

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 01/12/2025

Doc ID: COA/TP/419VUCPKL

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.	419VUCPKL
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)	(Present (P)/Not Present (NP))	
1	Universal Reagent Pack	Should be Present	P
2	Universal Cartridge Pack	Should be Present	P
3	Disposable Transfer Pipette (3 ml Graduated)	Should be Present	P
4	Package Insert	Should be Present	P
B	Pouch Seal Integrity	Specification	Observation
1	Pouch 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	28.11
2	Negative HBV	ND		ND	NA	27.53
3	Negative HCV	ND		ND	NA	27.20
4	Negative HIV-1	ND		ND	NA	26.45
5	Negative MTB Plus	ND		ND	NA	28.24
Positive Control						
1	Positive MTB	Test and Control should be detected		31.23	NA	26.59
2	Positive HCV Plasma	Test and Control should be detected		31.78	NA	26.23
3	Positive MTB Plus	Test and Control should be detected		29.46	NA	28.51
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 *IC- Internal Control *ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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


Name: Dr. Praveen Kumar
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Designation: QC Head



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