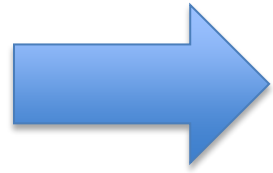CDRH Virtual Town Hall Series
Test Development and Validation During Public Health Emergencies
(#101: Monkeypox (mpox) and COVID-19)

February 15, 2023

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CDRH Learn

www.fda.gov/Training/CDRHLearn

In Vitro Diagnostics - (Updated 01/19/23)
IVD Development, CLIA, and Virtual Town Hall Series

Virtual Town Hall Series

Show 10 entries

Series Number	Topic	Date	Materials
100	Monkeypox (mpox) and COVID-19	01/11/2023	Presentation ↗ Transcript Printable Slides
99	Monkeypox (mpox) and COVID-19	12/14/2022	Presentation ↗ Transcript
98	Monkeypox and COVID-19	11/30/2022	Presentation ↗ Transcript
97	Monkeypox	11/09/2022	Presentation ↗ Transcript
96	COVID-19 and Monkeypox	10/26/2022	Presentation ↗ Transcript
95	Monkeypox	10/12/2022	Presentation ↗ Transcript
94	Monkeypox	10/05/2022	Presentation ↗ Transcript
93	COVID-19 and Monkeypox	09/28/2022	Presentation ↗ Transcript Printable Slides
92	Monkeypox	09/21/2022	Presentation ↗ Transcript
91	Monkeypox	09/14/2022	Presentation ↗ Transcript Printable Slides

Showing 1 to 10 of 102 entries

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2021 and 2020 virtual town hall presentations and transcripts are archived ↗ and located in the Specialty Technical Topics section as: Coronavirus (COVID-19) Test Development and Validation Virtual Town Hall Series.

Upcoming Virtual Town Hall

Date	Topic
March 22, 2023*	Monkeypox (mpox) and COVID

Time: 12:05 – 1 PM ET

This will be our last regularly scheduled virtual town hall; however, we will announce any ad hoc virtual town halls if and when special topics come up in the future.

Medical Device Webinars and Stakeholder Calls:
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

Opening Remarks – Monkeypox (mpox) Updates

- **2/10: Cepheid Xpert Mpox Test Authorized**
  - www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-mpox-emergency-use-authorizations-medical-devices

Opening Remarks - COVID-19 Updates

- **1/12: Updates to COVID-19 testing guidances to reflect duration of EUA declaration**
  - Policy for Coronavirus Disease-2019 Tests (Revised): Guidance for Developers and Food and Drug Administration Staff; www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
  - Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests: Guidance for Test Developers and Food and Drug Administration Staff; www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests

- **1/30: Biden Administration announced it will end the public health emergency declaration on May 11, 2023**
  - Refer to *What will happen with tests offered under EUA if the public health emergency expires and is not renewed?* www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2

- **2/6: Updates to the easy step-by-step guide to include information about reporting your over-the-counter (OTC) at-home COVID-19 test result to MakeMyTestCount.org**
  - Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results; www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results

Previously Emailed Questions

Resources for Monkeypox (mpox) 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
- For questions about Monkeypox (mpox) 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
- 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

Resources for COVID-19 Test Development and Validation

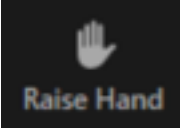**How to Receive Updates/Alerts and Ask Questions by Email**:

- 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
- For questions about COVID-19 IVD EUAs, email: COVID19DX@fda.hhs.gov
- For questions about laboratory data harmonization for COVID-19 testing, email: 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
- 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
- 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
- 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
- NIH Independent Test Assessment Program (ITAP): www.nibib.nih.gov/covid-19/radx-tech-program/ITAP

Let's Take Your Live Questions

- **To Ask a Question:** Raise Hand
    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 and Transcript will be available at:**
  - CDRH Learn: www.fda.gov/Training/CDRHLearn
  - Under the "In Vitro Diagnostics" section and "Virtual Town Hall Series" subsection

- **If you have additional questions about monkeypox (mpox) diagnostic development:**
  - Email: MPXDx@fda.hhs.gov

- **If you have additional questions about COVID-19 diagnostic development:**
  - Email: COVID19DX@fda.hhs.gov

- **Upcoming Webinars:**
  - www.fda.gov/CDRHWebinar

Next Virtual Town Hall (Monkeypox (mpox) and COVID-19) March 22, 2023 from 12:05 – 1 PM ET