## MOLBIO DIAGNOSTICS LIMITED

## EN ISO 13485:2016 certified company

## CERTIFICATE OF ANALYSIS

**License No.:** MFG/IVD/2021/000064

**Date:** 12/01/2026

**Doc ID:** COA/TP/206MSPT

| | |
|---|---|
| **Product Name** | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| **Generic Name** | Sample pre-treatment pack for MTB samples |
| **Lot No.** | 206MSPT |
| **Mfg. Date** | 2026-01 |
| **Exp. Date** | 2027-12 |
| **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)/Absent (A)] | |
| 1 | Lysis Buffer | Present | Present |
| 2 | Liquefaction Buffer | Present | Present |
| 3 | Disposable Transfer Pipette (1 ml Graduated) | Present | Present |
| 4 | Package Insert | Present | Present |

| Sr. No. | Specificity Tests | Specification | | Test Lot | |
|---|---|---|---|---|---|
| | | Test | Control | Test (Average) | Control (Average) |
| **Negative Control** | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | 26.57 |
| **Positive Control** | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 27.10 | 26.61 |
| 2 | Positive MTB | Test and Control should be detected | | 30.54 | 26.74 |
| **Non Template Control** | | | | | |
| 1 | NTC | Test and Control should not be detected | | ND | ND |

Performance on Truelab® Real Time micro PCR Analyzer

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

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

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