



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 25/10/2024

Doc ID: COA/TP/074MSPT/25T

|                   |                                              |
|-------------------|----------------------------------------------|
| Product Name      | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| Generic Name      | Sample pre-treatment pack for MTB samples    |
| Lot No.           | 074MSPT                                      |
| Mfg. Date         | 2024-10                                      |
| Exp. Date         | 2026-09                                      |
| Pack Size         | 25T                                          |
| 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     |



| 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             | 27.05               |
| Positive Control                                     |                   |                                         |                            |                |                     |
| 1                                                    | Positive MTB      | Test and Control should be detected     |                            | 25.44          | 27.52               |
| 2                                                    | Positive MTB      | Test and Control should be detected     |                            | 30.68          | 27.51               |
| 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.**

  
  
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**Designation:** QC Head