



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 29/07/2024

Doc ID: COA/TP/061MSPT/50T

| | |
|-------------------|--|
| Product Name | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| Generic Name | Sample pre-treatment pack for MTB samples |
| Lot No. | 061MSPT |
| Mfg. Date | 2024-07 |
| Exp. Date | 2026-06 |
| 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® 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

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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) |
| Negative Control | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | 28.23 |
| Positive Control | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 24.00 | 26.22 |
| 2 | Positive MTB | Test and Control should be detected | | 31.99 | 27.36 |
| 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

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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Designation: QC Head