



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

### CERTIFICATE OF ANALYSIS

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

Date: 08/02/2020

Product: Trueprep® AUTO Universal Cartridge Based Sample prep kit	
Trueprep® AUTO Universal Cartridge Based Sample prep kit	Lot No.: USPK264 Mfg Date: 2020-01 Exp Date: 2021-12
	A.R. No.: B-USPK-264
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® 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™ 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	26.57
2	Positive MTB	32.5	28.17
3	Negative HBV	ND	30
4	Positive HBV	27.43	29
5	Positive HCV	29.27	27
6	Positive HIV	29.4	27.6

\*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  
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