



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

### CERTIFICATE OF ANALYSIS

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

Date: 09/04/2020

<b>PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>			
Trueprep™ AUTO Universal Sample Pre-treatment Pack	Lot No.:	USPT034	Mfg Date: 2020-03 Exp Date: 2022-02
	A.R. No.:	B-USPT-034	
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™ 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™ 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	28.67
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		29	30.8
2	Pos HIV	Test and Control should be detected		27.8	28.67
3	Pos HCV	Test and Control should be detected		30.09	27.8

\*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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