

FDA Is Accepting EUA Requests for Monkeypox Tests, But Time is of the Essence

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The Food and Drug Administration (FDA) issued a guidance on development and emergency use authorization of diagnostic and serological tests for the monkeypox virus following the Secretary of the Department of Health and Human Services's declaration of a public health emergency under Section 564 of the Food, Drug and Cosmetic Act on [August 9, 2022](#). In short, the Section 564 declaration provides legal justification for the emergency use of medical countermeasures that may be necessary to diagnose, treat, or prevent serious disease caused by a biological agent when there are no adequate, approved, and available alternative therapies in the U.S. Such a declaration then empowers FDA to solicit and ultimately issue Emergency Use Authorizations (EUAs) for appropriate medical countermeasures, which may be devices, diagnostics, drugs, or vaccines, depending upon the circumstances. Subsequently, the Secretary [declared on September 7, 2022](#) that in vitro diagnostics for monkeypox were needed to respond to the public health emergency, and the FDA released its guidance on the same day. The monkeypox test guidance is similar to the guidance FDA issued on diagnostic and serological tests for COVID-19 early on in the coronavirus pandemic in that both guidance documents describe the agency's general expectations and approach for test development and validation, as well as the EUA request process.

Similar to the COVID-19 test guidance, the [monkeypox test guidance](#) covers diagnostic and serological tests developed by commercial manufacturers as well as high-complexity laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA). However, the monkeypox guidance is significantly different from its COVID-19 counterpart in that it imposes major restrictions on the EUA request process for diagnostic tests for monkeypox and on laboratory-developed tests (LDTs) for monkeypox. For commercial monkeypox tests, FDA intends to prioritize EUA requests based on the more limited need for monkeypox diagnostic tests as compared to the rapidly spreading and deadly COVID-19 virus. To be eligible for prioritization, a manufacturer must notify FDA of its intent to submit an EUA request within 30 days of the Federal Register announcement of the guidance, which was September 13, 2022 (i.e., notice must be submitted by October 13, 2022), and the test must incorporate high-throughput technology, allow for at-home specimen collection, or be a rapid diagnostic test that can be used at the point-of-care and generate results within 30 minutes. FDA will respond to these initial notices from manufacturers and indicate whether or not the agency intends to prioritize the request and, if not, will explain why the request is not eligible for prioritization.

In addition, during a virtual town hall meeting for test developers held on September 21, FDA indicated that over-the-counter test kits likely will not receive priority review at this time given the need for high-accuracy PCR and point-of-care testing.

FDA also states that it does not intend to object to LDTs for the detection of monkeypox virus, but only when the LDTs:

- use molecular PCR technology;
- use lesion swab specimens; and
- are appropriately validated.

In addition, the clinical laboratory must notify FDA of the completed validation within five business days of offering the LDT. The guidance states that the agency may consider LDTs that use different specimen types or technologies, but clinical labs that plan to develop and offer such tests must discuss their plans with the agency. During the September 21 virtual town hall, FDA confirmed that antigen tests and specimen collection kits other than lesion swabs (e.g., saliva collection kits for at-home collection) would not be considered valid LDTs for monkeypox at this time, but that the agency will consider a laboratory's validation plan and data when available. Furthermore, due to the immediate need for an increase in testing capacity, FDA only intends to accept notifications for monkeypox LDTs for 30 days following the Federal Register announcement of the guidance (i.e., laboratories must submit notices by October 13, 2022).

For serological tests, FDA will not object to the use of such tests for monkeypox when they are developed and performed by CLIA-certified, high-complexity laboratories for the primary purpose of conducting research, but may also be integrated into the patient care process. Such serological test reports must include information clarifying that the test cannot be used to diagnose an active infection and that the significance of the results has not been established. Clinical laboratories must also notify FDA of a completed validation for a serological test, with the guidance further encouraging laboratories to share the validation data with FDA.

As with COVID-19 tests, FDA is providing on its website [EUA templates](#) for monkeypox diagnostic tests, which include detailed recommendations for validation testing.

Importantly, both commercial diagnostic tests and LDTs for monkeypox have a 30-day deadline for notifying FDA of either intent to submit an EUA or completed validation, respectively. Interested manufacturers and laboratories should ensure that their development timelines are sufficient to meet the October 13, 2022 cutoff for notice.

FDA will hold [virtual town halls](#) for both monkeypox and COVID-19 test developers on the fourth Wednesday of each month.

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