



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 19/07/2021

Doc ID: COA/TP/USPT216

PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT216 Mfg Date: 2021-06 Exp Date: 2023-05
	A.R. No.: B-USPT-216
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 COVID-19	ND	Control should be detected	ND	26.6
2	Neg HBV	ND	Control should be detected	ND	31.0
Positive Control					
1	Pos HCV	Test and Control should be detected		29.89	29.4
2	Pos HBV	Test and Control should be detected		28.75	30.33
3	Pos HBV	Test and Control should be detected		29.67	31.0
4	Pos HIV	Test and Control should be detected		30.14	28.17
5	Pos HIV	Test and Control should be detected		30.75	29.43
6	Pos COVID-19	Test and Control should be detected		29.17	21.5

*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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