

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

Licence No.: MFG/IVD/2019/000018

Date: 08/11/2025

Document ID: COA/TN/TP120

| | |
|-------------------|---|
| Product Name | Truenat® MTB Plus |
| Generic Name | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No. | TP120 |
| Set No. | NA |
| Mfg. Date | 2025-10 |
| Exp. Date | 2027-09 |
| Pack Size | 5T,50T |
| Storage condition | 2°C to 30°C |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

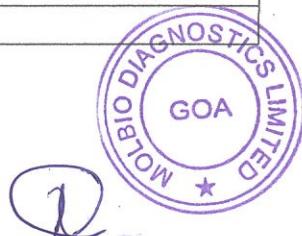
| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|-------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present | Present |
| 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 PLUS | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 27.77 ± 0.49 |
| Positive sample 1 | 23.10 ± 0.95 | 26.77 ± 0.56 |
| Positive sample 2 | 27.05 ± 0.84 | 28.55 ± 0.89 |
| Positive Sample 3 | 30.64 ± 0.37 | 26.91 ± 0.39 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

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



Name : Dr. Praveen Kumar MK
 Department: Quality Control
 Designation: QC Head