Molbio Diagnostics Limited
(Formerly Molbio Diagnostics Private Limited)
L-46, Phase II D, Verna Industrial Estate
Verna, Goa - 403722, India
+91 832 6724888 www.molbiodiagnostics.com

## MOLBIO DIAGNOSTICS LIMITED

### EN ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

**License No.:** MFG/IVD/2025/000136 **Date:** 06/11/2026

**Doc ID:** COA/TP/296MSPT

| | |
|---|---|
| **Product Name** | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| **Generic Name** | Sample pre-treatment pack for MTB samples |
| **Lot No.** | 296MSPT |
| **Mfg. Date** | 2026-11 |
| **Exp. Date** | 2028-10 |
| **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 |
| **B** | **Leak Test** | **Specification** | **Observation** |
| 1 | Leak test | Should Pass | Pass |



sales@molbiodiagnostics.com / admin@molbiodiagnostics.com | CIN: L33125GA2000PLC002909 | GSTIN: 30AACCM8275E1ZO

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| Performance on Truelab® Real Time micro PCR Analyzer | | | | | | |
|---|---|---|---|---|---|---|
| Sr. No. | Specificity Tests | Specification | | Test Lot | | |
| | | Target | Control | Target 1 (Average) | Target 2 (Average) | Control (Average) |
| **Negative Control** | | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | NA | 26.59 |
| **Positive Control** | | | | | | |
| 1 | Positive MTB | Target and Control should be detected | | 27.46 | NA | 26.74 |
| 2 | Positive MTB | Target and Control should be detected | | 31.34 | NA | 26.44 |
| **Non Template Control Test for MTB** | | | | | | |
| 1 | NTC | Target 1, Target 2 and Control should not be detected | | ND | ND | ND |

*ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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

MOLBIO DIAGNOSTICS LIMITED GOA

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



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