

**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

License No.: MFG/IVD/2021/000064

Date: 06/12/2024

Doc ID: COA/TP/189VUCPKL/50T

<b>Product Name</b>	Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit
<b>Generic Name</b>	Sample preparation kit for nucleic acid extraction on Trueprep <sup>®</sup> AUTO v2
<b>Lot No.</b>	189VUCPKL
<b>Mfg. Date</b>	2024-10
<b>Exp. Date</b>	2026-09
<b>Pack Size</b>	50T
<b>Storage condition</b>	2°C to 40°C


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

Sr. No.	Components in each kit	Specification	Observation
<b>A</b>	<b>Contents in the carton (Trueprep<sup>®</sup> AUTO v2 Universal Cartridge Based Sample prep kit)</b>	<b>(Present (P)/Not Present (NP))</b>	
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

Performance on Truelab <sup>®</sup> 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	26.44
2	Negative HBV	ND		ND	NA	27.16
3	Negative HCV	ND		ND	NA	28.09
4	Negative HIV-1	ND		ND	NA	26.98
3	Negative MTB Plus	ND		ND	NA	27.74
<b>Positive Control</b>						
1	Positive MTB	Test and Control should be detected		29.57	NA	27.52
2	Positive HCV	Test and Control should be detected		30.97	NA	28.13
3	Positive MTB Plus	Test and Control should be detected		26.96	NA	28.11
<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

**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

