



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 07/05/2021

Doc ID: COA/TP/USPT182

<b>PRODUCT : Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack</b>	
Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT182 Mfg Date: 2021-04 Exp Date: 2023-03 A.R. No.: B-USPT-182
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
<b>A</b>	<b>Contents in the carton (Trueprep<sup>®</sup> 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<sup>®</sup> micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
		Test	IC	Test	IC
<b>Negative Control</b>					
1	Neg COVID-19	ND	Control should be detected	ND	22.6
2	Neg COVID-19	ND	Control should be detected	ND	21.14
3	Neg DENGUE	ND	Control should be detected	ND	30.14
<b>Positive Control</b>					
1	Pos HIV	Test and Control should be detected		30.0	28.5
2	Pos HBV	Test and Control should be detected		30.89	29.6

\*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**

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*Dr. Praveen Kumar*  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
*for* Designation: QC Head

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