

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 15/08/2025

**Doc ID:** COA/TP/158MSPT

|                          |  |
|--------------------------|--|
| <b>Product Name</b>      | Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack |
| <b>Generic Name</b>      | Sample pre-treatment pack for MTB samples                |
| <b>Lot No.</b>           | 158MSPT  |
| <b>Mfg. Date</b>         | 2025-08  |
| <b>Exp. Date</b>         | 2027-07  |
| <b>Pack Size</b>         | 50T  |
| <b>Storage condition</b> | 2°C to 40°C  |

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

| Sr. No.  | Components in each kit  | Specification                         | Observation |
|----------|---|---------------------------------------|-------------|
| <b>A</b> | <b>Contents in the carton (Trueprep<sup>®</sup> AUTO MTB Sample Pre-treatment Pack)</b> | <b>(Present (P)/Not Present (NP))</b> |             |
| 1        | Lysis Buffer  | Present                               | Present     |
| 2        | Liquefaction Buffer   | Present                               | Present     |
| 3        | Disposable Transfer Pipette (1 ml Graduated)  | Present                               | Present     |
| 4        | Package Insert  | Present                               | Present     |

| Performance on Truelab® Real Time micro PCR Analyzer |                   |   |                            |                |                     |
|--|-------------------|---|----------------------------|----------------|---------------------|
| Sr. No.  | Control           |   | Specification (Ct Values)  |                | Test Lot (Ct Value) |
|  | Specificity Tests | Test                                    | IC                         | Test (Average) | IC (Average)        |
| Negative Control                                     |                   |   |                            |                |                     |
| 1  | Negative MTB      | ND                                      | Control should be detected | ND             | 27.11               |
| Positive Control                                     |                   |   |                            |                |                     |
| 1  | Positive MTB      | Test and Control should be detected     |                            | 26.50          | 27.16               |
| 2  | Positive MTB      | Test and Control should be detected     |                            | 29.16          | 27.61               |
| Non Template Control                                 |                   |   |                            |                |                     |
| 1  | NTC               | Test and Control should not be detected |                            | ND             | ND                  |

\*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

