



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

CERTIFICATE OF ANALYSIS

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

Date: 20/09/2019


PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack	
Trueprep™ AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT020 Mfg Date: 2019-09 Exp Date: 2021-08
	A.R. No.: B-USPT-020
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 Truelab™ Real Time micro PCR Analyzer					
Sr.No.	CONTROLS	Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	TEST	Control	TEST	Control
Negative Control					
1	Neg HBV	ND	Control should be detected	ND	26.43
Positive Control					
1	Pos HBV	Test and Control should be detected		27.5	28.8
2	Pos HIV	Test and Control should be detected		32.17	26.29
3	Pos HCV	Test and Control should be detected		27.42	29

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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