



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

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

Date: 07/06/2021

Doc ID: COA/TP/USPK473-P

<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.: USPK473-P Mfg Date: 2021-05 Exp Date: 2023-04</b>	
		<b>A.R. No.: B-USPK-473-P</b>	
<b>Pack size: 5, 25, 50 TESTS</b>		<b>Storage: 2°C to 40°C</b>	
<b>PRECAUTION: Refer Safety Data Sheet and follow instructions for use.</b>			
<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
<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>			
<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>
1	Negative MTB	ND	28.5
2	Positive MTB	28.8	30.5
3	Negative HIV	ND	30.4
4	Positive DENGUE	29.25	30.5
5	Positive HIV	30.4	28.4
6	Positive HCV	29.14	30.6

\*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  
Designation: QC Head

## Molbio Diagnostics Private Limited

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