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**EAST SIDE CLINICAL
LABORATORY**

A Sonic Healthcare Clinical Laboratory

Monkeypox Virus (MPX) by PCR

Effective July 25, 2022 East Side Clinical Laboratory is pleased to announce the availability of Monkeypox Virus by PCR testing.

Monkeypox Virus PCR test methodology is real-time PCR utilizing the CDC Non-variola Orthopoxvirus Real-Time PCR Primer and Probe Set. The assay detects non-variola *Orthopoxvirus* DNA in clinical specimens. Although this assay does not differentiate monkeypox virus from other *Orthopoxvirus* including vaccinia, cowpox, camelpox, ectromelia or gerbilpox virus a positive result with this assay in the United States is most likely due to monkeypox virus; however, potential exposure to other *Orthopoxviruses* should be considered.

The test results are intended to be utilized in conjunction with clinical presentation, epidemiological data, other diagnostic test results, and vaccination and exposure history. As monkeypox virus infections can present with rashes/lesions similar to that of varicella zoster virus, herpes simplex virus, and other sexually transmitted infections, consider testing for other pathogens as clinically indicated.

Test Code: 5900

Ordering recommendation: For detection of non-variola Orthopoxvirus, including monkeypox virus, DNA in clinical specimens.

Specimen Requirements: Double-Dry swab (polyester, rayon, or dacron) collection from skin lesion. Two swabs should be submitted to ensure adequate material is sampled. Break off or cut the tip of each swab into a sterile tube or container. Each swab should be placed in a separate tube or container. **Freezing sample is strongly recommended.**

Unsuitable specimen: Single swab. Cotton swab. Swabs with wooden or wire shafts. Swabs in media designed for preservation and/or transport.

Transport temperature: Frozen

Stability: 7 days refrigerated; 1 month frozen.

CPT codes: TBD

For questions, contact your East Side Clinical Laboratory Customer Service Representative.

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- **Laboratory Testing Guidelines:**

- Swab or brush the pustule/lesion **vigorously** with two separate sterile swabs.
- Collect at least two swabs from the same lesion.
- If possible, sample paired specimens from multiple lesions on different parts of the body and with differing appearances. CDC suggests 2-3 lesions total.
- Use a sterile nylon, polyester, or dacron swab with a plastic or thin aluminum shaft.
- Do not use other types of swabs. Do **NOT** use cotton swabs.
- Break off or cut the tip of each swab into a sterile tube or container.
- Place each swab into a separate **dry** sterile tube or container and ensure that the tube/container is **tightly sealed and leak proof**.
- Do **NOT** add transport media to specimen.
- Multiple specimens collected on a single patient should be submitted separately.
- Each individual specimen submitted for Monkeypox virus testing should be accompanied by its own separate requisition and transported in its own sealed bag.
- Refrigerate (2–8°C) or freeze (-20°C or lower) specimens within an hour after collection.
- **Freezing is strongly recommended.**
- Ship frozen (preferred) or refrigerated (acceptable). To maintain optimum specimen viability, transport the specimen to the laboratory as soon as possible.

- **Monkeypox: Interim Guidance from the CDC for Healthcare Providers**

Clinical features

- Caused by Monkeypox virus (MPXV)
 - Two clades: Central African (CAC) & West African (WAC). WAC is less virulent and is the predominant clade circulating in the US.
 - *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 MPX virus may remain infectious for months to years.
- Incubation period - 6 -13 days, up to 21 days.
- Signs/Symptoms
 - Fever, headache, **swollen lymph nodes** (which may differentiate it from smallpox), respiratory symptoms, 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
- Labs – Leukocytosis, elevated AST & ALT, low BUN, low Albumin
- Differential diagnosis - Smallpox, chickenpox/shingles, measles, bacterial skin infections, scabies, medication allergies, HSV, and syphilis.

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- 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: inactive virus, FDA approved
- Complications – Bacterial infection, sepsis, dehydration, diarrhea, encephalitis, death.
- Treatment – None, but smallpox anti-viral (TPOXX/tecovirimat) may be indicated for vulnerable populations.

Criteria to Guide Evaluation of Monkeypox Cases

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).	OR	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.

References:

Collection, Storage, and Shipment of Specimens for Monkeypox Diagnosis. CDC.
<https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html>

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>

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U.S. Monkeypox Outbreak 2022: Situation Summary. Centers for Disease Control and Prevention website. Accessed June 2022.

US Monkeypox outbreak 2022. CDC's 2022 U.S. Map & Case Count.
<https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>

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

KD Reed, et al., The detection of monkeypox in humans in the Western Hemisphere. *N Engl J Med.* 2004. 350, 342–350. <https://pubmed.ncbi.nlm.nih.gov/14736926/>

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