

January 12, 2021

Brian Ciccariello, RAC  
Head of Regulatory & Medical Affairs - Americas  
PerkinElmer, Inc.  
940 Winter Street  
Waltham, MA 02451

Device: PerkinElmer New Coronavirus Nucleic Acid Detection Kit

EUA Number: EUA200055

Company: PerkinElmer, Inc.

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

Qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab 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 any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection.

Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., 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) 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 Mr. Ciccariello:

On March 24, 2020, based on your<sup>1</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of 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 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

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to the PerkinElmer, Inc.

CLIA, 42 U.S.C. §263a, to perform high complexity tests. Based on your request, FDA also granted updates to the authorized labeling on April 1, 2020,<sup>2</sup> July 30, 2020,<sup>3</sup> and September 25, 2020.<sup>4</sup> On October 28, 2020, based on your request, FDA reissued the March 24, 2020, letter in its entirety with revisions incorporated.<sup>5</sup>

On October 29, 2020, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the October 28, 2020, 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 October 28, 2020, letter in its entirety with the revisions incorporated.<sup>6</sup> 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<sup>7</sup> 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.<sup>8</sup>

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<sup>2</sup> On April 1, 2020, your 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.

<sup>3</sup> On July 30, 2020, your request was granted via email to update the intended use of your product to add anterior nasal swab specimens and the IFU, Fact Sheet Healthcare Providers and Fact Sheet for Patients were also updated accordingly.

<sup>4</sup> On September 25, 2020, your 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.

<sup>5</sup> 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.

<sup>6</sup> The revisions to the October 28, 2020, letter and authorized labeling include: (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.

<sup>7</sup> For ease of reference, this letter will use the term “your product” to refer to the PerkinElmer New Coronavirus Nucleic Acid Detection Kit used for the indication identified above.

<sup>8</sup> 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 contained in the Instructions for Use (IFU - 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 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.<sup>9</sup>

## **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 test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a 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.

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 swab 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) 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

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<sup>9</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 upper respiratory specimens 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. 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from human oropharyngeal swab, nasopharyngeal swab, and anterior nasal swab specimens, using authorized extraction methods described in the 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 IFU. The PerkinElmer New Coronavirus Nucleic Acid Detection Kit includes the following materials and control materials or other authorized materials: nCoV reagent A, nCoV reagent B, nCoV enzyme mix, nCoV internal control, nCoV positive control, and nCoV negative control.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. below), that are to be run as outlined in the IFU. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the IFU:

- nCoV Internal Control - bacteriophage MS2 added clinical samples and controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- nCoV Negative Control - buffer used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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 IFU.

The labeling entitled “Instructions for PerkinElmer New Coronavirus Nucleic Acid Detection Kit” IFU (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>) and the following fact sheets pertaining to the emergency use, which is required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referenced as “authorized labeling”:

- Fact Sheet for Healthcare Providers: PerkinElmer, Inc.- PerkinElmer New Coronavirus Nucleic Acid Detection Kit
- Fact Sheet for Patients: PerkinElmer, Inc. - PerkinElmer New Coronavirus Nucleic Acid Detection Kit

The above described product, with 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:

##### **PerkinElmer, Inc. (You) and Authorized Distributor(s)<sup>10</sup>**

- 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 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 authorized labeling.
- D. You and authorized distributor(s) will include a physical copy of the authorized Instructions for Use with each shipped product to authorized laboratories.
- E. 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.
- F. 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 they distribute.
- G. 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.
- 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.

##### **PerkinElmer, 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).

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<sup>10</sup> “Authorized Distributor(s)” are identified by you, PerkinElmer, Inc., in your EUA submission as an entity allowed to distribute your product.

- 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 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 (OHT 7) - Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- L. You must comply with the following requirements pursuant to FDA regulations: 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).
- M. 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.
- N. 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.
- O. You must evaluate the analytical limit of detection and assess traceability<sup>11</sup> of your product with any FDA-recommended reference material(s). After submission to and concurrence with the date by FDA you must update your labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You must further evaluate the clinical performance of your product, with specimens collected from asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and FDA's review of and concurrence with the data, you must update the authorized labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You must further provide FDA additional agreed upon pooling information and *in*

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<sup>11</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

*silico* analysis across multiple geographical locations by January 28, 2020 (unless otherwise agreed to with DMD/OHT7- OIR/OPEQ/CDRH). After submission to and concurrence with the information by FDA, you must update authorized labeling to reflect the additional information collected. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

- R. You must develop a laboratory procedure whereby authorized laboratories can verify that the RUO instrument(s) authorized with your product is capable of performing the PerkinElmer New Coronavirus Nucleic Acid Detection Kit test with sufficient accuracy, as stated in the authorized labeling. You must submit the procedure to FDA within 21 calendar days of authorization. After DMD/OHT7-OIR/OPEQ/CDRH's review and concurrence, you must update the authorized labeling to reflect the laboratory procedure within 45 calendar days of authorization.
- S. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA in accordance with 21 CFR Part 803.

#### **Authorized Laboratories**

- T. 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.
- U. 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.
- V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- W. 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.
- X. 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.*"
- Y. 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.



- Z. 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.
- 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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and You (via email: [COVID-19.TechnicalSupport@PerkinElmer.com](mailto:COVID-19.TechnicalSupport@PerkinElmer.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 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.

**PerkinElmer, 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 must 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 applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act 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 test has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
  - This test 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 test 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,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosure