AfricaCDC
Centres for Disease Control and Prevention

Safeguarding Africa's Health

Mpox Molecular Diagnostic Tests(RT-PCR)

RECOMMENDATIONS AS PER MARCH 12, 2025

On 13 August 2024, Africa Centres for Disease Control and Prevention (Africa CDC) declared the ongoing mpox outbreak a Public Health Emergency of Continental Security (PHECS). The World Health Organization (WHO) followed this the next day, which extended the alert internationally as a Public Health Emergency of International Concern (PHEIC). After these declarations, many countries have made efforts to mobilize resources to introduce or expand laboratory testing, surveillance, and response activities.

Due to the increasing number of cases and the significant number of countries continuing to report new Mpox infections, WHO and Africa CDC have extended the PHEIC (Public Health Emergency of International Concern) and PHECS (Public Health Emergency of Continental Security), respectively, on the 24th and 25th February 2025 for the next three months.

One of the most pressing challenges remains the scarcity of laboratories, particularly in the most affected countries, creating an urgent need to expand testing capacity through laboratory decentralization. This aligns with the next six-month Mpox continental plan, which focuses on intensification, integration, and legacy.

However, access to appropriate, quality-assured diagnostics remains a challenge. There is limited information on key characteristics of available test kits, including their performance, reliability, and ability to detect relevant Mpox clades. Additionally, the lack of multiplex diagnostic tools capable of distinguishing Mpox from other pathogens with similar clinical presentations further complicates case detection and response efforts.

To address the challenge of mpox diagnostics access in the continent, the Africa CDC Diagnostic Advisory Committee (DAC) is continuously reviewing all available evidence on molecular tests for mpox and to shortlist tests that will be useful for mpox testing in countries. The shortlist aims to provide guidance to Africa CDC, countries and partners on appropriate high-quality molecular tests to procure and use for the mpox response. Africa CDC has published three editions of the shortlisted/ recommended tests.

This fourth edition, an update to the third edition has included one molecular point of care (POC) test for mpox. The POC molecular test known as the RADIONE mpox Detection kit is manufactured by KH Medical Co.Ltd, South Korea. The DAC reviewed the submission and concluded that the test fulfilled all the set criteria with additional data from independent clinical evaluation at INRB, DR Congo. The recommendation of the POC molecular tests by the DAC will be followed by engagement with the continental regulatory framework towards the Emergency Use Listing (EUL) by the African Medicines Regulatory Harmonisation (AMRH) programme.

To shortlist the appropriate molecular tests for mpox, the DAC review is based on current available literature, expert feedback in the field and the Target Product Profile (TPP) published by the World Health Organization (WHO) for mpox tests as guidance. Shortlisted tests for mpox must meet the following key minimum criteria::

- **Clade identification:** The test should specifically identify mpox clades I and II, even if precise differentiation between the two clades is not possible.
- **Limit of Detection (LoD):** The LoD should not exceed 1000 copies/ml.
- **Cross-reactivity:** There should be no cross-reactivity with non-Ortho poxviruses with similar signs and symptoms. At least one mpox specific target should not cross-react with known human Orthopox viruses.
- **Sample type:** The test should be compatible with sample types specified in the TPP. The manufacturer should indicate the sample type(s) for which the assay is designed.
- **Regulatory status:** The test should have regulatory approval or emergency use listing (for either *in vitro* diagnostic or research use) from at least one of the agencies recognized as a stringent regulatory agency, such as United States Food and Drug Authority (FDA), European Union CE, Japan Pharmaceutical and Medical Devices Agency (PMDA)or Australian Therapeutic Goods Administration (TGA), or others. The availability of performance evaluation data, especially from an African country, was considered an additional advantage. The Africa CDC's DAC will also consider approval by a National Regulatory Agency (NRA) or the African Continental process for regulation of *in-vitro* diagnostics (IVDs) supported by quality-assured performance evaluation data in future. Research Use Only (RUO) tests that have been independently evaluated or are widely used in laboratories across African countries and in the process of regulatory approval were also considered.

Using the above criteria and working with test information available from manufacturers and other sources, the DAC has identified the recommended list of molecular tests for mpox, shown in Table 1. The list of manufacturers is in alphabetical order. This list was produced based on available evidence and will be updated regularly as additional information on existing or, new or modified tests becomes available. The DAC will review this evidence and update the list with tests that meet the minimum requirements.

Table 1: Availble Recommended Real-Time PCR (RT-PCR) Tests for Mpox

Manufacturer, country	Name of test	Sample type	Clades	Limit of detection	Regulatory Status	Comments
Abbott, United States of America	ALINITY M MPXV	Lesion swab specimens	Detects clade I and II. Does not distinguish between clades.	200 copies/ml	EUA by US FDA	Limited opportunity for cross-reactivity in silico analysis
Bioperfectus Biotech, China	Bioperfectus Monkey-Pox Virus Genotyping RT-PCR kit	Tonsillar swab, Nasopharyngeal swab, lesion exudate, lesion crust, serum, whole blood	Detects and distinguishes between clades I and II.	250 copies/ml	CE-IVDD	
Certest Biotec SL, Spain	Viasure Monkeypox Virus Real Time PCR Detection Kit	skin lesion swab: vesicular fluid, pustular fluid, papules	Detects clades I and II. Does not distinguish between clades.	8 copies/ml	CE-IVDD. EUA by FDA revoked.	
Daan Gene, China	Detection Kit for Monkeypox Virus DNA (PCR-Fluorescence Probing)	Rashes, scabs, blister fluid, pustular fluid, or whole blood specimens	Detects clades I and II. Does not distinguish between clades.	200 copies/ml	CE, China NMPA	
Diacarta Inc, United States	QuantiVirus MPXV Test Kit	Swabs of acute pustular or vesicular rash	Detects clades I and II. Does not distinguish between clades.	25-80 copies/ml	CE-IVDD and EUA by US FDA	Reagents for extraction not included in the kit.
KH Medical Co.Ltd, South Korea	RADI FAST Mpox detection kit	Skin lesion, crust and swab	Detects clade I, IIb and IIa.?	1000 copies/ml	CE-IVDD	Independently evaluated in DRC. Has local regulatory approval in DRC.
KH Medical Co.Ltd, South Korea	RADIONE mpox Detection Kit	Skin lesion, crust and swab	Detects clade I and II, and can distinguish between clades. Detects clade Ia and Ib.	800 copies/ml	WHO EUL	Independently evaluated at INRB. This is the only point of care test which fulfils the DAC criteria.
Moldiag, Morocco	UM6P-MAScIR MPOX qPCR 1.0	Cutaneous (vesicle and crust), oropharyngeal, and blood	Clade I and II doesn't distinguish between clades	150 copies/ml	Local authorization for use by MoH Morocco	Evaluated at INRB, DRC. This is the first locally manufactured mpox kit in Africa.
Roche, United Stated of America	Cobas MPVX	Lesion swab samples	Detect clade I and II. Does not distinguish between clades.	36.5 copies/ml	EUA by US FDA	Limited opportunity for cross-reactivity in silico analysis.
Sansure Biotech. China	Monkey Pox Nucleic Acid Diagnostic Kit	Serum, whole blood, vesicles and pustules, nasopharyngeal swab, ororpharyngeal swab	Detects clades I and II. Does not distinguish between Clades	200 copies/ml	CE-IVDD	

***The TIBMolBiol test is currently used for surveillance purposes only as it is RUO.*

To submit information on tests to the DAC, please contact **Dr Noah Fongwen** via **FongwenN@africacdc.org**

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