



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

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

Date: 25/10/2021

Doc ID: COA/TP/USPK490-P

<b>Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: USPK490-P</b>	<b>Mfg. Date: 2021-07</b>	<b>Exp. Date: 2023-06</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPK-490-P</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® 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

**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 HBV	ND	30.0
2	Negative MTB	ND	29.5
3	Negative COVID-19	ND	27.5
4	Negative DENGUE	ND	30.6
5	Positive MTB	28.11	26.8

**Molbio Diagnostics Private Limited**

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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)
6	Positive MTB	28.4	27.33
7	Positive HBV	28.56	30.2
8	Positive HBV	29.13	29.6
9	Positive HCV	31.89	29.33
10	Positive HIV	30.33	30.33

\*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