

**MOLBIO DIAGNOSTICS LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

**Date:** 06/09/2025

**Doc ID:** COA/TP/USPT288

<b>Product Name</b>	Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack
<b>Generic Name</b>	Universal Sample Pre-treatment pack for Non MTB samples
<b>Lot No.</b>	USPT288
<b>Mfg. Date</b>	2025-07
<b>Exp. Date</b>	2027-06
<b>Pack Size</b>	05T
<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 Universal Sample Pre-treatment Pack)</b>	<b>(Present (P)/Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
3	Package Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers						
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 HBV	ND	Control should be detected	ND	NA	28.16
2	Negative HCV	ND	Control should be detected	ND	NA	27.45
Positive Control						
1	Positive HBV	Test and Control should be detected		30.00	NA	26.49
2	Positive HCV	Test and Control should be detected		31.07	NA	27.95
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

**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