



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/06/2021

Doc ID: COA/TP/USPT207

PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT207 Mfg Date: 2021-05 Exp Date: 2023-04
	A.R. No.: B-USPT-207
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	30.13
2	Neg COVID-19	ND	Control should be detected	ND	24.75
Positive Control					
1	Pos HIV	Test and Control should be detected		31.43	30.43
2	Pos HCV	Test and Control should be detected		31.6	30.17
3	Pos HBV	Test and Control should be detected		27.17	29.33
4	Pos HBV	Test and Control should be detected		28.2	29.17
5	Pos COVID-19	Test and Control should be detected		29.29	22.6
6	Pos DENGUE	Test and Control should be detected		30.1	27.5

*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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