



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 06/10/2018

PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack	
Trueprep™ AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT007 Mfg Date: 2018-09 Exp Date: 2020-08
	A.R. No.: B-USPT-007
Pack size :20 TESTS, 5 TESTS	STORAGE : 2°C to 40°C

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	IC	TEST	IC
Negative Control					
1	Neg HBV	ND	IC should be detected	ND	29.33
Positive Control					
1	Pos HBV	Test and IC should be detected		29.67	28.67
2	Pos HCV	Test and IC should be detected		28.61	28.5
3	Pos HIV	Test and IC should be detected		26.25	27.67

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL
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Designation: QC Head

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