

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 02/02/2024

Doc ID:COA/TP/MSPT194

Product Name	Trueprep [®] AUTO MTB Sample Pre-treatment Pack
Generic Name	Sample pre-treatment pack for MTB samples
Lot No.	MSPT194
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[®] AUTO MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
4	Package Insert	Present	Present



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	ND	Control should be detected	ND	27.95
Positive Control					
1	Positive MTB	Test and Control should be detected		24.47	27.73
2	Positive MTB	Test and Control should be detected		30.45	26.47
Non Template Control					
1	NTC	Test and Control should not be detected		ND	ND

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

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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