



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 12/05/2021

Doc ID: COA/TP/USPT187

<b>PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT187 Mfg Date: 2021-05 Exp Date: 2023-04
	A.R. No.: B-USPT-187
Pack size : 50T, 20T, 5T	STORAGE : 2°C to 40°C

**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	30.17
2	Neg COVID-19	ND	Control should be detected	ND	24.2
3	Neg COVID-19	ND	Control should be detected	ND	25.5
<b>Positive Control</b>					
1	Pos HCV	Test and Control should be detected		31.0	30.8
2	Pos HIV	Test and Control should be detected		29.6	30.5
3	Pos HBV	Test and Control should be detected		28.33	28.0

\*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  
for Designation: QC Head

Page 1 of 1

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO