



MOLBIO DIAGNOSTICS PVT. LTD.
An EN EN ISO 13485 certified company
CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 07/05/2018

PRODUCT : Trueprep™ AUTO MTB Sample Pre-Treatment Pack		
Lot No.: MSPT005	Mfg Date: 2017-10	Exp Date: 2019-09
A.R. No.: B-MSPT-005		
Pack size : 20 TESTS , 5 TESTS	STORAGE : 2°C to 40°C	

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton(MTB Sample Pre-treatment Pack)(Present (P)/Not Present (NP))		
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab™ Uno / Truelab™ Uno Dx					
Sr.No.	CONTROLS	Specification (Ct Values)		Test Lot (Ct Values)	
Specificity Tests		TEST	IC	TEST	IC
Negative Control					
1	Sample 1	ND	IC should be detected	ND	30.57
Positive Control					
1	Sample 1	Test and IC should be detected		23	29.67
2	Sample 2	Test and IC should be detected		22.8	29.33
3	Sample 3	Test and IC should be detected		23.33	29.67

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE

QUALITY CONTROL
Name: Praveen Kumar
Designation: QC Head



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