



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

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

Date: 18/07/2022

Doc ID: COA/TP/009VUCPK-PLM

<b>Product: Trueprep<sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: 009VUCPK-PLM</b>	<b>Mfg. Date: 2022-02</b>	<b>Exp. Date: 2024-01</b>
<b>Pack size: 50T, 5T</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-009-VUCPK-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 v2 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 HBV	ND	28
2	Negative HCV	ND	29.25
3	Negative HIV	ND	29.38
4	Negative MTB	ND	29.8
5	Positive HBV	30.6	28
6	Positive HBV	30.36	28.6



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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 HCV	29.6	27.88
8	Positive HCV	30.6	28.78
9	Positive HIV	29.38	29.23
10	Positive HIV	29.6	29.5
11	Positive MTB	30.63	29.43
12	Positive MTB	30.75	28.2

\*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



**Molbio Diagnostics Private Limited**

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