



Monkeypox Laboratory Testing Information for Healthcare Providers

Overview

There are a number monkeypox testing options available to healthcare providers, including testing for high suspect cases through the Montana Public Health Laboratory (MTPHL) with epi approval. This document will go over their different costs and methods of sample collection.

Please note: Some labs perform *orthopoxvirus* testing and some perform monkeypox-specific testing. According to CDC, a positive *orthopoxvirus* test result is enough for healthcare providers and public health authorities to take necessary actions for the patient and help prevent additional spread—the same actions they would take for a positive monkeypox test result.

Below is a table listing the laboratories mentioned in this document. Please pay special attention to whether swabs should be placed in a dry container or in viral transport media, as it varies by lab:

Laboratory	Pricing	Public Health Consult Required (Y/N)	Notes:	Pages
Montana Public Health Laboratory	\$0	Y	High suspect cases only. Epi consult required for testing. Non-variola <i>orthopoxvirus</i> test.	2-3
Mako	\$95.00	N	Monkeypox test. ≤48 hr turnaround time.	4
Aegis	\$150.00	N	Non-variola <i>orthopoxvirus</i> test. 24hr turnaround time.	5
Quest Diagnostics	\$100.00	N	Non-variola <i>orthopoxvirus</i> and monkeypox test. 2–3 days turnaround time.	6
Lab Corp	\$77.00	N	Non-variola <i>orthopoxvirus</i> test. 2–3 days turnaround time.	7



Montana Public Health Laboratory

The Montana Public Health Laboratory (MTPHL) in Helena has capacity to test for monkeypox for suspect cases in Montana. Currently, MTPHL will provide *orthopoxvirus* testing of skin lesion swabs for high suspect patients that have symptoms consistent with monkeypox and meet CDC epi criteria. For patients that are not high suspect for monkeypox according to clinical and epi criteria (i.e., clinicians would like to rule-out monkeypox), **it is recommended that specimens be sent to a reference lab for testing.**

Methodology:

PCR non-variola *orthopoxvirus* test. Positive tests are sent to CDC to confirm monkeypox.

Important Information

- For testing at MPTHL, an epi consult is required prior to submission of specimens to MTPHL to determine if the patient meets the CDC criteria.
- Please call your local health department or CDEpi (406-444-0273) to discuss if a patient is eligible for testing at MPTHL.
- If specimens arrive at MPTHL without a prior epi approval, specimens will be sent back to the ordering facility. It is the ordering facility's responsibility to send the specimens to a reference lab.

Collection

1. At minimum, collect two swabs from each lesion (in general, 2 different lesions should be sufficient, for a total of 4 swabs).
2. Personnel who collect specimens should use personal protective equipment (PPE) in accordance with CDC's recommendations.
3. Please consult with your laboratory or microbiology team to confirm you are using the correct specimen collection material.
4. Swab or brush lesion vigorously with two separate sterile dry swabs (polyester, nylon, Dacron, ect.) with a plastic, wood, or thin aluminum shaft. It is not necessary to de-roof the lesion before swabbing. If the lesions are healed over with a fresh layer of skin, they are not eligible for testing.
5. Swab other lesions.
6. Place swabs in individual leak proof sterile containers and label appropriately. **Do not add any viral or universal transport media.**



7. Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection.

Shipping

1. Refrigerated samples should be shipped within 7 days of collection and frozen sample within 60 days of collection.
2. Ship to MTPHL on Dry Ice as Category B in a separate box from any additional samples your facility is sending.
3. Complete one MTPHL laboratory requisition form using hard copy or online through Outreach (formerly known as COPIA). For paper requisitions, mark “Other Confirmation” under MicroSurveillance and “Monkeypox” in the comments box. For online orders, use “Orthopox NV PCR”.
4. **Specimens arriving at MTPHL without a CEpi consult will be returned to the ordering facility or provider.** DPHHS will follow-up with the ordering provider to get more information. However, this approach will delay testing. It is HIGHLY advised that ordering providers consult their local health jurisdiction before sending specimens to MTPHL.



Mako Monkeypox Virus Test

The Mako Monkeypox test is designed to test specifically for the monkeypox virus rather than the presence of an orthopox virus in general, making it so further confirmation from the CDC is not needed.

Methodology:

MAKO's test is a PCR test based on the same assay principles as the CDC's FDA-cleared test.

Turnaround Time:

Less than 48 hours upon receipt.

Test Name:

Monkeypox (MPXV)

Order Code:

725100

Collection

1. Swab the wound/lesion/pustule forcefully.
2. Place swab in a tube with **3 mL of viral transport media (VTM)**.
3. Secure tube cap.
4. Ship immediately to the lab at room temperature.

Shipping

1. Ship immediately at room temperature.
2. Ship as UN 3373 Biological Substance, Category B.
3. When submitting a specimen from a patient with a suspected or confirmed monkeypox infection, write "suspected monkeypox" on the MAKO packing list and specimen bag.



Aegis Monkeypox Virus Test

The Aegis Monkeypox test is an FDA-cleared, PCR based *Orthopoxvirus* DNA assay developed by the CDC.

Methodology:

PCR assay that detects the DNA of common non-variola *Orthopoxvirus* human pathogens, including Monkeypox, Vaccinia, and Cowpox.

Turnaround Time:

Within 24 hours upon receipt.

Order Code:

06575

Collection

1. Open and remove the first swab from packaging. Do not lay the swabs down or touch them to any surfaces other than the collection site before, during, or after specimen collection.
2. Using first swab, vigorously swab the lesion for 30 seconds.
3. Removed the screw cap from the provided transport tube and insert the swab, tip first, into the **dry, sterile tube. Do not add any transport media to the tube.**
4. Open and remove the second swab from the packaging.
5. Using the second swab, vigorously swab a different lesion for 30 seconds. A lesion that is in a different location on the body or which differs in appearance is preferable.
6. Insert the swab, tip first, into the tube. Do not add any transport media to the tube.
7. Break swab shafts at the break point and seal the tube by tightening the screw cap.
8. Label the specimen (Including First Name, Last Name, and Date of Birth) with the supplied demographics label located in the collection kit or on the requisition.
9. Place the labeled and sealed specimen in the biohazard specimen bag.
10. Seal the bag and place the requisition in the outside pocket, if applicable.

Shipping

1. Place the sealed specimen bag with an ice pack inside the silver InsulTote and seal the InsulTote.
2. Place the sealed InsulTote inside the provided kit box.
3. Place the kit box inside the provided FedEx Clinical Pak with UN 3373 markings.
4. Prepare FedEx Clinical Pak for shipping.



Quest Monkeypox Test

The Quest Monkeypox test can differentiate monkeypox viral DNA from other non-variola *orthopoxviruses* in a specimen, helping to enable a faster final diagnosis.

Methodology:

Dual target PCR detection of non-variola *orthopoxviruses* and monkeypox virus (West African clade) DNA.

Turnaround Time:

2-3 days upon receipt.

Test Name:

Monkeypox Virus DNA, Qualitative, Real-Time PCR

Order Code:

12084

Collection

1. Swab the pustule/lesion vigorously.
2. Place swab into a **3 mL viral culture media (or equivalent) tube**.
3. If clinically indicated, consider submitting additional swabs if multiple lesions with different stages are present.

Shipping

1. Multiple specimens collected on a single patient should be submitted separately and be accompanied by its own separate requisition and transported in its own sealed bag.
2. Transport container should be VCM, VTM, UTM, or equivalent.
3. The sample should be frozen when transported.



Lab Corp Monkeypox Test

The Lab Corp Monkeypox test is an FDA-cleared *orthopoxvirus* test developed by the CDC.

Methodology:

PCR assay that detects the DNA of common non-variola *Orthopoxvirus* human pathogens, including Monkeypox, Vaccinia, and Cowpox.

Turnaround Time:

2-3 days upon receipt.

Order Code:

140230

Collection

1. Take one of the swabs out of its package. Do not touch the tip of the swab with your hands.
2. The second swab may be discarded. Note, if multiple lesions with differing appearances are present, consider submitting additional swabs for each lesion.
3. Screw off the top of the **universal transport media (UTM) or viral transport media (VTM) tube**.
4. Hold swab in one hand and collection tube in the other.
5. Vigorously swab or brush the base of the lesion with the swab.
6. Insert the swab into the universal or viral transport medium and break off the end of the swab, if required, to tightly close the sample.
7. Screw the top of the collection tube back on.

Shipping

1. Label collection tube containing the sample with two unique patient identifiers such as name and date of birth.
2. Place in biohazard specimen bag and ensure the bag is subsequently sealed.
3. Submit sample on one laboratory requisition, with test code 140230 Monkeypox (Orthopoxvirus), DNA, PCR.
4. Request must include the patient's name, gender, race and ethnicity, complete address, phone number, and appropriated diagnosis code.
5. Billing and/or insurance information should be provided on the laboratory requisition, including client account number.
6. To avoid delays in turnaround time when requesting multiple tests on frozen samples, please submit separate frozen specimens for each test requested.
7. Ship refrigerated or frozen at -20°C as a UN3373 Biological Substance, Category B.