

# Mpox Testing at the New York City Public Health Laboratory

## Requesting Approval for Mpox Testing at the New York City (NYC) Public Health Laboratory (PHL)

Call the NYC Department of Health and Mental Hygiene (NYC Health Department) Provider Access Line at 866-692-3641 to request testing for suspected mpox. If testing at PHL is approved, read the specimen collection and submission instructions in this document.

## **Quick Facts About the Cepheid Xpert Mpox Assay**

PHL performs the Cepheid Xpert Mpox Assay to detect monkeypox virus (MPXV) clade II DNA in suspected mpox lesion swab specimens. This test was authorized by the U.S. Food and Drug Administration (FDA) on February 10, 2023, for emergency use by authorized laboratories for the qualitative detection and differentiation of MPXV clade II or non-variola *Orthopoxvirus*. The Cepheid Xpert Mpox Assay should be ordered for mpox testing at PHL. Note the following:

- If MPXV clade I infection is suspected, submitters must call the NYC Health Department Provider Access Line at 866-692-3641 to review case information and discuss testing and response guidance. For more information on MPVX clade I testing requirements, see the Suspected MPXV Clade I Infections section on Page 2.
- Submitters should request the "Xpert Mpox Assay" on eOrder.
- The assay gives results for the detection of non-variola *Orthopoxvirus* and MPXV clade II.
- Only one swab should be submitted per lesion site. Collect two specimens per patient.
- Testing will be performed on the Cepheid Xpert Dx platform.

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

## **Specimen Collection**

- Follow the Centers for Disease Control and Prevention (CDC)'s infection prevention and control recommendations when collecting specimens, available at cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html.
- Use sterile nylon swabs in viral transport media (VTM) or universal transport media (UTM) for collection.
- Collect two specimens per patient.
  - o Identify two lesions, preferably from two different sites, if possible.
  - Collect specimens following clinical standard practices. Follow the CDC's guidelines for collecting and handling specimens for mpox testing, available at cdc.gov/poxvirus/mpox/clinicians/prep-collection-specimens.html.
  - Swabs in VTM or UTM are the only accepted specimen type for the Cepheid Xpert Mpox Assay.

- Collect and submit only one swab per lesion site. Collect two specimens per patient.
  - o If MPXV clade I infection is suspected, see the Suspected MPXV Clade I Infections section.
  - Cotton swabs and swabs with metal or wooden shafts should not be used for collection.
    Specimens collected with these swabs will be rejected by 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, medical record number or referring lab accession number)
  - o The date and time the specimen was collected
  - The lesion site (such as the face, neck or left hand)

**Note:** Specimens from different lesion sites require separate eOrder test requisitions, so two eOrder test requisitions will need to be submitted per patient. To submit an eOrder test requisition, visit <a href="mailto:on.nyc.gov/phl-eorder-guide">on.nyc.gov/phl-eorder-guide</a>. The information on the specimen label and eOrder test requisition must match to prevent testing delays or rejection of specimens.

# **Suspected MPXV Clade I Infections**

For people who are suspected of having an MPXV clade I infection and have a documented travel or epidemiological link to a region of endemicity (such as the Democratic Republic of Congo), call the NYC Health Department Provider Access Line at 866-692-3641 for a consultation prior to requesting the testing of or submitting specimens. If, after consulting with the NYC Health Department, it is determined there is suspicion for MPXV clade I infection, two swabs will need to be collected from each lesion. Submit one swab in a vial of VTM or UTM and one dry swab in a sterile container for each lesion (up to two lesions per patient). If testing a specimen in VTM or UTM does not rule out MPXV clade I infection, the dry swab from the suspected lesion will be required for confirmatory testing at the CDC.

**Note:** Dry swabs are the only specimen type validated and accepted by the CDC for MPXV clade I testing.

#### **Specimen Storage**

Within one hour of collection, place specimens in a refrigerator (between 2 and 8 degrees Celsius). **Do not freeze specimens.** Specimens should be sent to 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 <a href="mailto:on.nyc.gov/phl-eorder-guide">on.nyc.gov/phl-eorder-guide</a>.
- 3. Complete one eOrder per specimen submitted.
- 4. Fill out required information and add the following to the specified fields:
  - Test: Xpert Mpox Assay
  - Specimen Container: Swab in VTM/UTM
  - Specimen Source: Other
  - Specimen Source Other: Lesion + Site of Lesion Swabbed (for example, left arm)
- 5. Fill in both 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 PHL and eOrders have been submitted.

## **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 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 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 212-336-4644. For questions about testing, call the PHL Molecular Virology Unit at 212-671-5890.