



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 31/08/2024

Doc ID: COA/TP/068MSPT/50T

|                   |  |
|-------------------|--|
| Product Name      | Trueprep <sup>®</sup> AUTO MTB Sample Pre-treatment Pack |
| Generic Name      | Sample pre-treatment pack for MTB samples                |
| Lot No.           | 068MSPT  |
| Mfg. Date         | 2024-08  |
| Exp. Date         | 2026-07  |
| Pack Size         | 50T  |
| 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 <sup>®</sup> 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     |

**Molbio Diagnostics Private Limited**

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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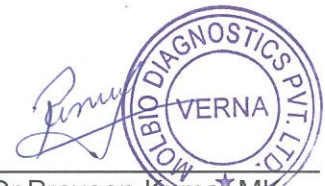
CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



| 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)        |
| <b>Negative Control</b>                              |                   |   |                            |                |                     |
| 1  | Negative MTB      | ND                                      | Control should be detected | ND             | 27.28               |
| <b>Positive Control</b>                              |                   |   |                            |                |                     |
| 1  | Positive MTB      | Test and Control should be detected     |                            | 25.86          | 27.50               |
| 2  | Positive MTB      | Test and Control should be detected     |                            | 31.36          | 27.22               |
| <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.**



**Name:** Dr.Praveen Kumar MK  
**Department:** Quality Control  
**Designation:** QC Head

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