



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date:21/10/2021

Doc.ID:COA/TP/USPT225

Product: Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT225	Mfg Date: 2021-07	Exp Date: 2023-06
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-225

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep <sup>®</sup> 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 <sup>®</sup> 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	Negative HBV	ND	Control should be detected	ND	30.8
2	Negative DENGUE	ND	Control should be detected	ND	29.75
3	Negative COVID-19	ND	Control should be detected	ND	26.0
4	Negative COVID-19	ND	Control should be detected	ND	27.33
<b>Positive Control</b>					
1	Positive HIV	Test and Control should be detected		30.33	29.67
2	Positive HCV	Test and Control should be detected		32.38	30.29
3	Positive HBV	Test and Control should be detected		28.11	29.5
4	Positive HBV	Test and Control should be detected		29.75	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  
Designation:QC Head

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