



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.:SW/IVD/MD-13/2024/00000326

Date: 07/10/2024

Doc ID:COA/TL/TTLB01/50T

Product Name	Truelyse™ Buffer
Generic Name	Rapid Cell lysis buffer for sample processing
Lot No.	TTLB01
Mfg. Date	2024-09
Exp. Date	2026-08
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 (Truelyse™ Buffer)	(Present (P)/Not Present (NP))	
1	Lysis Buffer for Truelyse™	Present	Present
2	Package Insert	Present	Present

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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



Performance on Truelab® Real Time micro PCR Analyzer					
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Value)
	Specificity Tests	Test	IC	Test (Average)	IC (Average)
Negative Control					
1	Negative MTB Ultima	ND	Control should be detected	ND	27.30
Positive Control					
1	Positive MTB Ultima	Test and Control should be detected		17.30	30.83
Non Template Control					
1	NTC	Test and Control should not be detected		ND	ND

*Ct-Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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



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

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