



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

### CERTIFICATE OF ANALYSIS

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

Date: 03/04/2020

Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample prep kit

Trueprep<sup>®</sup> AUTO Universal  
Cartridge Based  
Sample prep kit

Lot No.: USPK283 Mfg Date: 2020-02 Exp Date: 2022-01  
A.R. No.: B-USPK-283

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 Positive: Test- Detected		IC- Detected IC- Detected	
		Test (Ct)		IC (Ct)	
1	Negative MTB	ND		28.75	
2	Positive MTB	26.62		27.33	
3	Positive MTB	25.75		28.8	
4	Positive MTB	26.8		29.43	

\*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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