**Stepwise Specimen Collection Instructions: Updated October 10, 2024**

**Note:** Personnel should use contact and droplet precautions (gloves, eye protection, NIOSH-approved particulate respirator equipped with N95 filters or higher, and a gown). Please refer to CDC’s website for infection control guidance: <https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html>.

**Materials needed:**

* Sterile screw-capped plastic tube (e.g. urine container)
* Sterile, dry, synthetic swab (including but not limited to polyester, nylon, rayon, or Dacron) with plastic shaft. Do not use cotton tipped, foam swabs, or wooden shaft swabs. **Use of swabs with flexible shafts (e.g. nasopharyngeal (NP) swabs) are not recommended and may yield Inconclusive results due to ineffective swabbing and require recollection.**

Prepare to collect skin lesion specimen types (surface/exudate/crust in order of preference) from 1-2 lesions.

**NOTE: Clinicians should collect two swabs from each lesion in case additional testing, such as clade-specific testing, is needed; swabs from 1-2 different lesions per patient may be submitted. If the two different sites are in the same area (e.g., torso) please label as torso lesion #1, torso lesion #2, as for duplicates, label as torso lesion #1 and torso lesion #1 (duplicate).**

**Collection Instructions:**

1. Don personal protective equipment as described above. **There should be one specimen per tube/collection container only,** and ensure the specimen label has the:
* Patient name
* Date of birth
* Date of collection
* Site/source of the specimen (e.g., right finger/swab-vesicle fluid)
	+ *Note: if source of specimen is lesion or crust, please fill in specimen type as ‘other (Specify)’ and write in lesion or crust.*
1. Include the following information on the specimen submission form:
* Record the same specimen details on the submission form (e.g., right finger/swab-vesicle fluid) as the specimen tube label.
* Record the symptom onset date as the first day of fever, headache, muscle aches and backache, swollen lymph nodes, chills, exhaustion, or rash. The rash can look like pimples or blisters that appear on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus.
1. Procedure to collect lesion specimen types:
2. Do not clean the area prior to collection. Unroofing or aspiration of lesions (or otherwise using sharp instruments for mpox testing) before swabbing is not necessary, nor recommended due to the risk for sharps injury.
3. Use an approved swab type to vigorously swab lesion surface, exudate, or crust material (in order of preference) from around a vesicle edge or over a weeping lesion. For a dry, crusty lesion the swab may be moistened with sterile saline. Do not moisten the swab for an open, wet lesion.
4. Place the swab into a dry, sterile tube or urine container, break off/fold in the swab handle, before securing the lid.
5. Do not add transport medium or any liquid (e.g. saline) to the tube.

After specimen collection is complete, all protective materials worn by the specimen collector (gloves, mask, gown, etc.) and all used sample collection materials (vacutainer holders, swabs, etc.) should be discarded according to local biosafety policies and practices.

**Packaging and Shipping:**

1. Complete all fields on the submission form and ensure that the information on the form matches exactly the information on the specimen container. Place the form in the outer pocket of each specimen bag. Each specimen should have its own specimen bag.
	1. [**https://www.mass.gov/doc/specimen-submission-form/download**](https://www.mass.gov/doc/specimen-submission-form/download)
	2. Unlabeled or mislabeled (information on specimen that does not match exactly the information on the form) specimens will be rejected and require recollection.
2. Specimens should be packaged as a Category B. Both clade I and II Monkeypox virus (MPXV) are designated as Category B infectious substances under the Hazardous Materials Regulations (HMR). Specimens and material suspected to contain either clade I or clade II MPXVcan be shipped as UN 3373 Biological Substance, Category B. Refer to USDOT website for details: <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Transporting-Infectious-Substances-Safely.pdf>
3. After collection maintain and ship specimen at 2-8°C. Ship with cold packs. Specimen(s) submitted with wet ice will be rejected. Transport as soon as possible to the Massachusetts State Public Health Laboratory (MA SPHL) at 305 South Street, Jamaica Plain 02130. Questions about specimen submission should be directed to the MDPH Division of Epidemiology at 617-983-6800 (available 24/7).

**Test Results:**

* Confirmatory testing of dry swabs of skin lesion surface/exudate/crust will be performed at the MA SPHL with the CDC LRN non-variola orthopoxvirus Polymerase Chain Reaction (PCR) assay. (see result table below)
* If any specimen is positive with the non-variola orthopoxvirus PCR, clade identification will be confirmed by either whole genome sequencing (surveillance only) or clade-specific PCR.
* An inconclusive result may occur due to insufficient clinical specimen collection as noted by the inability to detect the human specimen control target.
* For results, ensure this form is completed: <https://www.mass.gov/doc/elr-access-request-form/download>

**Result Table**

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| **Test Result** | **Test Interpretation** |
| Positive for Non-variola *Orthopoxvirus*. | Non-variola *Orthopoxvirus* DNA detected by real-time PCR. The assay detects the DNA of common non-variola *Orthopoxvirus* human pathogens, including *Vaccinia*, *Cowpox* and *Monkeypox* viruses. This assay result must be used in conjunction with other diagnostic test results, clinical observations, and exposure history. |
| Negative for Non-variola *Orthopoxvirus*. | Non-variola *Orthopoxvirus* DNA not detected by real-time PCR primer and probe set. |
| Inconclusive for non-variola *Orthopoxvirus* DNA by real-time PCR.  | An inconclusive result may occur in the case of an inadequate specimen. If patient diagnosis has not been determined, submit additional specimens for analysis. |
| Equivocal for non-variola *Orthopoxvirus*. | Real-time PCR testing for non-variola *Orthopoxvirus* DNA result is equivocal. An equivocal result may occur in the case of an inadequate specimen or due to cross-contamination during specimen testing. If patient diagnosis has not been determined, submit additional specimens for analysis. |

**Reasons Specimens Will Be Rejected**

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| Specimen collected with viral transport media or saline. Dry swabs are required. |
| Specimen received warm (no ice pack). |
| Specimen received unlabeled. A confirmed link between the specimen and a submission form is not possible. Resubmission requested. |
| Information on specimen does not match information on submission form. |
| Specimen container/tube damaged or leaking prior to receipt at laboratory. Resubmission requested. |
| Missing second identifier on specimen. |
| Improper specimen type collected. See “Materials Needed” section above for appropriate swab types.  |