

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 01/12/2025

Doc ID: COA/TP/UCPK496L

Product Name	Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO v2
Lot No.	VUCPK496L
Mfg. Date	2025-10
Exp. Date	2027-09
Pack Size	50T
Storage condition	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)		
1	Universal Reagent Pack	Should be Present	Present
2	Universal Cartridge Pack	Should be Present	Present
3	Disposable Transfer Pipette (3 ml Graduated)	Should be Present	Present
4	Package Insert	Should be Present	Present
5	Desiccant pouch	Should be Present	Present
6	Colour of desiccant pouch	Should be Orange in Colour	Orange Colour
B	Seal integrity test	Should Pass	Pass

Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	26.23
2	Negative HBV	ND		ND	NA	26.58
3	Negative HCV	ND		ND	NA	26.77
4	Negative HIV-1	ND		ND	NA	26.25
5	Negative MTB Plus	ND		ND	NA	27.83
Positive Control						
1	Positive MTB	Test and Control should be detected		30.17	NA	26.76
2	Positive HCV	Test and Control should be detected		32.19	NA	26.91
3	Positive MTB Plus	Test and Control should be detected		31.08	NA	27.33
Non Template Control Test for COVID-19						
1	NTC	Test 1, Test 2 and Control should not be detected		ND	ND	ND

*Ct-Cycle Threshold
Template Control

*IC- Internal Control

*ND- Not Detected

*NA- Not Applicable

*NTC- Non

The lot is tested and verified as per QC Standards and is approved.



for **Name:** Dr.Praveen Kumar MK
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Designation: QC Head