

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

January 11, 2023

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Center for Devices and Radiological Health



Upcoming Virtual Town Halls

Date	Topic
Feb 15, 2023	Monkeypox (mpox) and COVID

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

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

In Vitro Diagnostics - (Updated 11/16/22)
 IVD Development, CLIA, and Virtual Town Hall Series

Virtual Town Hall Series

Show 10 entries

Series Number	Topic	Date	Materials
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
90	COVID-19	08/24/2022	Presentation Transcript

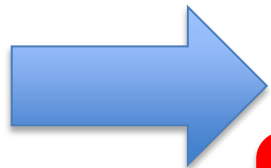
Showing 1 to 10 of 101 entries

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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.

CDRH Learn

www.fda.gov/Training/CDRHLearn



Opening Remarks – Monkeypox (mpox) Updates

Opening Remarks - COVID-19 Updates

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:

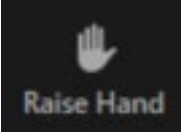
- To receive CDRH IVD update/alert emails, subscribe to the In Vitro Diagnostics Mailing List: www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists
- For questions about COVID-19 IVD EUAs, email: COVID19DX@fda.hhs.gov
- For questions about laboratory data harmonization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

**Next Virtual Town Hall (Monkeypox (mpox) and COVID-19)
Feb 15, 2023 from 12:05 – 1 PM ET**



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