



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 26/02/2023

Doc ID: COA/TP/USPK575

Product Name	Trueprep® AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep® AUTO
Lot No.	USPK575
Mfg. Date	2022-07
Exp. Date	2024-06
Pack Size	05T, 25T, 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 Cartridge Based Sample prep kit)	(Present (P)/Not Present (NP))	
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml Graduated)	Present	Present
4	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

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

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzers						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	26.46
2	Negative MTB	ND		ND	NA	26.67
3	Negative MTB	ND		ND	NA	26.72
4	Negative HBV	ND		ND	NA	28.29
5	Negative HBV	ND		ND	NA	27.83
6	Negative HBV	ND		ND	NA	28.57
7	Negative HCV	ND		ND	NA	28.07
8	Negative HCV	ND		ND	NA	28.46
9	Negative HCV	ND		ND	NA	27.71
10	Negative HIV	ND		ND	NA	28.87
11	Negative HIV	ND		ND	NA	28.91
12	Negative HIV	ND		ND	NA	28.46
Positive Control						
1	Positive HCV	Test and Control should be detected	31.2	NA	27.52	
2	Positive HCV		31.85	NA	27.41	
3	Positive HCV		31.32	NA	27.64	
4	Positive HBV		30.42	NA	27.1	
5	Positive HBV		30.07	NA	26.79	
6	Positive HBV		29.56	NA	27.24	

*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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