



Client Communication

## Monkeypox (MPX)

Under the guidance of the US Center for Disease Control and Prevention (CDC), Clinical Labs of Hawaii is closely monitoring the outbreak caused by monkeypox virus (MPXV). To date, over 4000 human infections have been confirmed in the US, involving over 45 states.

*Our sister lab, Sonic Reference Laboratory, was selected by the CDC to develop an FDA-approved, high-complexity NAAT (RT-PCR) molecular test to identify MPXV.*

**Effective August 2, 2022, Clinical Labs of Hawaii will be offering Monkeypox testing.**

### Monkeypox: Interim Guidance from the CDC for Healthcare Providers

- Caused by Monkeypox virus
  - Two clades: Central African (CAC) & West African (WAC). WAC is less virulent, and it is the clade circulating in the 2022 US outbreak.
  - *Orthopox* genus, which includes variola/smallpox, cowpox. MPXV is NOT related to varicella/chickenpox/shingles.
  - Demonstrates extraordinary resistance to drying, heat, and pH, which leads to **environmental persistence**. Materials with MPXV may remain infectious for months to years.
- Incubation 6-13 days, up to 21 days
- Signs/Symptoms
  - Fever, headache, **swollen lymph nodes** (which may differentiate it from smallpox), respiratory symptoms, and GI symptoms, including diarrhea.
  - Characteristic Rash - See photos and complete description, below.
    - May look like pimple or blister.
    - Appears on face, inside of mouth, genitals, and other body parts.
- Laboratory findings – leukocytosis, elevated AST & ALT, low BUN, low albumin.
- Differential diagnosis - Smallpox, chickenpox/shingles, measles, bacterial skin infections, scabies, medication allergies, HSV, and syphilis.
- Spread
  - Direct contact with the rash, respiratory secretions during prolonged face to face contact, intimate contact, fomites, placental transfer, animals handling.
  - Possible for up to several weeks.
- Prevention
  - Avoid contact, good hygiene, PPE.
  - Vaccine – JYNNEOS/Imvanex and ACAM2000: inactive virus, FDA approved.
- Complications – bacterial infection, sepsis, dehydration, diarrhea, encephalitis.
  - Treatment – For select cases, smallpox anti-viral (TPOXX/tecovirimat) may be indicated, especially for highly vulnerable populations.

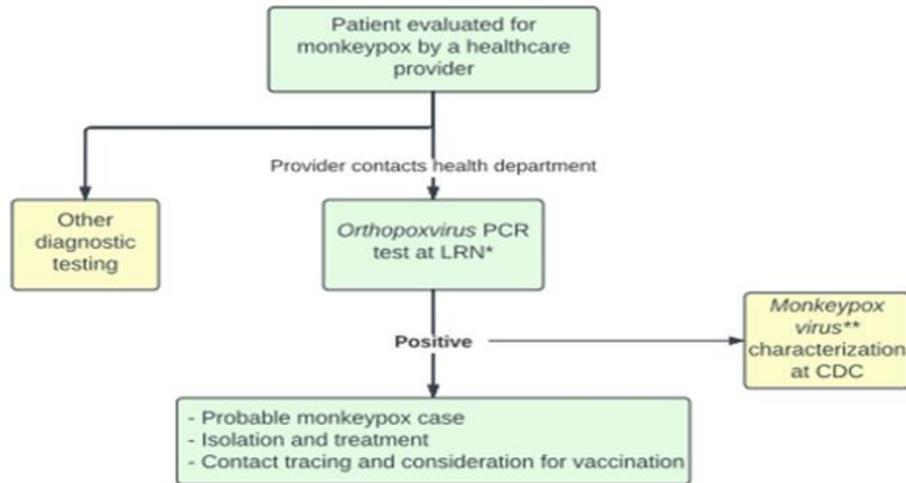
## Diagnostic/Laboratory Testing Guidelines

Monkeypox Virus by PCR (effective 8/2/22)	
Test Code	U590 (4383)
Ordering Recommendation	For detection of non-variola <i>Orthopoxvirus</i> , including monkeypox virus, DNA in clinical specimens.
Sample Type	Two swabs from a skin lesion ( <i>obtain custom Monkeypox kit from CLH</i> )
Specimen Collection	Vigorously swab or brush the suspected active lesion with two separate sterile synthetic swabs (i.e. Dacron, polyester, or nylon) with a plastic shaft. DO NOT use cotton swabs. Break off the tip of each swab and place each swab in its own separate sterile container. ***Please refer to the Monkeypox Test Collection Kit Instructions included in each CLH kit.
Specimen Processing	Refrigerate or freeze immediately after collection. Freezing is strongly recommended. Transport to the lab ASAP. NOTE: Label all specimens with the patient's name, date of birth, date/time of collection, and source.
Stability after collection	Refrigerated: 7 days; Frozen: 1 month
Performed at	Sonic Reference Laboratory
Turn-around Time	3-4 days (performed Mon-Fri)
Results	Qualitative
Reference Range	Negative
Methodology	Real-Time Polymerase Chain Reaction (RT-PCR)

### Protocol for Healthcare Providers:

- Refer to the most current Hawaii Department of Health (HDOH) Medical Advisory <https://health.hawaii.gov/docd/files/2022/06/MEDICAL-ADVISORY-Monkeypox-Identified-in-Hawaii-06032022.pdf>
- Report any clinically suspected cases of monkeypox immediately:
  - Oahu (Disease Reporting Line).....808-586-4586
  - Maui District Health Office.....808-984-8213
  - Kauai District Health Office.....808-241-3563
  - Big Island District Health Office-Hilo.....808-933-0912
  - Big Island District Health Office-Kona...808-322-4877
  - After Hours on Oahu.....808-600-3625
  - After Hours on Neighbor Islands.....808-360-2575 (toll free)
- HDOH may request photos of the lesions and provide next steps.
- If directed by HDOH to send specimen to HDOH directly, please coordinate with HDOH as they will perform testing.
- If directed by HDOH to send specimen to a commercial lab, please follow the above specimen collection/processing instructions and contact CLH for a pick up (CLH will not collect specimens- do not send patients for collection or to drop off their specimen).
- **Contact CLH to obtain Monkeypox Collection kits. Custom kits are designed only for CLH's Monkeypox PCR test.**

Diagnostic Process for *Monkeypox Virus* Testing



\*PCR - polymerase chain reaction; LRN - laboratory response network  
 \*\*Monkeypox is a member of the orthopox group of viruses.

Important Links and Contacts | Information for Laboratory Personnel | Preparation and Collection of Specimens | Emergency Operations Center: 770.488.7100 (Available 24/7) | LRN contact: Use the 'Contact Us' feature on the LRN website, Or [LRN@cdc.gov](mailto:LRN@cdc.gov) | Public Health contact list to pursue LRN lab testing

Criteria to Guide Evaluation of Monkeypox Cases

	Clinical Features		Epidemiological Risk
Suspect Case	New characteristic rash (see complete description, below)	OR	Meets one of the epidemiological criteria and has a high clinical suspicion for monkeypox. See below.
Probable Case	No suspicion of other recent <i>Orthopoxvirus</i> exposure (e.g., <i>Vaccinia virus</i> in ACAM2000 vaccination)	And	Demonstration of the presence of orthopoxvirus DNA
Confirmed Case	Demonstration of the presence of <i>Monkeypox virus</i> DNA by polymerase chain reaction testing or Next-Generation sequencing of a clinical specimen	OR	Demonstration of <i>Monkeypox virus</i> 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.)

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- 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
- Characteristic Rash
  - Deep-seated and well-circumscribed lesions, often with central umbilication.
  - Lesion progression through specific sequential stages—macules, papules, vesicles, pustules, and scabs.
  - May 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.



The outbreak caused by MPXV is rapidly evolving, and we will continue to monitor the situation and update you as new information becomes available.

Extensive additional information on monkeypox can be found at the CDC's website.

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/hcp/index.html>

### References:

1. Case Definitions† for Use in the 2022 Monkeypox Response. Centers for Disease Control and Prevention website. Accessed June 2022. <https://www.cdc.gov/poxvirus/monkeypox/clinicians/case-definition.html>
2. U.S. Monkeypox Outbreak 2022: Situation Summary. Centers for Disease Control and Prevention website. Accessed June 2022.
3. Brown K, Leggat PA. Human Monkeypox: Current State of Knowledge and Implications for the Future. *Trop Med Infect Dis.* 2016;1(1):8. Published 2016 Dec 20. doi:10.3390/tropicalmed1010008

If you have any questions, please contact our Client Services Department at 808-677-7998 (Oahu) or 1-866-281-6816 (toll-free).

**Thank you for choosing Clinical Labs of Hawaii.**

**Monkeypox test information and collection instructions are subject to change based on current CDC guidelines. This update is effective as of Monday, August 1, 2022.**

To report a suspected case of monkeypox and receive guidance, contact the DOH at (808)586-4586.

### **MONKEYPOX TEST COLLECTION KIT**

This Monkeypox collection kit is only to be used for specimens being sent to Clinical Labs of Hawaii. **Do not send patients to the laboratory for specimen collection. CLH does not perform monkeypox collections. Please carefully follow all instructions provided to minimize exposure and expedite testing. Any deviations from this protocol may result in specimen delays or rejections.**

#### **Instructions:**

1. Each monkeypox collection kit contains 2 sterile swabs and 2 sterile containers/tubes.
2. Label each container/tube with the following:
  - a. Patient's name (First and Last)
  - b. Date of birth (MM/DD/YYYY)
  - c. Date and time of collection
  - d. Lesion source location
3. Each swab should be used in the identical manner (e.g. swab the same lesion). The second swab is being requested by the CDC for confirmation testing ONLY if necessary.
4. Please follow the collection instructions from the HDOH or CDC, more information can be found at <https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html>  
"Two swabs from each lesion should be collected for testing. Using two sterile synthetic swabs (including, but not limited to polyester, nylon, or Dacron) with a plastic shaft, swab the lesion vigorously to collect adequate DNA. Do not use cotton swabs. It is not necessary to de-roof the lesion before swabbing. Break off the end of each swab's applicator into a sterile 5-10 mL screw-capped tube with O-ring or place the entire swab in a sterile plastic container that has a gasket seal and is able to be shipped under the required conditions.
5. Place **both** specimen tubes (containing one swab in each tube) in the biohazard bag provided with the requisition (lab order) in the outer pocket. Verify that all patient information on the label is accurate and complete.
6. If collecting from more than one lesion site, repeat steps above with another collection kit and submit in a separate biohazard bag with a separate requisition (lab order).
7. Each specimen/kit submission will be ordered as an individual test.
8. If collecting for other tests i.e. HSV, VZV, you will need to utilize a different collection kit. Please contact CLH Client Services at (808)677-7998 for specimen collection instructions for those viruses.
9. Contact CLH for a specimen pick up. Do not send the patient to a CLH location.
10. Store specimens in the refrigerator or freezer until specimen is picked up.  
*"For any questions, please contact CLH Client Services at (808) 677-7998 or from the neighbor islands 1-866-281-6816 (toll free).*