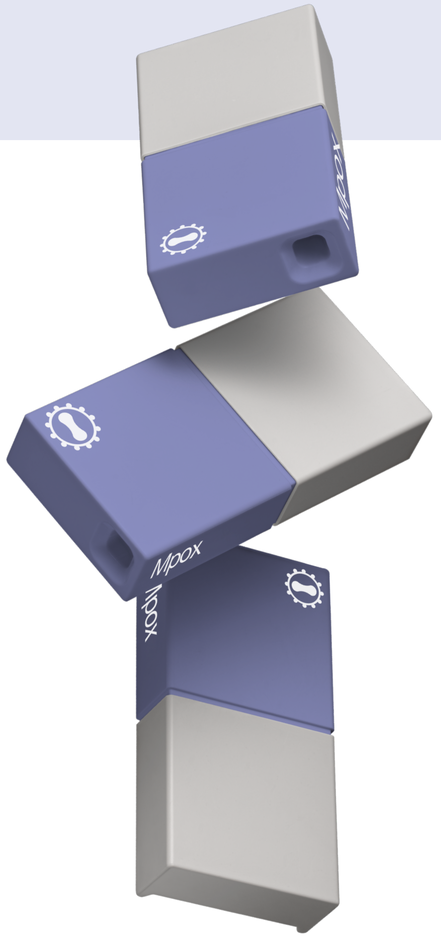
Cue Mpox Product Data Sheet

US FDA Emergency Use Authorization

Product Name	Cue Mpox (Monkeypox) Molecular Test
Catalog Number (REF#)	C3090-10
Technology	Isothermal nucleic acid amplification (NAAT)
Targets	Mpox Clade I/II: OPG001
Sample Types	Skin Lesion (Direct and Dipping in VTM)
Sample Extraction	Automated/Integrated
Pipetting	Not Required
Turn around Time	25 minutes from sample wand insertion to results
Hands on Time	< 1 min
Time from sample collection to testing	Within 5 minutes of collecting sample
Internal Cartridge Controls	RNase P for presence of human cellular material and proper assay execution
Clinical Analysis	PPA: 100% (95% CI: 88.4% - 100%) NPA: 100% (95% CI: 88.1% - 100%) Testing performed with 30 positives and 29 negative samples
LoD	Direct: 0.1 genome copies/uL Dipping in VTM: 0.15 genome copies/uL
Kit Storage	6 months, 59°F (15°C) – 86°F (30°C)
Commercial Controls	ZeptoMetrix Positive Control: Catalog number NATMPXV-ERC ZeptoMetrix Negative Control: Catalog number NATSARS(COV2)-NEG



Start testing with Cue

Contact **sales@cuehealth.com** or visit **cuehealth.com/hcp**.

Connect with our team to learn more about the Cue Mpox (Monkeypox) Molecular Test and how we can help you enhance patient care and health outcomes.

The Cue Mpox (Monkeypox) Molecular Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from monkeypox virus, not for any other viruses or pathogens. 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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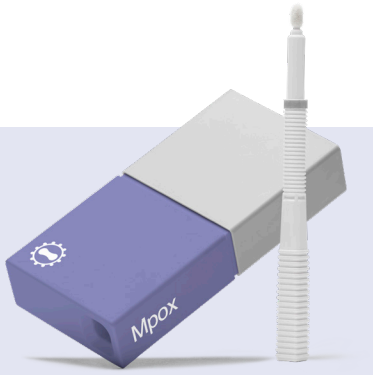

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