



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2021/000071

Date: 24/03/2022

Doc ID: COA/TN/005TB

| | |
|--------------|---|
| BRAND NAME | Truenat [®] MTB |
| GENERIC NAME | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| LOT No. | 005TB |
| MFG. DATE | 2022-03 |
| EXP. DATE | 2024-02 |
| PACK SIZE | 5T, 50T |
| STORAGE | 2°C to 30°C |
| | A.R. No.: B-005-TB |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

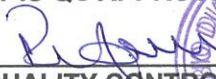
| Sr. No. | Components in each kit | Specification | Observation |
|---------|---|---------------|-------------|
| 1 | Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip | 5 no, 50 no. | Pass |
| 2 | Colour of desiccant pouch | Orange | Pass |
| 3 | Package insert | 01 no.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


| PERFORMANCE | | |
|--------------------|-------------|---------|
| CONTROLS | (Ct Values) | |
| Specificity Tests | MTB | Control |
| Negative Control | ND | 28.43 |
| | ND | 29.17 |
| Positive Control | 31 | 27 |
| | 31.1 | 28 |
| | 31.22 | 27.4 |
| | 29.75 | 27.8 |
| | 30.33 | 27 |
| | 30.29 | 27.33 |
| | 30.17 | 28 |
| | 29.67 | 27.17 |
| Standard deviation | +0.60 | +0.41 |

*ND- Not detected, Ct- Cycle threshold

*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 PURPOSE


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@molbioldiagnostics.com

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

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