

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 19/07/2025

Doc ID: COATP/VUCPK447L/50T

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.	VUCPK447L
Mfg. Date	2025-07
Exp. Date	2027-06
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	27.31
2	Negative HBV	ND		ND	NA	27.56
3	Negative HCV	ND		ND	NA	27.28
4	Negative HIV-1	ND		ND	NA	27.99
5	Negative MTB Plus	ND		ND	NA	28.31
Positive Control						
1	Positive MTB	Test and Control should be detected		31.24	NA	27.19
2	Positive HCV	Test and Control should be detected		30.79	NA	27.95
3	Positive MTB Plus	Test and Control should be detected		31.67	NA	28.53
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
Department: Quality Control
Designation: QC Head