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Molbio Diagnostics Limited
(Formerly Molbio Diagnostics Private Limited)
L-46, Phase II D, Verna Industrial Estate
Verna, Goa - 403722, India
+91 832 6724888 www.molbiodiagnostics.com

CERTIFICATE OF ANALYSIS

Product Name	Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2
License No.	MFG/IVD/2021/000064
Lot No.	662VUCPKL
Mfg. Date	2026-10
Exp. Date	2028-09
Catalogue No./(Pack Size)	60207AR50/(50T)
Storage condition	2°C to 40°C
Document ID	COA/TP/662VUCPKL
Date of Release	07/11/2026

PRECAUTION: Refer Safety Data Sheet and follow instructions for use.

Physical Verification data			
Sr. No.	**Components in each kit**	**Specification**	**Observation**
A	**Contents in the carton (Trueprep® AUTO MTB Sample Pre-treatment Pack)**	**[Present (P)/Absent (A)]**	
1	Universal Reagent Pack	Present	P
2	Universal Cartridge Pack	Present	P
3	Disposable Transfer Pipette (3 ml Graduated)	Present	P
4	Package Insert	Present	P
B	**Pouch Seal Integrity**	**Specification**	**Observation**
1	Leak Test	Should Pass	Pass

sales@molbiodiagnostics.com / admin@molbiodiagnostics.com | **CIN:** L33125GA2000PLC002909 | **GSTIN:** 30AACCM8275E1ZO

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Performance testing data						
Sr. No.	Specificity Tests	Specification		Test Lot		
		Target	Control	Target 1 (Average)	Target 2 (Average)	Control (Average)
Negative Control						
1	Negative MTB	ND	Control should be detected	ND	NA	26.84
2	Negative HCV	ND	Control should be detected	ND	NA	27.23
3	Negative HIV-1/ HIV-2	ND	Control should be detected	ND	NA	27.71
4	Negative MTB Plus	ND	Control should be detected	ND	NA	28.24
Positive Control						
1	Positive MTB	Target and Control should be detected		31.07	NA	26.61
2	Positive HCV	Target and Control should be detected		31.20	NA	26.78
Non Template Control						
1	NTC	Target and Control should not be detected		ND	ND	ND

Mfg- Manufacturing, Exp- Expiry, No.- Number, ID- Identification

The lot is tested and verified as per QC standards and is approved.

MOLBIO DIAGNOSTICS LIMITED GOA

07/11/25

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

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