Laboratory testing in patients with confirmed or clinically suspected mpox

Please note that this document should be used in tandem with other <u>Interim Management of Mpox</u> <u>documents</u>.

Readers should not rely solely on the information contained within these guidelines. Guidance information is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a health professional. Clinical judgement and discretion will be required in the interpretation and application of this guidance. This guidance is under constant review based upon emerging evidence at national and international levels and national policy decisions.

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Laboratory testing in patients with suspected or confirmed mpox*

Part 1: Blood tests (for example urgent microbiology, haematology, and biochemical tests)

All clinical laboratories in **acute healthcare settings** (*which does not include National Virus Reference Laboratory (NVRL*)) must plan for safe provision of essential and urgent laboratory services to patients in whom mpox is suspected on a 24/7 basis. This requires advance assessment of associated risks in the facility and planning how those risks are managed in the laboratory.

- Clinical specimens from patients with suspected mpox irrespective of the clade or sub-clade - can be packaged and transported as a CATEGORY B pathogen in accordance with local standard protocols and in line with HSE guidance for UN3373 category B samples (see figure, page 4).
- Essential urgent blood tests sent to the microbiology, haematology or biochemistry laboratory can be performed at Containment Level (CL)-2 level by trained staff following good laboratory practice including the use of appropriate PPE (gloves, laboratory coat +/- eye protection subject to risk assessment).
- Testing that is performed entirely on closed autoanalysers from patients with suspected or confirmed mpox can be performed according to standard laboratory procedures at CL-2 level#
- Where use of a centrifuge is needed, safety cups or sealed rotors should be used.
 Following centrifugation, the sealed bucket should be placed in a microbiological safety cabinet for 10 minutes and the user should open it carefully following good laboratory practice including use of appropriate PPE.
- As monkeypox virus (MPXV) is a Hazard Group 3 pathogen, any diagnostic testing performed on specimens from patients with suspected mpox by methods where there is a risk of generating aerosols, droplets or splashes, must be performed within a microbiological safety cabinet at CL-3, using appropriate PPE. This includes nucleic acid extraction from cutaneous swabs or other sample types prior to virus inactivation (e.g. molecular testing for pathogens such as HSV, VZV,

transport medium already includes lysis buffer validated for the inactivation of MPXV

 Microbiological samples requiring manual manipulation from probable or confirmed mpox cases, e.g. plating of swabs for culture, urine antigen testing, or manual manipulation of body fluids should be carried out in a microbiological safety cabinet at CL-3 level². Microbiological samples from individuals not meeting the case definition for probable or confirmed mpox can be processed at CL-2 level subject to local risk assessment

If samples require aliquoting into a secondary tube prior to loading onto the analyser, this manipulation should be carried out in a safety cabinet at CL-3 level

- Any manipulation of samples which would be regarded as aerosol-generating procedures should be performed in a CL-3 facility.
- Due to the potential risk for the generation of aerosols, splashes and/or droplets, the use of Point-of-Care/Near Patient Testing devices for the analysis of samples from patients with probable or confirmed mpox should be avoided unless a specific risk assessment can demonstrate that it can be undertaken safely, with appropriate PPE used, and the device/area can be adequately decontaminated²

Part 2: Testing for mpox, specimen handling, packaging and transport

Mpox testing should be carried out if the HPSC case definition is met. MPXV is categorised as a Hazard Group (HG) 3 organism. However, samples can be handled as Category B for transport and laboratory processing of both clade I and clade II MPXV¹.

The case definition for MPXV clade I and clade II can be found here: <u>Case Definition</u> - <u>Health Protection Surveillance Centre (hpsc.ie)</u>

^{*} Formerly known as Monkeypox

Sampling for mpox: hospital-based setting

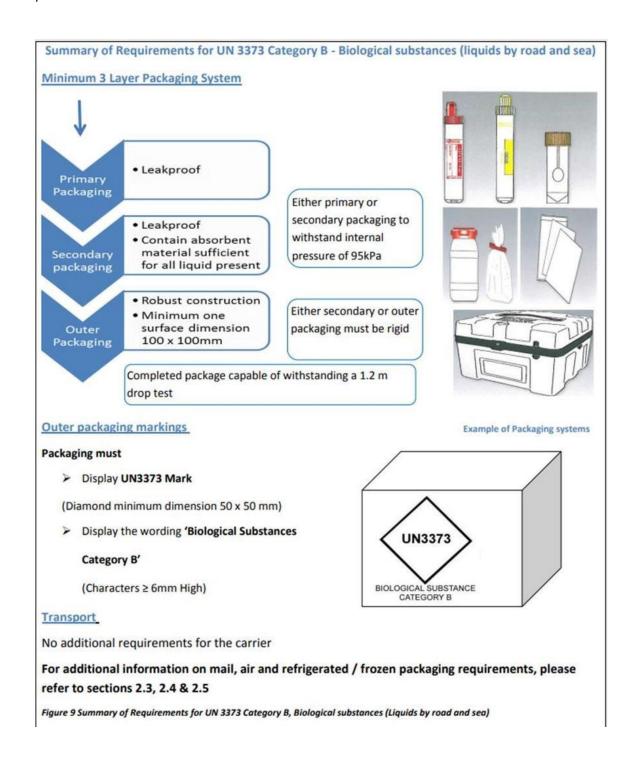
- 1. If testing for mpox is indicated, ensure that the specimen is collected with adherence to good infection prevention and control (IPC) practice including appropriate hand hygiene and use of PPE
- 2. The recommended sample of choice is <u>one</u> standard viral swab in viral transport medium (VTM) taken from a mucosal or cutaneous lesion: either ulcer or vesicular fluid if present.
- 3. If there are concerns that patient is presenting during the prodromal stage and there are no cutaneous lesions, or if pharyngeal lesions are present, a viral throat swab may be collected under the advice of an infection specialist
- 4. Follow-up samples from confirmed mpox cases are not required. If there are exceptional circumstances where follow up testing is considered discuss in advance with the NVRL
- 5. Clearly label the anatomical site of sample collection
- 6. Provide locally agreed patient identifiers on the request form: full name (or initials, in line with local clinical practice); date of birth; medical record number; and the name of the requesting clinician
- 7. Double bag the sample at the point of collection in the clinic setting
- 8. The referring clinician should inform the local microbiology laboratory if samples from probable mpox cases are being submitted for investigation
- 9. The double bagged sample should be taken to the microbiology laboratory in person and not via the pod/chute/pneumatic system. The bag should be clearly labelled as samples collected from a suspected mpox case.

Sampling for mpox: other clinical settings*

- Perform a clinical assessment and sampling as outlined in steps 1 to 6 above, including a **test for mpox** using one standard viral swab in *viral transport* medium (VTM).
- Package sample in line with UN3373 Category B sampling, the full HSE guidance on Preparation for transport of specimens and other biological materials is available here.

3. The summary requirements within the guidance are shown below.

* If testing is undertaken in non-hospital settings, mechanisms for transportation can be discussed with the local public health team



Local Microbiology Laboratory

- Samples from patients with suspected mpox can be packaged and transported as a CATEGORY B pathogen in accordance with local standard protocols.
- Samples should be clearly marked as probable mpox.
- Any sample taken for mpox investigations should be packaged separately to samples being sent to NVRL for other investigations.
- The courier should be informed as to which package contains sample(s) for mpox investigations in order to alert reception on arrival to the NVRL.
- All other sample types collected from suspected mpox cases that are deemed clinically necessary, should also be clearly marked as "probable mpox" and managed through the local laboratory (as section 1 above).

Mpox testing at the NVRL

- The sample will be inactivated in CL-3 conditions, prior to testing by real-time polymerase chain reaction (PCR) for the presence of orthopoxvirus DNA, and, concurrently, for MPXV clade differentiation#
- Samples will be tested concurrently for the presence of VZV, HSV-1 and HSV-2 DNA.
- In addition to routine reporting arrangements and notification requirements under public health legislation, positive mpox results will be communicated by telephone to the referring microbiology laboratory

[#] Unless prior discussion indicates a probable MPXV clade I case, samples returning an "Orthopoxvirus DNA DETECTED" result will undergo clade differentiation concurrently with a MPXV clade II-specific PCR. Samples returning a negative MPXV clade II-specific PCR result will be tested for the presence of MPXV clade I DNA.

Resources

- Guidance on regulations for the transport of infectious substances, 2023–2024.
 Geneva: World Health Organization; 2024. Link: https://www.who.int/publications/b/71576
 (Accessed: 24/07/2025)
- UKHSA Mpox (monkeypox): diagnostic testing. Link: https://www.gov.uk/guidance/monkeypox-diagnostic-testing
 (Accessed 24/07/2025)