



Xpert® Mpox

Datasheet — US EUA

Test Reagent Kit	Xpert Mpox
Catalog Number	GXMPX-10
Technology	Real-time RT-PCR
Targets	Monkeypox virus clade II and non-variola <i>Orthopoxvirus</i> OPXV-E9L-NVAR
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	Lesion Swabs in Viral Transport Media (VTM)
Sample Extraction	Automated/integrated
Pipetting	Single use disposable pipette provided (100µL)
TAT	Approximately 36 minutes [#]
Hands-on Time	<1 minute
Controls: Process	Sample Processing Control (SPC), Sample Adequacy Control (SAC)
Controls: Probe Function/Detection	Probe Check Control (PCC)
Limit of Detection	2.12 × 10¹ GC*/mL for MPXV and 4.23 × 10¹ GC/mL for OPXV
Clinical Performance	Positive predictive Agreement: 100% Negative Predictive Agreement: 96.6%
Sample Storage	Lesion swabs in VTM/UTM: 15-30°C up to 48 hours; 2-8°C up to 7 days
Kit Storage	2-28°C
Commercial Controls	Refer to Xpert Mpox Instructions for Use or Contact Cepheid Technical Support
GeneXpert® Systems	GeneXpert, Infinity & GenXpert Xpress Systems
GeneXpert System Software	GeneXpert Dx software version 4.7b or higher, Xpertise software version 6.4b or higher and GeneXpert Xpress software version 6,1 or higher [^]

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories; this product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

* GC- Genomic copies

[^] Refer to most current Instructions for Use TBC (for GeneXpert Dx and Infinity Systems) for complete details.

[#] Early assay termination available

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