NJDOH PUBLIC HEALTH LABORATORY RECOMMENDATION REGARDING LABORATORY TESTING FOR MPOX VIRUS

INTERIM GUIDANCE

Introduction

Mpox virus is a double-stranded DNA virus, a member of the orthopoxvirus genus within the Poxviridae family. Poxviruses cause disease in humans and many other animals; infection typically results in the formation of lesions, skin nodules or disseminated rash. Other orthopoxvirus (OPXV) species pathogenic to humans include cowpox virus and variola virus (causing smallpox, which has been eradicated). Mpox is an uncommon zoonotic viral disease endemic to central and western African countries. Prior to 2022, people diagnosed with mpox outside of Africa were rarely reported and typically associated with travel or exposure to an infected animal.

Since 2022, an outbreak of mpox has affected many countries across the world that previously did not have cases of mpox, including the United States. Additional information, including case counts for the United States, can be viewed on the CDC website here.

This guidance serves to provide interim recommendations to healthcare providers, hospitals, local health departments (LHDs) and laboratories involved in the diagnosis of mpox. This document is based on CDC recommendations and those with expertise in the development of diagnostic assays for OPXV.

REPORTING

Clinicians suspecting mpox infection should strictly adhere to infection control practices. Commercial laboratory testing and testing at the NJDOH Public Health and Environmental Laboratories (PHEL) is available for mpox. Clinicians should immediately notify the local health department (LHD) where the patient resides of suspect mpox cases, and of any mpox cases where testing at PHEL is requested. Additionally, all positive orthopoxvirus or mpox virus test results should be reported to the LHD. If healthcare providers are unable to reach their LHD, providers should contact NJDOH Communicable Disease Service (CDS) at 609-826-5964 during business hours or 609-392-2020 on evenings, weekends, and holidays to request testing.

TESTING AT PHEL

Testing for mpox is available at the New Jersey Department of Health's Public Health and Environmental Laboratories (PHEL) if commercial testing is not feasible, e.g., if patients are uninsured or underinsured, for patients with severe clinical disease, or in patients where a prompt turn-around time for results is necessary (such as a suspect case in a congregate setting where multiple exposures may have occurred). Testing must be approved by the LHD prior to sending specimens to PHEL. The LHD and/or NJDOH will provide guidance for suspected cases and coordinate testing for mpox when indicated. Information for healthcare providers and laboratories is available on the NJDOH Mpox webpage.

NJ PROCEDURE FOR COMMUNICATION AND APPROVAL OF SPECIMEN SUBMISSION TO PHEL FOR TESTING

Hospitals should contact their LHD if mpox is suspected and testing at PHEL is requested. The LHD will contact the NJDOH CDS.

Once approved for testing, the hospital/submitter will be given a CDS approval (case) number. This number should be used on all paperwork and specimen labels and will be used to track information regarding the case. The NJDOH PHEL will coordinate with the hospital/submitter to package and transport specimens to PHEL for initial testing.

Reminder: No specimens will be accepted without prior approval from the LHD and/or NJDOH.

SPECIMEN COLLECTION

Multiple specimens should be collected for preliminary and confirmatory testing as follows. To collect vesicular and pustular material:

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

2. Vigorously swab or brush lesion with two separate sterile **dry** nylon**,** polyester, or Dacron swab to ensure that adequate viral DNA is collected. Do not use cotton or other types of swabs. Swabs in viral transport medium (VTM) are also acceptable for testing. 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. It is recommended to swab multiple lesions - duplicate swabs should be taken for each lesion sampled. **Please do not sanitize the patient's skin with an alcohol wipe before swabbing or brushing the lesion.**

3. Break off end of applicator of each swab into a 1.5- or 2-mL screw-capped tube with O-ring or place each entire swab in a separate sterile container.

DRY SWABS ARE PREFERRED BUT PHEL WILL ACCEPT SWABS STORED IN VIRAL TRANSPORT MEDIA (VTM) ONLY, SWABS STORED IN UNIVERSAL TRANSPORT (UTM) WILL NOT BE ACCEPTED.

4. 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. Refrigerated specimens should be sent within 7 days of collection; frozen specimens should be shipped within 60 days of collection. Shipping on dry ice is strongly recommended.

   SWABS IN VTM MUST BE RECEIVED WITHIN 7 DAYS OF COLLECTION. SPECIMENS RECEIVED OUTSIDE OF ACCEPTABLE TEMPERATURE RANGES WILL BE REJECTED.

5. One swab will be tested at PHEL for orthopoxviruses. CDC can provide Monkeypox virus-specific testing on the second dry swab specimen if the first dry swab is presumptive positive at the PHEL.

6. After specimen collection is completed, all protective materials worn by the specimen collector (gloves, mask, gown, etc.) and all used sample collection materials (alcohol wipes, holders, etc.) must be placed in red biohazard bags and autoclaved or incinerated prior to disposal. Thorough handwashing using soap should be done immediately after specimen collection and following removal of personal protective equipment (PPE).

PRECAUTIONS

Staff should always wear PPE appropriate to the risk. Gloves, impermeable lab coat and face protection are required. Skin, eyes, nose, and mouth should be barrier protected.

SPECIMEN PACKAGING

1. For specimens that are thought to be related to the ongoing 2022-2023 outbreak in the U.S. (no history of travel to endemic countries in Africa), specimens should be packaged as Category B. All other specimens should be packaged as Category A according to the IATA packaging instruction. Use an overpack for cold packs to maintain the temperature at 2-8° C. Note: Freezing specimen is not a problem for this kind of analysis.

2. Prepare three copies of the Shipper's Certification for Ground Transport and one copy of the LAB-05 with Chain of Custody.

3. Specimen Storage: Accession, package and ship immediately after collection. If there is a delay in shipping, the package may be stored at 2-8°C until picked up by the courier. Secure package in a locked refrigerator until signed for by the courier.

4. Have the courier sign the Chain of Custody. Keep a copy of all paperwork.

SPECIMEN TRANSPORT TO PHEL

1. Specimen may be transported via hospital or PHEL emergency courier for same day delivery OR World Courier overnight.

2. All specimens transported from the hospital laboratory to PHEL should be labelled as Infectious substance, affecting humans (label as Suspected Category A or Suspected Category B Infectious Substance per instructions above) on the shipping papers and on the outer container.

3. Couriers must use the COC form - Dangerous Goods Shippers Declaration and PHEL LAB-05 Form.

4. The bag with labels/forms must be attached to the package.

5. The sentinel laboratory must notify the **BTRL Program Manager at 609-610-9889 and 856-313-4882** before the courier leaves the pickup site.

SHIPPING ADDRESS

Edward Acheampong, PhD
BioThreat Response Laboratory
New Jersey Department of Health
Public Health and Environmental Laboratories
3 Schwarzkopf Drive
Ewing, NJ 08628

MPOX TESTING AT NJDOH PHEL

Testing for Mpox is available at the New Jersey Department of Health (NJDOH) Public Health and Environmental Laboratories (PHEL). PHEL performs the Laboratory Response Network (LRN) and Centers for Disease Control & Prevention (CDC) Orthopoxvirus Real-Time PCR Assay and Non-variola Orthopoxvirus Real-Time PCR Assay. Specimens that test positive using this Orthopoxvirus Real-Time PCR Assay are considered presumptive positive and will be submitted to CDC for confirmatory testing and species typing.

TURN AROUND TIME (TAT) OF THE MPOX ASSAY AT NJDOH PHEL

Within 24 hours after receipt at PHEL (most specimens received by 8 am are tested and resulted by PHEL by 6 pm):

TAT by definition is the longest time that it could take to "turn a specimen around" and produce a result after a specimen is received in the laboratory. The TAT for the initial Orthopoxvirus Real-Time PCR Assay and Non-variola Orthopoxvirus Real-Time PCR Assay after the specimen is received in the PHEL laboratory will not exceed 24 hours. The TAT will vary (within the 24 hours), depending on:

- When the specimen is received (between 8AM and 5PM or after regular PHEL business hours).

- Whether there are problems associated with the specimen collection, handling, packaging and paperwork requiring correction before testing can proceed.

- Time the alert to on-call laboratory staff is provided for off hours testing requests. Time is needed to communicate to all partners in the chain to assemble staff for testing during off peak hours and for staff travel time to the laboratory.

RESULTS REPORTING AND INTERPRETATION

Specimens that test positive using Orthopoxvirus Real-Time PCR Assay and Non-variola Orthopoxvirus Real-Time PCR Assay are considered presumptive positive for Mpox virus and will be submitted to CDC for confirmatory testing and species typing. The initial results will be reported to the CDC using LRN Results messenger and will also be emailed to the submitter.

INFECTION CONTROL GUIDELINES

If a patient presenting for care at a hospital or other health care facility is suspected of having mpox, infection control personnel should be notified immediately.

For more information on infection prevention and control of mpox, please visit the CDC website for this situation at https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html or the mpox main information page at Mpox | Poxvirus | CDC.

RESOURCES

Monkeypox (mpox) (nj.gov)

Mpox | Poxvirus | CDC

Clinical Recognition | Mpox | Poxvirus | CDC

Infection Control: Healthcare Settings | Mpox | Poxvirus | CDC

Information For Laboratory Personnel | Mpox | Poxvirus | CDC