits"), manufactured by OraSure Technologies, Inc. are indicated for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal samples from individuals aged 18 years or older when the sample is self-collected or in individuals 2 years or older when the sample is collected by an adult or healthcare provider. The Test Kits are 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 48 hours between tests. A copy of the EUA (including any existing updates) for the Test Kits is attached hereto as **Exhibit A**. **The Test Kits are not returnable and purchase orders are non-cancellable**.

b. The Test Kits have not been FDA cleared or approved. The Test Kits have been authorized by the FDA under an EUA for use by Authorized Laboratories. "*Authorized Laboratories*" means laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high, moderate, or waived complexity tests. These Test Kits are 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.

c. Emergency use of these Test Kits is limited to Authorized Laboratories, and the Test Kits are 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 declaration is terminated or authorization is 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.

d. Please be sure to read the EUA carefully, as it includes specific obligations that apply to you, including obligations to keep all records associated with the Test Kits until otherwise notified by the FDA and obligations requiring you to collect and report information on the performance of the Test Kits, including any suspected occurrence of false positive results, false negative results, and significant deviations from the established performance characteristics of the Test Kits. Please notify HSI of any complaints about the Test Kits via telephone at 1-800-472-4346.

e. Please note that the EUA also lists material authorized to be used with the Test Kits.

f. Please carefully read the Fact Sheet for Healthcare Providers for the Test Kits attached hereto as **Exhibit B** and provide it to your Healthcare Providers.

g. Please carefully read the Fact Sheet for Patients attached hereto as **Exhibit C**, and use it as instructed by the EUA.

h. Updated copies of the "InteliSwab COVID-19 Rapid Test Pro Instructions for Use", "Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro", the Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, the "InteliSwab COVID-19 Rapid Test Pro Kit Controls" Instructions for Use and the "InteliSwab COVID-19 Rapid Test Pro Visual Reference Panel" Instructions for Use, are available on Henry Schein's website at www.henryschein.com/InteliswabProfessional.

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. Henry Schein shall have no obligation or liability to take back or replace any Test Kits.

EXHIBIT A

Emergency Use Authorization

(Starts on Following Page)

U.S. FOOD & DRUG ADMINISTRATION

January 27, 2022

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

Device:	InteliSwab COVID-19 Rapid Test Pro
EUA Number:	EUA210401
Company:	OraSure Technologies, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 2 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset 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 48 hours between tests. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	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.

Dear Ms. Miller:

On June 4, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the InteliSwab COVID-19 Rapid Test Pro, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the indication stated in the letter.[2] In addition, FDA established

[1] For ease of reference, this letter will use the term "you" and related terms to refer to OraSure Technologies, Inc.
[2] The June 4, 2021, letter authorized your product 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

additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[3]

On October 4, 2021, you requested to amend your EUA. Based on this request, and having concluded that revising the June 4, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the June 4, 2021, letter in its entirety with the revisions incorporated.[4] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[5] is now authorized for use consistent with the indications described above.

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.[6]

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

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in individuals 15 years or older when the sample is collected by an adult or healthcare provider. The test was 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 was 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 was 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.

[3] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

[4] The revisions to the June 4, 2021 letter include: (1) update the intended use to include use in individuals "*2* (updated from 15) *years or older when the sample is collected by an adult or healthcare provider*," (2) update the intended use when testing 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 48 hours* (updated from 36 hours) *between tests*," (3) updates to the Performance Characteristics section of the healthcare provider instructions for use (IFU) to include results of the usability study and clinical data used to support specimen collection from minors (2 - 14 years of age) and other updates, (4) updates to the Fact Sheet for Healthcare Providers to reflect the updated intended use and also for consistency with language used in more recent authorizations, (5) updates to the letter to reflect the updated intended use, (6) add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (T. and U. below), (7) removal of Conditions of Authorization R., S. and U. from June 4, 2021 letter (fulfilled), and (8) updates to the letter for consistency with language used in more recent authorizations.

[5] For ease of reference, this letter will use the term "your product" to refer to the InteliSwab COVID-19 Rapid Test Pro used for the indication identified above.

[6] 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).

relied upon is included in the "InteliSwab COVID-19 Rapid Test Pro 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.[7]

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 in anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 2 years or older when the sample is collected by an adult or healthcare provider. The test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset 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 48 hours between tests. 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 patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-

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

infection with other viruses. The agent detected may not be the definite cause of the disease.

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 a patient'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.

Testing of anterior nasal swab specimens using your product, as outlined in the "InteliSwab COVID-19 Rapid Test Pro Instructions for Use" is limited to laboratories certified under CLIA 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.

Your product is performed using anterior nasal samples from individuals 18 years or older or adult/healthcare provider collected anterior nasal samples from individuals age 2 years or older. When using your product, the individual performing the test must follow instructions provided in the "InteliSwab COVID-19 Rapid Test Pro Instructions for Use" and "Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro" when collecting the specimen, running the test procedure and interpreting the results.

The InteliSwab COVID-19 Rapid Test Pro includes the materials or other authorized materials (as may be requested under Condition P. below), required to collection the anterior nasal sample and perform the test procedure, as described in the "InteliSwab COVID-19 Rapid Test Pro Instructions for Use" and "Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro."

Your product requires various types of quality control, including the procedural internal control that is built in the 'control line (c)' of the test device and use of the InteliSwab COVID-19 Rapid Test Pro Kit Controls which are not included with the kit but are available from you with the "InteliSwab COVID-19 Rapid Test Pro Kit Controls" Instructions for Use, or other authorized control materials (as may be requested under Condition P. below). All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the "InteliSwab COVID-19 Rapid Test Pro Instructions for Use":

Your product also requires the use of additional authorized materials and authorized ancillary reagents (as may be requested under Condition P. below) that are not included with your product and are described in the Instructions for Use, including the InteliSwab COVID-19 Rapid Test

Pro Visual Reference Panel which are not included with the kit but are available from you with the "InteliSwab COVID-19 Rapid Test Pro Visual Reference Panel" Instructions for Use, to aid in results interpretation.

The labeling entitled "InteliSwab COVID-19 Rapid Test Pro Instructions for Use" and "Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro" (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 Providers: OraSure Technologies, Inc. - InteliSwab COVID-19 Rapid Test Pro
- Fact Sheet for Patients: OraSure Technologies, Inc. - InteliSwab COVID-19 Rapid Test Pro

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories 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:

- 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)[8]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (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 your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

F. You and authorized distributor(s) must collect information on the performance of your product. You will report 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) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

[8] "Authorized Distributor(s)" are identified by you, OraSure Technologies, Inc., in your EUA submission as an entity allowed to distribute your product.

G. You and authorized distributor(s) must make available the control material the InteliSwab COVID-19 Rapid Test Pro Kit Controls with the "InteliSwab COVID-19 Rapid Test Pro Kit Controls" Instructions for Use and the InteliSwab COVID-19 Rapid Test Pro Visual Reference Panel with the "InteliSwab COVID-19 Rapid Test Pro Visual Reference Panel" Instructions for Use, or other authorized materials (as may be requested under Condition P below), at the same time as your product.

H. 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.

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 (e.g., Fact Sheets).

K. You will include a physical copy of the InteliSwab COVID-19 Rapid Test Pro Instructions for Use" and "Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro" with each shipped product to authorized laboratories.

L. You must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

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 tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit 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 it within 48 hours of the request.

P. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

Q. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, You must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. 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.

S. You must complete the agreed upon real-time stability study for your product and 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.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRHEUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

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

Authorized Laboratories

W. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

X. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

Y. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Z. 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.

AA. 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 you (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.

BB. 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 authorized labeling.

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

CC. You, authorized distributor(s), and authorized laboratories 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.

Conditions Related to Printed Materials, Advertising and Promotion

DD. 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, as applicable, and FDA implementing regulations.

EE. 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.

FF. 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 for use by authorized laboratories;

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,

- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

August 3, 2022

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

Re: EUA210401/S005
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: June 1, 2022
Received: June 2, 2022

Dear Tiffany Miller:

This is to notify you that your request to update the InteliSwab COVID-19 Rapid Test Pro* to extend the shelf-life expiration date to 12 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210401/S005 support the requested update for the InteliSwab COVID-19 Rapid Test Pro. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the InteliSwab COVID-19 Rapid Test Pro re-issued on January 27, 2022.

Sincerely yours,

_____
Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

* The granted shelf-life extension does not include the InteliSwab COVID-19 Rapid Test Pro Kit Controls, which is sold separately from the InteliSwab COVID-19 Rapid Test Pro.

January 17, 2023

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

Re: EUA210401/S006
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: August 9, 2022
Received: August 9, 2022

Dear Tiffany Miller:

This is to notify you that your request to update authorized labeling of the InteliSwab COVID-19 Rapid Test Pro; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) include results of additional reactivity studies, (3) updates to the layout of the Quick Reference Guide InteliSwab COVID-19 Rapid Test Pro to improve usability, and (4) other minor general labeling updates, is granted. Upon review, we concur that the data and information submitted in EUA210401/S006 supports the requested updates for use with the InteliSwab COVID-19 Rapid Test Pro and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the InteliSwab COVID-19 Rapid Test Pro reissued on January 27, 2022.

Sincerely yours,

_____

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 23, 2023

Tamasha Parsons
Sr. Regulatory Affairs Specialist
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA210401/S008
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: February 13, 2023
Received: February 13, 2023

Dear Tamasha Parsons:

This is to notify you that your request to update the InteliSwab COVID-19 Rapid Test Pro* to extend the shelf-life expiration date to 18 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210401/S008 support the requested update for the InteliSwab COVID-19 Rapid Test Pro. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the InteliSwab COVID-19 Rapid Test Pro reissued on January 27, 2022.

Sincerely yours,

_____

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

* The granted shelf-life extension does not include the InteliSwab COVID-19 Rapid Test Pro Kit Controls, which is sold separately from the InteliSwab COVID-19 Rapid Test Pro.

April 4, 2023

Tamasha Parsons
Sr. Regulatory Affairs Specialist
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA210401/S007
Trade/Device Name: InteliSwab COVID-19 Rapid Test Pro
Dated: November 18, 2022
Received: November 18, 2022

Dear Tamasha Parsons:

This is to notify you that your request to update the InteliSwab COVID-19 Rapid Test Pro to (1) incorporate a change of raw material used in production of the COVID-19 Positive Control included in the InteliSwab COVID-19 Rapid Test Pro Kit Controls (required for use with the InteliSwab COVID-19 Rapid Test Pro and available separately), (2) update the Instructions for Use (IFU) of the InteliSwab COVID-19 Rapid Test Pro Kit Controls to reflect the raw material change, and (3) authorize a shelf-life of 7 months for the InteliSwab COVID-19 Rapid Test Pro Kit Controls manufactured with the new raw material, when stored at 2°C – 8°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210401/S007 support the requested updates for the InteliSwab COVID-19 Rapid Test Pro. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the InteliSwab COVID-19 Rapid Test Pro reissued on January 27, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

EXHIBIT B

Fact Sheet for Healthcare Providers

(Starts on Following Page)

INTELISWAB® COVID-19 RAPID TEST PRO

OraSure Technologies, Inc.

January 17, 2023

All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

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 Pro.

WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19?

For general information on COVID-19, including the symptoms of COVID-19, infection control precautions, and other information please check the CDC COVID-19 webpage (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

WHAT DO I NEED TO KNOW ABOUT COVID-19 TESTING WITH THIS PRODUCT?

- The InteliSwab® COVID-19 Rapid Test Pro can be used to test anterior nasal samples from individuals 18 years or older when the sample is self-collected or in individuals 2 years or older when the sample is collected by an adult or healthcare provider.
- The InteliSwab® COVID-19 Rapid Test Pro should be ordered for the detection of SARS-CoV-2 antigens by a healthcare provider.
- The InteliSwab® COVID-19 Rapid Test Pro is authorized for authorized for individuals who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.
- The InteliSwab® COVID-19 Rapid Test Pro is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.
- The InteliSwab® COVID-19 Rapid Test Pro 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.
- Please refer to the InteliSwab® COVID-19 Rapid Test Pro Instructions for Use for additional information.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19).*

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 antigens from SARS-CoV-2 were detected, and therefore the individual being tested is infected with the virus and presumed to be contagious. Laboratory 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 determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The InteliSwab® COVID-19 Rapid Test Pro has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 from other potentially COVID-19 positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts for symptoms, or other unintended adverse effects.

All laboratories using this test 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 serial test result for this test means that SARS-CoV-2 antigens was not present in the specimen above the limit of detection. All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 (such as discontinuation of isolation precautions). 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 seven (7) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients with symptom onset beyond seven (7) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

It is possible to test a person too early or too late during SARS-CoV-2 infection to make an accurate diagnosis via the InteliSwab® COVID-19 Rapid Test Pro.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual'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 individual'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. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result 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 COVID-19 spread within the community, or other unintended adverse events. 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 2021 through September 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?

Serial testing of individuals whose initial test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over three days for symptomatic individuals or five days for asymptomatic individuals with at least 48 hours between tests may decrease the risks of false negative results.

An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing who obtained two or more negative test results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing who obtained one or more positive results indicates that SARS-CoV-2 antigen is present in the patient's sample but does not rule out coinfection with other pathogens.

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 U.S. 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 the declaration is terminated or authorization is revoked sooner.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

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 DO I REPORT ADVERSE EVENTS?

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**

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/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/lab/guidelines-clinical-specimens.html

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

Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

FDA WEBPAGES:

General: www.fda.gov/novelcoronavirus

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

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EXHIBIT C

Fact Sheet for Patients

(Starts on Following Page)

INTELISWAB® COVID-19 RAPID TEST PRO

OraSure Technologies, Inc.

January 17, 2023

For the most up to date COVID-19 information, including symptoms, please visit Coronavirus Disease 2019 (COVID-19) | CDC

Your sample(s) was tested for COVID-19 using the InteliSwab® COVID-19 Rapid Test Pro.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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.

WHAT IS COVID-19 (CORONAVIRUS DISEASE 2019)?

COVID-19 is a disease caused by the SARS-CoV-2 virus.

WHAT IS THE INTELISWAB® COVID-19 RAPID TEST PRO?

The InteliSwab® COVID-19 Rapid Test Pro is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal samples.

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you may have COVID-19.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during specimen 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 A POSITIVE TEST RESULT MEAN?

If you have a positive test result with the InteliSwab® COVID-19 Rapid Test Pro, 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. You should follow CDC guidance to reduce the potential transmission of disease.

There is a chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

If your initial test result was negative, you should have serial testing performed (see below) and if after serial testing your test result is negative this means that antigens of the virus that causes COVID-19 were not found in your sample.

However, due to the sensitivity of antigen tests compared to molecular COVID-19 tests, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. For example, if you are tested too early during your infection. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than seven (7) days may be more likely to be negative compared to a molecular assay. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and COVID-19 antigen tests have lower sensitivity than COVID-19 molecular tests, false results may occur. Therefore, repeated testing can identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

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 one full day 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 5 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

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an 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. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated or authorization is revoked sooner.). An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

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.