



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/12/2021

Doc.ID: COA/TP/USPT231

Product: Trueprep[®] AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT231	Mfg. Date: 2021-12	Exp. Date: 2023-11
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-231

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)	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Negative HBV	ND	Control should be detected	ND	27.0
2	Negative COVID-19	ND	Control should be detected	ND	26.4
3	Negative Dengue	ND	Control should be detected	ND	26.07
Positive Control					
1	Positive HBV	Test and Control should be detected		29.4	28.6
2	Positive HBV	Test and Control should be detected		28.25	28.67
3	Positive HCV	Test and Control should be detected		28.0	29.4
4	Positive HCV	Test and Control should be detected		30.08	30.11
5	Positive HCV	Test and Control should be detected		28.6	30.8

*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

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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

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