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 *Orthopoxvirus* 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 (300µL)
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	**2.12×10^1 GC*/mL for MPXV** and **4.23×10^1 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 & GeneXpert **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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