

**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2019/000003

**Date:** 20/11/2024

**Doc ID:** COA/TP/MSPT247/50T

|                          |                                                          |
|--------------------------|----------------------------------------------------------|
| <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>           | MSPT247                                                  |
| <b>Mfg. Date</b>         | 2024-11                                                  |
| <b>Exp. Date</b>         | 2026-10                                                  |
| <b>Pack Size</b>         | 50T                                                      |
| <b>Storage condition</b> | 2°C to 40°C                                              |

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

| <b>Sr. No.</b> | <b>Components in each kit</b>                                                           | <b>Specification</b>                  | <b>Observation</b> |
|----------------|-----------------------------------------------------------------------------------------|---------------------------------------|--------------------|
| <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             | 26.61               |
| Positive Control                                     |                   |                                         |                            |                |                     |
| 1                                                    | Positive MTB      | Test and Control should be detected     |                            | 30.44          | 26.10               |
| 2                                                    | Positive MTB      | Test and Control should be detected     |                            | 24.27          | 25.80               |
| 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 MK  
**Department:** Quality Control  
**Designation:** QC Head  
*for*