

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:20/07/2022

Doc ID: COA/TN/TB189R/f

| | | | |
|---------------------|---|---------------------|------------------------------|
| BRAND NAME | Truenat® MTB | | |
| GENERIC NAME | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> | | |
| LOT No. | TB189R | CHIP LOT NO. | HDLW440 |
| MFG. DATE | 2022-07 | EXP. DATE | 2024-02 |
| PACK SIZE | 5T, 20T, 25T, 50T | | |
| STORAGE | 2°C to 30°C | | A.R. No.: B-TB-189R/f |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

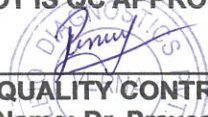
| Sr. No. | Components in each kit | Specification | Observation |
|---------|---|-------------------------------|-------------|
| 1 | Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip | 5 no, 20 no,25 no. 50 nos. | Pass |
| 2 | Colour of desiccant pouch | Orange | Pass |
| 3 | Package insert | 01 no. | Pass |

| PERFORMANCE | | |
|---------------------------|-------------|---------|
| CONTROLS | (Ct Values) | |
| Specificity Tests | MTB | Control |
| Negative Control | ND | 28.33 |
| | ND | 28.25 |
| Positive Control | 28 | 24.6 |
| | 28.5 | 25 |
| | 29 | 24.8 |
| | 28.5 | 24.33 |
| | 28.13 | 24.8 |
| | 28.5 | 24.5 |
| | 28.57 | 24.5 |
| | 28 | 24 |
| Average | 28.4 | 24.57 |
| Standard deviation | ± 0.34 | ± 0.31 |

*ND- Not detected, Ct- Cycle threshold, MTB- *Mycobacterium tuberculosis*

*A deviation of ≤ 1.5 is acceptable for Ct values

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


QUALITY CONTROL
 Name: Dr. Praveen Kumar
 Designation: QC Head
 Page 1 of 1

Molbio Diagnostics Private Limited

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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO