Monkeypox Testing Process: Indiana Department of Health Laboratories

Testing for monkeypox includes preliminary testing for non-variola orthopoxvirus at the Indiana Department of Health Laboratories (IDOHL), followed by characterization testing at the Centers for Disease Control and Prevention (CDC). Orthopoxvirus positive results during this outbreak are presumed to be monkeypox unless shown to be otherwise by CDC testing. Only specimens positive for orthopoxvirus at the IDOHL will be sent to CDC for characterization testing.

Monkeypox Testing Authorization

Clinicians requesting testing for monkeypox must first complete the Indiana Department of Health (IDOH) Monkeypox Specimen Authorization Request form.

Once approved, specimens should be submitted via the Biothreat page on LimsNet, an online system that will make results available as PDF files after they are released at the lab. Each set of lesion swabs (two swabs per one lesion) should be submitted separately in LimsNet, for no more than two submissions (two swabs each) per patient. To get a free LimsNet account established at your facility, call the help desk at 317-921-5506 or email LimsAppSupport@isdh.in.gov. Guidance on how to submit specimens in LimsNet is available here.

Turnaround Time and Results

Typical turnaround time for preliminary results is typically within a day of specimen receipt at IDOHL. Results will be released directly to the submitter via LimsNet. Submitters are responsible for relaying results to the provider and/or patient.

Specimen Collection Instructions

Personnel who collect specimens for monkeypox testing should use personal protective equipment (PPE) in accordance with CDC’s recommendations for healthcare settings.

Providers should collect swabs from more than one lesion, preferably from different locations on the body and/or from lesions with differing appearances. Providers should swab the lesion vigorously to collect adequate DNA; it is not necessary to de-roof the lesion before swabbing. Separate swabs must be used for each lesion, and two swabs must be submitted for each lesion sampled (one for preliminary and one for characterization testing). No more than two lesion sites (four swabs total) may be submitted for each patient. Only one swab should be placed in each screw-capped tube. Specimens must be clearly labeled with the site the specimen was collected from, patient name, date of birth, and date of specimen collection. If writing the location of the swabbed lesion cannot fit on the tube, please write it clearly on the biohazard specimen bag.
Specimen Collection Materials and Storage

Dry synthetic swabs must be used for collection. Acceptable swabs include:

- **Must be synthetic, for example: polyester, rayon, or Dacron**
  - Preferred: throat swabs, oropharyngeal swabs, strep throat, mumps testing, varicella testing
  - Other: flocked swabs used for COVID testing, influenza testing, nasopharyngeal swabs

After collection, swabs should be placed into an acceptable container, including:

- **Preferred**: 1.5- or 2-ml sterile, screw-capped tubes with O-ring or 15-ml sterile, screw-capped tubes
- **Other**: Urine collection container or TB sputum collection container

The specimen must be a dry swab. Do not use any transport media in the container. There should be nothing in the container other than the single lesion swab. Specimens must be stored at refrigerated temperatures within one hour after specimen collection. Specimens may be frozen if longer storage is required.

Specimen Submission Packaging and Shipping

Once collected, specimens should be shipped using **Category B** shipping materials. Specimens **MUST** be placed in a Styrofoam container with **sufficient cold packs to maintain refrigerated temperatures during transport**. To avoid specimen cancellation, please use additional ice packs during excessive heat. Specimens arriving at IDOH Laboratories at room temperature will not be tested, per regulatory requirements. Specimens should be shipped on dry ice if frozen or if transit time will be longer than 24 hours. Specimens must be shipped to arrive **COLD** at the IDOH Laboratories between 8:15 a.m. and 4:45 p.m. Monday – Friday. **Do not ship a specimen that will be transported over multiple days or the weekend** (e.g., shipping on Friday for Monday delivery).

Questions

Please contact the IDOH Epidemiology Resource Center with questions related to testing authorization and case investigation at 317-233-7125 during normal business hours (8:15 a.m. – 4:45 p.m. EDT, Monday-Friday) or 317-233-1325 after hours, weekends or holidays.

Please contact the IDOH Laboratory with questions related to specimen collection and laboratory submission at 317-921-5500 during normal business hours (8:15 a.m. – 4:45 p.m. EDT, Monday-Friday). If it is outside normal business hours, call the epidemiology duty officer at 317-233-1325.
## IDOHL: Specimen Submission Criteria

### Test

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<th>Non-variola Orthopoxvirus</th>
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### Specimen Requirements

1. Dry swab of lesion is preferred.
2. Vesicle fluid, skin, crust, “roof”

### Sampling Materials

1. Swab – Swab material should be synthetic, i.e., rayon, polyester, or Dacron. Calcium alginate or charcoal-impregnated swabs should not be used, nor should wood-shaft swabs.
2. 1.5- or 2-mL sterile, screw-capped tube with O-ring or 15-mL sterile, screw-capped tube.
3. For collection of vesicle fluid, a 26 or 27-gauge needle attached to a tuberculin syringe is necessary.
4. **Cold packs or dry ice.**
5. **Shipping boxes/containers with appropriate shipping labels (Category B Infectious Substance).**

### Procedural Notes

1. Don personal protective equipment per CDC guidance.
2. Be sure to properly label the specimen tube with the patient’s name, date of birth, date of collection, and location of the swabbed lesion. If there is not enough space on the tube to clearly write the location of the swabbed lesion (i.e., left forearm), write the location clearly on the outside of the biohazard specimen bag.
3. Special Instructions for Specimen Collection
   - Vigorously swab or brush lesion with two separate sterile dry polyester or Dacron swabs.
   - Insert the swab, swab-end down, into separate 1.5- or 2-mL screw-capped tube with an O-ring or place the entire swab in a separate sterile container (i.e., 15-mL sterile, screw-capped tube).
   - Break off the swabs at the scored line on each of the swab shafts. If the swab does not have a scored line, please cut the swab shaft to fit in the screw-capped tube.
   - Tightly cap the tubes for transport.
   - **DO NOT ADD OR STORE IN VIRAL OR UNIVERSAL TRANSPORT MEDIA.**
   - If the patient presents with more than one lesion, please repeat the collection steps for a second lesion, preferably on a different part of the body and/or with a different physical presentation.
   - If two sets of specimens are collected, please place these in **SEPARATE** biohazard specimen bags. Mark the ‘Refrigerated’ box on the specimen bag.
4. **After collection, all specimens should be stored at refrigerated temperature (2- 8°C) until shipped. If longer storage is required, specimens can be frozen.**
5. Specimens should be submitted through the Biothreat page on LimsNet, an online system that will make results available as PDF files after they are released at the lab. **Each set of lesion swabs (2 swabs per one lesion) should be submitted separately in LimsNet, creating up to two LimsNet submissions per one patient.**
   - To get a free LimsNet account established at your facility for electronic submission and results reporting, call the help desk at (317) 921-5506 or email to LimsAppSupport@isdh.in.gov.
6. If you have questions, please contact the IDOHL BT-Clinical Microbiology and Environmental Virology Division Director at 317-921-5842 or the Virology & Serology Division Director at 317-921-5555.

### Shipping Instructions

1. Wrap the labeled specimen container with absorbent material and place in a biohazard specimen bag. Be sure to package each patient’s specimens individually to avoid cross-contamination. Please ship non-variola orthopoxvirus specimens separately from any other specimens coming from the submitting laboratory.
2. Place the requisition form in the side pocket of the biohazard bag. Never place the requisition form in with the specimen in case the specimen leaks during transit. If the specimen bag does not have 2 compartments, place the paperwork in a separate Ziploc bag.
3. Place the specimen(s) in a **Styrofoam container with sufficient cold packs to maintain refrigerated temperature during shipment.** If needed, dry ice can also be used if the specimen is frozen and/or transport time may be longer than 24 hours. If dry ice is used, do not form an airtight seal on the Styrofoam container because dry ice releases carbon dioxide gas.
4. Place the Styrofoam container into a cardboard shipping box, close lid and seal.
5. **Ship or transport by courier, compliant with DOT and IATA regulations (Category B Infectious Substance).**
   - **a.** Ship to:
     - Indiana Department of Health Laboratories:
     - **Biothreat Laboratory**
     - 550 W. 16th St., Suite B
     - Indianapolis, IN 46202

### Reporting and TAT

1-2 business days. Specimens may be forwarded to the CDC for characterization testing.