

MOLBIO DIAGNOSTICS PVT. LTD. An ISO 9001 & ISO 13485 certified company CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 02/07/2019

PRODUCT : Trueprep™ AUTO MTB Sample Pre-treatment Pack

Lot No.: MSPT031

Mfg Date: 2019-06

Exp Date: 2021-05

A.R. No.: B-MSPT-031

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	
D	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	

Sr.No.	CONTROL S	ance on Truelab [™] Real Time micro P Specification (Ct Values)		Test Lot (Ct Values)	
Specificity Tests		TEST	Control	TEST	Control
Negativ	ve Control	*			
1	Sample 1	ND	Control should be detected	ND	29.2
Positiv	e Control		and the state of t		
1	Sample 1	Test and Control should be detected		31.4	27.0
2	Sample 2	Test and Control should be detected		31.17	29.17
3	Sample 3	Test and Control should be detected		30.33	28.17
		1			

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 Dr. Praveer Kumar Designation: 20 Head

Page 1 of 1

Molbio Diagnostics Pvt. Ltd.