



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 24/06/2024

Doc ID: COA/TP/122VUCPK/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.	122VUCPK
Mfg. Date	2024-04
Exp. Date	2026-03
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	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml Graduated)	Present	Present
4	Package Insert	Present	Present

**Molbio Diagnostics Private Limited**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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)
<b>Negative Control</b>						
1	Negative MTB	ND	Control should be detected	ND	NA	28.64
2	Negative HBV	ND		ND	NA	27.45
3	Negative HCV	ND		ND	NA	27.33
4	Negative HIV-1	ND		ND	NA	26.17
<b>Positive Control</b>						
1	Positive MTB	Test and Control should be detected		31.06	NA	27.90
2	Positive MTB Plus	Test and Control should be detected		29.54	NA	28.55
3	Positive HCV	Test and Control should be detected		31.24	NA	26.60
<b>Non Template Control Test for COVID-19</b>						
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

**Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.**



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