



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-4202]

### Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of Mpox; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocations of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.), for the TaqPath Monkeypox/Orthopox Virus DNA Kit, and Becton, Dickinson and Co., for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by these Authorization holders. The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

**DATES:** The Authorization for the Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.)'s, TaqPath Monkeypox/Orthopox Virus DNA Kit is revoked as of April 18, 2023. The Authorization for the Becton, Dickinson and Co.'s, VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System is revoked as of May 24, 2023.

**ADDRESSES:** Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

**FOR FURTHER INFORMATION CONTACT:** Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On December 13, 2022, FDA issued the Authorization to Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.) for the TaqPath Monkeypox/Orthopox Virus DNA Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on January 11, 2023 (88 FR 1587), as required by section 564(h)(1) of the FD&C Act. On December 23, 2022, FDA issued the Authorization to Becton, Dickinson and Co. for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on January 31, 2023 (88 FR 6262), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

## II. Authorizations Revocation Request

In a request received by FDA on April 13, 2023, Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.), requested the revocation of, and on April 18, 2023, FDA revoked, the Authorization for the Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.)'s TaqPath Monkeypox/Orthopox Virus DNA Kit. Because Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.), notified FDA that it is not commercially supporting the TaqPath Monkeypox/Orthopox Virus DNA Kit and no kit reagents were distributed in the United States and requested FDA revoke the Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.)'s TaqPath Monkeypox/Orthopox Virus DNA Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on May 22, 2023, Becton, Dickinson and Co., requested the withdrawal of, and on May 24, 2023, FDA revoked, the Authorization for the Becton, Dickinson and Co.'s VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System. Because Becton, Dickinson and Co., notified FDA that it is not commercially manufacturing the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System and no reagents were distributed in the United States and requested FDA revoke the Becton, Dickinson and Co.'s VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

## III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/>.

## IV. The Revocations

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Life Technologies Corp. (a part of Thermo Fisher Scientific Inc.)'s TaqPath Monkeypox/Orthopox Virus DNA Kit, and

Becton, Dickinson and Co.'s VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System. The revocations in their entirety follow and provide an explanation of the reasons for revocations, as required by section 564(h)(1) of the FD&C Act.



April 18, 2023

Stacey Moltchanoff  
Regulatory Affairs Manager  
Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.)  
5781 Van Allen Way  
Carlsbad, CA 92008

**Re: Revocation of EUA220461**

Dear Stacey Moltchanoff:

This letter is in response to the request from Life Technologies Corporation (a part of Thermo Fisher Scientific Inc.), in a letter received April 13, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for TaqPath Monkeypox/Orthopox Virus DNA Kit issued on December 13, 2022. Thermo Fisher Scientific Inc. has decided not to commercially support the EUA product and requested that the EUA be revoked. FDA understands that, as of the date of this letter, no TaqPath Monkeypox/Orthopox Virus DNA Kit reagents were distributed in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Thermo Fisher Scientific Inc. has requested that FDA revoke the EUA for the TaqPath Monkeypox/Orthopox Virus DNA Kit, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA220461 for the TaqPath Monkeypox/Orthopox Virus DNA Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath Monkeypox/Orthopox Virus DNA Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) 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



May 24, 2023

Melissa Bar Hoover, Ph.D., RAC  
Senior Regulatory Affairs Manager  
Becton, Dickinson and Company  
7 Loveton Circle,  
Sparks, MD 21152-0999

**Re: Revocation of EUA220453**

Dear Dr. Bar Hoover:

This letter is in response to the request from Becton, Dickinson and Company (“BD”), in a letter received May 22, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System issued on December 23, 2022. BD has decided not to manufacture or sell these kits moving forward and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, no VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System reagents were distributed in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BD has requested that FDA withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA220453 for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) 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

Dated: October 4, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*