



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/04/2021
Doc ID: COA/TP/USPT163

PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT163 Mfg Date: 2021-04 Exp Date: 2023-03 A.R. No.: B-USPT-163
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	29.2
2	Neg HIV	ND	Control should be detected	ND	30.0
3	Neg COVID-19	ND	Control should be detected	ND	26.2
Positive Control					
1	Pos HCV	Test and Control should be detected		30.4	29.4
2	Pos COVID-19	Test and Control should be detected		30.86	30.67
3	Pos COVID-19	Test and Control should be detected		29.6	30.0

*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


VERNA
MOLBIO DIAGNOSTICS PVT. LTD.
QUALITY CONTROL
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