January 17, 2023

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

Device:	InteliSwab COVID-19 Rapid Test Rx
EUA Number:	EUA210276
Company:	OraSure Technologies, Inc.
Indication:	Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus. This test is authorized for prescription home use with self-collected (unobserved) anterior nasal (nares) swab samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 2 years or older who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests .

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 Rx, 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] FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[3] Based on your request, FDA reissued the letter in its entirety with revisions incorporated on January 27, 2022.[4] In addition, based on your request, FDA granted an

[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 the InteliSwab COVID-19 Rapid Test Rx for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test was authorized for prescription home use with self-collection (unobserved) of anterior nasal samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 15 years or older who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset.
[3] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.
[4] On January 27, 2022, the revisions to the June 4, 2021, letter and authorized labeling included: (1) updates to the intended use to include use with "adult collected anterior nasal samples from individuals age 2 years or older," (2)

update to the authorized labeling on August 3, 2022.[5] Further, FDA revised the authorized uses and established one additional Condition of Authorization requiring updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests on November 1, 2022.[6]

On July 29, 2022, you requested to amend your EUA. Based on this request, and having concluded that revising the January 27, 2022, 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 January 27, 2022, letter in its entirety with the revisions incorporated.[7] 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[8] is now authorized for use consistent with the indication 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.[9]

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updates to the intended use to include use of the InteliSwab Connect app. for test result reporting - "*Individuals should report all results obtained with this product to their healthcare provider and the InteliSwab Connect app. The app will report all test results received,*" (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) addition of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (now R. and S.. below), (7) removal of Conditions of Authorization P., Q. and R. from the June 4, 2021 letter (fulfilled), and (8) updates to the letter for consistency with language used in more recent authorizations.

[5] On August 3, 2022, your request was granted to update the InteliSwab COVID-19 Rapid Test Rx 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.

[6] The Repeat Testing Revision Letter - November 1, 2022, can be accessed at: https://www.fda.gov/media/162799/download.

[7] The revisions to the January 27, 2022 letter include: (1) incorporating your 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, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) discontinue the previously authorized "InteliSwab COVID-19 Rapid Test Rx Positive Test Results Additional Reference Images," label as the necessary information is contained in the authorized "InteliSwab COVID-19 Rapid Test Rx Instructions for Use," (3) include results of additional reactivity studies, (4) update the design of the test stand component included in the kit, (5) addition of Condition of Authorization L. (below), and (6) updating the Letter of Authorization and Fact Sheet for Healthcare Providers to reflect the revised intended use, and for consistency with language used in more recent authorizations.

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

[9] 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 Rx 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.[10]

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 virus. This test is authorized for prescription home use with self-collected (unobserved) anterior nasal (nares) swab samples from individuals 18 years or older or adult collected anterior nasal samples from individuals age 2 years or older who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

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

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

necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Individuals who test positive should self-isolate and seek additional care from their healthcare provider.

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Persons 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 report all results obtained with this product to their healthcare provider and using the InteliSwab Connect application (app). The app will report all test results received 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 the Centers for Disease Control and Prevention (CDC).

Once the patient is provided with a prescription for your product by a healthcare provider the test kit is obtained by the patient. Your product is performed unobserved using anterior nasal samples from individuals 18 years or older or adult 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 Rx Instructions for Use" when collecting the specimen, running the test procedure and interpreting the results.

The InteliSwab COVID-19 Rapid Test Rx includes the materials or other authorized materials (as may be requested under Condition K. below), required to collection the anterior nasal sample and perform the test procedure, as described in the "InteliSwab COVID-19 Rapid Test Rx Healthcare Provider Instructions for Use" and the "InteliSwab COVID-19 Rapid Test Rx Instructions for Use." In addition, individuals should report all results obtained with your product to their healthcare provider and using the InteliSwab Connect app.

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 Rx Healthcare Provider Instructions for Use" and the "InteliSwab COVID-19 Rapid Test Rx Instructions for Use."

The labeling entitled "InteliSwab COVID-19 Rapid Test Rx Healthcare Provider Instructions for Use", the "InteliSwab COVID-19 Rapid Test Rx Instructions for Use" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the "InteliSwab COVID-19 Rapid Test Rx" box label(s)[11], and the "Fact Sheet for Healthcare Providers: OraSure Technologies,

[11] "InteliSwab COVID-19 Rapid Test Rx" box labels include boxes for 1-pack and "InteliSwab COVID-19 Rapid Test Rx" box labels for additional test kits numbers/options as may be requested, and for which you receive

Inc.- InteliSwab COVID-19 Rapid Test Rx"[12] pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as "authorized labeling."

The above described product, when accompanied by 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:

- 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

appropriate authorization, in accordance with Condition L. below. InteliSwab COVID-19 Rapid Test Rx kits numbers/options are described in the "InteliSwab COVID-19 Rapid Test Rx Healthcare Provider Instructions for Use."

[12] Note that the information typically found in a Fact Sheet for Patients is contained in the "InteliSwab COVID-19 Rapid Test Rx Instructions for Use."

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)[13]

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 on your website(s) all authorized labeling. You and authorized distributor(s) must additionally make available the "InteliSwab COVID-19 Rapid Test Rx Instructions for Use" for your product in the shipped kit using the "InteliSwab COVID-19 Rapid Test Rx" box label (see Footnote 11).

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 your product 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 such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (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

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

does not exceed, the terms of this letter of authorization.

OraSure Technologies, Inc. (You)

H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. 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.

J. You must make the authorized "InteliSwab COVID-19 Rapid Test Rx Healthcare Provider Instructions for Use" and the "Fact Sheet for Healthcare Providers" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "InteliSwab COVID-19 Rapid Test Rx Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Providers" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

K. 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/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

L. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7/OPEQ/CDRH 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.

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 traceability[14] 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/OPEQ/CDRH.

Q. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7/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/OPEQ/CDRH.

R. 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: CDRH-EUA-Reporting@fda.hhs.gov).

S. 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/OPEQ/CDRH.

Healthcare Providers

T. All prescribing healthcare providers must collect information on the performance of your product in the ordinary course of business and report to DMD/OHT7/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.

U. All prescribing healthcare providers must report all test results they receive from patients who use your 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 the Centers for Disease Control and Prevention (available at: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html).

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

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

V. You, authorized distributors, and healthcare providers 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

W. 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.

X. 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.

Y. 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,

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure