



Department of Health

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Guidance on Testing at Commercial and Public Health Labs

July 25, 2022

Testing for Orthopoxvirus is now available at several commercial laboratories including LabCorp (PFI 2502), Aegis Sciences Corporation (PFI 9512); Mayo Clinic (PFI 3263 and PFI 8221), Sonic Healthcare (PFI 8922), UR Medicine Labs (PFI 8305) and Quest Diagnostics Nichols Institute (PFI 2478). Questions about testing at these facilities should be directed to the appropriate laboratory. Contact information for laboratories can be found by searching the laboratory PFI number at: <https://www.wadsworth.org/regulatory/clep/approved-labs>.

NYSDOH Wadsworth Center recently released streamlined guidance for the validation of molecular detection assays for Orthopoxvirus and/or monkeypox virus. This guidance is available for clinical laboratories that have a Clinical Laboratory Evaluation Program permit and are interested in building this capability. The Pox Virus Validation Guidance can be found at: <https://www.wadsworth.org/monkeypox-testing-guidance>

TESTING AT PUBLIC HEALTH LABORATORIES

Testing for monkeypox is also available at NYSDOH Wadsworth Center and the New York City Public Health Laboratory. **Specimen collection and submission must be coordinated with the LHD and/or NYSDOH. Within NYC, coordination must be done in consultation with the NYC Department of Health and Mental Hygiene (NYSDOHMH).**

NYSDOH Wadsworth Center will accept specimens collected and transported in viral transport media (VTM) OR collected and transported dry. Specimens in VTM can be tested for orthopoxvirus, varicella zoster virus, and herpes simplex viruses I and II. Specimens collected dry can only be tested for orthopoxvirus. Testing for other viruses should be done locally.

The New York City Public Health Laboratory will only accept specimens collected and transported dry. They will only be tested for orthopoxvirus. Testing for other viruses should be done locally.

Specimen Collection

	<i>FOR SPECIMENS COLLECTED FROM NYS RESIDENTS AND TESTED AT THE NYSDOH WADSWORTH CENTER</i>	<i>FOR SPECIMENS COLLECTED FROM NYC RESIDENTS AND TESTED AT THE NYC PUBLIC HEALTH LABORATORY</i>
Specimen Types	1. Swab in viral transport media (VTM) or dry swab. Collect two samples from each of two lesions, for a total of 4 samples.	1. Dry Swab ONLY (two for each lesion). Collect two samples from each of two lesions, for a total of 4 samples.

<p>Collection</p>	<ol style="list-style-type: none"> 1. Identify two (2) lesions 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. Use separate sterile swabs (synthetic- Dacron, nylon, polyester, Rayon). 3. Storage containers: Place each swab in tubes containing VTM (can be tested for more viruses) OR place swabs in a dry sterile container (can only be tested for orthopoxvirus). See below for more information. 	<ol style="list-style-type: none"> 1. Identify two (2) lesions 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.) <p>For additional information on specimen collection refer to the Specimen collection, storage, and transport instructions section on the Instructions for Submission of Specimens for Monkeypox Testing to the New York City Public Health Laboratory guidance located here: https://www1.nyc.gov/assets/doh/downloads/pdf/labs/monkeypox-specimen-testing.pdf</p>
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<p>Submission information</p>	<p>A Wadsworth Center Infectious Disease Request Form must accompany all samples; Remote Order Entry on the Health Commerce System is preferred.</p> <p>Label all tubes and swab holders with the patient's name, unique identifier, date of collection, source of specimen (vesicle/pustule) and name of person collecting the specimen.</p> <p>Specimens should be stored and shipped refrigerated or frozen. Should not be shipped at ambient temperature.</p> <p>Refer to the online test request/requisition page on the Wadsworth Center website for more information on remote ordering: https://www.wadsworth.org/electronic-test-request-reporting-new</p>	<p>A New York City Public Health Test Requisition (available upon request) must accompany each sample/ collection site.</p> <p>Label all tubes and swab holders with the patient's name, unique identifier, date of collection, source of specimen (vesicle/pustule), collection site, and name of person collecting the specimen.</p> <p>Refer to Test ordering instructions on the NYC PHL guidance document at https://www1.nyc.gov/assets/doh/downloads/pdf/labs/monkeypox-specimen-testing.pdf</p> <p>Briefly, go to https://a816-phleorder.nyc.gov/PHLeOrder/ and perform the following</p> <ol style="list-style-type: none"> 1. Sign in using credentials or register as a new user. 2. Fill out required information and add the following to the specified fields: <ul style="list-style-type: none"> 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). 3. Communicate with your clinical laboratory that specimens are to be delivered to PHL and that an eOrder has been submitted.
<p>Shipping Address</p>	<p>Dr. Christina Egan DAI 3021, Biodefense Laboratory, Wadsworth Center, NYS Dept. of Health 120 New Scotland Avenue Albany, NY 12208</p>	<p>Dr. Scott Hughes New York City Public Health Lab Biothreat Response Unit 455 1st Avenue New York, NY 10016</p>
<p>Questions</p>	<p>Call the Wadsworth Center Biodefense Laboratory at 518-474-4177 (business hours) or the duty officer 866-881-2809 (after hours).</p>	<p>Call the NYC Biothreat Response Laboratory at 212-671-5834 (business hours) or Poison Control at 212-764-7667; ask for PHL duty officer (after hours).</p>

Specimen Collection

To collect vesicular and pustular material:

1. Perform hand hygiene and don gloves, gown, face, and eye protection.
2. Sanitize the patient's skin with an alcohol wipe and allow skin to air dry (do not "wave" the site to facilitate drying).
3. For swabs in tubes containing VTM (NYS), label a swab holder and remove swab from the outer sheath. Collect cells from the lesion base by 1) vigorously swabbing or brushing lesion with two separate sterile synthetic swabs (Dacron, nylon, polyester, or Rayon); 2) Place each swab in a separate sterile tube containing VTM. Secure each tube with parafilm.
4. For the dry swabs (NYC and NYS) label a swab holder and remove swab from the outer sheath. Collect cells from the lesion base by 1) vigorously swabbing or brushing lesion with two separate sterile dry polyester, nylon, or Dacron swabs; 2) 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. Do not add or store in viral or universal transport media.
5. Repeat this process on different lesions.
 - a. For NYS there should be two specimens collected for each lesion: two sets of plastic tubes from each lesion for a total of 4 tubes.
 - b. For NYC there should be two swabs for each lesion
6. After specimen collection is completed, all personal protective equipment (PPE) worn by the specimen collector and all waste generated during the specimen collection (e.g., alcohol wipes, holders, etc.) should be discarded according to facility's usual procedures for what is considered regulated medical waste (i.e., there are no changes to what is considered regular waste versus regulated medical waste when caring for someone with suspect or confirmed orthopox/monkeypox). All sharp devices used to open vesicles (e.g., needles, blades, etc.) used to open vesicles should be disposed of in an appropriate sharps container. Hand hygiene should be performed before and immediately after specimen collection and following removal of PPE. Alcohol-based hand sanitizers are preferred unless hands are visibly soiled. If hands are visibly soiled, hand hygiene should be performed using soap and water.
7. Other sample types such as serum and whole blood may also be requested.

Please note: Monkeypox virus can be cultivated in several cell culture types routinely used by the viral testing laboratory. Although laboratories should not attempt to isolate this virus, if you become aware that your laboratory has isolated monkeypox using cell culture, you should **immediately** contact the Wadsworth Center or the NYC PHL.