

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 01/04/2026

**Doc ID:** COA/TP/VUCPK518L

<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>	VUCPK518L
<b>Mfg. Date</b>	2026-03
<b>Exp. Date</b>	2027-12
<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)/Absent (A)]</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 <sup>®</sup> Real Time micro PCR Analyzer						
Sr. No.	Specificity Tests	Specification		Test Lot		
		Test	Control	Test 1 (Average)	Test 2 (Average)	Control (Average)
<b>Negative Control</b>						
1	Negative MTB	ND	Control should be detected	ND	NA	26.86
2	Negative HCV	ND		ND	NA	28.07
3	Negative HIV-1	ND		ND	NA	27.98
4	Negative MTB Plus	ND		ND	NA	27.72
<b>Positive Control</b>						
1	Positive MTB	Test and Control should be detected		31.02	NA	26.80
2	Positive HCV	Test and Control should be detected		31.46	NA	28.18
3	Positive MTB Plus	Test and Control should be detected		29.60	NA	27.41
<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 \*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