



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001:2015 & ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 15/01/2020

Product: Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample prep kit	
Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample prep kit	Lot No.: USPK253 Mfg Date: 2019-12 Exp Date: 2021-11
	A.R. No.: B-USPK-253
Pack size: 5, 25 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	29.33
2	Positive MTB	27.0	27.8
3	Negative HBV	ND	30.33
4	Positive HBV	30.0	29.5
5	Positive HCV	30.06	28.67
6	Positive HIV	25.6	31.25

\*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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