Laboratory Guidelines for the Detection and Diagnosis of Monkeypox Virus Infection

27 August 2024

This document is an update of the Pan American Health Organization Laboratory Guidelines for the Detection and Diagnosis of Monkeypox Virus Infection published on 15 August 2024. The document was modified to include the most recent recommendation regarding the shipment of clinical samples from mpox suspected or confirmed cases.
This document is based on World Health Organization interim guidance on Laboratory testing for monkeypox virus, 10 May 2024, and is intended to provide guidance to National Reference Laboratories on monkeypox virus laboratory detection.

Monkeypoxvirus (MPXV) is a double-stranded DNA virus, a member of the *Orthopoxvirus* genus within the *Poxviridae* family. Poxviruses cause disease in humans and many other animals; infection typically results in the formation of lesions, skin nodules or disseminated rash. All orthopoxviruses (OPXV) are antigenically related and other species pathogenic to humans include cowpox virus and variola virus (causing smallpox, which has been eradicated). Vaccinia virus is also an OPXV that has been used as an attenuated vaccine and was a key tool for the eradication of smallpox, achieved in 1980.

MPXV is named due to its initial detection in monkeys and can primarily be found in rodents; however, the reservoir is undetermined. There are two known clades of MPXV now referred to as Clade I (former Congo Basin clade) and Clade II (former West African clade). Clade II consists of two subclades, IIa and IIb. The 2022/2023 multi-country outbreak of mpox was associated with clade IIb virus spread which was determined to constitute a public health emergency of international concern (PHEIC) from 23 July 2022 to 11 May 2023. Clade IIb continues to circulate worldwide, and is to date the only one detected in the Americas.

In December 2022, the Democratic Republic of the Congo (DRC) declared a nationwide outbreak of mpox and since September 2023 the outbreak that affected South Kivu province has spread and affected other provinces of the DRC. Additionally, in the past month four new countries in Eastern Africa (Burundi, Kenya, Rwanda, and Uganda) reported their first mpox cases. All cases in East and Central Africa sequenced to date belong to a new subclade of clade I, clade Ib. Separately, Côte d'Ivoire is experiencing an outbreak of mpox linked to clade II MPXV and South Africa has reported two more confirmed cases. On 14 August 2024, the upsurge of mpox in the DRC and other countries in Africa was determined to constitute a PHEIC. On 15 August 2024, the first case of clade I outside of the African Region was detected in Sweden.

After an incubation period ranging from 6 to 16 days, the typical presentation of mpox initiates with a short febrile prodromal period followed by progressive development of a classic rash with indurated and umbilicated (centrally depressed) lesions, starting on the head or face and progressing to the limbs and trunk. Lesions progress all at the same stage from macules, to papules, to vesicles, to pustules and eventually to crusts which dry up and fall off after two to four weeks. There are often enanthems (sores or ulcers) in the mouth and lesions can affect the eyes and/or genital area.

Because of range of conditions that cause skin rashes and because clinical presentation may more often be atypical in this outbreak, it can be challenging to differentiate mpox solely based on the clinical presentation. Therefore, the decision to test should be based on both clinical and epidemiological factors, linked to an assessment of the likelihood of infection.

Given the current multiple detections of MXPV worldwide, any individual meeting the definition for a suspected case should be offered testing. In this sense, the Pan American Health Organization / World Health Organization (PAHO/WHO) recommends to Member States to ensure the timely identification of suspect cases, the timely collection of samples and the implementation of molecular detection protocols at the National Public health Laboratories according to the existing capacity. When necessary, shipping of samples to Regional or Global Reference laboratories might be considered. Contact PAHO Regional Office for further advice and procedures.

SAMPLE COLLECTION AND MANAGEMENT

Safety procedures

Use of adequate standard operating procedures (SOPs) must be ensured, and laboratory personnel must be trained for appropriate use of personal protective equipment (PPE) including disposable antifluid gown, latex gloves, goggles or full-face cover, lab hat, respiratory protection, and shoe covers, and for the elimination of used PPE. Additionally, staff should be appropriately trained for specimen collection, storage, packaging, and transport.

Biological risk management

Measures should be taken to minimize the risk of laboratory transmission based on a **risk assessment at institutional level** when testing routine clinical specimens from confirmed or suspected mpox patients. These may include limiting the number of staff testing specimens only to staff with proven competency, wearing appropriate PPE, using rigorously applied standard precautions, using effective disinfectants (which include quaternary ammonium compounds and 0.5% (or 200ppm) bleach (0.5%), and avoiding any procedures that could generate aerosols.

Rigorous adherence to infection prevention and control guidelines must be ensured during specimen collection and handling.

It is recommended that all manipulations of specimens originating from suspected, probable or confirmed cases of mpox in the laboratory be conducted according to a risk-based approach. Each laboratory should conduct an institutional risk assessment.

When manipulating biological specimens, core biosafety requirements, similar to those previously referred to as biosafety level 2, must be met and heightened control measures should be applied based on local risk assessment.

MPXV may be contracted at the lab during the specimen processing stage from contaminated material or inadequate lab practices. Therefore, heightened biosafety measures are recommended in addition to the core requirements, including the following for the purpose of clinical testing without virus propagation:

- Specimens from patients with suspected MPXV infection must be handled in a reviewed (according to the PAHO laboratory maintenance manual), or certified Class II biosafety cabinet, prior to sample inactivation. Properly inactivated specimens do not require a biosafety cabinet.
- Laboratory personnel should wear appropriate PPE, especially for handling specimens before inactivation.

- Where use of a centrifuge is required for a procedure, safety cups or sealed rotors should be used.

Additional control measures should be considered for specific procedures, including aerosol-generating procedures, according to the local risk assessment. For more information on core biosafety requirements and heightened control measures, please see the fourth edition of the WHO Biosafety Manual.

Types of samples

The recommended specimen type for laboratory confirmation of mpox is skin lesion material, including:

- Swabs of lesion surface and/or exudate,
- Roofs from more than one lesion, or
- Lesion crusts.

Lesions swabs, crusts and vesicular fluids should not be mixed in the same tube.

After carefully cleaning with sterile saline or PBS, swab the lesion vigorously using Dacron or polyester flocked swabs, to ensure adequate viral DNA is collected. There is no need to deroof or puncture the lesions before swabbing. Both dry swabs and swabs placed in viral transport media (VTM) can be used. Although collection of lesion swabs is usually sufficient for testing, collecting roofs or crusts might be useful particularly if the progression of the case is advanced. In this instance, sharps injury prevention measures should be strictly followed. Two lesions of the same type should be collected in one single tube, preferably from different locations on the body and which differ in appearance.

In addition to a lesion specimen, the collection of an oropharyngeal swab is encouraged. However, data on the accuracy of this specimen type for diagnosis is limited for mpox, therefore a negative throat swab specimen should be interpreted with caution.

Because the current outbreak is still under investigation, collection of additional specimen types for research purposes can be considered if allowed by the appropriate ethical review board, and there is sufficient laboratory and medical expertise for their safe collection, handling, and storage. These may include urine, semen, rectal and/or genital swab on indication based on clinical presentation including location of lesions.

Samples storage

Samples should be refrigerated (2 to 8°C) or frozen (-20°C or lower) within one hour after collection. If transport exceeds 7 days for the sample to be tested, specimens should be stored at -20°C or lower.

Longer term specimen storage (>60 days from collection) is recommended at -70°C. Repeated freeze-thaw cycles should be avoided because they can reduce the quality of specimens.

Other sample types

Additional specimens type (not intended for routine diagnostic and do not need to be collected outside of research settings) are (1) EDTA blood that can be used to support MPXV detection of but may not contain the high level of virus found in lesion samples, as any viremia occurs early in the course of infection, usually in the prodromal period, and before skin lesions become manifest; (2) lesion biopsy during the macular stage that should be considered only if clinically indicated and only be performed by personnel with appropriate training.

SHIPMENT OF SAMPLES

Specimens should be stored refrigerated or frozen within an hour of collection and transported to the laboratory as soon as possible after collection. Correct handling and storage of specimens during transportation is essential for accurate diagnostic testing.

Transport of specimens should comply with any applicable national and/or international regulations, including the UN Model Regulations regarding the recommendations for transport of dangerous substances, and any other applicable regulations depending on the mode of transport being used.

> For international transport, clinical specimens from suspected or confirmed cases of mpox can be shipped as "Category B, Biological substance – UN3373".
>
> Viral cultures should be transported as "Category A, Infectious substance, affecting humans – UN2814" (it is not recommended to attempt virus isolation).

All specimens being transported should have appropriate triple packaging, labelling and documentation. Shipping requires a dangerous goods certified shipper. Please see the WHO Guidance on regulations for the transport of infectious substances 2023-2024 for information on infectious substances shipping requirements (available at: https://www.who.int/publications/i/item/789240089525).

For international shipping, please contact the PAHO Laboratory Response group at: ricoj@paho.org or laboratoryresponse@paho.org

LABORATORY TESTING

Testing for the presence of MPXV should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures. Measures should be taken to minimize the risk of laboratory transmission based on risk assessment when testing routine clinical specimens from confirmed or suspected mpox patients.

VIRAL ISOLATION SHOULD NOT BE ATTEMPTED

Countries with no molecular diagnostic protocol implemented for MPXV detection should send suspected clinical samples (strictly fitting case definition) to a reference laboratory designated by PAHO. For support, please contact PAHO Laboratory Response Team (ricoj@paho.org).

Molecular testing

Confirmation of MPXV infection is based on nucleic acid amplification testing (NAAT), using real-time or conventional polymerase chain reaction (PCR), for detection of unique sequences of viral DNA. PCR can be used alone, or in combination with sequencing according to the suggested algorithms.

DNA extraction

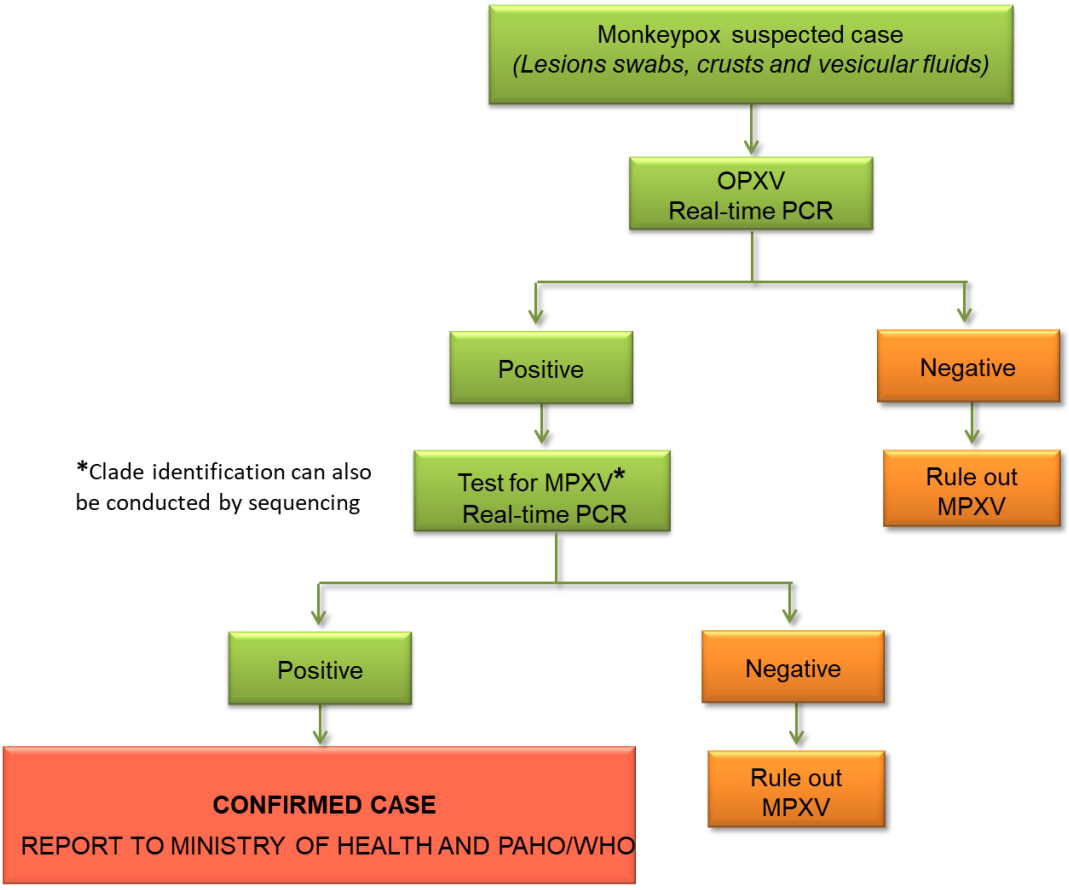
DNA can be extracted from samples mentioned above using any standard extraction protocols or kits. In general, the sample lysis step in DNA extraction inactivates any live virus. Thus, it is recommended that the sample lysis step is performed under a biosafety cabinet. For crust samples, DNA extraction kit for tissue samples should be used to insure appropriate sample lysis.

PCR protocols

Several groups have developed PCR protocols for the detection of OPXV or MPXV, as well as protocols for the differentiation and specific confirmation of MPXV clades I and II. Depending on the protocol available, two algorithms can be used for the screening of the virus and the specific detection:

Algorithm 1

In the first algorithm, a PCR that detects any OPXV, but does not identify which the viral species, is used. Positive samples are then further characterized by PCR or sequencing to specifically detect MPXV (see below, Algorithm 1). While it is preferable to perform MPXV specific confirmatory testing, positive detection using OPXV PCR assay is considered sufficient for laboratory confirmation of suspected cases in countries where no other orthopoxvirus circulates.



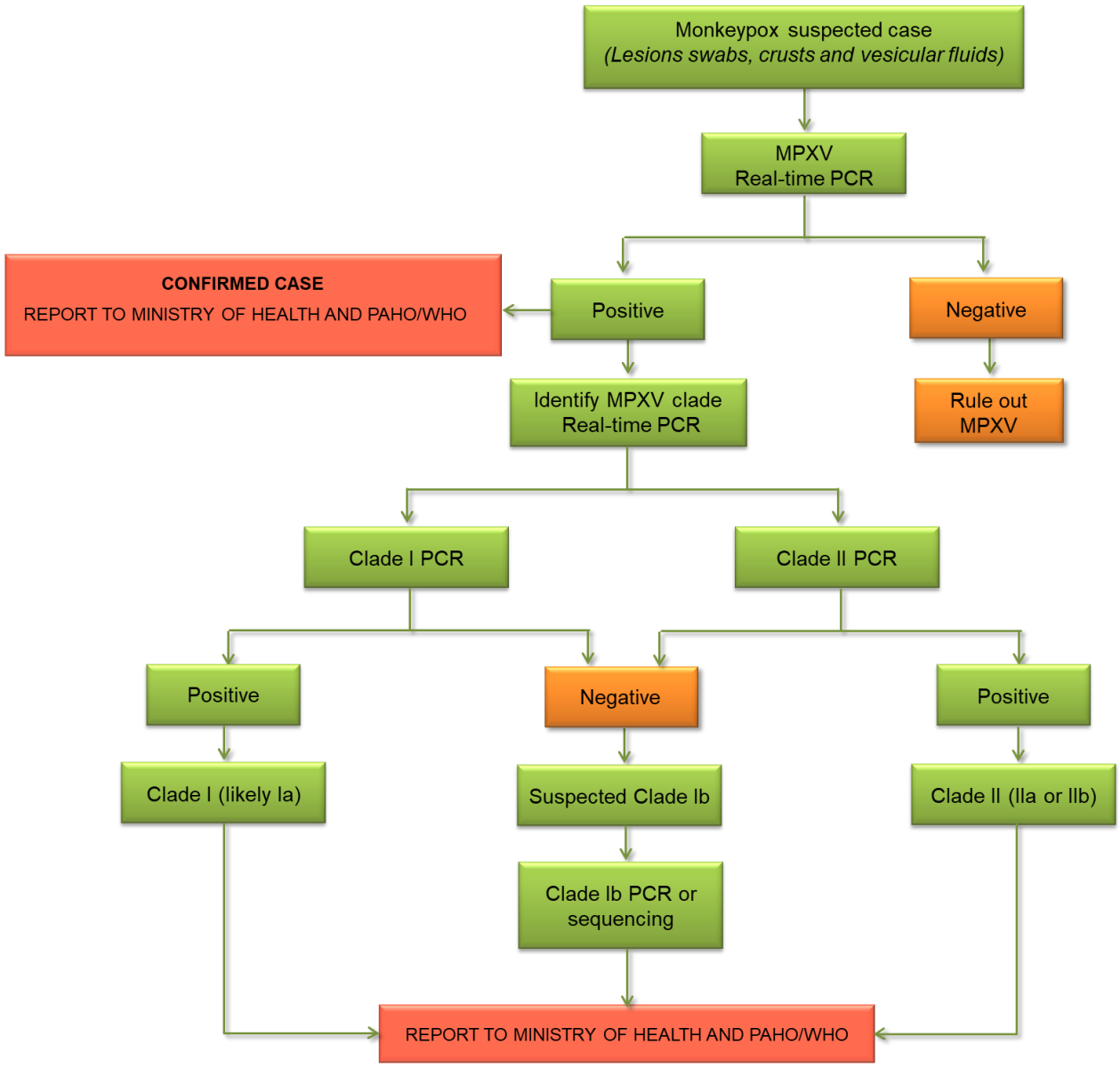
Algorithm 2

The second algorithm (recommended) is based on the initial generic detection of MPXV (which confirms the etiology), followed by specific differentiation of clades using additional PCR assays.

Since 2022, PAHO has worked with Member States in the implementation of this algorithm for MPXV molecular testing. The recommended protocol (Li *et al.*, *Journal of Virological Methods.* 2010. **169**, 223–7) has been published and is available on the following link: https://doi.org/10.1016/j.jviromet.2010.07.012. A working protocol is enclosed in this document (Annex 1).

This protocol is based on the initial identification of MPXV through a generic real-time PCR that detects **all** MPXV strains, including clades Ia, Ib, IIa, and IIb. If the generic PCR is positive, it is followed by subsequent reactions targeting specifically the two MPXV clades: clade I and clade II. Clade II specific PCR can detect viruses from clades IIa and IIb. However, sequencing data from the current clade Ib outbreak in the African Region shows that a deletion in these viruses results in a loss of detection with the clade I specific PCR. Thus, when using the recommended protocol, a positive result with the generic assay combined with a negative result for both clade I- and clade II-specific assays might indicate the presence of a clade Ib virus. This finding should be confirmed by sequencing. Alternatively, newly designed assays are currently available for the detection of clade Ib viruses (including, Leonard *et al.*, *Euro Surveill*. 2024. **29**:pii=2400486. Available at: https://doi.org/10.2807/1560-7917.ES.2024.29.32.2400486) (see Algorithm 2 below).

Reagents (primers, probes, and positive controls) for these assays are being distributed by PAHO/WHO throughout the Region. Additionally, Clade Ib specific protocols are being currently assessed, and the corresponding reagents will be distributed depending on the validation results.



Sequencing

Genetic sequence data (GSD) is useful for the identification of MPXV clades and subclades. It can also be used to monitor the potential impact of the virus evolution on the performance of PCR assays. Additionally, it provides valuable information to help understand the origins, epidemiology, and characteristics of the virus, for example whether cases arise from a single introduction or multiple introductions from other locations. Countries and laboratories are encouraged to share GSD, including raw data whenever possible in a timely manner through the publicly available databases.

Differential diagnosis

It is important to consider other potential causes of discrete skin lesions or a disseminated rash and other etiologies for similar-appearing skin lesions at the different stages of development including herpes simplex virus, varicella zoster virus, molluscum contagiosum virus, enterovirus, measles, scabies, Zika, Chikungunya, dengue, Treponema pallidum (syphilis), bacterial skin infections, medication allergies, parapoxviruses and chancroid, among others.

Sample, collection material and storage temperature for MPXV diagnostic and differential purpose

Specimen type	Collection materials*	Storage temperature	Collection purpose
Skin lesion material, including: • Swabs of lesion surface and/or exudate • Lesion roofs • Lesion crusts	Dacron or polyester flocked swabs with VTM or dry swab	Refrigerate (2-8 °C) or freeze (- 20°C or lower) within 1 hour of collection; -20°C or lower after 7 days	Recommended for diagnosis
Oropharyngeal swab	Dacron or polyester flocked swabs with VTM or dry swab	Refrigerate (2-8 °C) or freeze (- 20°C or lower) within 1 hour of collection; -20°C or lower after 7 days	Recommended for diagnosis if feasible, in addition to skin lesion material
Serum	Serum-separating tubes	Refrigerate (2-8 °C) or freeze (- 20°C or lower) within 1 hour of collection; -20°C or lower after 7 days	To be considered for serology to aid diagnosis or research (following ethics guidelines)
Plasma	collection tube with EDTA	Refrigerate (2-8 °C) or freeze (- 20°C or lower) within 1 hour of collection; -20°C or lower after 7 days	To be considered for serology to aid diagnosis or research (following ethics guidelines)

*Aside from specific collection materials indicated, other requisite materials and equipment include: transport containers and specimen collection bags and triple packaging, coolers and cold packs or dry ice, sterile blood-drawing equipment (e.g. needles, syringes and tubes), labels and permanent markers, PPE, and materials for decontamination of surfaces.

Expansion of the diagnostic network

Centralized MPXV testing might lead to increased turnaround times depending on the number of samples received, sample transport system, national laboratory capacity, and the integration of surveillance and information systems. Thus, to ensure timely case confirmation, contact tracing, and implementation of public health measures, decentralization of MPXV PCR might be necessary. When planning for the expansion of the MPXV laboratory network it is important to consider:

- The coordination and supervision of the network by the national public health laboratory
- National and local regulations
- Biosafety and biosecurity requirements
- Training of personnel
- Quality control
- PCR assays to be used

The suggested in-house protocol (Li *et al.*, *Journal of Virological Methods.* 2010. **169**, 223–7, see above) could be implemented depending on laboratory capacity and is recommended as the reference protocol.

Additionally, several commercial kits are available. These include, but are not limited to, the kits listed in the Annex 2. **However, to date, no commercial kit has been recommended by PAHO/WHO and any kit should be only used after proper verification / validation in close collaboration with the national public health laboratory.** Monitoring the potential impact of MPXV evolution on the performance of these kits is also essential as mutations (including deletions) can affect MPXV generic and/or clade-specific kits.

TESTING IN ANIMALS

Mpox is a zoonotic disease and small mammals in endemic areas likely act as viral reservoirs. A large number of animal species are susceptible to MPXV infection, including squirrels, giant-pouched rats, dogs, hedgehogs, monkeys, and possibly some strains of mice, rats, and domestic rabbits. For many other species, susceptibility is unknown. To date, no reptiles, amphibians, or birds have been shown to be susceptible to MPXV, or any other orthopoxvirus, infection.

In the current outbreak, cases of transmission of MPXV from humans to pets through close contact have been described sporadically. Pets or other animals that have been in contact with a human probable or confirmed mpox case and **that develop mpox symptoms** within 21 days of having contact should be tested for MXPV. Symptoms in infected animals are not fully described but might include rash or other skin lesions, conjunctivitis, lethargy, loss of appetite, cough, labored breathing, nasal secretions or crust, and/or fever.

The procedures described above should be followed for the collection, handling, and shipping of animal samples. In animals with rash, skin samples should be prioritized (in particular, swabs of the lesion surface and/or fluid, and crusts). In animals with no skin involvement, oropharyngeal, nasal, or anal swabs might be useful. However, data on the sensitivity of detection in these specimen types for diagnosis is limited, therefore negative results should be interpreted with caution.

As in humans, testing for MPXV infection in animals relies on the detection of viral DNA using PCR. Thus, the assays described above can be used for testing animal samples. Depending on local and national regulations, testing of animal samples might be performed in the same or in different laboratories as human samples. In

settings where testing is not available in animal health laboratories and where animal samples cannot be received by public health laboratories, countries might consider having DNA extraction performed at an animal health laboratory and the PCR at a public health laboratory.

References

World Health Organization. Multi-country outbreak of mpox, External situation report#35- 12 August 2024. Geneva: WHO; 2024. Available from: https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox--external-situation-report-35--12-august-2024

Pan American Health Organization. Epidemiological Alert Mpox (MPXV clade I) - 8 August 2024. Washington, DC: PAHO; 2024. Available from: https://www.paho.org/en/documents/epidemiological-alert-mpox-mpxv-clade-i-8-august-2024

World Health Organization. Laboratory testing for the monkeypox virus (MPXV): interim guidance, 10 May 2024. Geneva: WHO; 2024. Available from: https://www.who.int/publications/i/item/WHO-MPX-Laboratory-2024.1

World Health Organization. Surveillance, case investigation and contact tracing for mpox (monkeypox): Interim guidance, 20 March 2024. Geneva: WHO; 2024. Available from: https://www.who.int/publications/i/item/WHO-MPX-Surveillance-2024.1

World Health Organization. Guidance on regulations for the transport of infectious substances 2023-2024. Geneva: WHO; 2024. Available from: https://www.who.int/publications/i/item/789240089525

World Health Organization. Monkeypox: experts give virus variants new names. 12 August 2022. Geneva: WHO; 2021. Available from: https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names

Li Y, Zhao H, Wilkins K, Hughes C, Damon IK. Real-time PCR assays for the specific detection of monkeypox virus West African and Congo Basin strain DNA. J Virol Methods. 2010 Oct;169(1):223-7. doi: 10.1016/j.jviromet.2010.07.012

Pan American Health Organization. Maintenance Manual for Laboratory Equipment. Available at: https://www.paho.org/en/node/69262

World Health Organization. International Health Regulations (2005) Third Edition. Geneva: WHO; 2016. Available from: https://www.who.int/publications/i/item/9789241580496

Annex 1

Monkeypox virus (MPVX)
Real-time PCR protocol

Assays for the generic detection of MPXV (species: *Orthopoxvirus monkeypox*, genus: *Orthopoxvirus*) and the detection of its two clades:[1]

- Assay with G2R_G primers and probe: detects all MPXV strains
- Assay with C3L primers and probe: detects clade Ia but not clade Ib viruses
- Assay with G2R_WA primers and probe: detects clade II viruses (both clade IIa and IIb)
- Primers and probes sequences at the end of the document.
- All probes are hydrolysis ("TaqMan") probes labelled with the FAM dye and the BHQ-1 quencher.

1. Master mixes

Master mixes for each assay (G2R_G, G2R_WA or C3L) should be prepared separately.

Component	Volume per reaction **EXPRESS qPCR Supermix Universal** [2]	Volume per reaction **TaqMan® Universal PCR Master Mix** [3]
water (RNAse/DNAse free) [4]	3.0 µl	3.0 µl
reaction buffer (2x) [4]	10.0 µl	10.0 µl
forward primer (10 µM)	0.8 µl	0.8 µl
reverse primer (10 µM)	0.8 µl	0.8 µl
probe (10 µM)	0.4 µl	0.4 µl
Total per reaction	**15 µl**	

2. DNA

Add **5 µl** of DNA to the 15 µl of master mix (total reaction volume: 20 µl)

Include positive and negative **controls** to assess the validity of the run.

[1] Li *et al.*, *Journal of Virological Methods* **169**, 223–7 (2010).

[2] Invitrogen, cat. no.: 11785-200, 11785-01K, 11795-200 or 11795-01K.

[3] Applied Biosystems, cat. no.: 4304437, 4364338, 4364340, 4305719, 4318157 or 4326708.

[4] The volumes are for the indicated kits and should be adjusted when other kits are used.

3. Cycling[5]

G2R_G assay or C3L assay	
EXPRESS qPCR Supermix Universal	**TaqMan® Universal PCR Master Mix**
2 steps:	2 pasos de:
50°C - 2 minutes (UNG incubation)	50°C - 2 minutes (UNG incubation)
95°C - 6 minutes (polymerase activation)	95°C - 10 minutes (polymerase activation)
45 PCR cycles:	45 PCR cycles:
95°C - 15 seconds	95°C - 15 seconds
60°C - 30 seconds **(acquire fluorescence at this step)**	60°C - 30 seconds **(acquire fluorescence at this step)**

G2_WA assay	
EXPRESS qPCR Supermix Universal	**TaqMan® Universal PCR Master Mix**
2 pasos de:	2 pasos de:
50°C - 2 minutes (UNG incubation)	50°C - 2 minutes (UNG incubation)
95°C - 6 minutes (polymerase activation)	95°C - 10 minutes (polymerase activation)
45 PCR cycles:	45 PCR cycles:
95°C - 15 seconds	95°C - 15 seconds
62°C - 30 seconds **(acquire fluorescence at this step)**	62°C - 30 seconds **(acquire fluorescence at this step)**

[5] The duration of UNG incubation and polymerase activation are for the indicated kits and should be adjusted when other kits are used.

4. Primers and probes sequences

G2R_G assay (MPXV generic detection)	
G2R_G forward primer	5'-GGAAAATGTAAAGACAACGAATACAG
G2R_G reverse primer	5'-GCTATCACATAATCTGGAAGCGTA
G2R_G probe	5'FAM-AAGCCGTAATCTATGTTGTCTATCGTGTCC-3'BHQ1

G2_WA assay (detection of clade II viruses)	
G2R_WA forward primer	5'-CACACCGTCTCTTCCACAGA
G2R_WA reverse primer	5'-GATACAGGTTAATTTCCACATCG
G2R_WA probe	5'FAM-AACCCGTCGTAACCAGCAATACATTT-3'BHQ1

C3L assay (detection of clade Ia viruses)	
C3L forward primer	5'-TGTCTACCTGGATACAGAAAGCAA
C3L reverse primer	5'-GGCATCTCCGTTTAATACATTGAT
C3L probe	5'FAM-CCCATATATGCTAAATGTACCGGTACCGGA-3'BHQ1

Annex 2

Potential commercial options for MPXV PCR

Company	Name of the kit	Supplier Codes	Target	Kit components & controls	Transport	Additional reagents required	Review	Shelf-Life
Shanghai ZJ Bio-Tech Co	Liferiver Monkeypox Virus Real Time PCR Kit	ZD-0076-02 25 tests/kit	MPXV F2L/F3L genes Internal control	DNA Extraction Buffer Master mix Enzyme mix Positive control	Ship on dry ice	None	WHO desk review Validation ongoing	12 months
Tib Molbiol	LightMix® Modular Monkeypox	53-0550-96 96 tests/kit (distributed by Roche too)	MPXV J2L/J2R gene Internal control	Lyophilized primers/probes Lyophilized positive control	Ship at 4-25 °C	Extraction kit Enzyme: 1-step RT qPCR (Product code: 90-9999-96, 96 reactions/kit, ship at 4-25 °C) or other enzyme	WHO desk review Validation ongoing	12 months
Jiangsu Bioperfectus Technologies	Monkeypox Virus Real Time PCR Kit	YJC70115NW- 50T 50 tests/kit	MPXV F3L gene Internal control	Reaction mix Detection mix (primers/probes) Positive control	Ship on dry ice	Extraction kit	Validated by NCDC (Nigeria)	12 months
KH Medical	RADI Monkeypox Detection Ki	RV015 100 tests/kit	Clade I Clade II Internal control	Master mix Enzyme mix Positive control	Ship on dry ice	Extraction kit	Validated by INRB (DRC) vs in house CDC protocol with clade I samples	12 months
Genes2Life	PoxVirDetect	G2LPVSP-01 120 tests/kit (export limitations)	MPXV (generic or clade-specific) Internal control	Reaction mix Positive control	Ship on dry ice	Extraction kit	Verified by InDRE (Mexico)	12 months

Disclaimer: The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the Pan American Health Organization in preference to others of a similar nature that are not mentioned.