FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

CDRH Virtual Town Hall Series

Test Development and Validation During Public Health Emergencies

(#102: Monkeypox (mpox) and COVID-19)

March 22, 2023

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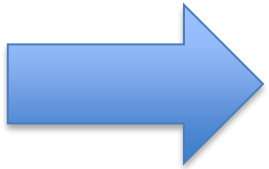
CDRH Learn

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

Previous 1 2 3 4 5 ... 11 Next

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.

Opening Remarks – Town Hall General Updates

Based on current COVID-19 trends, the U.S. Food and Drug Administration (FDA) decided that Wednesday, March 22, 2023, will be the last recurring virtual town hall on test development and validation during the mpox and COVID-19 public health emergencies. Over the last three years, the FDA hosted more than 100 virtual town halls on test development and validation to provide information and answer questions about COVID-19 and mpox tests.

If you continue to have questions about test development and validation, please email COVID19Dx@fda.hhs.gov or MPXDx@fda.hhs.gov.

The FDA may schedule ad hoc webinars on special topics in the future.

Opening Remarks – Monkeypox (mpox) Updates

Opening Remarks - COVID-19 Updates

On January 30th The Biden Administration announced it will end the public health emergency declaration on May 11, 2023.

This does NOT impact the COVID-19 EUA declaration under section 564 of the FD&C Act, which continues until the Secretary of HHS terminates it.

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

Refer to *Draft Guidance Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*
www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease

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:**
  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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