

PHLN GUIDANCE ON MPOX PATIENT REFERRAL, SPECIMEN COLLECTION AND TEST REQUESTING

Revision history

Version	Date published	Revision notes
1.2	8 January 2025	 Inclusion of note that pre-travel MPXV testing in asymptomatic persons is not recommended.
		 Updating reference to the <u>Mpox – CDNA National</u> <u>Guidelines for Public Health Units</u> for personal protection management in a healthcare setting
1.1	9 October 2024	 All references to 'Monkeypox' disease amended to 'mpox'.
		 All references to 'Monkeypox virus' amended to 'MPXV'
		 Updates to guidance to ensure recommendations remain up to date to current clinical laboratory knowledge.
		 ensure alignment with the Monkeypox virus infection – CDNA National Guidelines for Public Health Units.
		• Updating important information to include when referring specimens to a laboratory for mpox testing.
1.0	27 July 2022	Initial document.

Executive Summary

- Mpox¹ is confirmed by laboratory testing using nucleic acid amplification (NAA).
- Diagnostic testing capacity for *Orthopoxvirus monkeypox* (MPXV) is available throughout Australia. If mpox is suspected, testing is recommended.
- Mpox is nationally notifiable. Healthcare practitioners should follow jurisdictional notification policy.
- Please read this guidance in conjunction with the <u>Public Health Laboratory Network (PHLN) Mpox</u> (<u>Monkeypox</u>) <u>Laboratory Case Definition (LCD</u>).
- Please raise any questions about specimen collection with a specialist microbiologist².

Who to refer?

- Patients with a clinical presentation consistent with mpox. For example, vesicular exanthem, and who present with a history suggestive of exposure to mpox based on epidemiological factors outlined in the <u>Mpox – CDNA National Guidelines for Public Health Units</u>.
- A clinically consistent presentation with mpox includes fever, headache, myalgia, backache, lymphadenopathy, chills, and exhaustion. Lesions can develop in the anorectum, genitals, face, mouth, and/or other areas of the body. Proctitis with or without typical lesions can also occur. Symptoms usually begin between 7–14 days (but can range from 5–21 days) after exposure. Atypical presentations with prolonged prodromal symptoms or atypical rashes may occur.
- Include mpox vaccination history and relevant clinical and epidemiological information (including country of suspected infection acquisition, symptoms, travel history, history suggestive of exposure to mpox, contact with travellers or country of suspected mpox acquisition, other underlying diseases (such as HIV), and any high-risk settings or activities) on the pathology request form or in the electronic referral system.
- At present <u>it is not recommended</u> to test for MPXV in asymptomatic individuals at high risk of infection as there are insufficient data on the utility or cost effectiveness of screening for mpox. Similarly, pre-travel MPXV testing in asymptomatic persons is also not recommended.
- Consider specimen collection for other infections, such as herpes simplex, varicella-zoster and syphilis. Molluscum contagiosum and orf are other differential diagnoses, but these are generally made without laboratory testing.

Advice from jurisdictional public health units may determine how each patient will be prioritised for testing.

2

¹ Monkeypox is caused by viruses in the species *Orthopoxvirus monkeypox* (2023 Release, MSL #39) in the genus *Orthopoxvirus*.

²For example, when obvious lesions are absent and in patients presenting with proctitis.

Specimens and specimen collection

Personal Protective Equipment

Please refer to the <u>Mpox – CDNA National Guidelines for Public Health Units</u> (Section 8 Case Management) for further information on personal protection management in a healthcare setting.

Wear appropriate personal protective equipment (PPE) while collecting specimens from patients with suspected mpox. This includes a full-length gown, fluid-repellent surgical mask, disposable gloves, eye goggles or a face shield. Standard and transmission-based precautions, including contact and droplet precautions, are considered the minimum level of PPE when collecting a sample from a person with suspected, probable, and confirmed mpox.

Consider wearing a fit-checked P2/N95 particulate filter respirator (PFR) or equivalent if:

- the patient has respiratory symptoms, or
- varicella or measles is suspected, or
- there are other high-risk exposure events. For example, prolonged exposure with the patient (such as a hospitalised patient) or aerosol-generating activities.

Wipe the specimen container after the specimen has been collected. Use a suitable detergent, followed by a Therapeutic Goods Administration (TGA) approved hospital-grade disinfectant with activity against viruses. This will be recorded on the label and product information. Alternatively, use a bleach solution. You can also use a TGA-listed 2-in-1 (single step) combined cleaning and disinfection product with activity against viruses. For more information, please refer to the Therapeutic Goods Administration <u>website</u> for a list of suitable hospital-grade disinfectants.

Suitable disinfectants are also available from the <u>United States Environmental Protection Agency</u> <u>website</u>. After the specimen collection, conduct environmental cleaning as per ICEG advice on the interim guidance on Monkeypox for health workers.

Suitable specimens and specimen collection

Collect lesion material from persons with suspected mpox with an active lesion or rash. Acceptable specimen types include skin lesion swabs, fluid, tissues, crusts or skin biopsy. It is recommended at least two swabs from morphologically distinct lesions and/or different anatomical locations are collected. Collect material using a dry sterile swab (for example, nylon, polyester, or Dacron) suitable for NAA testing. Collect specimens on the tip of the swab, ideally with visible exudate. Throat or oropharyngeal swabs are also suitable specimens. For patients presenting with proctitis and no visible lesion, insert a swab to sample the anorectal mucosa, avoiding excess faecal contamination as this may affect test performance.

Vigorously rub the bottom of the lesion to ensure you collect cellular material from the lesion base to ensure sufficient MPXV DNA, if present, is in the sample submitted for testing.

If there is no obvious lesion, for example, macular rash alone, discuss approaches with a specialist microbiologist. Testing may need to be repeated as lesions progress to increase the diagnostic yield and reduce the risk of a false negative result. Place each specimen in individual sterile containers or collection tubes.

4

To collect material for testing the following is acceptable^{3,4}:

- A dry sterile swab (preferred)
- Swab containing viral transport media (VTM) or liquid Amies
- Lesion tissue or crust in a dry container

A dry sterile swab is the preferred option to collect material for testing to avoid the risk of leakage during transport and allows for laboratory staff to process the specimen appropriately. However, if swabs in VTM or liquid Amies is being used please ensure the lid is appropriately secured. Use of bacterial culture swabs (e.g. containing gel media for bacterial preservation) is not acceptable to perform NAA testing

NAA of blood may be considered in specific cases where discussion with a specialist microbiologist has been conducted. Whole blood or serum specimens can be tested by NAA to detect the presence of MPXV. However, these are often negative due to the transient nature of viraemia. Therefore, NAA testing of whole blood or serum specimens should not be used to exclude mpox. If collected, a minimum of 5 mL of EDTA whole blood or 10 mL of serum is recommended.

Although MPXV may be detected in semen, evidence is still emerging about the diagnostic yield of this specimen type⁵ and it is not recommended as the sole specimen type for initial diagnostic testing^{6, 7, 8, 9}.

Make sure specimen containers and tubes that contain fluid is securely shut to prevent leakage during transport. Following collection, place all samples for testing of MPXV and other pathogens into specimen bags. The specimen bag should contain sufficient absorbent material (for example, cotton wool or tissue), to absorb the entire contents of the primary receptacle in case there is any leakage for samples that contain fluid (including but not limited to swabs placed in transport or liquid media, blood or urine).

Submit specimens to the testing laboratory as soon as possible. If there is a delay in transport to the laboratory, refrigerate specimens (approximately 4 °C) for up to 7 days or freeze (–20 °C or lower) if delay is more than 7 days. Keep the specimens refrigerated during transport to the laboratory.

Specimen transport guidelines

Laboratory-based NAA testing for specimens *suspected or confirmed* to contain MPXV are handled at a different level of risk compared to MPXV cultures. If there is doubt about the associated level of risk, or any other questions about transport requirements, discuss these cases with the specialist

³ https://iris.who.int/bitstream/handle/10665/354488/WHO-MPX-Laboratory-2022.1-eng.pdf

⁴ https://www.cdc.gov/mpox/?CDC_AAref_Val=https://www.cdc.gov/poxvirus/mpox/pdf/MPoxTestingPatients.pdf

⁵ Antinori, A., et al. (2022). "Epidemiological, clinical and virological characteristics of four cases of monkeypox support transmission through sexual contact, Italy, May 2022." Euro Surveill 27(22)

⁶ UKHSA: Guidance Mpox (monkeypox): diagnostic testing

⁷ European Centre for Disease Prevention and Control: Factsheet for health professionals on mpox (monkeypox)

⁸ <u>Center for Disease Control and Prevention: Science Brief: Detection and Transmission of Mpox (Formerly Monkeypox) Virus During the 2022 Clade IIb Outbreak</u>

⁹ World Health Organization: Mpox Q&A

5

microbiologist to whom the specimens are referred to before transportation.

For transport between laboratories, place bagged specimens into a second container or box before transport. For additional details on specimen packaging and transportation, refer to the Requirements for the packaging and transport of pathology specimens and associated materials (Fifth Edition 202<u>2</u>) and Recommendations on the Transport of Dangerous Goods Volume I (Twenty-third revised edition 2023).https://www.safetyandquality.gov.au/publications-and-resources/resource-library/requirements-packaging-and-transport-pathology-specimens-and-associated-materials-fourth-edition-2013 Note that except for MPXV cultures, samples may be transported as category B biological hazards (UN 3373). MPXV cultures should be transported as category A biological hazards (UN 2814).

Raise any questions about specimen collection and transport with the specialist microbiologist to whom the specimen is being referred.