



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No. : MFG/IVD/2020/000119

Date: 22/01/2021

PRODUCT : Trueprep[®] AUTO Universal Sample Pre-treatment Pack	
Trueprep[®] AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT136 Mfg Date: 2020-12 Exp Date: 2022-11
	A.R. No.: B-USPT-136
Pack size : 50T, 20T, 5T	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
Negative Control					
1	Neg HBV	ND	Control should be detected	ND	27.5
2	Neg HIV	ND	Control should be detected	ND	30.67
3	Neg COVID-19	ND	Control should be detected	ND	23.4
Positive Control					
1	Pos HBV	Test and Control should be detected		29.6	28.0
2	Pos HCV	Test and Control should be detected		27.89	27.4
3	Pos COVID-19	Test and Control should be detected		28.0	21.13

*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
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