



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

### CERTIFICATE OF ANALYSIS

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

Date: 11/02/2020

<b>Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample prep kit</b>	
<b>Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample prep kit</b>	<b>Lot No.: USPK268 Mfg Date: 2019-12 Exp Date: 2021-11</b>
	<b>A.R. No.: B-USPK-268</b>
<b>Pack size: 5, 25 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<sup>®</sup> AUTO 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

<b>Performance on Truelab<sup>™</sup> micro PCR Analyzers</b>			
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	29.5	28.14
3	Positive MTB	29.13	28
4	Positive MTB	29.8	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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0