



# CLINICAL PRACTICE UPDATES



## AMP Alert: Update on FDA Deadlines for Monkeypox Test Notification and EUA Intent to Apply

Dear Colleagues,

As shared by AMP on September 8th, the HHS issued a [declaration](#) under section 564 of the Federal, Food, Drug, and Cosmetic Act which allows the FDA to issue emergency use authorizations (EUAs) for in vitro diagnostic tests for monkeypox. Along with this declaration, the FDA published [final guidance](#) on September 13 describing the agency's requirements for diagnostics for monkeypox including laboratory developed testing procedures (LDPs). The information below is gathered from the final guidance document and clarifies certain deadlines, time limitations, and important dates that laboratories performing or who intend to perform monkeypox diagnostic testing will need to keep in mind.

### **Notification Only Pathway for Certain Laboratory Developed Testing Procedures (LDPs)**

As a reminder, FDA does not intend to object to the offering of monkeypox tests developed and performed in a CLIA-certified high complexity laboratory where the test (1) uses PCR, (2) tests lesion swabs, and (3) has been appropriately validated. There is specific direction based on whether you currently offer versus plan to offer one or more molecular PCR LDPs, as follows:

#### **For clinical laboratories *already offering* one or more qualifying molecular PCR LDPs:**

- Laboratories will need to notify the FDA as described below by **today**, September 14.

#### **For clinical laboratories *who plan to offer* one or more qualifying molecular PCR LDPs:**

- Laboratories will have **five business days** from the launch day of the test to notify the FDA that they are offering such a test.

- The agency will accept such notifications for 30 days. After October 13, FDA will require all qualifying tests to be EUA-authorized prior to use.

#### **FDA email notification requirements:**

- Email notification will need to include information about the test's validation as well as information about the laboratory (see pages 11-12 of the [guidance](#)), including its CLIA ID number, test methodology and estimated initial capacity per week.

#### **EUA Requirements for Certain Laboratory Tests**

**Any LDPs using other technology types, home specimen collection methods, at-home tests, or tests using specimen types other than lesion swabs are not eligible for the notification-only pathway described above:**

- If a laboratory would like to use the test to inform patient care, FDA is expecting the laboratory to obtain an EUA prior to its use.
- As a reminder, FDA intends to prioritize review of applications for these types of tests from experienced developers with high manufacturing capacity that inform FDA of their intent to submit an EUA request by October 13. FDA may adjust priorities in the future.

**“Experienced developers” who expect to submit an EUA for a high-throughput diagnostic test, a test with home specimen collection, or a rapid diagnostic test:**

- In order to receive priority review, the developer is expected to send an email stating their intent to submit an EUA by October 13.
- The email, titled “Intent to Submit EUA Request,” should include information about the test technology, manufacturing capacity, throughput, expected timeline through the submission of an EUA request, and “any available validation data.” Upon receipt of that email, “FDA’s goal will be to respond promptly by return email on a rolling basis,” and FDA will also let the developer know at that time if their product meets the priorities.
- FDA has defined an “experienced developer” as a firm already holding an EUA or a formal marketing application or “similar experience” (potentially, but not explicitly, including CE marks or other non-U.S. regulatory authorizations) and with which the agency “does not have current compliance concerns.”

#### **Allowable EUA Cleared / Authorized Test Modifications**

**High-complexity CLIA laboratories can make certain modifications to a cleared/authorized test if the modification does not change the indication for use as authorized by the FDA or the analyte specific reagents (e.g., the modifications do not change the PCR primers and/or probes or enzymes).** FDA states that including new/different extraction kits or instruments would not be expected to change the indication for use. FDA also states that modifications to specimen types, test settings (e.g., point-of-care), and new patient populations, among others, do not fall under this policy. Similar to the policy regarding changes to COVID-19 diagnostic tests, the clinical laboratory would

only need to submit validation data, not an EUA supplement or new submission, to the FDA. However, these laboratories are “encouraged” to work with the original developer “so that validation data supporting the modifications can be submitted by the original developer to FDA”. For tests that have been modified but not yet authorized/cleared in that form, the developer and/or laboratory would need to be clear in offering the test that it has not been reviewed by the FDA.

**Commercial developers can make certain changes to its own EUA authorized or 510(k) cleared (i.e., the CDC assay) monkeypox test, and launch the updates, without the FDA authorizing the change so long as the modification does not impact the test’s indication for use or the analyte specific reagents.** However, the test developer would need to submit validation data that supports the modification to the FDA in either “a supplemental EUA request or a new premarket submission” although, as noted, they could launch the modification before the request is cleared or authorized. For now, it is not clear if such a “new premarket submission” could include a new EUA after the initial call for EUA request notifications.

**Links to information for clinical laboratories are available on our [MPX Resources Website](#).** This resource will be updated throughout the Monkeypox response.

AMP maintains that any actions taken by FDA to regulate LDPs is outside of its authority; however, AMP will notify our members promptly if FDA issues any clarifications to or changes this policy. We hope information about FDA’s guidance is helpful to your efforts to contribute to patient care.

If you have questions about the FDA guidance itself, please contact FDA directly at [MPXDx@fda.hhs.gov](mailto:MPXDx@fda.hhs.gov).

If you identify concerns or opportunities for AMP to assist in MPX response please contact [Robyn Temple-Smolkin](#) (Senior Director, Clinical & Scientific Affairs) or [Sarah Thibault-Sennett](#) (Director, Public Policy & Advocacy).

Thank you,

AMP’s Advocacy & Clinical Practice Teams