

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2019/000003

**Date:** 04/08/2025

**Doc ID:** COA/TP/VUCPK457L/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>	VUCPK457L
<b>Mfg. Date</b>	2025-07
<b>Exp. Date</b>	2027-06
<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>		
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>B</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	28.08
2	Negative HBV	ND		ND	NA	28.69
3	Negative HCV	ND		ND	NA	27.21
4	Negative HIV-1	ND		ND	NA	26.45
5	Negative MTB Plus	ND		ND	NA	27.47
Positive Control						
1	Positive MTB	Test and Control should be detected		31.23	NA	27.78
2	Positive HCV	Test and Control should be detected		31.67	NA	27.66
3	Positive MTB Plus	Test and Control should be detected		31.56	NA	27.29
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.**



*pk*

**Name:** Dr.Praveen Kumar MK

**Department:** Quality Control

**Designation:** QC Head

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