

MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS
License No.: MFG/IVD/2019/000003

Date: 19/01/2026

Doc ID: COA/TP/MSPT304

| | |
|--------------------------|--|
| Product Name | Trueprep® AUTO MTB Sample Pre-treatment Pack |
| Generic Name | Sample pre-treatment pack for MTB samples |
| Lot No. | MSPT304 |
| Mfg. Date | 2026-01 |
| Exp. Date | 2027-12 |
| 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. | Specificity Tests | Specification | | Test Lot | | |
| | | Test | Control | Test 1 (Average) | Test 2 (Average) | Control (Average) |
| Negative Control | | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | NA | 27.50 |
| Positive Control | | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 31.56 | NA | 26.11 |
| 2 | Positive MTB | Test and Control should be detected | | 26.76 | NA | 27.28 |
| 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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