



MOLBIO DIAGNOSTICS PRIVATE LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence No.: MFG/IVD/2019/000018

Date: 18/10/2024
Document ID: COA/TN/TB271b/5T

| | |
|-------------------|---|
| Product Name | Truenat [®] MTB |
| Generic Name | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No. | TB271 |
| Set No. | b |
| Mfg. Date | 2024-10 |
| Exp. Date | 2026-09 |
| Pack Size | 5T |
| Storage condition | 2°C to 30°C |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|-------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present | Present |
| 03 | Colour of desiccant pouch | Should be present and Orange in Colour | Present / Orange Colour |
| 04 | Package Insert | Should be present | Present |
| 05 | Seal integrity test | Should pass | Pass |

| Performance testing data | | |
|--------------------------|--------------|--------------|
| Samples | Ct Values | |
| | MTB | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 28.01 ± 0.46 |
| Positive sample 1 | 23.77 ± 0.29 | 27.69 ± 0.65 |
| Positive sample 2 | 27.17 ± 0.53 | 27.32 ± 0.12 |
| Positive Sample 3 | 30.13 ± 0.50 | 26.63 ± 0.90 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.



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