State of California—Health and Human Services Agency
California Department of Public Health

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TO: California Healthcare Providers
SUBJECT: Healthcare Provider Health Advisory: Updates on Laboratory Testing and Treatment for Monkeypox (MPX) Virus Infection in California

NOTE: THIS IS A RAPIDLY EVOLVING SITUATION. UPDATES AND MODIFICATIONS TO THIS INFORMATION WILL BE PROVIDED AS THEY BECOME AVAILABLE.

This alert provides updated information for California healthcare providers for testing of suspected MPX cases and treatment of suspected, probable, and confirmed MPX cases at risk for severe outcomes. Thank you for your tireless work in helping to keep Californians healthy.

I. Situation Summary

The California Department of Public Health (CDPH) continues to work with local health departments (LHDs) and California healthcare providers on the ongoing MPX outbreak impacting the United States and other countries not usually endemic for MPX. As of August 29, 2022, over 48,000 cases of MPX have been reported from 92 non-endemic countries in the current outbreak, which began in May 2022. In the United States, there have been over 18,000 confirmed cases from 51 states and territories, including over 3,000 California residents. Reports from investigations in several countries and the U.S., including in California, suggest that person-to-person transmission through close skin-skin contact is fueling spread and that clinical case presentations have not always been characteristic of classic MPX infections.
Testing for Orthopoxvirus and/or MPX virus is currently available through 11 public health laboratories and is also available at multiple commercial laboratories, including, but not limited to, the following: Quest, Labcorp, Aegis, Sonic, ARUP, and Mayo (not available in California). For some laboratories, confirmatory MPX testing is done at CDC.

II. Background

Since the first MPX case in the U.S. in 2022 was diagnosed in a traveler who returned to Massachusetts from Canada on May 17, cases have been identified throughout the country. The strain circulating in the U.S. and globally belongs to a clade that causes milder illness (Clade II). To date, 15 deaths associated with MPX infection have been reported worldwide to the World Health Organization (WHO) and one death is under investigation in the United States.
In California, there have been 99 hospitalized MPX cases to date. Case lesions can be present in sensitive areas, such as genital and perianal areas, and be very painful. Reported complications

of MPX in the United States include severe pain, bacterial superinfection, severe pharyngeal swelling with concern for airway compromise and inability to eat/drink. The risk of severe disease is greater in certain people, such as those who are immunocompromised.
Close, sustained skin-to-skin contact, including sexual contact, with a person with MPX appears to be the most significant risk factor associated with MPX transmission among recent cases. In this outbreak, many of the reported infections in the U.S., including those in California, have been in gay, bisexual, or other men who have sex with men (MSM). However, it is important to remember that any person, regardless of gender identity or sexual orientation, can acquire and spread MPX.
If you have a suspect pediatric case, please contact your local health department as we are strongly encouraging consultation and testing of suspect pediatric cases within the California public health lab network. It is also very helpful to submit lesion photos if they're available.

II. Testing Patients for MPX

Please see CDC guidance on testing patients for MPX, which includes important updated information on specimen collection.

Monkeypox Testing Criteria

- As previously stated in the July 28, 2022 CDC HAN, testing should be performed on specimens from persons for whom MPX is suspected based on clinical presentation and epidemiologic criteria.
- Positive diagnostic results from testing of skin lesion specimens for Orthopoxvirus or MPX virus DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing.
- If there are no identified epidemiologic risk criteria for MPX infection, other possible causes of rash in adults should be considered, including secondary syphilis, herpes simplex, varicella zoster, and enteroviruses. In children without identified epidemiologic risk criteria for MPX, varicella zoster, molluscum contagiosum (MC), herpes simplex, and enteroviruses should be considered in the differential diagnosis.

III. Commercial Lab Testing for MPX

On June 22, 2022, the CDC released information regarding the approval for commercial MPX testing through five commercial laboratories: Aegis Science, Labcorp, Quest Diagnostics, Mayo, and Sonic Healthcare. The labs with currently available testing capability will be discussed in detail below. This is not an exhaustive list, and more labs may be added.
Please refer to CDC media updates for expanded commercial testing as available. No approval from the LHD or CDC is needed for samples sent to commercial labs for testing. Please note the differences in specimen requirements across the laboratories (e.g., dry swab vs. VTM [viral transport media] and number of swabs per lesion).
Samples sent to public health labs will need to be coordinated with the LHD. As testing is increasingly available, including in large commercial labs, providers should use these commercial testing resources for most suspect MPX patients.

Quest Diagnostics (Click for link to website)

- Real-Time Polymerase Chain Reaction for non-variola Orthopoxvirus DNA and MPX Virus DNA (Clade II)
- Testing hub in California (San Juan Capistrano)
- Number of swabs per lesion: 1
- Sample Collection: Swab the pustule/lesion vigorously and place the swab into a viral culture media (or equivalent) tube.
- Each individual specimen submitted for MPX virus testing should be accompanied by its own separate requisition and transported in its own sealed bag. Multiple specimens collected on a single patient should be submitted separately.
- Ship frozen (preferred) or refrigerated (acceptable).

Labcorp (Click for link to website)

- MPX (Orthopoxvirus), DNA, PCR Test
- Number of swabs per lesion: 1
- Sample Collection: Vigorously swab or brush the base of the lesion with a sterile dry polyester, rayon or Dacron swab. Insert the swab into the tube containing UTM or VTM. Carefully break the swab at the score line and tightly close the sample. Some UTM kits may contain two swabs; however, only one swab needs to be collected and submitted for testing. If multiple lesions with differing appearances are present, consider submitting an additional UTM/VTM collection, as described above, for each lesion. The test sample must be collected by a clinician at the site where the patient is being seen. Labcorp cannot collect this sample at a patient service center. Shipping and storage: Ship refrigerated or frozen at -20°C; room temperature swabs are not acceptable.

Sonic Healthcare/Westpac (Click for link to website)

- Real-Time Polymerase Chain Reaction for non-variola Orthopoxvirus DNA
- Can be ordered at all Sonic clinical laboratories across the United States, testing performed at reference laboratory in Austin, TX.
- Number of swabs per lesion: 2
- Sample Collection: Vigorously swab or brush active lesion with two separate sterile synthetic swabs (e.g., Dacron, polyester, or nylon) with a plastic shaft and a break point close to the tip. Do not use cotton swabs.
- Break off the tip of each swab into one 2-mL screw-capped tube with O-ring or place swabs in a sterile container with a gasket seal.
- Do not add transport media to specimens.
- Refrigerate or freeze specimen immediately after collection.

ARUP Laboratories (Click for link to website)

- Real-Time Polymerase Chain Reaction for non-variola Orthopoxvirus DNA
- Samples sent to Sonic Reference Laboratory for processing
- Number of swabs per lesion: 2

- Sample Collection: Swab the lesion vigorously to collect adequate DNA. It is not necessary to deroof the lesion before swabbing.
- Place lesion swab in Viral Transport Media.
- When collecting multiple swabs from the same lesion, place two swabs in a single container and submit both under the same order. When collecting from different body sites or lesions, place in separate containers and submit one order per body site or lesion.

Aegis (Click for link to website)

- Real-Time Polymerase Chain Reaction for non-variola Orthopoxvirus DNA
- Number of swabs per lesion: 2
- Sample Collection: A lesion swab will be utilized for MPX testing. Collections should be completed in accordance with the Centers for Disease Control and Prevention (CDC) guidelines. Aegis will supply kits and all necessary instructions for proper transport of specimens.

Lab Testing Guide:

Commercial Lab	Quest	Labcorp	Sonic Healthcare	ARUP	Aegis
Assay type	RT-PCR	DNA, PCR	RT-PCR	RT-PCR	RT-PCR
Viruses detected	Non-variola Orthopox **and MPX***	Non-variola Orthopox†	Non-variola Orthopox†	Non-variola Orthopox†	Non-variola Orthopox†

* Quest testing includes both non-variola Orthopox and MPX virus testing.
† A positive Orthopoxvirus test is considered to meet the case definition for probable MPX virus infection since there are no other circulating Orthopoxviruses within the United States that cause systemic disease.

For information regarding specimen collection please refer to the individual commercial lab websites, CDC, and reference guide.

Other labs also currently performing MPX testing include Renegade Labs (Berkeley) and Stanford (can test blood and urine in addition to lesions). The UC San Diego clinical lab is now offering MPX testing and UC Davis and UC Los Angeles will be starting to test soon. Please contact specific labs for updates and test information.

IV. Prioritizing Samples for Testing

Testing may be available from your LHD for certain situations. Please contact your LHD for more information. When possible, providers should prioritize the use of commercial laboratory testing for most suspect MPX specimens. For samples collected from people in the groups below, providers should coordinate with their LHD to have these samples tested through their local LRN lab. Identification of exposed people and effective isolation of suspect cases will help

reduce community spread. Patients with financial barriers to using commercial testing may also be directed to LRN labs.

- **People previously vaccinated for MPX in 2022**
- **People at increased risk of more severe infection**
    - Children <8 years of age
    - Who are pregnant or breastfeeding
    - Who are immunocompromised
    - With a history of atopic dermatitis of eczema
    - With HIV infection and a CD4 count <350mm^3
- **People in settings with an increased risk for transmission**
    - Healthcare settings
    - Homeless and migrant shelters, emergency shelters, and residential drug treatment facilities
    - Correctional facilities and detention centers
    - Long-term care, adult and senior care facilities, and in-home services involving physical care
    - Childcare and preschool settings that provide care for children from infancy through pre-school
    - K-12 schools and other settings (e.g., before/after school programs) that provide care for school-aged children younger than age 8 or older children who require physical care

CDPH has updated sections 2500 and 2505 of Title 17 of the California Code of Regulations, to make MPX or Orthopoxvirus infections explicitly reportable by healthcare providers and laboratories to public health.

Providers must specify ordering facility and provider address on commercial lab orders to ensure results are routed to the appropriate LHD.

V. Treatment Guidance

People with suspected monkeypox should isolate while awaiting testing results and if confirmed positive continue isolation until all lesions are healed or criteria are met per the CDPH Monkeypox Home Isolation Guidance for the General Public.
Supportive care and treatment of symptoms should be initiated for all patients with MPX infection. This may include topical medicines or other clinical interventions to control itching, nausea, vomiting, and pain. See NY City treatment guidance and CDC resources below.

- PDF-Dear-Colleague-Monkeypox.pdf (nastad.org)
- Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC
- MPX-treatment-guidance-interim.pdf (nyc.gov)

Tecovirimat (also called TPOXX), an antiviral medication available through an expanded access Investigational New Drug (EA-IND) protocol for the treatment of MPX infection, is available at

an increasing number of sites in California. Contact your LHD if you need information about sites where you can refer your patient.
Providers should consider tecovirimat treatment for high-risk suspect cases who have pending lab testing results and suspect cases who are experiencing severe symptoms.
Antiviral treatment of MPX infection should be considered for people with severe infection, illness complications (including pain not controlled with supportive care), and risk factors for progression to severe infection (children <8 years of age, immunocompromised or pregnant people, or those with a history of atopic dermatitis or eczema).
Supplies of tecovirimat are maintained by the Strategic National Stockpile (SNS) in the Office of the Assistant Secretary for Preparedness and Response. TTPOXX can be ordered through your local MHOAC: Obtaining and Using TPOXX (Tecovirimat) | MPX | Poxvirus | CDC. The web posting clarifies the forms and other documentation required for obtaining tecovirimat, which have been streamlined. For more information on prescribing or accessing tecovirimat for your patients, please contact your LHD or submit an inquiry to CDPH.