



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000003

Date:18/01/2023

Doc ID:COA/TP/USPT249

Product Name	Trueprep® AUTO Universal Sample Pre-treatment Pack
Generic Name	Universal Sample pre-treatment pack for Non MTB samples
Lot No.	USPT249
Mfg. Date	2023-01
Exp. Date	2024-12
Pack Size	5T,50T
Storage condition	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))	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
3	Package Insert	Present	Present

Molbio Diagnostics Private Limited

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

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzers						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test 1	Test 2	IC
Negative Control						
1	Negative HBV	ND	Control should be detected	ND	NA	27.23
2	Negative HBV	ND		ND	NA	27.45
3	Negative HBV	ND		ND	NA	27.10
4	Negative HCV	ND		ND	NA	28.52
5	Negative HCV	ND		ND	NA	27.52
6	Negative HCV	ND		ND	NA	27.21
7	Negative HIV	ND		ND	NA	28.00
8	Negative HIV	ND		ND	NA	27.33
9	Negative HIV	ND		ND	NA	29.06
Positive Control						
1	Positive HBV	Test and Control should be detected		30.07	NA	27.04
2	Positive HBV	Test and Control should be detected		30.17	NA	27.01
3	Positive HBV	Test and Control should be detected		30.12	NA	27.31
4	Positive HCV	Test and Control should be detected		30.71	NA	27.91
5	Positive HCV	Test and Control should be detected		30.31	NA	26.61
6	Positive HCV	Test and Control should be detected		29.89	NA	27.01

*Ct-Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



Name: Dr. Praveen Kumar MK
 Department: Quality Control
 Designation: QC Head

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