

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

Licence no.: MFG/IVD/2025/000148

Date: 06/05/2026  
Document ID: COA/TN/PCI065

|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> Positive Control Kit - Panel I   |
| Generic Name      | Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1 |
| Lot No.           | PCI065  |
| Mfg. Date         | 2026-04   |
| Exp. Date         | 2027-03   |
| Pack Size         | 8T  |
| Storage condition | 2°C to 40°C   |

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit  | Specification     | Observation |
|---------|---|-------------------|-------------|
| 01      | Negative control  | Should be present | Present     |
| 02      | Positive control (08- strip tubes containing dried down positive control) | Should be present | Present     |
| 03      | Package insert  | Should be present | Present     |

| Performance testing data |                                |  |                  |
|--------------------------|--------------------------------|--|------------------|
| Sr. No.                  | Truenat <sup>®</sup> test name | Positive control                             | Negative control |
| 1                        | MTB                            | 31.33 ± 0.30                                 | ND               |
| 2                        | MTB Plus                       | 28.55 ± 0.60                                 | ND               |
| 3                        | MTB-RIF Dx                     | RIF Resistance detected                      | Indeterminate    |
| 4                        | SARS CoV-2                     | 27.57 ± 0.31                                 | ND               |
| 5                        | COVID-19                       | Orf 1A: 26.99 ± 0.40<br>E gene: 26.39 ± 0.32 | ND               |
| 6                        | H1N1                           | 27.00 ± 0.52                                 | ND               |

\*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

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