

Iowa Laboratory Response Network (ILRN) Update: Monkeypox Guidance for Clinical Diagnostic Laboratories

June 20, 2022

Purpose

To provide ILRN members and clinical diagnostic laboratories throughout Iowa with important details about recent monkeypox cases and instructions for obtaining laboratory testing for monkeypox virus through SHL or the Centers for Disease Control and Prevention (CDC).

What is new in this update?

- As of 6/15/2022, in addition to dry swabs, CDC (and SHL) will accept swabs stored in viral transport media (VTM) and lesion crusts for monkeypox testing.
 - Acceptable specimen collection kits, including a Monkeypox Dry Swab Kit and a Monkeypox VTM Kit, are available for ordering on the [SHL website](#). Both are acceptable specimen types and facilities may order either kit at their discretion.
 - Specimens suspected to contain the West African clade of monkeypox virus should be triple packed and shipped as Category B Biological Substances.
 - Specimens approved by IDPH for testing at SHL should be submitted using a current IDPH Epidemiological Investigation Test Request Form (TRF) obtained by contacting IDPH CADE. An SHL Viral and Bacterial PCR TRF is no longer recommended.
 - SHL requests facilities submit one TRF for each swab. This is a change from the original announcement on 6/1/22.
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Background

[Monkeypox](#) is a rare disease caused by infection with monkeypox virus, a member of the *Orthopoxvirus* genus. Since May 20, 2022, the CDC has published a variety of [Health Advisories](#) and the Iowa Department of Public Health has published several [Epi Updates](#) describing recently identified cases of monkeypox in multiple U.S. states and other countries. The identification of West African monkeypox cases in many countries that do not have endemic disease and involving patients with no direct travel history to an area with endemic monkeypox, suggest person-to-person community spread. This outbreak investigation is ongoing.

Clinical Information

[CDC's 2022 United States Monkeypox Response and Recommendations webpage](#) includes the current U.S. case count and geographical information, recommendations for clinicians and health departments,

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current case definitions, vaccine guidance for persons at risk for occupational exposure, and links to a variety of other useful resources.

Reporting Requirements

Clinicians must report suspected monkeypox cases to the IDPH Center for Acute Disease Epidemiology (CADE) as soon as monkeypox is suspected and PRIOR TO COLLECTING SPECIMENS.

IDPH will consult with CDC and SHL to determine the need and plan for laboratory testing.

Contact Information

- IDPH CADE..... (business hours) 515-242-5935 | (non-business hours) 515-323-4360
- SHL..... 319-335-4500 or 1-800-421-4692

Specimen Collection and Transport

After consultation with IDPH, appropriately collected samples should be sent to SHL for testing by real-time polymerase chain reaction (PCR).

More than one lesion should be sampled, preferably from different locations on the body and/or from lesions with differing appearances. For each lesion sampled, collect **two** lesion specimens.

- CDC and SHL will accept the following specimen types for testing: dry swabs, swabs stored in viral transport media (VTM), and lesion crusts.
- Specimen collection kits with acceptable materials are now available for order on the SHL website. Facilities may choose to order the dry swab kit or the VTM kit at their discretion. Either are acceptable. [ORDER A CLINICAL TEST KIT](#).
 - Monkeypox Dry Swab Kit – each kit contains 2 swabs appropriate for testing one lesion.
 - Return to SHL via CDS of Iowa double-bagged with the specimen bags provided.
 - If shipping through FedEx, UPS, or USPS, ensure packaging meets full requirements of a Category B Biological Substance.
 - Monkeypox VTM Kit – each kit contains 2 swabs and 2 tubes of VTM appropriate for testing one lesion.
 - Return to SHL via CDS of Iowa. Place the specimen container inside the bag provided and enclose within the mailing tube.
 - If shipping through FedEx, UPS, or USPS, ensure packaging meets full requirements of a Category B Biological Substance.

Collection instructions

- Swab or brush lesion vigorously with two separate sterile dry swabs. Use a sterile nylon, polyester, or Dacron swab with a plastic, wood, or thin aluminum shaft. Cotton and Rayon swabs are NOT acceptable. Do not use other types of swabs.
- One specimen may be tested at SHL, Iowa's Laboratory Response Network (LRN) reference laboratory, for preliminary results. SHL can forward the second specimen to CDC for monkeypox virus-specific testing if the first specimen tests positive at SHL.
- Place specimens in individual sterile containers.

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- Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection. Store refrigerated specimens for up to 7 days and frozen specimens for up to 60 days. The testing facility should receive refrigerated specimens within seven days and frozen specimens within 60 days of collection. Ship refrigerated specimens on ice packs. Shipping frozen specimens on dry ice is strongly recommended.

When patients do not meet current case definitions and monkeypox is not highly suspected testing for other rash illnesses, including syphilis, herpes simplex, and chickenpox, if indicated, is recommended, using your routine laboratory procedures or standard reference lab.

Packaging and Shipping

- Specimens suspected to contain the West African clade of monkeypox virus should be triple packed and shipped as Category B Biological Substances.
- Include all test request forms in the outer pocket of the specimen bag, NOT inside the bag with the specimens.
- Specimens must be maintained at appropriate temperature during transportation. Ship refrigerated specimens on ice packs and frozen specimens on dry ice.

Submitting Specimens for Laboratory Testing

Please be sure that IDPH and SHL have been contacted PRIOR to submitting specimens for laboratory testing. Specimens that have been approved by IDPH for preliminary testing at SHL should be submitted to SHL using a current IDPH Epidemiological Investigation Test Request Form obtained by contacting IDPH CADE. One TRF should be completed for each swab. Each pair of swabs should be labeled such that lab staff can easily identify paired swabs from a single lesion (e.g., Left arm swab #1 and Left arm swab #2).

On the TRF:

- Under “Sample Information” select “other” and provide a description of the sample type on the line provided, e.g., “Left arm swabs (#1 and #2).”
- Under “Test(s) Requested At No Charge” → select “Other Public Health Significance” and enter “Suspected monkeypox”.

Include the completed Test Request Forms with your specimen submission. Specimens may be transported to SHL via [CDS of Iowa](#), FedEx, UPS, private courier or other routine means.

Turnaround time for preliminary test results from SHL is 1-2 days. SHL will forward specimens that test presumptive positive for *Orthopoxvirus* to CDC for confirmatory monkeypox virus testing. Turnaround time for confirmatory test results from CDC is 5 days from specimen receipt, although 1-2 days is typical. Shipping to CDC may take 1-2 days following a presumptive positive test result at SHL.

Laboratory Biosafety Guidance

Measures should be taken to minimize the risk of laboratory transmission when testing routine clinical specimens from confirmed or suspected monkeypox patients. Virus may enter the body through the mucous membranes, broken skin, ingestion, parenteral inoculation, or by inhalation of droplets or fine-

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particle aerosols. Increased caution should be used when collecting, handling, or testing specimens obtained from patients suspected or confirmed to have monkeypox, especially lesion fluids or crusts, respiratory secretions, body fluids, and other tissues.

All laboratory facilities should perform a biosafety risk assessment prior to collecting, handling, storing, or performing any tests on specimens suspected to contain monkeypox virus. Based on the risk assessment, some important biosafety practices may include limiting the number of staff testing specimens, wearing appropriate personal protective equipment, using rigorously applied standard precautions, avoiding any procedures that could generate infectious droplets or aerosols, and ensuring thorough disinfection of work surfaces. If droplet/aerosol-generating procedures are unavoidable, perform them in a certified class II (or higher) biological safety cabinet and/or implement respiratory protection for staff working in the area or room. At MINIMUM, all routine work should be performed using BSL-2 facilities with BSL-2 practices. All manipulation of lesion samples for monkeypox testing should be conducted with BSL-3 practices.

Smallpox vaccine is not recommended for personnel handling and processing routine clinical specimens from monkeypox patients (e.g., urine for urinalysis, blood for CBC, chemistries, microbiology).

See [Information For Laboratory Personnel | Monkeypox | Poxvirus | CDC](#) for more information.

Other Regulatory Considerations

Currently, cases of monkeypox linked to this outbreak have been found to be caused by the West African clade of monkeypox virus. According to the Federal Select Agent Program, clinically severe human disease associated with West African strains is rare and this virus clade has not been associated with human mortality. Therefore, the Federal Select Agent Program has classified the West African clade of monkeypox virus as [EXEMPT](#) from the select agent regulations (effective 12-4-2012). The Congo Basin/Central African clade of monkeypox virus is subject to 42 CFR § 73 and requires strict reporting, transfer, and security precautions following confirmation.

Contact Us

Please contact the Drew Fayram, SHL Biothreat Coordinator and Biosafety Officer with any questions about this update (drew-fayram@uiowa.edu, 319-335-4864).