July 18, 2024

Maria Sur
Senior Director, Regulatory Affairs
Laboratory Corporation of America
8790 Devon Ridge Court
Sunbury, Ohio 43074

Device:	Labcorp Monkeypox PCR Test Home Collection Kit
EUA Number:	EUA230044
Company:	Laboratory Corporation of America ("Labcorp")
Indication:	For the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected), presenting with acute, generalized pustular or vesicular rash suspected of mpox[1] when determined to be appropriate by a healthcare provider.
Authorized Laboratories:	Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

Dear Maria Sur,

On March 22, 2024, based on your[2] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Labcorp Monkeypox PCR Test Home Collection Kit, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter[3].

[1] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term "mpox" as a synonym for monkeypox, the disease caused by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

[2] For ease of reference, this letter will use the term "you" and related terms to refer to Laboratory Corporation of America ("Labcorp").

[3] The March 22, 2024, letter authorized the Labcorp Monkeypox PCR Test Home Collection Kit for the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected), presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare

On May 22, 2024, you requested that FDA amend your EUA. Based on this request, and having concluded that revising the March 22, 2024, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the March 22, 2024, letter in its entirety with the revisions incorporated.[4] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section III) of this reissued letter, your product[5] is now authorized for use consistent with the indication described above.

On August 9, 2022, 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, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.[6] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[7]

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 virus that causes mpox can cause a serious or life-threatening disease or condition to humans infected by this virus;

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provider. Emergency use of this product was limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

[4] The revisions to the March 22, 2024, letter and authorized labeling include: (1) addition of the accessioning procedure titled "Accessioning of Mpox Specimens Collected with Labcorp Home Collection Kits," and (2) correcting typographical errors in the kit component details listed in the EUA summary and the specimen collection step in the Instructions for Use.

[5] For ease of reference, this letter will use the term "your product" to refer to the Labcorp Monkeypox PCR Test Home Collection Kit used for the indication identified above.

[6] 87 FR 50090 (August 15, 2022)

[7] 87 FR 56074 (September 13, 2022)

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the virus that causes mpox by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect this virus DNA from the collected human specimen, and that the known and potential benefits of your product when used for such use, 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.[8]

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 collection kit intended for the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected) presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare provider.

Collection kit supplies for your product are sent to the designated entity by the authorized distributor, The Dot Corporation, where they are assembled and distributed to patients, when determined to be appropriate by a healthcare provider. Individuals using your product then collect the specimen according to the provided authorized sample collection instructions (summarized in the authorized labeling below) and ship the specimen to Labcorp via FedEx according to the specimen return instructions.

The lesion swab specimens collected using your product are transported at ambient temperature in transport media for testing at an authorized laboratory. The non-variola *Orthopoxvirus* nucleic acid from the lesion swab is maintained in the specimen packaging. Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

The Labcorp Monkeypox PCR Test Home Collection Kit includes specimen collection and storage materials (or other authorized materials as may be requested under Condition Q. below) as well as instructions for shipping the specimen to Labcorp via FedEx described in the "Labcorp Monkeypox PCR Test Home Collection Kit Instructions for Use."

The labeling entitled "Labcorp Monkeypox PCR Test Home Collection Kit Instructions for

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

Use," the EUA Summary (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), the following standard operating procedures (SOPs): "Accessioning of Mpox Specimens Collected with LabCorp Home Collection Kits," "SQNM-MPX-101 Accessioning Acceptance Questionnaire", and "Handling and Processing of Samples Submitted for SQNM-MPX-101 SOP", and the documents provided to authorized entities as part of the contract provisions is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling."

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used 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 infection with the monkeypox virus by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect monkeypox virus DNA from the collected human specimen, 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), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

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

Labcorp (You) and Authorized Distributor(s)[9]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. Your product must comply with the following quality system requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

E. You and authorized distributor(s) must make available all instructions related to the self-collection of lesion swab specimens using the Labcorp Monkeypox PCR Test Home Collection Kit both in the shipped kit and on your website.

F. 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 authorized labeling.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.

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.

I. You and authorized distributor(s) must maintain customer complaint files on record.

[9] "Authorized Distributor(s)" are identified by you, Laboratory Corporation of America ("Labcorp"), in your EUA submission as an entity allowed to distribute your product.

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.

J. You and authorized distributors 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 performance claimed in the authorized labeling.

K. If requested by FDA, you and authorized distributors must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of the Labcorp Monkeypox PCR Test Home Collection Kit 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.

Labcorp (You)

L. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

M. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

N. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

O. If requested by FDA, you must submit associated documents and records related to your quality system for FDA review within 48 hours of the request.

P. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials.

Q. You may request modifications 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 modification to this EUA should be submitted to Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA.

R. You must have a process in place to track adverse events associated with the Labcorp Monkeypox PCR Test Home Collection Kit, including any occurrences of false results with your product, 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/OPEQ/CDRH (via email: CDRH-

EUAReporting@fda.hhs.gov).

S. You must further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

T. You must submit to FDA a summary report summarizing the results of any testing performed inclusive of the first ten positive lesion swab specimens collected with the Labcorp Monkeypox PCR Test Home Collection Kit, including the positivity rate for lesion swab specimens.

Authorized Laboratories

U. Authorized laboratories testing lesion swab specimens collected using your product must follow the applicable accessioning Standard Operating Procedure (SOP) when accepting specimens for testing.

V. Authorized laboratories using your product must use it only in conjunction with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA test consistent with its EUA.

W. Authorized laboratories must have a process in place to track adverse events associated with your product and report to you (1-800-833-3935 or OnDemandSupport@Labcorp.com) and to FDA pursuant to 21 CFR Part 803.

Labcorp (You), Authorized Distributor(s), and Authorized Laboratories

X. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov). In addition, authorized distributor(s) and authorized laboratories report to you (1-800-833-3935 or OnDemandSupport@Labcorp.com).

Y. 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

Z. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

AA. 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 monkeypox virus or other non-variola orthopoxviruses.

BB. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the collection and maintenance of lesion swab specimens as an aid in detection of nucleic acid from non-variola *Orthopoxvirus*, including monkeypox virus, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, 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 infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure