

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

Final Guidance

Policy for Monkeypox Tests to Address the Public Health Emergency

September 14, 2022

Emergency Use of IVDs for Monkeypox

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Actions Taken September 7, 2022



FDA Takes Significant Action to Help Expand Access to Testing

www.fda.gov/news-events/press-announcements/monkeypox-update-fda-takes-significant-action-help-expand-access-testing

- HHS Secretary issues 564 declaration for the emergency use of IVDs for monkeypox
www.hhs.gov/about/news/2022/09/07/hhs-secretary-becerra-issues-564-declaration-to-expand-the-availability-of-testing-for-monkeypox.html
- FDA Guidance: Policy for Monkeypox Tests to Address the Public Health Emergency
www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency
- FDA issues first monkeypox emergency use authorization (EUA)
www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices

Assistance for Monkeypox Test Developers

- EUA Templates to assist developers
www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices#templates
- Frequently Asked Questions on Testing for Monkeypox
www.fda.gov/medical-devices/monkeypox-and-medical-devices/faqs-testing-monkeypox
- Virtual Town Halls / Webinar on the Policy for Monkeypox Tests
www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-webinars-and-stakeholder-calls
Submit questions in advance to: CDRHWebinars@fda.hhs.gov with “*Question for the Monkeypox Tests Webinar*” in the subject line.
- Email questions, pre-EUAs, and EUA submissions to: MPXDx@fda.hhs.gov

Policy for Monkeypox Tests To Address the Public Health Emergency



- Describes FDA's review priorities of emergency use authorization (EUA) requests for monkeypox diagnostic tests
- Describes FDA's enforcement policies for certain diagnostic tests that are developed by and performed in a single-site laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) that meets the requirements to perform tests of high complexity
- Provides recommendations for diagnostic test validation
- Describes FDA's enforcement policies for FDA-cleared or authorized monkeypox diagnostic tests that are modified
- Describes FDA's enforcement policies for certain serology tests

EUA Request Review Priorities

For monkeypox (MPX) diagnostic tests, FDA intends to prioritize review of EUA requests for:

- **High-throughput diagnostic tests**
- Tests with **home specimen collection**
- **Rapid diagnostic tests**

All from experienced developers with high manufacturing capacity that:

- Inform FDA (within 30 days of the guidance) of their intent to submit an EUA request

Overview for Laboratories Developing MPX Diagnostic Tests



- **FDA will *not* expect EUA requests** for *certain* MPX diagnostic tests when the laboratory notifies FDA (within 5 business days of offering test or from date of guidance if already being offered)
 - **Developed and performed in a single site CLIA-certified laboratory** certified to perform tests of **high complexity**;
 - Molecular **PCR** technology;
 - **Lesion swabs samples**; and
 - Appropriately **validated**.
- **FDA will *not* expect EUA requests** for *certain* validated modifications to a cleared or authorized MPX diagnostic test with notification to FDA

FDA intends to **accept notifications for 30 days** after publication of guidance.

Overview for Commercial Manufacturers of MPX Diagnostic Tests

- FDA expects developers to **submit** an EUA request or premarket submission and **receive authorization** or clearance **prior to offering or distributing** a monkeypox test
 - Inform FDA within 30 days of guidance of intent to submit an EUA request – MPXDx@fda.hhs.gov
- **FDA does not intend to object to implementation** of *certain* modifications to a developer's own cleared or authorized MPX diagnostic test while FDA conducts its review

Monkeypox Diagnostics: Validation & Templates



- Validation Recommendations in Voluntary Templates
www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices#templates
 - EUA Summary Template for Developers of Molecular Diagnostic Tests for Monkeypox
 - EUA Template for Developers of Molecular Diagnostic Tests for Monkeypox
- FDA intends to update recommendations as appropriate as the outbreak evolves

Monkeypox Serology Tests



- Not used to diagnose, or aid in the diagnosis of, an active infection
- Not tests of immunity
- May further understanding of the disease process

FDA does not intend to object to the use of monkeypox tests developed and performed in a high-complexity CLIA-certified laboratory that is part of an entity that conducts research on diseases and is integrated into the direct medical care of the patient (often referred to as academic medical center laboratories) where:

- the laboratory **notifies FDA** of validation, and
- certain information is included in the test reports.

First Monkeypox EUA

Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR

www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices#molecular

- Intended to detect monkeypox and other non-variola *Orthopoxvirus* DNA using lesion swab specimens



Resources for Monkeypox Test Development and Validation



How to Receive Updates/Alerts and Ask Questions by Email:

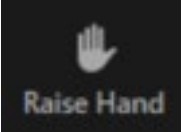
- Subscribe to CDRH Email Lists: www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists
 - **Monkeypox and Medical Devices**
 - **In Vitro Diagnostics**
- For questions about Monkeypox IVD EUAs, email: MPXDx@fda.hhs.gov

Where to Find Information:

- Monkeypox and Medical Devices: www.fda.gov/medical-devices/emergency-situations-medical-devices/monkeypox-and-medical-devices
- Monkeypox Emergency Use Authorizations for Medical Devices: www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices
- Policy for Monkeypox Tests To Address the Public Health Emergency: www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency

Let's Take Your Live Questions



- **To Ask a Question:**
 1. Raise your hand in Zoom 
 2. Moderator will announce your name and invite you to ask your question
 3. Unmute yourself when prompted in Zoom to ask your question
- **When Asking a Question:**
 4. Announce your first, last, and business name
 5. Ask one question only
 6. No questions about specific submissions
- **After Question is Answered:**
 7. Mute yourself and lower your hand
 8. If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation, Slides and Transcript will be available at:**
 - CDRH Learn: www.fda.gov/Training/CDRHLearn
 - Section “Specialty Technical Topics”
 - Sub-Section “Public Health Emergencies”
- **If you have additional questions about monkeypox:**
 - Email: MPXDx@fda.hhs.gov
- **Upcoming Webinars:**
 - www.fda.gov/CDRHWebinar

Next Virtual Town Hall
September 21, 2022 from 12:05 – 1 PM ET



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