



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

Mfg.Lic. No. : MFG/IVD/2020/000003

Date: 11/02/2021

<b>PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	
<b>Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	<b>Lot No.: USPT145 Mfg Date: 2021-02 Exp Date: 2023-01</b>
	<b>A.R. No.: B-USPT-145</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
A	Contents in the carton (Trueprep® AUTO Universal Sample Pre-treatment Pack)(Present (P)/Not Present (NP))	(Present (P)/ Not Present (NP))	
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	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Neg HBV	ND	Control should be detected	ND	28.2
2	Neg HIV	ND	Control should be detected	ND	28.5
3	Neg COVID-19	ND	Control should be detected	ND	24.5
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		29.6	28.5
2	Pos HCV	Test and Control should be detected		29.6	28.2
3	Pos COVID-19	Test and Control should be detected		27.5	22.33

\*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  
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