



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001:2015 & ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 06/03/2020

<b>PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>	
<b>Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>	<b>Lot No.: USPT032 Mfg Date: 2020-02 Exp Date: 2022-01</b>
	<b>A.R. No.: B-USPT-032</b>
<b>Pack size : 20 TESTS, 5 TESTS</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
<b>A</b>	<b>Contents in the carton (Trueprep™ 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™ 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	30.57
2	Neg HCV	ND	Control should be detected	ND	29.75
<b>Positive Control</b>					
1	Pos HIV	Test and Control should be detected		29.2	29.6
2	Pos HCV	Test and Control should be detected		28.75	29.33

\*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**  
Name: Dr. Praveen Kumar  
Designation: QC Head

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