



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company  
**CERTIFICATE OF ANALYSIS**

Mfg.Lic. No.: MFG/IVD/2021/000064

Date: 11/07/2022

Doc ID: COA/TP/011USPK-PLM

<b>Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: 011USPK-PLM</b>	<b>Mfg. Date: 2022-01</b>	<b>Exp. Date: 2023-12</b>
<b>Pack size: 50T, 25T, 5T</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-011-USPK-PLM</b>

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

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample prep kit)	(Present (P)/Not Present (NP))	
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette graduated (3 ml)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzers			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative HCV	ND	28
2	Negative HIV	ND	27.67
3	Negative HBV	ND	28
4	Negative MTB	ND	27.83
5	Positive HBV	30.2	28.67
6	Positive HBV	29.5	27.75

## Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzers			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
7	Positive HIV	30	28.25
8	Positive HIV	30.75	28
9	Positive HCV	30.5	28.1
10	Positive HCV	30.8	27.75
11	Positive MTB	30.67	28.33
12	Positive MTB	31	29.57

\*Ct- Cycle threshold

\*IC- Internal Control

\*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE.

  
  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head