



# CLINICAL PRACTICE UPDATES



Dear Colleagues,

As you are aware, previously on August 4th, HHS Secretary Becerra declared a [public health emergency](#) for monkeypox. Yesterday, he issued a second [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 diagnostics to expand the availability of tests for monkeypox. Coinciding with this new declaration, the FDA also published final guidance on “[Policy for Monkeypox Tests to Address the Public Health Emergency](#),” describing the agency’s requirements for diagnostics including laboratory developed testing procedures (LDPs).

Last, the FDA also announced the first EUA for a monkeypox diagnostic was issued to Quest Diagnostics and has created a [webpage](#) with links to EUA submission templates for monkeypox tests and up to date information on authorizations. Note that the CDC authorized test is not listed on this page as it has full clearance.

Of note in the final guidance released yesterday:

#### *Prioritization of Review:*

FDA intends to prioritize review of EUA applications for high-throughput diagnostic tests, tests with home specimen collection, or rapid diagnostic tests all from experienced developers with high manufacturing capacity that inform FDA within 30 days of publication of the guidance in the Federal Register of their intent to submit an EUA request. “Experienced developers” refers to developers who have successfully been issued an EUA for a test during a public health emergency, received approval or clearance for a diagnostic test, or have similar experience and are developers for whom FDA does not have current compliance concerns.

#### *Requirements of LDPs:*

To address immediate capacity needs at this time, 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 uses PCR, tests lesion swabs, has been appropriately validated, and the laboratory notifies the FDA within five business days of offering the test. This does not apply to at-home specimen collection or other specimen types.

If FDA identifies a significant problem or concern with a test, FDA will notify the laboratory by email and work to address the concerns in a timely manner. If concerns cannot be

addressed, FDA would expect the laboratory to stop offering the test, conduct a recall, and/or notify the end-user.

Test reports should prominently disclose that the test has not been reviewed by the FDA.

*Modifications to FDA-cleared or EUA-authorized Diagnostic Tests:*

Developers may modify tests without seeking a new or amended EUA/clearance as long as the test has been validated, the modifications do not adversely affect test performance, and the laboratory notifies FDA.

*Notification Requirements:*

Laboratories will notify the FDA about their tests via email to [mpxdx@fda.hhs.gov](mailto:mpxdx@fda.hhs.gov) with a subject line “FDA Notification of Development and Validation of Monkeypox Test” and include information on the lab name, test name, methodology, lab director, address, CLIA ID#, date testing was or intends to be initiated, point of contact, testing capacity, and if for a modification, a short description of the modifications made to the test.

*FDA Discretion:*

FDA retains discretion and may decide not to object to the offering of tests using different specimen types or a different technology. FDA will monitor the situation, including capacity news, and may adjust and/or revise this policy as appropriate.

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

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