



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 02/03/2021

Product: Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK097 Mfg Date: 2021-02 Exp Date: 2023-01
	A.R. No.: B-VUCPK-097
Pack size: 50 TESTS	Storage: 2°C to 40°C

PRECAUTION: Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep [®] AUTO v2 Universal Cartridge Based Sample prep kit)	(Present (P)/Not Present (NP))	
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab [®] micro PCR Analyzers			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	27.5
2	Negative MTB	ND	28.0
3	Negative MTB	ND	27.2
4	Positive MTB	27.0	27.67
5	Positive MTB	26.8	26.43
6	Positive MTB	26.6	26.67

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL
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Designation: QC Head