



WHO Emergency Use List: Monkeypox virus IVDs/ Nucleic Acid Tests

Last updated 03 November 2025

Date Listed	Manufacturer name	Product name	Product code(s)	Regulatory version	EUL application number	Packaging	Link to access public report
3 October 2024	Abbott Molecular Inc	Alinity m MPXV assay (Alinity m MPXV Amplification (AMP) Kit & Alinity m MPXV Control (CTRL) Kit)	AMP kit: 09R06-095 CTRL kit: 09R06-085	USFDA EUA	MPXV-12644-027-00	Alinity m MPXV Amplification (AMP) Kit: 48 tests/tray, 192 tests/kit Alinity m MPXV Control (CTRL) Kit: 12 tubes per level	Available here
14 October 2024	Roche Molecular Systems, Inc.	cobas MPXV Qualitative assay for use on the cobas 6800/8800 Systems	cobas MPXV: 09863338190 Control kit: 09863320190 Buffer Negative Control Kit: 07002238190, 09051953190	USFDA EUA	MPXV-12647-046-00	cobas MPXV: 192 test cassette Control Kit: 1 x 16 mL Buffer Negative Control Kit: 1 x 16 mL	Available here
28 October 2024	Cepheid	Xpert Mpx	GMPX-10	USFDA EUA	MPXV-12646-070-00	10 Xpert Mpx Cartridges with Integrated Reaction Tubes Disposable 300 µL Transfer Pipettes: Two bags of 12 per kit	Available here
06 March 2025	KH Medical Co., Ltd	RADIONE Mpx Detection Kit	RP001	Rest of the World	MPXV-13227-214-00	Pre-filled PCR Tube: 4 well-strip tube X 24 EA	Available here
09 May 2025	UStar Biotechnologies Ltd	EasyNAT Monkeypox Virus Assay	U202028-20	CE-Mark	MPXV-13201-208-00	20 cartridges, 1 positive control tube (1.2mL), 1 negative control tube (1.2 mL)	Available here
13 May 2025	UStar Biotechnologies Ltd	PortNAT Monkeypox Virus Test	U202031-20	CE-Mark	MPXV-13202-208-00	Box A: 20 cartridge-A, 20 swabs, 20 zip-lock bag Box B: 20 cartridge-B	Available here
09 September 2025	CerTest Biotec, S.L.	VIASURE Monkeypox virus Real Time PCR Detection Kit	VS-MPX101L VS-MPX101H VS-MPX106L VS-MPX106H VS-MPX112L VS-MPX112H VS-MPX113L VS-MPX113H VS-MPX101 VS-MPX136 VS-MPX172 VS-MPX196T	CE-Mark	MPXV-12649-243-00	VS-MPX101L: 1 x 8-well strips, low profile VS-MPX101H: 1 x 8-well strips, high profile VS-MPX106L: 6 x 8-well strips, low profile VS-MPX106H: 6 x 8-well strips, high profile VS-MPX112L: 12 x 8-well strips, low profile VS-MPX112H: 12 x 8-well strips, high profile VS-MPX113L: 96-well plate, low profile VS-MPX113H: 96-well plate, high profile VS-MPX101: 2 x 4-well strips, Rotor-Gene VS-MPX136: 9 x 4-well strips, Rotor-Gene VS-MPX172: 18 x 4-well strips, Rotor-Gene VS-MPX196T: 4 tubes x 24 reactions	To be published
17 September 2025	Shanghai ZJ Bio-Tech Co., Ltd.	Monkeypox Virus Lyo-PCR Kit	W-ZD-0580-02-48A W-ZD-0580-02-96A	Rest of the World	MPXV-13393-139-00	W-ZD-0580-02-48A: 48 MPXV reaction tubes, Positive control: 3 bags, one vial dry powder/bag, Negative control: 3 tubes x 400 µL, 3 tubes of molecular grade water x 1000µL W-ZD-0580-02-96A: 96 MPXV reaction tubes, Positive control: 6 bags, one vial dry powder/bag, Negative control: 6 tubes x 400 µL, 6 tubes of molecular grade water x 1000µL	Available here
17 October 2025	HA TECH PTY Ltd	Monkeypox Virus Real-Time PCR Diagnostic Kit (NAT-17WE)	NAT-17 (L) NAT-17 (M) NAT-17 (S)	Rest of the World	MPXV-13345-14133-00	NAT-17 (L): NAR01 PCR Mastermix 1 x 1000µL, NAR24 PCR Multiple Mix 1 x 500 µL, NAR25 PCR positive control 1 x 50µL, NAR05 PCR negative control 1 x 1000µL NAT-17 (M): NAR01 PCR Mastermix 1 x 500µL, NAR24 PCR Multiple Mix 1 x 250 µL, NAR25 PCR positive control 1 x 40µL, NAR05 PCR negative control 1 x 500µL NAT-17 (S): NAR01 PCR Mastermix 1 x 250µL, NAR24 PCR Multiple Mix 1 x 125 µL, NAR25 PCR positive control 1 x 30µL, NAR05 PCR negative control 1 x 250µL	To be published
27 October 2025	Jiangsu Macro & Micro-Test Med-Tech Co., Ltd	Monkeypox Virus Nucleic Acid Detection Kit (Fluorescence PCR)	HWTS-07071C	Rest of the World	MPXV 13330-248-00	MPXV reaction buffer: 1mL/vial x 50 tests MPXV Positive Control: 600µL/vial x 50 tests MPXV Positive Control: 600µL/vial x 50 tests	To be published
30 October 2025	Taizhou Cowingene Biotech Co., Ltd.	Cowingene Monkeypox Virus Typing Detection Kit	ST08003W	Rest of the World	MPXV-13599-18058-00	Cartridge: 24 vials Lysis buffer: 2 tubes x 5000µL Positive control: 1 tube x 500µL Negative control: 1 tube x 500µL Transfer dropper for lysis buffer: 24 pieces (400µL) Transfer dropper for sample: 24 pieces (400µL)	To be published