



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 14/05/2024

Doc ID: COA/TP/LR034

Product Name	Trueprep [®] MAG Sputum Liquefaction Reagent
Generic Name	Reagent Pack for Liquefaction of Sputum samples
Lot No.	LR034
Mfg. Date	2024-03
Exp. Date	2025-02
Pack Size	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 [®] MAG Sputum Liquefaction Reagent)	(Present (P)/Not Present (NP))	
1	Liquefaction Reagent	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	Control	Test (Average)	Control (Average)
Samples					
1	Sputum	ND	Control should be detected	ND	28.14
2	Sputum	ND		ND	28.04
3	Sputum	ND		ND	28.00
Non Template Control					
1	NTC	Test 1 and Control should not be detected		ND	ND

*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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