

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 12/05/2025

Doc ID: COA/TP/ALR005/50T

Product Name	Trueprep [®] AUTO Liquefaction Reagent
Generic Name	Reagent Pack for Liquefaction of samples
Lot No.	ALR005
Mfg. Date	2025-04
Exp. Date	2027-03
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[®] AUTO 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	27.18
2	Sputum	ND		ND	26.71

3	Sputum	ND		ND	27.16
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

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

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