

Disclaimer: This list does not reflect a decision on EUL assessment and must not be used to inform procurement as it does not constitute an endorsement or WHO listing of the products.

R information requested from manufacturer	in process	stage complete	F follow-up amendments	
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Last update: 18 September 2025

Monkeypox virus IVDs/ Nucleic Acid Tests: progress of the active applications in the emergency use listing assessment

Manufacturer name	Product name	Product code(s)	Dossier review	QMS Desk Assessment	EUL application number
Jiangsu Bioperfectus Technologies Co.	• • • • • • • • • • • • • • • • • • • •		R	•	MPXV-13195-202-00
Jiangsu Macro & Micro-Test Med-Tech Co., Ltd	Micro-Test Med-Tech (Fluorescence PCR)		*	•	MPXV 13330-248-00
HA TECH PTY Ltd	Mpox Virus Real-Time PCR Diagnostic Kit	NAT-17	•	•	MPXV-13345-14133-00
Shanghai ZJ Bio-Tech Co., Ltd.	Monkeypox Virus Lyo-PCR Kit	W-ZD-0580-02-48A W-ZD-0580-02-96A	•	•	MPXV-13393-139-00
Diagnostics for the Real World Ltd	SAMBA III Mpox I/II Test	P/N 7100-12		*	MPXV-1343-072-00
DiaCarta	QuantiVirus MPXV Test Kit	DC-04-0009E DC-04-0005E DC-04-0006E			MPXV-13490-263-00
Taizhou Cowingene Cowingene Monkeypox Virus Typing Biotech Co., Ltd. Detection Kit		ST08003W		*	MPXV-13599-18058-00