Centers for Disease Control and Prevention

Mpox

Guidelines for Collecting and Handling Specimens for Mpox Testing

Updated April 29, 2024

General Guidance

Review Biosafety Laboratory Guidance for Handling and Processing Mpox Specimens for recommended laboratory procedures and biosafety guidelines when collecting, handling, and processing specimens.

Specimen collection, storage, and shipping of human specimens are subject to Clinical Laboratory Improvement Amendments (CLIA) restrictions. Therefore, it is recommended to contact the laboratory testing facility to determine their specific requirements. See below guidance for suspected or confirmed mpox lesion collection, storage, packaging, and shipping.

For additional information:

- Infection Prevention and Control of Mpox in Healthcare Settings
- Clinical Management and Infection Prevention and Control for Mpox | WHO
- Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard | OSHA
- ACIP Smallpox Vaccine Recommendations

Collection

Unroofing or aspiration of lesions (or otherwise using sharp instruments for mpox testing) is not necessary, nor recommended, due to the risk for sharps injury.

All recommended PPE should be worn when collecting a specimen from a person with suspected or confirmed mpox.

Only sterile, synthetic swabs (including but not limited to polyester, nylon, or Dacron) with plastic, wood, or thin aluminum (wire) shafts should be used to collect suspected or confirmed mpox specimens for diagnostic testing. Do not use cotton swabs.

Skin lesion material, including swabs of lesion surface, exudate, or lesion crusts are the recommended specimen types for laboratory testing of mpox virus specimens. Procedures and materials used for collecting specimens may vary depending on the phase of the rash (e.g., swabs from lesion surface or crust from healing lesion). Collect two swabs from each lesion, preferably from different locations on the body or from lesions that differ in appearance (e.g., a pair of swabs for each lesion with a total of 2-3 lesions). Vigorously swab each lesion, avoiding contamination of gloved hands, to ensure adequate viral DNA is collected. Unroofing or aspiration of lesions (or otherwise using sharp instruments for mpox testing) before swabbing is not necessary, nor recommended due to the risk for sharps injury. Place swabs from lesions, crusts, and exudate in separate tubes.

The type of acceptable specimen (dry swab or wet swab in transport media) for diagnostic testing may vary depending on the laboratory. Contact the appropriate laboratory facility to determine the specimen types accepted. At CDC, only dry swabs or swabs in viral transport media (VTM) from lesions, or lesion crusts are currently accepted for testing. Swabs in media designated for bacterial preservation may cause PCR inhibition and are not recommended.

Insert each swab into a sterile container such as a sterile tube or urine container. Glass containers are not recommended. Carefully bend to break the swab's shaft to fit inside the sterile container (if applicable, or place the entire swab into the container) . After completely securing the lid, wipe the container with an EPA-approved disinfectant for emerging viral pathogens . Placing parafilm around the lid of the container is recommended for additional leak-proof protection, but not required. Remove gloves, wash your hands (hand hygiene), and don a new pair of gloves.

Specimen Collection Printout

MPOX

CDC

Testing Patients for Mpox

What specimen to collect

- Skin lesion material, including swabs of lesion surface, exudate, or lesion crusts are the recommended specimen types for laboratory testing of mpox virus specimens.
- Laboratories may not be able to perform testing on all specimen types. Contact the testing laboratory for specifics on acceptable specimen types.

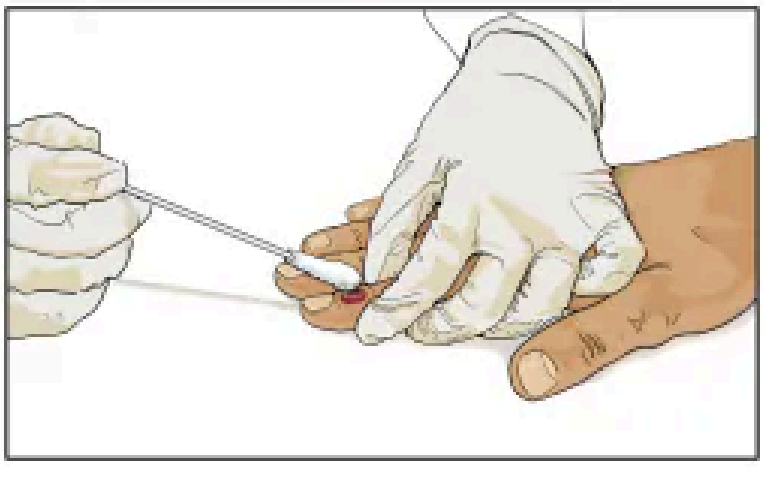
- For further testing of a specimen at CDC, three types of specimens are accepted.
  - Dry swabs of lesion material
  - Swabs of lesion material in viral transport media (VTM)*
  - Lesion crusts

* Not currently accepted for clade I mpox testing.

See Test Directory | Submitting Specimens to CDC | Infectious Diseases Laboratories for more information.

How to collect lesion specimens

1. Wear appropriate personal protective equipment (PPE).
2. Collect two swabs from each lesion, preferably from different locations on the body or from lesions which differ in appearance.
   - Use sterile, dry synthetic swabs (including, but not limited to polyester, nylon, or Dacron swabs) with a plastic, wood, or thin aluminum shaft. (Any type of shaft is acceptable as long as it can be broken or cut).
   - Do not use cotton swabs.



3. Generally, with vigorous swabbing, sufficient monkeypox virus DNA is present on the surface of a lesion, and you don't need to de-roof the lesion before swabbing. Put each swab into a separate container, either:
   - By breaking off or cutting the end of each swab's applicator into a 1.5- or 2-mL screw-capped tube with O-ring or other sterile leak-proof container (e.g. sterile urine cup) or
   - By putting the entire swab in a sterile container that has a gasket seal. Use a plastic container instead of a glass container, when possible.

How to ship specimens

- All mpox specimens except clade I mpox viral cultures (materials containing or contaminated with intentionally laboratory propagated virus) can be shipped as UN 3373 Biological Substance, Category B.

- Specimens should first be tested by a public health or clinical laboratory unless you are authorized to send specimens directly to CDC.

- If you are authorized to send specimens directly to CDC, or if you are sending specimens to CDC for viral characterization: Store refrigerated (2-8°C) or frozen (-20°C or lower) within an hour of collection.
  - Ship specimens on dry ice, when possible.
  - Specimens received outside of acceptable temperature ranges will be rejected.
  - Include an electronic Global File Accessioning Template (GFAT) form and ensure that each specimen is labeled with a unique identifier GFAT.

If fewer than 20 specimens are being submitted to CDC, a CDC 50.34 form for each specimen may be submitted instead of a GFAT.

Please include a printed manifest of your specimens with your shipment. Password protect, then email, the GFAT form to Poxviruslab@cdc.gov

For patients with confirmed mpox, health care providers may send serum to CDC directly for pox serology test. See CDC Poxvirus Serology for details.

For more information, see CDC's Mpox: Information for Healthcare Professionals page.

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PRINTOUT
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File Details: 1 MB, 1 page

Specimen Label

Clinical Laboratory Improvement Amendments (CLIA) require laboratories to ensure positive specimen identification and optimum integrity of a patient's specimen using 2 identifiers and the specimen information.

Clearly label the specimen container with the patient identifiers and include the appropriate specimen information prior to collecting the specimen. Identifiers must be visible, and labels cannot cover the identifiers. Patient identifiers should include at least 2 of the following:

- Patient name (full first and last name, no initials)
- Patient date of birth (MM/DD/YYYY)
- Patient sex assigned at birth
- A unique ID generated at the time of collection (e.g., a medical record number). A State Public Health Lab ID does not satisfy the requirement

Specimen information should include but is not limited to:

- Collection site (e.g., left arm, upper left groin, right cheek, etc.)
- Collection date
- Specimen type

Contact the laboratory facility if additional information is required on the label.

When accessioning specimens, confirm the specimen has been collected correctly from the individual being tested.

Storage

After specimen collection, store specimens in sterile leak-proof containers. Use a durable container for the required shipping and temperature conditions. Glass containers are not recommended.

If testing occurs at an external laboratory, contact the appropriate laboratory facility to determine specimen storage requirements. For testing at CDC, if specimen testing does not occur promptly after specimen collection, refrigerate (2-8°C) or freeze (-20°C or lower) the specimens until testing occurs. Dry swabs, swabs in VTM, or lesion crust(s) that are stored at 2-8°C can be tested up to 7 days from collection. Swab specimens in VTM and lesion crust(s) that are stored frozen (-20°C or lower) can be tested up to 30 days from collection whereas dry swabs that are stored frozen (-20°C or lower) can be tested up to 60 days from collection. For additional information regarding specimens shipped to CDC, see Requirements for Shipping Specimens to CDC.

Pneumatic Tube Transportation

CDC recommends that each laboratory perform a risk assessment before using the pneumatic tube system to transport suspected or confirmed mpox specimens. Each facility should conduct a site- and activity-specific risk assessment of the procedures performed, identifying the hazards involved in the process, the competency level of the personnel performing the methods, and the laboratory facility. An institution's biosafety professional, laboratory management, scientific/clinical, and safety staff should conduct the risk assessment process to determine the appropriate specimen transport practices to implement at the facility.

Facilities should ensure that all personnel transporting specimens via pneumatic tubes are trained in safe handling practices, specimen management, and spill decontamination procedures.

For additional information about performing a risk assessment, refer to the Biological Risk Assessment: General Considerations for Laboratories and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition [4.3 MB, 604 pages], Section II – Biological Risk Assessment, pages 9-20.

Shipment

Laboratory testing has indicated that the current mpox outbreak is associated with Clade II (formerly known as the West African clade) of mpox virus. The U.S. government does not consider Clade II of mpox virus as meeting the definition of Category A infectious substance under the Managing Solid Waste Contaminated with a Category A Infectious Substance (page 94). Ship specimens and material suspected or confirmed to contain Clade II of mpox virus as UN 3373 Biological Substance, Category B.

When preparing specimens for shipment, consider individually bagging specimens so that if a leak does occur, it does not cause the rejection of all specimens.

Ship specimens on dry ice, if available. Do not ship specimens at room temperature. Specimens received outside of acceptable temperature ranges will be rejected. If mpox test confirmation occurs at an external laboratory, contact the appropriate laboratory facility to determine shipping recommendations.

The primary receptacle and secondary packaging should maintain their integrity at the temperature of the refrigerant used, even if the refrigerant's temperature changes. Packages containing dry ice should be designed to prevent pressure buildup, package rupture, and allow gas release. Personnel trained per U.S Department of Transportation (DOT) hazmat transportation training requirements should pack and ship specimens.

Ensure the outer package is appropriately marked and labeled as follows:

- Sender's name and address
- Recipient's name and address
- Biological substance label
- Proper shipping name, Biological substance, Category B
- UN identification number, UN 3373
- Name and telephone number of the person responsible for shipment (available during regular business hours; optional if the information is on the airway bill)
- Shipper's Declaration is not required for UN 3373 Biological Substances Category B shipped specimens
- If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373 Biological Substance, Category B" and the number of packages
- Class 9 label, including UN 1845, and net weight, if packaged with dry ice and identified as Carbon Dioxide, solid, or Dry ice

See U.S. Department of Transportation's (DOT) Transporting Infectious Substances Safely [2.8 MB, 24 pages] .

Requirements for Shipping Specimens to CDC

In most situations, specimens should be sent to the appropriate state public health laboratory (SPHL) or a commercial laboratory for initial testing. If authorized to send directly to CDC for testing, see the requirements listed below. For more information, contact poxviruslab@cdc.gov regarding specimen types accepted, labeling, specimen storage, and shipping timeframes for testing specimens at CDC.

- CDC only accepts lesion material from dry swabs, swabs in VTM, and crust(s) from the lesion(s). Swabs in media labeled universal transport media or M4 transport media cannot be accepted for testing at CDC.
    - Refrigerated specimens (2-8°C)
        - Dry swabs, swabs in VTM, or lesion crust(s) must be tested within 7 days from collection
    - Frozen specimens (-20°C or lower)
        - Swabs in VTM or lesion crust(s) must be tested within 30 days from collection

        - Dry swabs must be tested within 60 days from collection
- The temperature at arrival determines whether CDC can accept the specimen:
    - Swabs in VTM or lesion crust(s) that arrive at -20°C or lower can be tested within 30 days from collection
    - Dry swabs that arrive at -20°C or lower can be tested within 60 days from collection
    - Specimens (dry swabs, swabs in VTM, or lesion crust(s)) that arrive between -20°C and 8°C can be tested within 7 days from collection
    - Shipment using dry ice is highly recommended
    - Specimens received outside of acceptable temperature ranges will be rejected

- Two unique specimen identifiers are required:
    - Combination of full first and last name (patient initials are not permitted),
    - Date of birth
    - Sex and age (must be together to count as 1 identifier)
    - A unique ID that is generated at the time of collection
      NOTE: Specimen ID, laboratory information management system (LIMS) ID, state public health laboratory (SPHL) ID, or case ID are not acceptable identifiers.
    - Identifiers must be visible, and labels cannot cover the identifiers.

- Swabs cannot have foam or other material placed at the bottom.
- Specimens do not have to be transported in 2 mL O-ring tubes if the original container is sterile and leak-proof. Leaking specimens, and specimens contaminated by contact with a leaked specimen, will not be tested. Consider individually bagging specimens, if possible.
- Commercial laboratories must provide a State ID on the accessioning forms; CDC cannot provide a report to the SPHL without a State ID.
- Include CDC 50.34 forms for each specimen when submitting less than 20 specimens. If your laboratory is submitting bulk specimens (more than 20 specimens), use a global file accessioning template (GFAT). Contact poxviruslab@cdc.gov to receive this form.

For more information on specimen submission to CDC

- Submitting Specimens to CDC
- Test Order – Poxvirus Molecular Detection
- Test Order – Poxvirus Serology

Personal Protective Equipment Resources

Personal Protection Equipment (PPE)

Sequence for Putting on Personal Protection Equipment [2.85 MB, 3 pages]

Last Reviewed: April 29, 2024