



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 05/05/2021

Doc ID: COA/TP/USPT181

PRODUCT : Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack	
Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT181 Mfg Date: 2021-04 Exp Date: 2023-03
	A.R. No.: B-USPT-181
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 <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	Neg HIV	ND	Control should be detected	ND	29.6
2	Neg HCV	ND	Control should be detected	ND	29.6
3	Neg COVID-19	ND	Control should be detected	ND	21.6
4	Neg COVID-19	ND	Control should be detected	ND	22.17
<b>Positive Control</b>					
1	Pos HIV	Test and Control should be detected		29.33	29.67
2	Pos HBV	Test and Control should be detected		28.17	30.5

\*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

## Molbio Diagnostics Private Limited

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