



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

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

Date: 25/01/2021

Product: Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit	
Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: USPK433-P Mfg Date: 2021-01 Exp Date: 2022-12
	A.R. No.: B-USPK-433-P
Pack size: 5, 25, 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 <sup>®</sup> AUTO 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<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	29.5
2	Positive MTB	28.5	28.75
3	Negative HBV	ND	28.5
4	Positive HBV	28.0	28.8
5	Negative HIV	ND	30.17
6	Positive HCV	28.45	28.5

\*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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