



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

### CERTIFICATE OF ANALYSIS

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

Date: 25/04/2020

<b>PRODUCT : Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack</b>	
Trueprep <sup>®</sup> AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT038 Mfg Date: 2020-04 Exp Date: 2022-03 A.R. No.: B-USPT-038
Pack size : 20 TESTS, 5 TESTS	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 HBV	ND	Control should be detected	ND	29.69
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		29.17	30.4
2	Pos HIV	Test and Control should be detected		28.56	30.6
3	Pos HCV	Test and Control should be detected		29.42	29.5

\*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**

  
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