GUIDELINES AND RESOURCES

Interim Biosafety Guidelines for Laboratory Personnel Handling Human and Animal Specimens for Monkeypox Testing

This document provides interim biosafety guidance for laboratory personnel working with specimens from humans or animals with suspected or confirmed monkeypox infection. These guidelines should be used by laboratory directors and/or safety officers to perform risk assessments and develop safety protocols that take into consideration the unique facility and personnel characteristics of their particular institutions.

General Considerations

Effective communication between specimen collection teams and laboratory staff is essential in maximizing safety in the manipulation of these specimens. This is especially relevant in hospital settings, where laboratories routinely process specimens from patients with a variety of infectious and/or noninfectious conditions. A labeling system should be in place to clearly indicate specimens, such as those from monkeypox patients, that require special handling. Specific protocols for specimen collection are available on the CDC monkeypox website (Interim Guidance for Collection of Diagnostic Specimens from Persons with Suspect Monkeypox at www.cdc.gov/ncidod/monkeypox/diagspecimens.htm, and Interim Guidance for Necropsy Testing at www.cdc.gov/ncidod/monkeypox/necropsy.htm and Animal-Specimen Collection for Laboratory Testing at www.cdc.gov/ncidod/monkeypox/pdf/specimenform.pdf)

When possible, successfully vaccinated (i.e., smallpox vaccination within the past 3 years) persons should perform laboratory work that involves handling specimens that may contain monkeypox virus. However, vaccination is not an absolute requirement for handling specimens. When only non-immunized persons are available, additional personal protection equipment and practices should be used to further reduce the risk for exposures. Smallpox vaccine is not recommended for personnel handling and processing routine clinical specimens from monkeypox patients (e.g., urine for urinalysis, blood for CBC, chemistries, microbiology).

Laboratory exposures to poxviruses occur primarily through needle-stick injuries, other direct contact with the specimen, or aerosols that may be generated by laboratory procedures. Sharps should not be included with any specimens, and should be disposed of in appropriate puncture-resistant containers for autoclave of infectious waste. Guidelines for monitoring health-care workers who have unprotected exposures to patients with monkeypox or laboratory specimens from these patients can be found at www.cdc.gov/ncidod/monkeypox/infectioncontrol.htm. Post-exposure vaccination may be appropriate in cases of direct exposure to monkeypox specimens. Guidelines for the use of smallpox vaccine can be found at www.cdc.gov/ncidod/monkeypox/vaccination.htm

Use of a certified Class II Biological Safety Cabinet (BSC) is recommended for manipulations of monkeypox specimens. If a BSC cannot be used, the risk of exposure to an inadvertent sample release should be reduced by the appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors). Use sealed centrifuge rotors or sample cups for centrifugation. Ideally, these rotors or cups should be unloaded in a BSC.

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If procedures that generate fine-particle aerosols cannot be contained within a BSC, acceptable methods of respiratory protection include disposable particulate respirators (e.g. N-95, N-99, or N-100); these respirators provide the minimum level of respiratory protection. Facilities may consider the use of higher levels of respiratory protection, particularly if vaccination status of staff is not confirmed or if personnel cannot be correctly fitted to disposable models. These higher levels may include:

- Powered air purifying respirator (PAPRs) designed with loose-fitting facepieces that form a partial seal with the face;
- PAPRs with hoods that completely cover the head and neck and may also cover portions of the shoulder and torso;
- PAPRs with tight-fitting facepieces (both half and full facepiece);
- Full facepiece elastomeric negative pressure (i.e. non-powered) respirators with N, R, or P100 filters.

Respirators should be used in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) regulations. This includes training and fit testing to ensure a proper seal between the respirator's sealing surface and the wearer's face. Detailed information on respirator programs, including fit test procedures can be accessed at www.osha.gov/SLTC/etools/respiratory.

Careful hand hygiene is essential. Hands should always be washed after removal of gloves and especially before touching the eyes or mucosal surfaces.

Decontamination of work surfaces after the completion of work or at the end of the day is essential. Any Environmental Protection Agency (EPA)-registered hospital detergent-disinfectant currently used by health-care facilities for environmental sanitation may be used. Manufacturer's recommendations for use-dilution (i.e., concentration), contact time, and care in handling should be followed.

All cultures, stocks, and other regulated wastes should be decontaminated before disposal by using an approved method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory should be placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility should be packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

If the appropriate safety equipment and/or protocols are not available, consideration should be made to refer specimens to a suitably equipped reference laboratory.

It should be noted that monkeypox virus is regulated as a Select Agent under Federal Code 42 part 73. Further guidance regarding the possession, transfer, and handling of confirmed monkeypox virus cultures can be found at the CDC Select Agent Program (www.cdc.gov/od/sap , lrsat@cdc.gov, phone: 404-498-2255, FAX: 404-498-2265).

Routine Clinical Laboratory Procedures

A. Microbiology
   For laboratories with personnel vaccinated within the past 3 years, specimens may be handled in Biosafety Level 2 (BSL-2) facilities, using BSL-2 practices as indicated in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 4th edition (BMBL; www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm). Specimen manipulations should be carried out in a certified Class II BSC, especially if there is a potential to generate fine-particulate aerosols (e.g., vortexing or sonication of specimens in an open tube). Directional air flow (negative air

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pressure with respect to the surrounding area) is recommended, but not required for BSL-2 laboratory facilities.

For laboratories without vaccinated personnel, routine specimen processing may be handled in BSL-2 facilities, but with more stringent BSL-3 work practices (BMBL www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm). Laboratory workers must wear protective equipment, including disposable gloves, solid front gowns with cuffed sleeves, and face protection (snugly fitting goggles are preferred; if a face shield is used, it should have crown and chin protection plus wrap around the face to the point of the ear) to provide a barrier to mucosal surface exposure. Centrifugation must be performed using safety cups or sealed rotors. Rotors or safety cups should be opened in a BSC after centrifugation involving monkeypox specimens.

B. Routine Chemistry, Hematology, and Urinalysis
These procedures may be performed using rigorously applied Standard (previously Universal) Precautions. Special care should be taken to avoid the production of infectious aerosols. The use of sealed rotors and safety cups is encouraged for centrifugation of monkeypox specimens.

C. Clinical Pathology, Molecular Testing, and Analysis of Bacterial or Mycotic Cultures
BSL-2 facilities with standard BSL-2 work practices may be used for the following activities:
   1. Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
   2. Molecular analysis of extracted nucleic acid preparations
   3. Electron microscopic studies with glutaraldehyde-fixed grids
   4. Routine examination of bacterial and mycotic cultures
   5. Routine staining and microscopic analysis of fixed smears

Handling of Monkeypox Cultures

Culture-based testing should be limited to laboratories with appropriately trained and vaccinated staff.

The BMBL provides the following guidance for research and reference laboratories handling large volumes or numbers of monkeypox cultures:

All persons working in or entering laboratory or animal care areas where activities with vaccinia, monkeypox, or cowpox viruses are being conducted should have documented evidence of satisfactory vaccination within the preceding 10 years. BSL-2 practices and facilities are recommended for all activities involving the use or manipulation of poxviruses, other than variola, that pose an infection hazard to humans. Activities with vaccinia, cowpox, or monkeypox viruses, in quantities or concentrations greater than those present in diagnostic cultures, may also be conducted at BSL-2 by immunized personnel, provided that all manipulations of viable materials are conducted in Class I or II BSCs. Immunosuppressed individuals are at greater risk of severe disease if infected with a poxvirus (www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm).

For more information, visit www.cdc.gov/ncidod/monkeypox or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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