



Client Communication

Monkeypox Testing

Test Announcement

Informed by guidance from the CDC and other public health authorities, Clinical Pathology Laboratories (CPL) is closely monitoring the outbreak caused by monkeypox virus (MPXV). As of July 14, 2022, more than 1000 infections are confirmed in the US, identified in 42 states. Sonic Healthcare USA has been approved by the CDC to offer their FDA-approved, amplified nucleic acid (RT-PCR) molecular test to identify MPXV. Sonic Reference Laboratory (SRL) has completed validation of the CDC MPXV assay. **CPL has established test code 7410 to refer Monkeypox RT-PCR testing to SRL.**

Monkeypox Background:

- **Etiology:** Monkeypox virus
 - Two clades: Central African (CAC) & West African (WAC). WAC is less virulent group circulating in the US.
 - *Orthopoxvirus* genus: includes smallpox and cowpox. **MPXV is not related to varicella/chickenpox/shingles.**
 - Virus characteristics: Extraordinary resistance to drying, heat, and pH, which leads to **environmental persistence**. Materials contaminated with MPXV may remain infectious for months to years.
- **Incubation:** 6-13 days, may be up to 21 days
- **Signs/Symptoms:**
 - Systemic symptoms: Fever, headache, lymphadenopathy, respiratory symptoms, and GI symptoms, including diarrhea.
 - Characteristic Rash:
 - May look like pimple or blister.
 - May appear on face, in mouth, on genitals, or on other body parts (for more information, and examples, see <https://www.cdc.gov/poxvirus/monkeypox/symptoms.html>).



Monkeypox Background (continued):

- **Spread:**
 - Direct contact with the rash, respiratory secretions during prolonged face-to-face contact, intimate contact, fomites, placental transfer, animal handling.
 - Possible for up to several weeks.
- **Clinical differential diagnosis:** Rash: Chickenpox/shingles, measles, bacterial skin infections, scabies, medication allergies, HSV, and syphilis. Proctitis/urethritis: STIs.
- **Complications:** Bacterial infection, sepsis, dehydration, diarrhea, encephalitis.

Diagnostic Testing:

Sonic Healthcare uses the CDC-developed Non-smallpox Orthopoxvirus RT-PCR assay. The CDC assay does not differentiate monkeypox virus from such other Orthopoxvirus such as Vaccinia, Cowpox or other animal poxviruses, but in the absence of recent vaccinia vaccination, a positive result is most consistent with monkeypox virus. Results should be used with clinical presentation, epidemiological data, other diagnostic test results, and vaccination and exposure history. Other viral or infectious rashes may need to be considered (e.g. varicella zoster virus, herpes simplex virus); other STIs may be in the differential diagnosis of monkeypox.

- See below for collection instructions.
- Positive specimens will be referred to CDC for monkeypox virus characterization.
- Test results are reported to public health authorities as required.

Diagnostic Criteria and Classification for Monkeypox Cases:

Suspect Case:

- New characteristic rash* OR
- Meets an epidemiologic criterium (see below) with high clinical suspicion for MPX.

Probable Case:

- No suspicion of other recent *Orthopoxvirus* exposure (e.g. Vaccinia vaccination) AND
- Presence of *Orthopoxvirus* DNA by polymerase chain reaction of a clinical specimen
- **Note:** CPL offers the CDC-approved *Orthopoxvirus* PCR Assay. Positive tests results from Sonic Reference Lab will represent a "probable case." Positive cases are referred to CDC for confirmatory MPXV testing.

Confirmed Case:

- Demonstration of MPX DNA by PCR testing of a clinical specimen.

Diagnostic Criteria and Classification for Monkeypox Cases (continued):

Epidemiologic Criteria:

- Within 21 days prior of a characteristic illness onset:
 - Contact with a person having a similar rash or one who received a diagnosis of confirmed or probable monkeypox OR
 - Close physical contact in a social network experiencing MPX disease spread OR
 - Travel outside the US to a country with confirmed cases of or endemic MPX OR
 - Close contact with dead or live animals or pets associated with African reservoir species or animal products derived from reservoir species.

Exclusion Criteria (case is excluded 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 testing is negative for *Orthopoxvirus* or MPXV.

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

Test Information:

Unit Code Component	Description
Unit Code	7410
Reporting Title	MONKEYPOX VIRUS BY PCR
Component Codes	74101: Result 74102: Source 74103: Symptomatic (Y/N) 74104: Symptom onset (date)
Container Type	2 SWABS IN STERILE COLLECTION CONTAINER
Transport Temperature	PREFERRED: FROZEN ACCEPTABLE: REFRIGERATED
CPT Code	87593
Collection Instructions	<ul style="list-style-type: none"> ■ Collect at least two swabs from each lesion. ■ Vigorously swab active lesion with two separate sterile synthetic swabs (e.g. Dacron, polyester, or nylon) with a plastic shaft. Do not use cotton swabs or swabs with wooden or metal shafts. ■ Break the tip of each swab into a sterile tube or container. Swab tips should be no longer than 35 mm. Parafilm may be used to ensure a leak-proof seal. ■ Refrigerate (2–8°C) or freeze (-20°C or lower) specimens within an hour after collection. Freezing is preferred. ■ If possible, sample several lesions, preferably from different parts of the body or those with differing appearances, using 2 swabs for each location. CDC suggests 2-3 different lesions total. ■ Separate collection devices or swabs should be used to assess for the differential diagnostic considerations (e.g. HSV, VZV, chlamydia, gonorrhea). MPXV swabs cannot be shared with other departments.

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