



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:16/05/2022

Doc ID: COA/TN/TB195

| | | | |
|--------------|---|--------------|-----------------------|
| BRAND NAME | Truenat [®] MTB | | |
| GENERIC NAME | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> | | |
| LOT No. | TB195 | CHIP LOT NO. | 044HDLW |
| MFG. DATE | 2022-05 | EXP. DATE | 2024-04 |
| PACK SIZE | 5T, 20T, 25T, 50T | | |
| STORAGE | 2°C to 30°C | | A.R. No.:B-TB-195 R/d |

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 | 28.5 |
| | ND | 27.67 |
| Positive Control | 29.67 | 26.4 |
| | 29.29 | 26.29 |
| | 28.63 | 26.75 |
| | 29.14 | 26.75 |
| | 29.71 | 26 |
| | 28.67 | 26.17 |
| | 30.14 | 26.8 |
| | 28.57 | 25.8 |
| Average | 29.22 | 26.37 |
| Standard deviation | ± 0.58 | ± 0.37 |

*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
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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

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