Mpox Testing at the NYC Public Health Laboratory

Requesting Approval for Mpox Testing at the NYC Public Health Laboratory (PHL)

Monkeypox virus (MPXV) has two distinct genetic clades, clade I and II. MPXV clade I is found in countries in both central and eastern Africa, and MPXV clade II is endemic to countries in western Africa and was responsible for the large, multinational outbreak in 2022. Mpox caused by either MPXV clade I or MPXV clade II can present similarly in patients.

Routine, widely available, and U.S. Food and Drug Administration (FDA)-authorized MPXV testing can identify generic non-variola *Orthopoxvirus* (NVO) DNA lesion swab specimens and differentiate clade II MPXV. However, MPXV clade I-specific testing is not widely available. Clinical laboratories and providers should carefully review test results from in-house testing or reference lab send-out testing prior to requesting testing by the PHL.

- **For specimens that are NVO-positive and clade II-negative, consult the NYC Health Department's Provider Access Line (PAL) at 866-692-3641 and follow the clade I testing guidance on Page 2.**
- **For specimens positive solely for MPXV generic DNA (an assay specifically detects MPXV but does not differentiate between clades), alert the PAL regarding patient travel or exposure to an individual with recent travel to central or eastern Africa.**

Commercial testing is recommended for routine suspected clade II mpox cases. However, if testing is not available or clade I mpox is suspected, request mpox testing from the PHL by calling the PAL. Alert the PAL regarding patient travel or exposure to an individual with recent travel to central or eastern Africa. These cases may have additional specimen submission requirements for MPXV clade differentiation. If testing at the PHL is approved, follow the specimen collection and submission instructions in this document.

Quick Facts About MPXV Testing at the PHL

The PHL performs the Cepheid Xpert Mpox Assay to detect MPXV clade II DNA in suspected mpox lesion swab specimens. This test was authorized by the FDA on February 10, 2023, for emergency use by authorized laboratories for the qualitative detection and differentiation of MPXV clade II or NVO. The Cepheid Xpert Mpox Assay should be ordered for MPXV testing at the PHL. Please note the following:

- Submitters should request the Mpox Assay in the PHL's eOrder system.
    - For more information, see Test Ordering (eOrder) Instructions on Page 3.
- The assay gives results for the detection of NVO and MPXV clade II.
- Testing at the PHL can only rule out infection with clade II MPXV.
- Clade I testing is currently performed by the Centers for Disease Control and Prevention (CDC).
    - For more information on MPVX clade I testing requirements, see the suspected MPXV clade I infections section on Page 2.

For more information, refer to the following FDA fact sheets:

- Fact sheet for health care providers: fda.gov/media/165319/download
- Fact sheet for patients: fda.gov/media/165320/download

Reminder: Call the PAL at 866-692-3641 for consultation prior to requesting the testing of or submitting specimens.

Specimen Collection

- Follow the CDC's infection prevention and control recommendations when collecting specimens (available at cdc.gov/mpox/hcp/infection-control/healthcare-settings.html).
- Use sterile nylon swabs in viral transport media (VTM) or universal transport media (UTM) for collection. Cotton swabs and swabs with metal or wooden shafts should not be used for collection. Specimens collected with these swabs will be rejected by the PHL.
- Label each container with **all** the following information:
    - The patient's first and last name
    - At least one identifier (such as the patient's date of birth, the patient's medical record number, or the referring lab accession number)
    - The date and time the specimen was collected
    - The lesion site (such as the face, neck, or left hand)

For suspected MPXV clade II lesions (NYC Health Department Sexual Health Clinics only):

- Identify **two** lesions, preferably from two different sites. Collect a total of **two specimens per patient (one swab per lesion)**.
    - Collect specimens following clinical standard practices. Follow the CDC's guidelines for collecting and handling specimens for mpox testing (available at cdc.gov/mpox/hcp/diagnosis-testing/collecting-specimens.html).
- For each lesion, collect one lesion swab specimen. Place each swab in an individual vial of VTM or UTM.
    - Swabs in VTM or UTM are the **only** accepted specimen type for the Cepheid Xpert Mpox Assay.

For suspected MPXV clade I lesions (all submitters after PAL approval):

- Identify **two** lesions, preferably from two different sites, if possible. Collect a total of **four specimens per patient (two swabs per lesion)**.
    - Collect specimens following clinical standard practices. Follow the CDC's guidelines for collecting and handling specimens for mpox testing (available at cdc.gov/mpox/hcp/diagnosis-testing/collecting-specimens.html).
- For each lesion, collect duplicate lesion swab specimens. Duplicate swabs are **required** for MPXV clade I testing.
    - Submit one swab in a vial of VTM or UTM.
    - Submit one dry swab in a sterile collection container. Ensure the container is labeled clearly so the PHL can link the appropriate dry swab and VTM or UTM specimen.

Note: If testing the VTM or UTM specimen at the PHL does not rule out MPXV clade I infection, the dry lesion swab will be submitted to the CDC for confirmatory testing. **Dry swabs are the only**

specimen type validated and accepted by the CDC for MPXV clade I testing.

Specimen Storage

Place specimens in a refrigerator (between 2 and 8 degrees Celsius) within one hour of collection. **Do not freeze specimens.** Specimens should be sent to the PHL with cold packs within five days of collection.

Test Ordering (eOrder) Instructions

1. Visit a816-phleorder.nyc.gov/PHLeOrder.
2. Sign in or register as a new user. For instructions on creating an account, visit on.nyc.gov/phl-eorder-guide.
3. Complete **one eOrder per specimen** submitted.
4. Fill out the required information and add the following to the specified fields:
    - Test: **Mpox Assay**
    - Specimen Container: **Swab in VTM/UTM**
    - Specimen Source: **Other**
    - Specimen Source - Other: **Lesion + Site of Lesion Swabbed** (for example, left arm)

    Note: For duplicate dry swabs submitted for MPXV clade I testing, a second test requisition form will be provided by the PHL during the approval process. This form is needed to accession the specimen for send-out to the CDC if further testing is indicated. Clearly label corresponding dry swabs and swabs in VTM or UTM.
5. Fill in both the collection date and collection time fields as shown on the specimen containers.

    Note: Results will be provided to the submitter via eOrder. The submitter must then make the results available to the ordering provider, who should relay those results to the patient.
6. Inform your clinical laboratory that specimens should be delivered to the PHL and eOrders have been submitted. Print eOrder forms and include with the corresponding swab specimen.

Note: Specimens from each lesion swab require separate eOrder test requisitions. The information on the specimen label and eOrder test requisition must match to prevent testing delays or rejection of specimens. In addition, indicate the lesion site on both the specimen tube and corresponding eOrder.

Specimen Packaging and Transport

1. Containers containing specimens in VTM or UTM should be wrapped in Parafilm to prevent leaking during transport.
2. Specimens should be placed into individual sealed biohazard bags with an absorbent in case of leaking during transport.
3. Send specimens by courier to the PHL using Category B packaging and shipping guidelines (available at bit.ly/usdot-transporting-substances).
    - Place each individual specimen container in a leakproof primary receptacle (such as a sealed biohazard bag).
    - Place each individual container in a leakproof secondary receptacle.
    - Place all items together in a rigid or strong outer packaging.
    - Place a list of contents and each printed eOrder test requisition form (one per specimen)

between the secondary receptacle and outer packaging.

- Specimens should be transported on ice packs if refrigerated.
- Transport specimens to the PHL at:

  New York City Public Health Laboratory
  455 First Ave.
  New York, NY 10016

Obtaining Test Results

eOrder users should:

1. Navigate to the Results section of the dashboard.
2. Click **Final Result**.
3. Use the search fields at the bottom of the screen to filter for specific orders.

For more instructions on accessing reports, visit on.nyc.gov/phl-eorder-guide.

PHL Contact Information

If you have questions about eOrder or test results, call the PHL at 212-336-4644. For questions about testing, call the PHL at 212-671-5700.

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