



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/01/2022

Doc.ID: COA/TP/USPT236

Product: Trueprep[®] AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT236	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-236

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	Package Insert	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab[®] micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
		Test	IC	Test	IC
Negative Control					
1	Negative HCV	ND	Control should be detected	ND	29.43
2	Negative COVID-19	ND	Control should be detected	ND	26.0
Positive Control					
1	Positive HBV	Test and Control should be detected		28.0	30.43
2	Positive HBV	Test and Control should be detected		28.31	29.25
3	Positive HCV	Test and Control should be detected		30.42	30.17
4	Positive HIV	Test and Control should be detected		30.4	29.57
5	Positive HIV	Test and Control should be detected		29.2	27.33
6	Positive COVID-19	Test and Control should be detected		28.67	24.0

*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

For 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