



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date:29/05/2024

Doc ID:COA/TP/ALR003/50T

Product Name	Trueprep <sup>®</sup> AUTO Liquefaction Reagent
Generic Name	Reagent Pack for Liquefaction of samples
Lot No.	ALR003
Mfg. Date	2024-05
Exp. Date	2026-04
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 <sup>®</sup> AUTO Sputum Liquefaction Reagent)	(Present (P)/Not Present (NP))	
1	Liquefaction Reagent	Present	Present

Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzer					
Sr. No.	Control		Specification (Ct Values)		Test lot (Ct Values)
	Specificity Tests	Test	Control	Test (Average)	Control (Average)
<b>Samples</b>					
1	Sputum	ND	Control should be detected	ND	28.00
2	Sputum	ND		ND	26.38
3	Sputum	ND		ND	27.25

FM/QT/224-01

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## Molbio Diagnostics Private Limited

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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.

*for*    
Name: Dr.Praveen Kumar MK  
Department: Quality Control  
Designation: QC Head