



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date:27/02/2023

Doc ID:COA/TP/VUCPK253L

Product Name	Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO v2
Lot No.	VUCPK253L
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 v2 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@molbiodiagnostics.com

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1	Test 2	IC
Negative Control						
1	Negative HBV	ND	Control should be detected	ND	NA	26.59
2	Negative HBV	ND		ND	NA	26.99
3	Negative HBV	ND		ND	NA	26.78
4	Negative HCV	ND		ND	NA	27.28
5	Negative HCV	ND		ND	NA	28.30
6	Negative HCV	ND		ND	NA	27.34
7	Negative HIV	ND		ND	NA	26.39
8	Negative HIV	ND		ND	NA	26.72
9	Negative HIV	ND		ND	NA	26.74
Positive Control						
1	Positive MTB	Test and Control should be detected		30.07	NA	26.71
2	Positive MTB	Test and Control should be detected		29.44	NA	27.01
3	Positive MTB	Test and Control should be detected		29.19	NA	26.95
4	Positive HCV	Test and Control should be detected		30.03	NA	27.75
5	Positive HCV	Test and Control should be detected		31.63	NA	27.73
6	Positive HCV	Test and Control should be detected		31.81	NA	26.93

*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

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