

**MOLBIO DIAGNOSTICS LIMITED**  
**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2025/000136

**Date:** 23/09/2026

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|                          |                                                          |
|--------------------------|----------------------------------------------------------|
| <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>           | 286MSPT                                                  |
| <b>Mfg. Date</b>         | 2026-09                                                  |
| <b>Exp. Date</b>         | 2028-08                                                  |
| <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            |
| <b>B</b> | <b>Leak Test</b>                                                                        | <b>Specification</b>                  | <b>Observation</b> |
| 1        | Leak test                                                                               | Should Pass                           | Pass               |

| 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                 | 26.96             |
| Positive Control                                     |                   |                                                       |                            |                    |                    |                   |
| 1                                                    | Positive MTB      | Target and Control should be detected                 |                            | 25.58              | NA                 | 26.78             |
| 2                                                    | Positive MTB      | Target and Control should be detected                 |                            | 30.92              | NA                 | 26.91             |
| 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.




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