



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 27/02/2021

| | |
|---|---|
| PRODUCT: Trueprep[®] AUTO MTB Sample Pre-treatment Pack | |
| Trueprep[®] AUTO MTB Sample Pre-treatment Pack | Lot No.: MSPT092 Mfg Date: 2021-01 Exp Date: 2022-12 |
| | A.R. No.: B-MSPT-092 |
| Pack size: 50T, 20T, 5T | STORAGE: 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 (MTB Sample Pre-treatment Pack) | (Present (P)/Not Present (NP)) | |
| 1 | Lysis Buffer | Present | Present |
| 2 | Liquefaction Buffer | Present | Present |
| 3 | Disposable Transfer Pipette (1ml) | Present | Present |

| Performance on Truelab [®] Real Time micro PCR Analyzers | | | | | |
|---|--------------------------|-------------------------------------|----------------------------|----------------------|-----------|
| Sr. No. | Controls | Specification (Ct Values) | | Test Lot (Ct Values) | |
| 1 | Specificity Tests | Test | IC | Test | IC |
| Negative Control | | | | | |
| 1 | Sample 1 | ND | Control should be detected | ND | 28.4 |
| 2 | Sample 2 | ND | Control should be detected | ND | 29.17 |
| 3 | Sample 3 | ND | Control should be detected | ND | 28.33 |
| Positive Control | | | | | |
| 1 | Sample 1 | Test and Control should be detected | | 27.4 | 29.6 |
| 2 | Sample 2 | Test and Control should be detected | | 26.33 | 28.0 |
| 3 | Sample 3 | Test and Control should be detected | | 26.4 | 28.17 |

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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