U.S. FOOD & DRUG ADMINISTRATION

May 21, 2020

Mary Smith
Sr. Manager, Regulatory Affairs
P23 Labs, LLC
500 S. University Ave., Suite 504
Little Rock, AR 72205-5306

Device:	P23 Labs TaqPath SARS-CoV-2 Assay
Company:	P23 Labs, LLC
Indication:	Qualitative detection of nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens as well as bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also for use with saliva specimens that are either self-collected at home or in a healthcare setting under the supervision of a healthcare provider (HCP), or collected by a HCP, using the OMNIgene·ORAL OM-505 Collection Device, when determined to be appropriate by a HCP.
Authorized Laboratories:	Testing is limited to P23 Labs, LLC (P23), located in Little Rock, AR, that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Ms. Smith:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to P23 Labs, LLC.
[2] For ease of reference, this letter will use the term "your product" to refer to the P23 Labs TaqPath SARS-CoV-2 Assay used for the indication identified above.

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.[3]

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 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.[4]

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 oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens as well as bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

Saliva specimens may also be collected for use with your product using the OMNIgene·ORAL OM-505 Collection Device to self-collect saliva specimens either at home under the supervision of a healthcare provider (HCP) or in a healthcare setting, or collected by a HCP when determined to be appropriate by a HCP. Testing is limited to P23 Labs, LLC (P23), located in Little Rock,

[3] 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).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

AR, that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens as well as bronchoalveolar lavage (BAL) and saliva. 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 P23 Labs TaqPath SARS-CoV-2 Assay 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, 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 procedures submitted as part of the EUA request:

- MS2 (Internal Positive Control) – added to each clinical specimen and the Negative Extraction Control (NEC) prior to extraction - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- External Positive Control - monitors the integrity of nucleic acid extraction and RT-PCR.
- Negative Extraction Control (NEC) – monitors for cross-contamination during RNA extraction and RT-PCR.
- Nuclease-Free Water (Negative Control; NTC) - Nuclease-free, molecular-grade water 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 Instructions for Use.

When using the OMNIgene·ORAL OM-505 Collection Device, individuals must follow all specimen collection and mailing instructions provided with the device (Self-Collection Kit Instructions for Patients).

The above described product, is authorized to be accompanied with the labeling submitted as part of the EUA request, and as described in the EUA summary (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), 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: P23 Labs TaqPath SARS-CoV-2 Assay
- Fact Sheet for Patients: P23 Labs TaqPath SARS-CoV-2 Assay

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, Master Standard Operating Procedure (SOP) for the P23 Labs TaqPath SARS-CoV-2 Assay, the Self-Collection Kit Instructions for Patients, the Sample Registration and Accessioning in LIMs SOP and the Specimen Acceptance and Rejection (Home-Collection) (referenced to as "authorized labeling") is authorized to be to be used by the laboratory that developed the authorized test, 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 authorized product, 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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:

P23 Labs, Inc.

A. Your authorized test 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 will inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your authorized test and authorized labeling.

C. You will notify the relevant public health authorities of your intent to run your authorized test.

D. You will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. You will include with result reports of your authorized test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

F. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients and the OMNIgene·ORAL OM-505 Collection Device Self-Collection Kit Instructions for Patients, and any other home specimen collection kit instructions authorized for use with your product.

G. You are authorized to make available additional information relating to the emergency use of your authorized test that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You will use your authorized test as outlined in the authorized test procedures submitted as part of the EUA request. Deviations from the authorized test procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.

I. You will collect information on the performance of your authorized test. You will report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your authorized test of which you become aware.

J. You may request changes to the Scope of Authorization (Section II in this letter) of your authorized test. Such requests will be made in consultation with DMD/OHT7-

OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition of other instruments and associated software for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other extraction methods for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other specimen types for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition and/or substitution of primers or probes for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition and/or substitution of control materials for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition and/or substitution of other ancillary reagents and materials for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You may request the addition and/or substitution of home specimen collection kits or kit components for use with the authorized P23 Labs TaqPath SARS-CoV-2 Assay. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You will evaluate the analytical limit of detection and assess traceability of your authorized test with any FDA-recommended reference material(s), if requested by FDA[5]. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, FDA will update the EUA summary to reflect the additional testing. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[5] 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 concerning your authorized test.

T. You will track adverse events, including any occurrence of false results with your authorized test and report any such events to FDA under 21 CFR Part 803.

U. All laboratory personnel using your authorized test must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your authorized test in accordance with the authorized test procedure.

V. You will ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

W. You will additionally track adverse events associated with the OMNIgene·ORAL OM-505 Collection Device, or any other home specimen collection kit authorized for use with your product, including occurrences of false results and report to FDA under 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).

X. You will make available all instructions related to the self-collection of saliva specimens using the OMNIgene·ORAL OM-505 Collection Device, or any other home specimen collection kit authorized for use with your product, both in the distributed kit and on your website.

Y. You will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using saliva specimens collected with the OMNIgene·ORAL OM-505 Collection Device during that timeframe, including how many kits were requested and granted for home collection, how many kits were shipped and returned, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the OMNIgene·ORAL OM-505 Collection Device.

Conditions Related to Printed Materials, Advertising and Promotion

Z. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

AA. No descriptive printed matter, including 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.

BB. All descriptive printed matter, including 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;
- This test 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
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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 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

Enclosures