



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 09/04/2021

Doc ID: COA/TP/USPT157

<b>PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	
<b>Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	<b>Lot No.: USPT157 Mfg Date: 2021-03 Exp Date: 2023-02</b>
	<b>A.R. No.: B-USPT-157</b>
<b>Pack size : 50T, 20T, 5T</b>	<b>STORAGE : 2°C to 40°C</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 Sample Pre- treatment Pack)(Present (P)/Not Present (NP))</b>	<b>(Present (P)/ Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1ml)	Present	Present


Performance on Truelab® micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	<b>Specificity Tests</b>	<b>Test</b>	<b>IC</b>	<b>Test</b>	<b>IC</b>
<b>Negative Control</b>					
1	Neg HBV	ND	Control should be detected	ND	27.5
2	Neg COVID-19	ND	Control should be detected	ND	21.0
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		31.0	29.4
2	Pos HCV	Test and Control should be detected		28.0	28.5
3	Pos COVID-19	Test and Control should be detected		28.43	24.0
4	Pos HIV	Test and Control should be detected		28.6	29.5

\*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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## Molbio Diagnostics Private Limited

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