AfricaCDC
Centres for Disease Control and Prevention

Safeguarding Africa's Health

Mpox Molecular Diagnostic Tests(RT-PCR)

RECOMMENDATIONS AS PER 13 AUGUST 2024

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). This was followed the next day by the World Health Organization (WHO), 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. In particular, as the number of suspected cases surges in the Democratic Republic of Congo (DRC), Burundi, and the Central African Republic, and an increasing number of new countries report cases, there is an urgent need to implement testing to strengthen the Mpox response. However, access to appropriate quality assured diagnostics is a challenge. There is limited information on important characteristics, such as available test kits' performance and ability to detect relevant clades.

To address the challenge of mpox access in the continent, the Africa CDC Diagnostic Advisory Committee (DAC) met in Kigali from 19-23 August 2024 to review the available evidence on molecular tests for Mpox and to shortlist tests that may 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.

To shortlist the molecular tests for Mpox, the DAC reviewed the current available literature and used the Target Product Profile (TPP) published by the World Health Organization (WHO) for Mpox tests as guidance. Tests that were shortlisted had to meet the following key minimum criteria:

- Clade identification: The test should identify mpox clades I and II even if precise differentiation is not possible.
- Limit of Detection (LoD): The LoD should be within the WHO recommended range(equivalent to at least 1000 copies per ml of specimen).
- Cross-reactivity: There should be no cross-reactivity with non-orthopox pathogens that present with similar signs and symptoms. At least one MPXV-specific target should not cross-react with known human orthopoxviruses.
- 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 by the WHO as a stringent regulatory agency, such as United States FDA, European Union CE, Japan PMDA or Australian TGA, or others. The availability of performance evaluation data, especially from an African country, was considered an advantage. Regulatory approval by an African country or the African Continental process for regulation of in-vitro diagnostics (IVDs) supported by quality assured performance evaluation data would also be considered in the future..

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 the list updated with tests that meet the minimum requirements.

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

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 MonkeyPox 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.	
Cue Health, United States	**Cue Mpox (Monkeypox) Molecular Test**	skin lesion swab: vesicular fluid, pustular fluid, papules	Detects clades I and II. Does not distinguish between clades.	100 copies/ml	EUA by US FDA	'cross reactivity' tested in silico only: No cross reaction with non-orthopox pathogens with similar signs and symptoms. Cross-reaction with cowpox (72-92%)
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 II.	1000 copies/ml	CE-IVDD	Independently evaluated in DRC. Has local regulatory approval in DRC.
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 distinquish Clades	200 copies/ml	CE-IVDD	

Table: List of Recommended Real-Time(RT) PCR Tests for Mpox