

**MOLBIO DIAGNOSTICS LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

License No.: MFG/IVD/2021/000064

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Doc ID: COA/TP/212MSPT

|                          |  |
|--------------------------|--|
| <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>           | 212MSPT  |
| <b>Mfg. Date</b>         | 2026-02  |
| <b>Exp. Date</b>         | 2028-01  |
| <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 <sup>®</sup> Real Time micro PCR Analyzer |                   |   |                            |                |                   |
|--|-------------------|---|----------------------------|----------------|-------------------|
| Sr. No.  | Specificity Tests | Specification                           |                            | Test Lot       |                   |
|  |                   | Test                                    | Control                    | Test (Average) | Control (Average) |
| <b>Negative Control</b>  |                   |   |                            |                |                   |
| 1  | Negative MTB      | ND                                      | Control should be detected | ND             | 26.98             |
| <b>Positive Control</b>  |                   |   |                            |                |                   |
| 1  | Positive MTB      | Test and Control should be detected     |                            | 26.96          | 26.88             |
| 2  | Positive MTB      | Test and Control should be detected     |                            | 31.21          | 27.17             |
| <b>Non Template Control</b>                                      |                   |   |                            |                |                   |
| 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.**



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