



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

### CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 03/11/2018


<b>PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>	
<b>Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>	<b>Lot No.:</b> USPT008 <b>Mfg Date:</b> 2018-10 <b>Exp Date:</b> 2020-09
	<b>A.R. No.:</b> B-USPT-008
<b>Pack size :20 TESTS, 5 TESTS</b>	<b>STORAGE : 2°C to 40°C</b>

**PRECAUTION:** The product is offered without warranty for any other specific use than that specified in the 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))		
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1ml)	Present	Present

Performance on True Lab Uno					
Sr.No.	CONTROLS	Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	TEST	Control	TEST	Control
<b>Negative Control</b>					
1	Neg HBV	ND	IC should be detected	ND	28.33
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		27.2	26.8
2	Pos HCV	Test and Control should be detected		24.07	28.0
3	Pos HIV	Test and Control should be detected		27.0	27.33

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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## Molbio Diagnostics Pvt. Ltd.

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