

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.
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- 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-reac-• tivity 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, Unit- ed States of America	ALINITY M MPXV	Lesion swab specimens	Detects clade I and II. Does not distinguish between clades.	200 cop- ies/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, Naso- pharyngeal swab, lesion exudate, lesion crust, serum, whole blood	Detects and distin- guishes between clades I and II.	250 cop- ies/ml	CE-IVDD	
Certest Biotec SL, Spain	Viasure Mon- keypox Virus Real Time PCR Detection Kit	skin lesion swab: vesic- ular fluid, pustular fluid, papules	Detects clades I and II. Does not distin- guish between clades.	8 copies/ ml	CE-IVDD. EUA by FDA revoked.	
Cue Health, United States	Cue Mpox (Mon- keypox) Molecu- lar Test	skin lesion swab: vesic- ular fluid, pustular fluid, papules	Detects clades I and II. Does not distin- guish between clades.	100 cop- ies/ml	EUA by US FDA	'cross reactivity' tested in silico only: No cross reaction with non-orthopox pathogens with similar signs and symp- toms. Cross-reaction with cowpox (72-92%)
Daan Gene, China	Detection Kit for Monkeypox Virus DNA (PCR-Flu- orescence Probing)	Rashes, scabs, blister fluid, pustular fluid, or whole blood specimens	Detects clades I and II. Does not distin- guish between clades.	200 cop- ies/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 distin- guish between clades.	25-80 cop- ies/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 cop- ies/ml	CE-IVDD	Independently evaluated in DRC. Has local regulatory approval in DRC.
Roche, Unit- ed Stated of America	Cobas MPVX	Lesion swab samples	Detect clade I and II. Does not distinguish between clades.	36.5 cop- ies/ml	EUA by US FDA	Limited opportunity for cross-reactivity in silico analysis.
Sansure Bio- tech. China	Monkey Pox Nucleic Acid Diagnostic Kit	Serum, whole blood, vesicles and pustules, nasopharyngeal swab, ororpharyngeal swab	Detects clades I and II. Does not distin- quish Clades	200 cop- ies/ml	CE-IVDD	

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

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