NJDOH PUBLIC HEALTH LABORATORY RECOMMENDATION REGARDING LABORATORY TESTING FOR MONKEYPOX VIRUS

INTERIM GUIDANCE

Introduction

Monkeypox 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). Monkeypox is an uncommon zoonotic viral disease endemic to central and west African countries. People diagnosed with monkeypox outside of Africa rarely have been reported and typically are associated with travel or exposure to an infected animal.

Since May 14, 2022, multiple people diagnosed with monkeypox have been reported in several countries outside of Africa, including the United States, United Kingdom, Spain, Portugal, and Canada.

On May 20, 2022, the CDC issued a Health Advisory regarding a confirmed case of monkeypox virus infection in Massachusetts as well as multiple clusters of monkeypox virus infections in other countries. Multiple other cases of monkeypox have been confirmed in the United States since then. 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 monkeypox. This document is based on CDC recommendations and those with expertise in the development of diagnostic assays for OPXV**.**

REPORTING

Clinicians suspecting monkeypox infection should strictly adhere to infection control practices and immediately contact their local health department (LHD). If they 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.

TESTING

Testing for monkeypox is available at the New Jersey Department of Health's (PHEL) Public Health and Environmental Laboratories (PHEL). Testing must be approved by NJDOH prior to sending specimens to PHEL. NJDOH will provide guidance for suspected cases and coordinate testing for monkeypox when indicated. Information for healthcare providers and laboratories is available on the NJDOH Monkeypox webpage.

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

Hospitals should contact their LHD if monkeypox is suspected. The local health department will contact the NJDOH Communicable Disease Service (CDS).

The need for testing will be determined in consultation with NJDOH and the CDC. If public health authorities determine a need for testing the patient, 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 NJ DOH's Public Health and Environmental Laboratories will coordinate with the hospital/submitter to package and transport specimens to PHEL for initial testing.

Reminder: No specimens will be accepted without prior consultation with CDS.

SPECIMEN COLLECTION

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

1. Sanitize the patient's skin with an alcohol wipe and allow skin to dry.

2. Vigorously swab or brush lesion with two separate sterile **dry** polyester or Dacron swabs. It is recommended to swab multiple lesions- duplicate swabs should be taken for each lesion sampled.

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 SOTRED 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. Needles, blades, etc. used to open vesicles should be disposed of in an appropriate sharp's container. Thorough handwashing using soap should be done immediately after specimen collection and following removal of personal protective equipment

PRECAUTIONS

Staff should always wear PPE appropriate to the risk. If a Biological Safety Cabinet is available, the next step should be conducted in the cabinet.

Gloves, impermeable lab coat and face protection are required. Skin, eyes, nose and mouth should be barrier protected.

SPECIMEN PACKAGING

1. 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 that are being transported from the hospital laboratory to NJ PHEL should be labelled as Infectious substance, affecting humans (Suspected Category A Infectious Substance) 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

MONKEYPOX TESTING AT NJ PHEL

Testing for Monkeypox 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 MONKEYPOX ASSAY AT NJ 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 Monkeypox 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

A combination of Standard, Contact, and Droplet Precautions should be applied in all healthcare settings when a patient presents with fever and vesicular/pustular rash. Recommendations include wearing disposable gown and gloves for patient contact, using a NIOSH-certified N95 (or comparable) filtering disposable respirator that has been fit-tested, and using eye protection (e.g., face shields or goggles) if medical procedures may lead to splashing or spraying of a patient's body fluids.

In addition, a patient with suspected or confirmed monkeypox infection should be placed in a single-person room. The door should be kept closed (if safe to do so) and the patient should have a dedicated bathroom. Transport and movement of the patient outside of the room should be limited to medically essential purposes. If the patient is transported outside of their room, they should use well-fitting source control (e.g., medical mask) and have any exposed lesions covered with a sheet or gown. Intubation and extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room. **If a patient presenting for care at a hospital or other health care facility is suspected of having monkeypox, infection control personnel should be notified immediately.**

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

the monkeypox main information page at https://www.cdc.gov/poxvirus/monkeypox/index.html.

Resources

https://www.nj.gov/health/cd/topics/monkeypox.shtm
https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html

https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/index.html