



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/06/2021

Doc ID: COA/TP/USPT209

PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT209 Mfg Date: 2021-05 Exp Date: 2023-04
	A.R. No.: B-USPT-209
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	29.4
2	Neg COVID-19	ND	Control should be detected	ND	21.75
Positive Control					
1	Pos HIV	Test and Control should be detected		31.6	30.2
2	Pos HCV	Test and Control should be detected		31.13	29.33
	Pos HCV	Test and Control should be detected		30.06	29.58
3	Pos HBV	Test and Control should be detected		28.86	29.0
	Pos HBV	Test and Control should be detected		29.57	29.67
4	Pos COVID-19	Test and Control should be detected		29.33	27.0

*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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