NYC Health + Hospitals Monkeypox Testing Protocol for Home Isolation Patients

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1) PURPOSE & SCOPE

PURPOSE:

This protocol outlines the steps required by NYC Health + Hospitals staff in taking care of a person suspected to have Monkeypox, as determined by NYC DOHMH, and where testing for Monkeypox virus is indicated and home isolation is appropriate (i.e. no clinical need for hospitalization).

SCOPE:

This protocol applies for individuals suspected of having Monkeypox who are identified at NYC Health + Hospitals in the following healthcare settings:

- Suspected Monkeypox patient identified by DOHMH and referred for testing at H+H: Start with **Step 3**
- Suspected Monkeypox patient identified in ED or hospital clinic-based setting: Start with **Step 5**
- Suspected Monkeypox patient identified in Gotham clinic-based setting: Start with **Step 5**
- Suspected Monkeypox patient identified in Virtual ExpressCare: Skip to **Appendix B**

2) CASE DEFINITIONS

DOHMH	Refers to the NYC Department of Health and Mental Hygiene.
PUI	Refers to a designation given by DOHMH for a “Person Under Investigation” who meets the case definition of monkeypox. See “Case Definition” for additional information.
EVS	Refers to Environmental Services.
OHS	Refers to Occupational Health & Safety.

Case Definitions for Use in the 2022 Monkeypox Response

Suspect Case

- New characteristic rash* OR
- Meets one of the epidemiologic criteria and has a high clinical suspicion† for monkeypox

Probable Case

- No suspicion of other recent Orthopoxvirus exposure (e.g., Vaccinia virus in ACAM2000 vaccination) AND demonstration of the presence of
  - Orthopoxvirus DNA by polymerase chain reaction of a clinical specimen OR
  - Orthopoxvirus using immunohistochemical or electron microscopy testing methods OR
  - Demonstration of detectable levels of anti-orthopoxvirus IgM antibody during the period of 4 to 56 days after rash onset

Confirmed Case

- Demonstration of the presence of Monkeypox virus DNA by polymerase chain reaction testing or Next-Generation sequencing of a clinical specimen OR isolation of Monkeypox virus in culture from a clinical specimen

Epidemiologic Criteria

Within 21 days of illness onset:

- Reports having contact with a person or people with a similar appearing rash or who received a diagnosis of confirmed or probable monkeypox OR
- Had close or intimate in-person contact with individuals in a social network experiencing monkeypox activity, this includes men who have sex with men (MSM) who meet partners through an online website, digital application (“app”), or social event (e.g., a bar or party) OR
- Traveled outside the US to a country with confirmed cases of monkeypox or where Monkeypox virus is endemic OR
- Had contact with a dead or live wild animal or exotic pet that is an African endemic species or used a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.)

Exclusion Criteria

A case may be excluded as a suspect, probable, or confirmed case if:

- An alternative diagnosis* can fully explain the illness OR
- An individual with symptoms consistent with monkeypox does not develop a rash within 5 days of illness onset OR
- A case where high-quality specimens do not demonstrate the presence of Orthopoxvirus or Monkeypox virus or antibodies to orthopoxvirus

†Clinical suspicion may exist if presentation is consistent with illnesses confused with monkeypox (e.g., secondary syphilis, herpes, and varicella zoster).

*The characteristic rash associated with monkeypox lesions involve the following: deep-seated and well-circumscribed lesions, often with central umbilication; and lesion progression through specific sequential stages—macules, papules, vesicles, pustules, and scabs.; this can sometimes be confused with other diseases that are more commonly encountered in clinical practice (e.g., secondary syphilis, herpes, and varicella zoster). Historically, sporadic accounts of patients co-infected with Monkeypox virus and other infectious agents (e.g., varicella zoster, syphilis) have been reported, so patients with a characteristic rash should be considered for testing, even if other tests are positive.

3) Identification of Facility for Specimen Collection Only by NYC DOHMH

When DOHMH is notified of a suspected Monkeypox patient and determines the patient needs monkeypox testing (patient is now considered a person under investigation or PUI) prior to recommending home isolation, DOHMH may determine that it is necessary for the patient to travel to an H+H facility to undergo testing.

3A) DOHMH Determination and Notification of Testing Facility

- DOHMH will determine the most appropriate facility to refer the patient for Monkeypox testing based on the patient's location and access to private transportation (travel by subway, taxi, or ride share is discouraged).
- Within H+H, only the 11 acute care hospital locations will be considered by DOHMH for testing referral:
    - Hospital Emergency Departments will serve as the default testing venue unless pre-existing alternative Special Pathogens area has been identified.
- DOHMH will notify the desired testing facility to ensure capability to receive patient.
    - Emergency Dept leadership / Hospital Points of Contact have been provided to DOHMH.

3B) DOHMH Expectations Prior to PUI Arrival

- DOHMH will coordinate all remote communication with the PUI including:
    - Instruction on getting to facility and any designated point of entry.
    - Instruction on covering all lesions/masking and avoiding direct contact with others.
- DOHMH will communicate with facility personnel to:
    - Confirm the proper / preferred designated point of entry to facility, prior to instructing the PUI.
    - Relay the Estimated Time of Arrival (ETA) of the PUI.
    - Provide PUI's full name, date of birth, preferred language, and mobile contact info (if applicable).

3C) Facility Expectations Upon DOHMH Notification

- If not already done, designate a point of entry into the facility. Ideal entry points are those with low foot traffic, clear signage, and closest to patient designated room for testing.
- Once notified by DOHMH of the expected PUI arrival, the facility point-of-contact should immediately notify:
    - Facility infectious disease leadership or infection prevention and control personnel
    - Facility leadership, including specifically:
        - Laboratory for packaging and shipping of patient specimen
        - EVS for suspected monkeypox patient untreated regulated medical waste handling

4) Pre-Arrival and Registration

4A) Pre-Arrival Processes

- Alert staff (e.g., Hospital Police) stationed at the point of entry to maintain watch for the PUI.
- Consider calling or sending a text message to the PUI (if mobile contact available) to coordinate arrival and ensure avoid unnecessary exposure of other individuals upon arrival.

4B) Registration

- Pre-register patient with preliminary information given by NYC DOHMH.
- Once patient arrives and is isolated in a private room, complete registration.

5) Patient Isolation

- Isolation should occur:
  - Immediately upon PUI arrival to facility (when advanced notification from DOHMH)
  - Immediately upon PUI identification (when new PUI identified for first time at facility)
    - See **Appendix B** on "Alerting DOHMH of Potential New PUI"
- Isolate by placing PUI in an Airborne isolation infection room (AIIR). *(Note: If AIIR is unavailable, place PUI in a single-person room with door closed. AIIR is not necessary unless any aerosol-generating procedures (AGPs) are anticipated to be performed.)*

6) Infection Prevention and Control and PPE

- Ensure patient is masked with a surgical or procedure mask. This is always required if patient is outside of their exam room. Any exposed lesions should be covered with a sheet or gown other than during a physical exam or specimen collection.
- Ensure appropriate PPE is available for any staff who may enter the room (SP level 1 ensemble: N95 respirator, isolation gown, 1 pair of gloves, eye protection).
- Place signage on the door to remind staff to don appropriate PPE and transmission-based precautions: airborne + contact + eye protection or enhanced droplet + contact + eye protection.
- Minimize entry/exit to room and start staff log for anyone who enters the room.

7) Specimen Collection and Clinical Laboratory Notification

- Facility to notify its lab that a patient is being tested for monkeypox, so they can ensure all specimens coming from the patient are handled appropriately to protect lab staff in accordance with current NY State DOH guidance.
- Perform testing for monkeypox according to protocol (See **Appendix A**), along with any other routine lab/micro diagnostic testing where indicated (e.g., STIs, varicella if indicated).
- Notify DOHMH per protocol upon completion of specimen and to schedule DOHMH courier for specimen pick up: 866-692-3641

8) Room Cleaning and Disinfecting and Waste Management

- Keep all waste in the room and notify facility EVS to terminally clean the room and handle any waste according to H+H protocol for Monkeypox Waste Management.
- End user (e.g., medical staff) should clean and disinfect any re-usable medical equipment using EPA-registered hospital-grade disinfectant with emerging viral pathogen claim, ensuring sufficient contact time.
- Room should not be used for next patient until environment is cleaned, and waste removed by EVS, and medical equipment properly cleaned by end user.

9) Lab Order Documentation

- **An Epic order for Monkeypox is currently UNDER DEVELOPMENT**: Select EPIC order for monkeypox - Clinical Pox RT PCR (PHL/DOHMH) (SEND OUT). **Note: While the EPIC order is under development, please follow this lab ordering workflow*
    - In Epic, order specimens as “Miscellaneous”.
    - Free text Procedure order as “R/O Monkeypox”.
    - 2 Miscellaneous orders are needed. 1 per swab site.
    - Each lesion site needs its own unique order/accession number. This means the 2 tubes with dry swabs of the same site will have the same order label. The duplicate part of the label will be placed in the pouch on the side of the specimen bag.
- Prior to completion of Epic order, a lab requisition form will be provided by DOHMH to be completed by testing facility and maintained with testing specimen.

10) Occupational Health & Safety (OHS)

- Submit staff entry log to OHS and infection control so that HCW monitoring protocol can be implemented.

11) Patient Discharge

- Discharge patient to home upon specimen collection unless any other evaluation is needed.
- Refer to CDC “Home Isolation” Guidance and refer patient to speak to NYC DOHMH for any additional instructions. Link: www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html

Appendix A: Specimen Collection, Storage, Transport, and PHL e-ordering

Note: Testing for monkeypox is available at NYSDOH Wadsworth Center Biodefense Laboratory and the New York City Public Health Laboratory. Specimen collection and submission must be coordinated with the local health department and/or NYSDOH. Within NYC, coordination must be done in consultation with the NYC Health Department.

Specimen collection, storage, and transport instructions:

If the NYC Health Department may recommend testing for monkeypox. Testing is only performed by PHL. Specimens should be collected by the provider and transported to PHL for testing.

Ensure proper infection control practices and procedures when performing specimen collection. See current CDC Infection Prevention and Control (IPC) recommendations at
https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Materials Needed:

1. Four Dry Swabs: sterile nylon, polyester, or Dacron swab (e.g., Eswab). Do not add or store the swabs in viral or universal transport media.
2. Four separate (individual) sterile containers for each swab (without liquid or transport media).

To collect vesicular and pustular material:

1. IDENTIFY TWO (2) LESIONS ONLY per patient to sample, preferably from different locations on the body and/or with differencing appearances. (A total of four swabs should be collected).
2. COLLECT THE SAMPLE using the sterile swab, by scrubbing the base of the lesion vigorously enough to ensure that cells from the lesion are collected.
3. STORAGE CONTAINERS - Place each swab (break off stick if necessary) in its own sterile container (i.e., conical tube or urine cup). (Reminder, do not add or store in viral or universal transport media.)
4. eORDER - Each lesion site that is sampled requires a separate eOrder test requisition to be completed (e.g., hand, face, etc.). If two (2) lesions are sampled, two (2) eOrders should be submitted. See instructions below.
5. LABEL each container with a swab and test requisition with:
    a. Patient first and last name;
    b. At least one identifier: date of birth, medical record number, or referring lab accession number; and
    c. The lesion collection site (i.e., face, neck, left hand, etc.).
    d. *Please note that the patient first and last name and identifier on the specimen container and the eOrder test requisition must match to prevent any delays in testing.*

Specimen Storage:

1. Within one hour of collection, keep specimens refrigerated at 2–8°C or frozen at -20°C or below while awaiting transport to PHL.
    a. If refrigerated, specimens can be stored at 2–8°C for up to 7 days. Refrigerated specimens should be sent to PHL within 5 days of collection to allow testing and shipment to CDC.
    b. If frozen, specimens can be stored at -20C or below for up to 60 days. Frozen specimens should be sent to PHL within 50 days of collection to allow testing and shipment to CDC.

Specimen Transport:

1. Send specimens using Category B packaging and shipping guidelines.
2. Triple pack the specimens using the following procedure:
    a. Place specimen container in a leakproof primary receptacle (i.e., sealed biohazard bag); multiple primary receptacles should be individually wrapped.
    b. Subsequently, place items in a leakproof secondary receptacle (i.e., sealed bag).
    c. Finally, place items in rigid or strong outer packaging.
    d. Place a list of contents and paperwork (PHL eOrder test requisition) between the secondary receptacle and outer packaging.
    e. Specimens must be kept cold with cold ice packs. Several cold ice packs should be used to ensure specimens remain cold during transport to PHL.
    f. Transport specimens to PHL:
        Attention: NYC Public Health Laboratory
        Biothreat Response Laboratory
        455 First Avenue
        New York, NY 10016

Test ordering instruction and to Submit an eOrder to PHL

1. Go to https://a816-phleorder.nyc.gov/PHLeOrder/

2. Sign in using credentials or register as a new user. See https://www1.nyc.gov/assets/doh/downloads/pdf/labs/phl-eorder-user-guide.pdf for instructions on creating an account. If you are not registered with eOrder, please contact phleordersupport@health.nyc.gov, ssuleiman@health.nyc.gov, and wcai@health.nyc.gov to register for an account.

3. Fill out required information and add the following to the specified fields:
    a. Test: Clinical Poxvirus
    b. Specimen Container: Swab
    c. Specimen Source: Other
    d. Specimen Source Other: Skin or Lesion + site of lesion swabbed (e.g., Left arm)
    e. Fill in both collection date and collection time fields (required).
    f. Each lesion site that is sampled requires a its own eOrder requisition to be completed.

For example, one eOrder requisition for two swabs from one lesion site.

4. Communicate with your clinical laboratory that specimens are to be delivered to PHL and that an eOrder has been submitted

If you have any questions related to monkeypox testing, you may contact the LRN Biothreat Response staff at (212) 671-5834

Appendix B: Potential New Suspected Monkeypox Patient Identified in ExpressCare

If a new Monkeypox PUI (see Case Definition) is identified by a NYC Health + Hospitals clinician in ExpressCare, the clinician should request the patient goes to the nearest emergency department or urgent care for monkeypox evaluation and testing if indicated. There may be scenarios of limited evaluations in Virtual ExpressCare due to inability of a patient to do a video-based visual examination of skin lesions, which may prompt the need for in-person evaluation based on clinical risk factors.

Nearest Emergency Department or Urgent Care

- Refer patient to go to the nearest emergency department of urgency care for evaluation and possible testing (if indicated based on meeting case definition) based on the patient's location and access to private transportation (travel by subway, taxi, or ride share is discouraged).
    - If NYC H+H hospital is nearest emergency department, alert ED leadership at that facility to expect patient for monkeypox evaluation.
    - Relay to patient which preferred designated point of entry to enter H+H facility.
    - Relay the Estimated Time of Arrival (ETA) of the patient to H+H ED (if available)
    - Provide patient's full name, date of birth, MRN, preferred language, and mobile contact info (if applicable).

Infection Control Guidance to Patient While Traveling to Emergency Department or Urgent Care

- Provide guidance to patient on safe travel measures to prevent spread of potential monkeypox virus to others. This includes:
    - Wear a mask.
    - Cover all lesions with clothing (example, long sleeve shirt if lesions on arms, long pants if lesions on legs, gloves if lesions on hands).
    - Avoid direct contact with others.

Patient Counseling on What is Monkeypox

- Monkeypox is currently circulating in NYC, primarily among the social networks of men who have sex with men. The disease is often self-limiting, with most infected persons making a full recovery.
- To ensure the patient gets evaluated and receives the medical care they need (including if treatment is indicated based on health status of patient and disease progression), it is important the patient gets tested for monkeypox.
- Testing is also important to help identify any close contacts or those who may have been exposed, if positive, and offer preventative measures such as monkeypox vaccination to anyone exposed.
- For more information on monkeypox, visit CDC website: www.cdc.gov/poxvirus/monkeypox/about.html