



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 24/01/2021

<b>Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</b>	
<b>Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</b>	<b>Lot No.: VUCPK079-P Mfg Date: 2021-01 Exp Date: 2022-12</b>
	<b>A.R. No.: B-VUCPK-079-P</b>
<b>Pack size: 50 TESTS</b>	<b>Storage: 2°C to 40°C</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 v2 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 (3 ml)	Present	Present
4	Package Insert	Present	Present

#### Performance on Truelab® micro PCR Analyzers

Sr. No.	Sample Negative/Positive	Negative: Test- ND IC- Detected Positive: Test- Detected IC- Detected	
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	29.0
2	Positive MTB	30.0	28.2
3	Negative HBV	ND	27.5
4	Positive HBV	29.4	29.67
5	Positive HCV	28.89	28.0
6	Negative HIV	ND	27.5

\*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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## Molbio Diagnostics Private Limited

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