May 17, 2021

Malgorzata Jaremko, PhD, FACMG, DABMG, FACB, MBA
CLIA Laboratory Director
Senior Executive Vice President, Clinical Laboratory & Molecular Diagnostics
Phosphorus Diagnostics LLC
400 Plaza Drive, 4th Floor
Secaucus, NJ 07094

Device:	Phosphorus COVID-19 RT-qPCR Test
EUA:	EUA200359
Company:	Phosphorus Diagnostics LLC
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in: (1) oropharyngeal (throat) swabs, nasopharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates as well as bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider (HCP). (2) saliva specimens that are self-collected at home or in a healthcare setting using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit by any individuals 18 years or older, including from individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to the authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Phosphorus Diagnostics LLC that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Dr. Jaremko:

On June 4, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Phosphorus COVID-19 RT-

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Phosphorus Diagnostics LLC.

qPCR Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).[2] Based on your request, FDA granted updates to the authorized labeling on June 24, 2020[3] and March 1, 2021.[4] FDA also reissued the letter in its entirety on December 15, 2020.[5]

On April 8, 2021, you requested to revise your EUA. Based on that request, and having concluded that revising the December 15, 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 December 15, 2020, letter in its entirety with the revisions incorporated.[6] 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,[7] is now intended for 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

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[2] On June 4, 2020, your product was authorized for qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens from individuals suspected of COVID-19 by their healthcare provider (HCP) that were either self-collected at home or in a healthcare setting using the Oragene Dx OGD-510 collection device, when determined to be appropriate by a HCP. Testing was limited to Phosphorous Diagnostics LLC located in Seacaucus, NJ that is certified under CLIA, , 42 U.S.C. §263a, to perform high complexity tests.

[3] On June 24, 2020, FDA granted updates to: (1) update the Instructions for Use (EUA Summary) of the Phosphorus COVID-19 RT-qPCR Test to include upper respiratory specimens (including oropharyngeal (throat) swabs, nasopharyngeal swabs, anterior nasal and mid-turbinate swabs, nasopharyngeal washes/aspirates) and bronchoalveolar lavage (BAL) specimens, and (2) update the Healthcare Provider Fact Sheet accordingly.

[4] On March 1, 2021, FDA granted updates to the authorized labeling "Phosphorus COVID-19 RT-qPCR Test: InClinic Ordering Guide," and the "Phosphorus COVID-19 RT-qPCR Test: At-Home Step-by-Step Instructions."

[5] On December 15, 2020, revisions to the June 4, 2020, letter and authorized labeling included: (1) updates to incorporate amendments granted June 24, 2020, with minor rewording of the indication and inclusion of nasal aspirates, (2) updates to add an additional authorized laboratory (and their brand name for your product) that meets the requirements under CLIA to perform high complexity tests, (3) updates to authorize this test for use with the Phosphorus saliva collection kit, which includes the Oragene Dx OGD-510, which is used for saliva specimen collection and (4) updates to the Conditions of Authorization to reflect these revisions, and (5) updates to use language more consistent with recent authorizations.

[6] Revisions to the December 15, 2020, letter and authorized labeling include: (1) update the name of the saliva collection device from "Phosphorus saliva collection kit" to "Pinpoint by Phosphorus COVID-19 Test Home Collection Kit", (2) updates to the intended use and labeling to authorized use of saliva specimens that are self-collected at home or in a healthcare settingusing the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit by any individuals 18 years or older, including from individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider, and remove reference to a medical questionnaire (3) updates to the intended use and labeling to expand testing to laboratories designated by Phosphorus Diagnostics LLC, that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high-complexity tests, (4) updates to the analytical limit of detection, inclusivity analysis, and clinical testing in specimens collected from individuals without symptoms of COVID-19, (5) updated limitations with respect to circulating SARS-CoV-2 variants and testing of asymptomatic individuals, (6) updates to the Conditions of Authorization to reflect these revisions, and (7) updates to use language more consistent with recent authorizations.

[7] For ease of reference, this letter will use the term "your product" to refer to the Phosphorus COVID-19 RT-qPCR Test used for the indication identified above.

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.[8]

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 EUA Summary (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.[9]

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 qualitative test for the detection of nucleic acid from SARS-CoV-2 in (1) oropharyngeal (throat) swabs, nasopharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates as well as bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider (HCP) and (2) saliva specimens that are self-collected at home or in a healthcare setting using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit by and individuals 18 years or older, including from individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.

[8] 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).

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

Testing is limited to laboratories designated by Phosphorus Diagnostics LLCthat are certified under CLIA, 42 U.S.C. §263a, to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory 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. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA 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 either upper respiratory specimens or saliva specimens collected using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit, which contains: Kit Box, Prepaid Return Shipment Pack, Biohazard Bag with Absorbent Pouch, DNA Genotek OGD-510 Saliva Collection Device and Instructions, Pre-populated Test Requisition Form with Label Stickers, and At-Home Step-By-Step Instructions. Individuals must follow all specimen collection and mailing instructions provided with the collection kit. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The Phosphorus COVID-19 RT-qPCR Test uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

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

- Internal Control (Hs_RPP30) – targets RNase P to verify that nucleic acid is present in every clinical specimen processed; controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- External Positive Control (2019-nCoV_N_Positive Control) – monitors the integrity of RT-PCR assay.
- No Template Control (NTC) – Molecular grade, nuclease -free water monitors for contamination of extraction and RT-PCR assay reagents.
- Negative Extraction Control (NEC) – monitors for 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 authorized labeling, as defined below.

Your product is authorized to be accompanied with the labeling submitted as part of the EUA request (described below), and as described in the “EUA Summary” (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 product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Phosphorus Diagnostics LLC - Phosphorus COVID-19 RT-qPCR Test
- Fact Sheet for Patients: Phosphorus Diagnostics LLC - Phosphorus COVID-19 RT-qPCR Test.

The above described product, when accompanied by the "EUA Summary," Fact Sheet for Healthcare Providers, Fact Sheet for Patients, "Phosphorus COVID-19 RT-qPCR Test" Standard Operating Procedure (SOP) that includes the "COVID-19 RNA Extraction" SOP and the "Phosphorus COVID-19 RT-qPCR Test" SOP, and the "COVID-19 Sample Accessioning for Phosphorus COVID-19 RT-qPCR Test" SOP, is authorized to be to be distributed and used by the authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit with the "Pinpoint by Phosphorus COVID-19 Test Home Collection Kit: In-Clinic Ordering Guide," and "Pinpoint by Phosphorus COVID-19 Test Home Collection Kit: At-Home Step-by-Step Instructions" with the "Oragene Dx" instructions is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to the "EUA Summary," Fact Sheet for Healthcare Providers, Fact Sheet for Patients, "Phosphorus COVID-19 RT-qPCR Test" Standard Operating Procedure (SOP) that includes the "COVID-19 RNA Extraction" SOP and the "Phosphorus COVID-19 RT-qPCR Test" SOP, the "COVID-19 Sample Accessioning for Phosphorus COVID-19 RT-qPCR Test" SOP, "Pinpoint by Phosphorus COVID-19 Test Home Collection Kit: In-Clinic Ordering Guide," and the "Pinpoint by Phosphorus COVID-19 Test Home Collection Kit: At-Home Step-by-Step Instructions" with the "Oragene Dx" instructions.

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 for diagnosing COVID-19 and when used consistently 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 consistently 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.

IV. Conditions of Authorization

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

Phosphorus Diagnostics LLC (You) and Authorized Distributor(s)[10]

A. You and authorized distributors must make available all instructions related to the self-collection of saliva specimens using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit both in the shipped kit and on your website.

B. You and authorized distributor(s) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

C. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit is distributed.

D. You and authorized distributor(s) must maintain customer complaint files 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.

E. 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.

Phosphorus Diagnostics LLC (You)

[10] "Authorized Distributor(s)" are identified by you, Phosphorus Diagnostics LLC, in your EUA submission as an entity allowed to distribute the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit. This currently includes Wheeler Labs.

F. 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).

G. You must notify FDA of any authorized distributor(s) of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit including the name, address, and phone number of any authorized distributor(s).

H. You must provide authorized distributor(s), relevant public health authorities, and authorized laboratories with a copy of this EUA and communicate to authorized distributor(s), relevant public health authorities, and authorized laboratories any subsequent authorized revisions that might be made to this EUA and the authorized accompanying materials.

I. 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 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.

J. You must evaluate the analytical limit of detection and assess traceability of your test with any FDA-recommended reference material(s), if requested by FDA.[11] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

K. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using saliva specimens collected with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit by individuals without symptoms or other reasons to suspect COVID-19 infection when determined to be appropriate by a healthcare provider used with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized self-collection kit.

[11] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events

L. You must complete the agreed upon winter stability profile on self-collected saliva specimens using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit in an FDA agreed upon post authorization study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the study data, and review and concurrence with the data by FDA, you must update your 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.

M. You must ensure authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

N. You must have a process in place in accordance with 21 CFR Part 803 to track adverse events, including any occurrence of false results with your product, including with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

O. You must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

Authorized Laboratories

P. 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.

Q. 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.

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

S. 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.

T. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-

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concerning your product.

Reporting@fda.hhs.gov) and you (support@phosphorus.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 laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your product in accordance with the product procedure.

Phosphorus Diagnostics LLC (You), Authorized Distributor(s) and Authorized Laboratories

V. You, authorized distributor(s) and authorized laboratories must ensure that any records associated with this EUA, including test usage, 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

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 the applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act 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 (except the Oragene Dx instructions), 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 the two 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
- 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure