



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

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

Date: 20/09/2021

Doc ID: COA/TP/USPK479-PL

<b>Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: USPK479-PL</b>	<b>Mfg Date: 2020-11</b>	<b>Exp Date: 2022-10</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPK-479-PL</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

<b>Performance on Truelab® micro PCR Analyzers</b>			
Sr. No.	Sample Negative/Positive	Negative: Test- ND Positive: Test- Detected	IC- Detected IC- Detected
		Test (Ct)	IC (Ct)
1	Negative HBV	ND	28.33
2	Positive HBV	28.6	28.5
3	Positive HCV	29.45	27.75
4	Positive HCV	27.6	29
5	Positive HIV	29.4	29.17
6	Negative MTB	ND	28.29

**Molbio Diagnostics Private Limited**

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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<b>Performance on Truelab® micro PCR Analyzers</b>			
<b>Sr. No.</b>	<b>Sample Negative/Positive</b>	<b>Negative: Test- ND</b>	<b>IC- Detected</b>
		<b>Positive: Test- Detected</b>	<b>IC- Detected</b>
		<b>Test (Ct)</b>	<b>IC (Ct)</b>
7	Positive MTB	27.33	28.14
8	Negative COVID-19	ND	26.6
9	Positive COVID-19	27.5	22.5

\*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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