

CDRH Virtual Town Hall Series  
**Test Development and Validation During  
Public Health Emergencies**  
(#93: Monkeypox and COVID-19)

September 28, 2022

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# Upcoming Virtual Town Halls

Date	Topic
October 5	Monkeypox
October 12	Monkeypox

**Time: 12:05 – 1 PM ET**

**Medical Device Webinars and Stakeholder Calls:**

[www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-webinars-and-stakeholder-calls](http://www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-webinars-and-stakeholder-calls)

**Virtual Town Hall Series - Test Development and Validation During Public Health Emergencies (COVID-19 and Monkeypox):**

[www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-test-development-and-validation-during-public-health-emergencies-covid-19](http://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-test-development-and-validation-during-public-health-emergencies-covid-19)

# Opening Remarks

# Monkeypox Policy – Important Date



- October 13, 2022 = 30 days after publication of the notice of availability of the guidance
  - Section IV.A.1: Prioritization of Review of EUA Requests
    - Inform FDA of intent to submit an EUA request within 30 days after publication of the notice of availability of the guidance
  - Section IV.A.2: Notification to FDA for certain diagnostic tests developed and performed by laboratories
    - Notify FDA within 5 business days of offering the test that the laboratory has appropriately validated such test
    - FDA intends to accept notifications within 30 days after publication of the notice of availability of the guidance

Email to: [MPXDx@fda.hhs.gov](mailto:MPXDx@fda.hhs.gov)

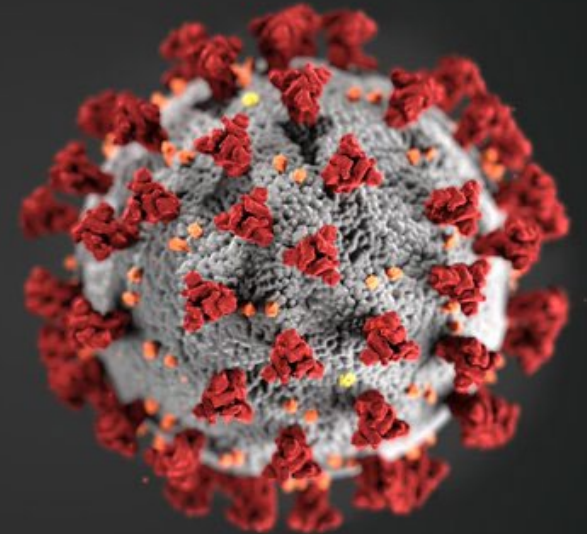
# COVID-19 Test Policy – Guidance Update

Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality (OPEQ)  
CDRH | Food and Drug Administration

[COVID19Dx@fda.hhs.gov](mailto:COVID19Dx@fda.hhs.gov)

## Coronavirus Update:

FDA updates COVID-19 test policy, encourages developers to seek traditional premarket review for most test types



# COVID-19 Test Policy Update

## September 27, 2022



FDA Updates COVID-19 Test Policy, Encourages Developers to Seek Traditional Premarket Review for Most Test Types

[www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-updates-covid-19-test-policy-encourages-developers-seek-traditional](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-updates-covid-19-test-policy-encourages-developers-seek-traditional)

- Reissued Guidance: Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

[www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)

- Updated Frequently Asked Questions on Testing for SARS-CoV-2

[www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)

# COVID-19 Test Policy Updates



Guidance updated to ensure continued access to tests while encouraging the transition to traditional premarket review pathways

- Effective September 27, 2022, FDA generally expects COVID-19 tests to have been issued an EUA (or marketing authorization) prior to the tests being distributed or offered
  - Continuing prior enforcement policy for tests already being offered during ongoing FDA review
- FDA intends to review only a small subset of new EUA requests for COVID-19 diagnostic tests
  - Tests for which EUA authorization requests are pending prior to this announcement will remain in the queue
  - Traditional premarket review pathways for other types of COVID-19 tests (de novo classification or 510(k) clearance premarket review pathways)

# COVID-19 EUA Request Review Priorities

FDA generally intends to focus its review on EUA requests and supplemental EUA requests from experienced developers for:

- Diagnostic tests that are likely to have a **significant benefit to public health** (such as those that employ new technologies);
- Diagnostic tests that are likely to **fulfill an unmet need** (such as diagnosing infection with a new variant or subvariant);
- Supplemental EUA requests for previously authorized tests when the request is intended to **fulfill a condition of authorization** or includes a modification that will **significantly benefit public health or fulfill an unmet need**; and
- Tests for which the EUA request is **from (or supported by) a US government stakeholder**, such as tests funded by BARDA or NIH RADx.



# COVID-19 Tests – Marketing Authorization



- FDA strongly encourages developers of new tests and existing tests for which modifications are sought to pursue traditional premarket review pathways
  - De Novo classification
  - 510(k) premarket clearance
  
- Level of evidence for authorization under traditional pathways is higher than for an EUA
  - FDA can provide recommendations specific to a test developer's situation
    - [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)
    - Pre-Submission interactions



# State Authorization Policy

## **Maintaining the policy from the November 15, 2021, policy, without further revision**

- For the States and territories listed on the notification list on FDA's website prior to November 15, 2021, that are continuing to authorize laboratories within that State or territory to develop and perform a test for COVID-19, FDA does not intend to object to the use of such tests for specimen testing where the notification of SARS-CoV-2 test validation is not submitted to FDA and the laboratory does not submit an EUA request to FDA, and where instead the State or territory takes responsibility.
- This policy applies only to tests designed, developed, and used within a single, high-complexity CLIA-certified laboratory.
- This policy does not apply to at-home tests or tests with home specimen collection, or any testing outside of a high-complexity CLIA-certified laboratory.

# Distribution and Offering During FDA Review



- Generally continuing policies from November 2021 with clarifying edits
- FDA does not intend to object to the continued distribution or offering of the test while under FDA review for:
  - Tests on one of the [notification lists](#) on FDA's website at the time of issuance of the updated guidance
  - Laboratory developed tests (LDTs) offered prior to November 15, 2021, where an EUA request was submitted to FDA as described in Section IV.C.2 of the November 15, 2021, version of this guidance document
- FDA generally expects developers to cease distributing, marketing, and offering their tests within 15 calendar days of notice from FDA that FDA declines to review, declines to issue, or otherwise decides not to authorize the test for any reason

# Modifications to COVID-19 Diagnostic Tests



- In general, FDA **expects modified tests to be authorized** under an EUA or traditional marketing authorization **before being distributed or offered**
  - FDA generally does **not intend to object to continued implementation** during FDA review of **modifications made *prior*** to updated guidance, per policies in prior version of guidance
  - FDA does **not intend to object to implementation**, without a new EUA, of ***certain validated modifications*** made by a **high-complexity CLIA-certified laboratory** to an authorized COVID-19 diagnostic test
- FDA intends to review supplemental EUA requests for previously authorized tests when the request is intended to **fulfill a condition of authorization** or includes a **modification within priorities** outlined in the guidance
  - For modifications that are ***beyond*** the scope of priorities, FDA encourages developers to consider including the modification in a submission through a traditional premarket review pathway



# Previously Emailed Questions

# Resources for Monkeypox Test Development and Validation

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

- Subscribe to CDRH Email Lists (e.g., **Monkeypox and Medical Devices, In Vitro Diagnostics**): [www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists](http://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists)
- For questions about Monkeypox IVD EUAs, email: [MPXDx@fda.hhs.gov](mailto: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](http://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](http://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](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency)
- EUA Templates to assist developers: [www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices#templates](http://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](http://www.fda.gov/medical-devices/monkeypox-and-medical-devices/faqs-testing-monkeypox)

# Resources for COVID-19 Test Development and Validation



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

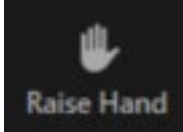
- To receive CDRH IVD update/alert emails, subscribe to the In Vitro Diagnostics Mailing List: [www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists](http://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists)
- For questions about COVID-19 IVD EUAs, email: [COVID19DX@fda.hhs.gov](mailto:COVID19DX@fda.hhs.gov)
- For questions about laboratory data harmonization for COVID-19 testing, email: [SHIELD-LabCodes@fda.hhs.gov](mailto:SHIELD-LabCodes@fda.hhs.gov)

## **Where to Find Information:**

- In Vitro Diagnostics EUAs: [www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas](http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas)
- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency: [www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)
- FAQs on Testing for SARS-CoV-2 (*Includes: Notifications and Emergency Use Authorizations, At-Home COVID-19 Diagnostic Tests, Test Development and Review, Test Uses, Testing Supplies, and COVID-19 Related Test Data and Reporting*): [www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2](http://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2)
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: [www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program)
- NIH Independent Test Assessment Program (ITAP): [www.nibib.nih.gov/covid-19/radx-tech-program/ITAP](http://www.nibib.nih.gov/covid-19/radx-tech-program/ITAP)

# 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](http://www.fda.gov/Training/CDRHLearn)
    - Section “Specialty Technical Topics”
    - Sub-Sections “Public Health Emergencies” and “Coronavirus (COVID-19) Test Development and Validation Virtual Town Hall Series”
- **If you have additional questions about monkeypox diagnostic development:**
  - Email: [MPXDx@fda.hhs.gov](mailto:MPXDx@fda.hhs.gov)
- **If you have additional questions about COVID-19 diagnostic development:**
  - Email: [COVID19DX@fda.hhs.gov](mailto:COVID19DX@fda.hhs.gov)
- **Upcoming Webinars:**
  - [www.fda.gov/CDRHWebinar](http://www.fda.gov/CDRHWebinar)

**Next Virtual Town Hall (monkeypox)  
October 5, 2022 from 12:05 – 1 PM ET**



**U.S. FOOD & DRUG**  
ADMINISTRATION