



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 25/02/2021

Product: Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK093-P Mfg Date: 2020-11 Exp Date: 2022-10
	A.R. No.: B-VUCPK-093-P
Pack size: 50 TESTS	Storage: 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 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

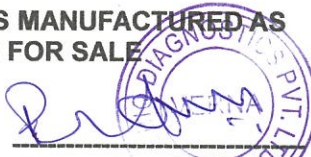
Performance on Truelab <sup>®</sup> micro PCR Analyzers			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	28.17
2	Positive MTB	27.5	28.6
3	Negative HBV	ND	29.0
4	Positive HBV	29.0	28.33
5	Positive HCV	29.56	30.43
6	Negative HIV	ND	30.8

\*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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