

## MOLBIO DIAGNOSTICS PVT. LTD. An ISO 9001 & ISO 13485 certified company

## **CERTIFICATE OF ANALYSIS**

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

Date: 17/05/2019

PRODUCT: Trueprep™ AUTO Universal Cartridge Based Sample prep kit

Trueprep™ AUTO Universal

Lot No.: USPK156 Mfg Date: 2019-04 Exp Date: 2021-03

STORAGE: 2°C to 40°C

Cartridge Based

A.R. No.: B-USPK-156

Sample prep kit

Pack size: 5, 25 TESTS

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
Α	Contents in the carton(Trueprep <sup>™</sup> AUTO Universal Cartridge Based Sample prep kit [Present (P)/Not Present (NP)]		
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml)	Present	Present
4	Package Insert	Present	Present

Sr.No.	Sample Negative/Positive	Negative:TEST-ND Positive:TEST-Detected	Control-Detected Control-Detected	
		TEST	Control	
01	Negative MTB	ND	28.33	
02	Positive MTB	29.4	28.0	
03	Positive MTB	31.13	27.75	
01	Negative MTB Plus	ND	28.33	
02	Positive MTB Plus	29.4	29.6	
03	Positive MTB Plus	30.11	26.8	

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. Praveen Kumar
Designation: QC Head

Page 1 of 1

## Molbio Diagnostics Pvt. Ltd.