



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 13/02/2024

Doc ID: COA/TP/LR033

Product Name	Trueprep® MAG Sputum Liquefaction Reagent
Generic Name	Reagent Pack for Liquefaction of Sputum samples
Lot No.	LR033
Mfg. Date	2024-01
Exp. Date	2025-12
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

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	26.99
2	Sputum	ND		ND	26.92
3	Sputum	ND		ND	26.80

FM/QT/224-01

Page 1 of 2

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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



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

for **Designation:** QC Head

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