

January 31, 2024

Lisa Vershave
Regulatory Affairs Manager
Revvity, Inc.
940 Winter Street
Waltham, MA 02451

Device: New Coronavirus Nucleic Acid Detection Kit

EUA Number: EUA200055

Company: Revvity, Inc.

Indication: This test is authorized for the following indications for use:

Qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal and nasopharyngeal swab specimens collected by a healthcare provider (HCP), and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from individuals suspected of COVID-19 by their HCP.

Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected using the SalivaSecure Saliva Collection Kit either by an HCP or self-collected under the supervision of an HCP in a healthcare setting from individuals suspected of COVID-19 by their HCP.

Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media.

Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Ms. Vershave:

On March 24, 2020, based on PerkinElmer, Inc.'s request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the PerkinElmer New Coronavirus Nucleic Acid Detection Kit 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.¹ Based on PerkinElmer, Inc.’s requests, the March 24, 2020, letter has been revised and reissued by FDA on October 28, 2020,² January 12, 2021,³ February 5, 2021,⁴ July 15, 2021,⁵ and March 23, 2023.⁶ FDA also granted updates to the authorized labeling at PerkinElmer, Inc.’s

¹ The March 24, 2020, letter authorized the PerkinElmer New Coronavirus Nucleic Acid Detection Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to laboratories certified under CLIA, 42 U.S.C. §263a, to perform high complexity tests.

² On October 28, 2020, the revisions to the March 24, 2020, letter and authorized labeling included: (1) revisions to the authorized labeling to add 4 additional PCR instruments for use with your product, (2) revisions to the intended use and authorized labeling documents to include testing of pooled samples containing up to five individual upper respiratory swab specimens (oropharyngeal, nasopharyngeal, or anterior nasal swabs), where each specimen is collected under observation or by a healthcare provider using individual vials containing transport media, (3) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations, and (4) revisions to the Conditions of Authorization as a result of the new intended use and for consistency with recent authorizations.

³ On January 12, 2021, the revisions to the October 28, 2020, letter and authorized labeling included: (1) revisions to the intended use to include testing of oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP, and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection, (2) update the inclusivity study data to include information about the emergence of mutations in one of the SARS-CoV-2 target (N) forward primer sequences, and (3) revisions to the Conditions of Authorization for consistency with recent authorizations.

⁴ On February 5, 2021, the revisions to the January 12, 2021, letter included: (1) addition of condition of authorization Q in section IV below to address electromagnetic compatibility (EMC) testing, (2) removal of condition of authorization Q in the letter issued on January 12, 2021, requiring the submission of additional pooling information and *in silico* analysis across multiple geographical locations, that is fulfilled.

⁵ On July 15, 2021, the revisions to the February 5, 2021, letter included: (1) modification of the intended use to add saliva collected using the SalivaSecure Collection Kit as an authorized specimen type, (2) edits to the Instructions for Use related to saliva specimens, edits to the extraction procedure, addition of two limitations related to saliva specimens and additional edits to reflect language used in more recent authorizations, (3) revisions to the letter and Conditions of Authorization (Section IV) to remove Condition R related to the required addition of instrument verification procedures (fulfilled), addition of new Condition R related to performance of an additional stability study, addition of new Conditions of Authorization related to saliva specimens (Conditions T and U, and revision of Condition S), additional new Conditions related to circulating variants (Conditions V and W) and additional edits to reflect language used in more recent authorizations, and (4) revisions to the Fact Sheets for HCPs and Patients related to the addition of saliva as a specimen type and additional edits to reflect language used in more recent authorizations, and revisions to the Fact Sheet for HCPs related to the performance with circulating variants.

⁶ On March 23, 2023, the revisions to the July 15, 2021, letter included: (1) modification of the Intended Use to remove the claim for testing the asymptomatic population, based on additional clinical performance data, (2) removal of limitations related to asymptomatic testing, (3) removal of Condition of Authorization P. in the letter issued on July 15, 2021, that is fulfilled, (4) addition of a limitation related to saliva specimen testing to be consistent with recent authorizations that include a saliva specimen claim, (5) update the *in silico* inclusivity analysis to reflect more recent SARS-CoV-2 sequences, (6) addition of the Design and Data Analysis software v2.4.3 for the QuantStudio 12K and QuantStudio 7 Flex RT-PCR instruments, and (7) provide minor updates.

request^{7,8,9,10,11,12,13,14} In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.¹⁵

On January 18, 2024, you¹⁶ requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the March 23, 2023, 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 March 23, 2023, letter in its entirety with the revisions incorporated.¹⁷ 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 product¹⁸ is now authorized for use consistent with the indication described above.

On February 4, 2020, and as amended on March 15, 2023, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that

⁷ On April 1, 2020, PerkinElmer, Inc.'s request was granted to update the Instructions for Use (IFU) of your product to; (1) add an additional nucleic acid extraction method which utilizes the chemagic Viral DNA/RNA 300 Kit H96 on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor related changes and edits to the IFU.

⁸ On July 30, 2020, PerkinElmer, Inc.'s request was granted via email to update the intended use of your product to add anterior nasal swab specimens and the IFU, Fact Sheet for HCPs and Fact Sheet for Patients were also updated accordingly.

⁹ On September 25, 2020, PerkinElmer, Inc.'s request was granted via email to update the IFU of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing.

¹⁰ On April 1, 2021, PerkinElmer, Inc.'s request was granted to update the IFU of your product to; (1) add instrument verification procedures, (2) add a limitation related to performance with circulating variants, and (3) updating the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations,

¹¹ On October 15, 2021, PerkinElmer, Inc.'s request was granted via email to update lot release and statistical sampling criteria.

¹² On December 10, 2021, PerkinElmer, Inc.'s request was granted to update the Instructions for Use (IFU) of your product to; (1) update the saliva sample stability claims based on additional stability testing performed to fulfill Condition R of the July 15, 2021 letter and (2) update the in silico inclusivity analysis. In addition, minor updates were made to the IFU to reflect more recent authorizations.

¹³ On February 2, 2022, PerkinElmer, Inc.'s request was granted to update the Instructions for Use (IFU) of your product to; (1) include use of the QuantStudio 12K Flex and QuantStudio 7 Flex RT-PCR instrument platforms and (2) add two collection media types (Mawi iSwab and saline).

¹⁴ On September 12, 2022, PerkinElmer, Inc.'s request was granted to update the Instructions for Use (IFU) of your product to extend the product shelf-life claim from 12-months to 24-months. In addition, FDA updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations.

¹⁵ The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: <https://www.fda.gov/media/152406/download>.

¹⁶ For ease of reference, this letter will use the term “you” and related terms to refer to Revvity, Inc.

¹⁷ The revisions to the March 23, 2023, letter and authorized labeling include: (1) updating ownership of the EUA from PerkinElmer, Inc. to Revvity, Inc. due to company rebranding, (2) updating the name of the EUA device from “PerkinElmer New Coronavirus Nucleic Acid Detection Kit” to “New Coronavirus Nucleic Acid Detection Kit,” (3) updating the manufacturing site for the EUA device, (4) delete Condition of Authorization S. in the March 23, 2023 letter as fulfilled through data and information provided to the FDA for review, (5) revise Condition of Authorization U. (below – previously Condition of Authorization V. in the March 23, 2023 letter) to require submission of summary report following the first 10 saliva specimens collected with the SalivaSecure Saliva Collection Kit, and (6) updating the Fact Sheet for Healthcare Providers and the Letter of Authorization to reflect the updates made and for consistency with language used in more recent authorizations.

¹⁸ For ease of reference, this letter will use the term “your product” to refer to the New Coronavirus Nucleic Acid Detection Kit used for the indication identified above.

there is a public health emergency, or a significant potential for a public health emergency, that affects, or 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.¹⁹

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 contained in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” Instructions for Use (IFU) (identified below). FDA has granted a De Novo classification request and cleared tests for the qualitative detection of nucleic acid from SARS-CoV-2, but these are not adequate and available alternatives to your product.²⁰

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 Section 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 for diagnosing COVID-19.²¹

¹⁹ 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. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3(b). March 15, 2023 (“Amended Determination”).

²⁰ To date, the FDA granted a De Novo classification request for the BioFire Respiratory Panel 2.1 (RP2.1) (Product Code: QOF; DEN200031) and cleared various tests (Search FDAs 510(k) Premarket Notification database; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>; Product codes: QOF, QWR, QXX) for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory clinical specimens. Available information indicates that these are not adequate and available alternatives to your product.

²¹ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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.

The Authorized Product

Your product is a real-time RT-PCR in vitro diagnostic test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal and nasopharyngeal swab specimens collected by a healthcare provider (HCP), and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from individuals suspected of COVID-19 by their HCP.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected using the SalivaSecure Saliva Collection Kit either by an HCP or self-collected under the supervision of an HCP in a healthcare setting from individuals suspected of COVID-19 by their HCP.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If patient's clinical signs and symptoms are inconsistent with a negative result and results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in oropharyngeal and nasopharyngeal swab specimens and saliva during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 nucleic acid from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from human oropharyngeal swab, nasopharyngeal swab, anterior nasal swab, or saliva specimens,

using authorized extraction methods described in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time PCR instrument described in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU. Your product includes the materials (or other authorized materials as may be requested under Condition N. Below) described in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU.

Your product requires control materials (or other authorized control materials as may be requested under Condition N. below), that are to be run as outlined in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU.

The labeling entitled “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU and the “SalivaSecure Saliva Collection Kit” IFU (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, are 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: Revvity, Inc.- New Coronavirus Nucleic Acid Detection Kit
- Fact Sheet for Patients: Revvity, Inc. - New Coronavirus Nucleic Acid Detection Kit

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.

The SalivaSecure Saliva Collection Kit when accompanied by the “SalivaSecure Saliva Collection Kit” IFU is authorized to be distributed and used as part of the above described product as set forth in this EUA.

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:

Revvity, Inc. (You) and Authorized Distributor(s)²²

- A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (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 Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

²² “Authorized Distributor(s)” are identified by you, Revvity, Inc., in your EUA submission as an entity allowed to distribute your product.

- D. You and authorized distributor(s) must include a physical copy of the “Instructions for New Coronavirus Nucleic Acid Detection Kit” IFU with each shipped product to authorized laboratories.
- E. You and authorized distributor(s) must make available the “SalivaSecure Saliva Collection Kit” Instructions for Use related to collection of saliva specimens using the SalivaSecure Saliva Collection Kit in each shipped collection kit and on your website.
- F. Through a process of inventory control, you and authorized distributor(s) must keep records of the number and locations to which the SalivaSecure Saliva Collection Kit is distributed.
- G. You and authorized distributor(s) must maintain customer complaint files concerning the SalivaSecure Saliva Collection Kit on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.
- H. 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/or authorized labeling.
- I. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number of your product they distribute.
- J. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- K. 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.

Revvity, Inc. (You)

- L. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- M. 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).
- N. 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 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 Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

- O. 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).
- P. 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.
- Q. 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 products 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.
- R. You must evaluate the analytical limit of detection and assess traceability²³ of your product with any FDA-recommended reference material(s) if requested by FDA. After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- S. You must have a process in place to track adverse events, including any occurrence of false results with your product (including with the SalivaSecure Saliva Collection Kit) and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must be immediately reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- T. Upon request, you must conduct post-authorization studies and/or data analysis concerning the performance of saliva specimens with your authorized test. Such studies and/or data analysis must be agreed upon between you and FDA. After submission to FDA and DMD/OHT7/OPEQ/CDRH's review of the data, FDA will consider whether additional action is appropriate, such as revision or revocation of the EUA.
- U. You must submit to FDA a summary report summarizing the results of any testing performed using the first ten saliva specimens collected with the SalivaSecure Collection Kit, including the positivity rate for saliva specimens.
- V. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's

²³ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

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.

- W. 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.

Authorized Laboratories

- X. Authorized laboratories using your product must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Y. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Z. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- AA. 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.
- BB. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that *“Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”*
- CC. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Specimen Pooling Implementation and Monitoring Guidelines” provided in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- DD. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring Guidelines. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

EE. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and You (via email: COVID-19.TechnicalSupport@Revvity.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.

FF. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Revvity, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

GG. 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 must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

HH. 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.

II. 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.

JJ. 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 for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid 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,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure