



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 26/04/2021

Doc ID: COA/TP/USPT161

PRODUCT : Trueprep[®] AUTO Universal Sample Pre-treatment Pack	
Trueprep[®] AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT161 Mfg Date: 2021-04 Exp Date: 2023-03
	A.R. No.: B-USPT-161
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	24.4
2	Neg HBV	ND	Control should be detected	ND	29.29
Positive Control					
1	Pos HCV	Test and Control should be detected		29.44	28.8
2	Pos HBV	Test and Control should be detected		28.83	30.75
3	Pos HIV	Test and Control should be detected		30.33	29.33
4	Pos COVID-19	Test and Control should be detected		28.33	24.8

*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
Name: Dr. Praveen Kumar
Designation: QC Head

Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO