

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

Licence No.: MFG/IVD/2019/000018

Date: 11/12/2025

Document ID: COA/TN/LM003

|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> M.Leprae                                 |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium leprae</i> |
| Lot No.           | LM003   |
| Set No.           | NA  |
| Mfg. Date         | 2025-11   |
| Exp. Date         | 2027-10   |
| Pack Size         | 5T, 20T, 25T  |
| Storage condition | 2°C to 30°C   |

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

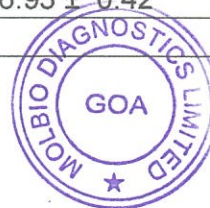
| Sr. No. | Components in each kit   | Specification                          | Observation             |
|---------|--|--|-------------------------|
| 01      | Number of pouches as per pack size   | Should be present                      | Present                 |
| 02      | Pouches Contents: 1 chip, 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    |              |
|                          | M.Leprae     | Control      |
| Non Template Control     | ND           | ND           |
| Negative Sample          | ND           | 26.17 ± 0.26 |
| Positive sample 1        | 23.68 ± 1.47 | 26.28 ± 0.63 |
| Positive sample 2        | 26.28 ± 0.49 | 27.27 ± 0.28 |
| Positive Sample 3        | 30.20 ± 0.94 | 26.93 ± 0.42 |

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

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



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