



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

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

Date: 21/07/2022

Doc ID: COA/TP/012USPK-PLM

<b>Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: 012USPK-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-012-USPK-PLM</b>

**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® AUTO Universal Cartridge Based Sample prep kit)</b>	<b>(Present (P)/Not Present (NP))</b>	
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

<b>Performance on Truelab® Real Time micro PCR Analyzer</b>			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative HCV	ND	28.56
2	Negative HIV	ND	28.4
3	Negative HBV	ND	29.08
4	Negative MTB	ND	29.8
5	Negative MTB	ND	28.57
6	Positive HBV	30	27.4

## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab® 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	29.33	29.33
8	Positive HCV	30.31	28.63
9	Positive HCV	30.55	28
10	Positive MTB	32.83	27.8
11	Positive MTB	31.29	28.33

\*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

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