



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 23/09/2024

Doc ID: COA/TP/069MSPT/50T

| | |
|--------------------------|--|
| Product Name | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| Generic Name | Sample pre-treatment pack for MTB samples |
| Lot No. | 069MSPT |
| Mfg. Date | 2024-09 |
| Exp. Date | 2026-08 |
| 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 |



| 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 | 26.49 |
| Positive Control | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 25.88 | 27.69 |
| 2 | Positive MTB | Test and Control should be detected | | 30.50 | 27.12 |
| 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
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Designation: QC Head