



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:12/07/2021

Doc ID: COA/TN/TP028

| | |
|---------------------|---|
| BRAND NAME | Truenat [®] MTB Plus |
| GENERIC NAME | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| LOT No. | TP028 |
| MFG. DATE | 2021-07 |
| EXP. DATE | 2023-06 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No. : B-TP-028 | |

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, 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 | 26.5 |
| | ND | 27.33 |
| Positive Control | 29.5 | 29.5 |
| | 28.4 | 30.25 |
| | 29.6 | 30 |
| | 30.17 | 30.33 |
| | 28.8 | 29.25 |
| | 29.75 | 30.33 |
| | 30 | 30.33 |
| | 29.75 | 30.25 |
| Standard deviation | +0.60 | +0.42 |

*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
for
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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO