

July 10, 2020

Mary Smith
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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 (HCP).

This test is also for use with saliva specimens that are self-collected at home or in a healthcare setting with or without the supervision and/or assistance of an HCP, by individuals using the P23 At-Home COVID-19 Test Collection Kit, when determined to be appropriate by an HCP based on the results of a COVID-19 medical questionnaire.

This test is also for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, when determined to be appropriate by an HCP.

Authorized Laboratories: Testing is limited to P23 Labs, LLC (P23), located at 500 S. University Ave., Suite 504, Little Rock, AR 72205, or other laboratories designated by P23 Labs, LLC that are also certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Ms. Smith:

On May 21, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of your product,^{2,3} pursuant to Section

¹ For ease of reference, this letter will use the term “you” and related terms to refer to P23 Labs, LLC.

564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Subsequently, on June 17, 2020, FDA granted your request to update the authorized labeling.⁴

On June 18, 2020, FDA received a request from P23 Labs, LLC to amend the EUA. In response to that request, and having concluded that revising your 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 May 21, 2020, letter in its entirety with the amendments incorporated⁵ to authorize the emergency use of your product. Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product is now intended for the indication 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.⁶

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.

³ The May 21, 2020, letter authorized your product for the qualitative 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 BAL specimens from individuals suspected of COVID-19 by their HCP. 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 an HCP, or collected by an HCP, using the OMNIgene·ORAL OM-505 Collection Device, when determined to be appropriate by an HCP. Testing was limited to P23 Labs, LLC (P23), located in Little Rock, AR, that is certified under CLIA, 42 U.S.C. §263a, to perform high complexity tests.

⁴ On June 17, 2020, your request was granted to update the EUA Summary and laboratory Standard Operating Procedures to: (1) update the Intended Use to include “*The P23 Labs TaqPath SARS-CoV-2 assay can be used with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit when determined to be appropriate by a healthcare provider,*” (2) include the Everlywell COVID-19 Test Home Collection Kit as an authorized home collection kit for use with the test and associated supporting data, (3) add an RNase P RT-PCR assay that will be run on all Everlywell collected samples, prior to running the P23 Labs TaqPath SARS-CoV-2 Assay, to control for adequate human specimen collection, (4) add previously collected clinical data for nasopharyngeal swab performance, and (5) add minor edits and clarifications.

⁵ The amendments include: (1) updates granted on June 17, 2020, as described above (2) revision of the indication and Scope of Authorization to update use of your product with saliva specimens that are self-collected at home or in a healthcare setting, with or without the supervision and/or assistance of an HCP, by individuals using the P23 At-Home COVID-19 Test Collection Kit when determined to be appropriate by an HCP based on the results of a COVID-19 medical questionnaire, (3) revision of the indication and Scope of Authorization to update use of your product at P23 Labs, LLC (P23), located in at 500 S. University Ave., Suite 504, Little Rock, AR 72205, or other laboratories designated by P23 Labs, LLC that are also that is certified under CLIA, 42 U.S.C. §263a, and meet requirements to perform high complexity tests, (4) revision of the Scope of Authorization to include use of an RNase P RT-PCR assay run on all specimens self-collected by individuals using authorized collection kits (nasal and saliva), prior to running the P23 Labs TaqPath SARS-CoV-2 Assay, to control for adequate human specimen collection, and (5) additional conditions of authorization specific to authorized laboratories. In addition, the HCP and Patient Fact Sheets were updated to reflect the revisions herein.

⁶ 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).

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.⁷

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 P23 At-Home COVID-19 Test Collection Kit, that contains the OMNIgene·ORAL OM-505 Collection Device, to self-collect saliva specimens at home or in a healthcare setting, with or without the supervision and/or assistance of an HCP, when determined to be appropriate by an HCP based on the results of a COVID-19 medical questionnaire.

Your product can also be used with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, when determined to be appropriate by an HCP.

Testing is limited to P23 Labs, LLC (P23), located at 500 S. University Ave., Suite 504, Little Rock, AR 72205 or other laboratories designated by P23 Labs, LLC that are also certified under CLIA, 42 U.S.C. §263a, and meet requirements to perform high-complexity tests.

⁷ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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. 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 the specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument.

Your product 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 specified under Condition K 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 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.
- An RNase P RT-PCR assay run on all nasal or saliva specimens self-collected by individuals using authorized collection kits, prior to running the P23 Labs TaqPath SARS-CoV-2 Assay, to control for adequate human specimen collection.

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 P23 At-Home COVID-19 Test Collection Kit, which contains the OMNIgene·ORAL OM-505 Collection Device, individuals must follow all specimen collection and mailing instructions provided with the device, as described in the “P23 At-Home COVID-19 Test Collection Kit Saliva – HCP Supervised Instructions for Patients” or the “P23 At-Home COVID-19 Test Collection Kit Saliva – Unsupervised - 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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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: 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 P23 At-Home COVID-19 Test Collection Kit Saliva – HCP Supervised Instructions for Patients, the P23 At-Home COVID-19 Test Collection Kit Saliva – Unsupervised - Instructions for Patients, the COVID-19 Medical Questionnaire, the Sample Registration and Accessioning in LIMs SOP and the Specimen Acceptance and Rejection (Home-Collection) (collectively referenced as “authorized labeling”) is authorized to be distributed to and used by P23 Labs, LLC (P23), located in at 500 S. University Ave., Suite 504, Little Rock, AR 72205, or other laboratories designated by P23 Labs, LLC, 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 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:

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 other authorized laboratories and 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 make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, the P23 At-Home COVID-19 Test Collection Kit Saliva – HCP Supervised Instructions for Patients, and the “P23 At-Home COVID-19 Test Collection Kit Saliva – Unsupervised - Instructions for Patients, and any other home specimen collection kit instructions authorized for use with your product.
- D. 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.
- E. 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 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 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.
- F. 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.

- G. 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.
- H. 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.
- I. 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.
- J. 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.
- K. 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.
- L. 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.
- M. 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.
- N. 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 FDA⁸. 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.
- O. 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.
- P. You will additionally track adverse events associated with the P23 At-Home COVID-19 Test Collection Kit, 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,

⁸ 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.

should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

- Q. You will make available all instructions related to the self-collection of saliva specimens using the P23 At-Home COVID-19 Test Collection Kit, or any other home specimen collection kit authorized for use with your product, both in the distributed kit and on your website.
- R. 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 P23 At-Home COVID-19 Test Collection Kit 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 P23 At-Home COVID-19 Test Collection Kit.

P23 Labs, Inc. (You) and Other Authorized Laboratories

- S. You and other authorized laboratories using your product will 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.
- T. You and other authorized laboratories using your product will 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 home specimen collection kits, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- U. You and other authorized laboratories when testing authorized specimens self-collected using home-collection kits authorized for use with your product you must follow any specimens accessioning protocol provided with the self-collection kit and/or outlined in the P23 Labs Master SOP when accepting specimens for testing.
- V. You and other authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- W. You and other authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- X. You and other authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (info@p23labs.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.

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

Conditions Related to Printed Materials, Advertising and Promotion

- AA. All descriptive printed matter, including 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 the Act and FDA regulations.
- BB. 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.
- CC. 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure