# Mpox Readiness Survey

Email Support

## Introduction

The Association of Public Health Laboratories (APHL) has developed the following survey to determine the capabilities of public health and Department of Defense (DoD) laboratories in detecting mpox virus (MPXV). We ask that, if applicable, your laboratory's BT Response Coordinator complete the survey, with review and approval from the Laboratory Director. If your laboratory does not have a BT Response Coordinator, we ask that the laboratory director complete the survey..

Many laboratories perform the Centers for Disease Control and Prevention (CDC) Non-variola Orthopoxvirus Real-time PCR test. This test does not distinguish between the two clades of MPXV. However, some laboratories have utilized Laboratory Developed Tests (LDTs) or sequencing in order to determine clades. There are two clades of MPXV: clade I, previously known as the Congo Basin clade; and clade II, previously called the West African clade; each clade has 2 distinct subclades. On August 14, 2024, the World Health Organization (WHO) declared a Public Health Emergency of International Concern regarding the rising number of Clade I mpox cases in the Democratic Republic of the Congo.. Both mpox Clade Ia and Ib are circulating in DRC and have now been detected in neighboring countries as well as Sweden and Thailand.

Aggregate responses captured from this survey will be shared with the CDC and other partners to support national response needs and inform decision-making. Individual responses may also be shared with these partners. By completing this survey, you consent to the identifiable information being shared. If you have concerns, please contact APHL at emergency.preparedness@aphl.org or Rana Rahmat, Specialist, Laboratory Response Network, at rana.rahmat@aphl.org or 240.485.2763.

Kindly complete this short survey no later than September 30, 2024.

Please note: based on your responses to certain questions you may not be required to provide responses to all the questions in the survey.

## Component A: Clinical Specimen

1. Can your laboratory detect non-variola orthopoxviruses?

- ○ Yes
- ○ No (Skip Q2)

2. What assay does your facility utilize to detect non-variola orthopoxviruses?

*Please select all that apply.*

- ☐ CDC LRN-B deployed FDA 510 (k) Non-variola Orthopox (NVO) Real-Time PCR Assay
- ☐ Test with Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA), (please specify)
- ☐ Laboratory Developed Test (LDT), please specify
- ☐ Not Applicable

3. Does your facility have mpox (monkeypox) specific PCR assays?

*Please select all that apply.*

- ☐ Yes, generic mpox real-time PCR assay
- ☐ Yes, Clade I Real-Time PCR assay (does not distinguish between Clade Ia and Clade Ib)
- ☐ Yes, Clade Ia Real-Time PCR assay
- ☐ Yes, Clade Ib Real-Time PCR assay
- ☐ Yes, Clade II Real-Time PCR assay
- ☐ Yes, other PCR assay e.g., trioplex/triplex assay, (please specify)

3a. Please provied the Platform (s) and Capacity. (Carried forward based on selection in Q3)

| | Platform (s) | Capacity |
|---|---|---|
| » Yes, generic mpox real-time PCR assay | | |

| | Platform (s) | Capacity |
|---|---|---|
| » Yes, Clade I Real-Time PCR assay (does not distinguish between Clade Ia and Clade Ib) | | |
| » Yes, Clade Ia Real-Time PCR assay | | |
| » Yes, Clade Ib Real-Time PCR assay | | |
| » Yes, Clade II Real-Time PCR assay | | |
| » Yes, other PCR assay e.g., trioplex/triplex assay, (please specify) | | |

4. Does your laboratory perform sequencing for mpox?

*Please select all that apply.*

- ○ Yes
- ○ No (Skip to Q7)

5. Is sequencing performed under CLIA at your laboratory?

- ○ Yes
- ○ No

6. Is your laboratory able to identify mpox clades via sequencing?

- ○ Yes, but the approach/analysis was designed for clade II
- ○ Yes, the approach/analysis is not affected by clade or subclade
- ○ Yes, but not sure about approach/analysis performance for different clades/subclades
- ○ No

7. What is the biosafety level (BSL) your laboratory is utilizing for inactivation of specimens prior to testing for mpox?

- ○ BSL-2
- ○ BSL-2 with BSL-3 practices

- ○ BSL-3

8. What is the biosafety level (BSL) your laboratory is utilizing for **testing suspect mpox specimens**?

- ○ BSL-2
- ○ BSL-2 with BSL-3 practices
- ○ BSL-3

9. For the week of **September 8 – 14**, how many specimens did your laboratory receive for testing?

| | Number of Specimens Tested/Analyzed |
|---|---|
| CDC LRN-B deployed FDA 510 (k) Non-variola Orthopox (NVO) Real-Time PCR Assay | |
| Test with Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) | |
| Laboratory Developed Test (LDT), | |
| Sequencing | |

10. Which days of the week your laboratory is open and conducts testing?

- ○ Only Tests M-F (Weekdays)
- ○ M-F and Weekends (Sat and/or Sun)

10a. What is your current average turnaround time (TAT) from receipt of specimen to your laboratory to results reporting (in hours)?

*Please type the number of hours.*

| | |
|---|---|
| Overall | |
| M-F only (Weekdays) | |
| M-F and Weekends (Sat and/or Sun) | |

11. Which automated extraction platform has your laboratory verified for mpox testing?

*Please select all that apply.*

- ☐ Qiagen EZ1 Advanced XL
- ☐ Roche MagNA Pure 24
- ☐ Roche MagNA Pure 96
- ☐ NUCLISENS easyMAG
- ☐ Other, (please specify)

12. Assuming unlimited reagent availability, what is your estimated **standing capacity** and **internal surge capacity?** This number should include both manual and automated extraction. Please reference APHL's Surge Capacity Planning Tool for the LRN-B for complete definitions of standing, internal and overall surge capacity.

*Hover over bold text for definitions.*

| | Number of Specimens | NVO Assay | Triplex/Quadplex | Clade 1a, II, RP |
|---|---|---|---|---|
| Daily Standing | | | | |
| Weekly Standing | | | | |
| Daily Internal Surge | | | | |
| Weekly Internal Surge | | | | |

## Component B: Wastewater Surveillance Samples

13. Are there laboratories in your jurisdiction performing wastewater surveillance for mpox?

- ○ Yes
- ○ No (End Survey)

14. What assay is utilized for testing wastewater samples?

- ○ CDC Non-variola Orthopox (NVO) Real-Time PCR Assay
- ○ Other Assay, (please specify)
- ○ Not known

15. Please describe why your jurisdictions is not utilizing the CDC NVO assay.