



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 06/03/2021

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK099-P Mfg Date: 2021-02 Exp Date: 2023-01
	A.R. No.: B-VUCPK-099-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
A	Contents in the carton (Trueprep® 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 (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	28.5
2	Positive MTB	27.17	27.4
3	Negative HBV	ND	27.0
4	Positive HBV	30.67	28.0
5	Positive HCV	28.25	29.14
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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