

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2021/000064

**Date:** 25/09/2025

**Doc ID:** COA/TP/398VUCPKL

<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>	398VUCPKL
<b>Mfg. Date</b>	2025-09
<b>Exp. Date</b>	2027-08
<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	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>B</b>	<b>Pouch Seal Integrity</b>	<b>Specification</b>	<b>Observation</b>
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	27.80
2	Negative HBV	ND		ND	NA	28.00
3	Negative HCV	ND		ND	NA	28.08
4	Negative HIV-1	ND		ND	NA	28.28
5	Negative MTB Plus	ND		ND	NA	28.50
Positive Control						
1	Positive MTB	Test and Control should be detected		31.90	NA	27.11
2	Positive HCV Plasma	Test and Control should be detected		32.85	NA	27.39
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  
**Department:** Quality Control  
**Designation:** QC Head