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

Licence No.: MFG/IVD/2019/000018

Date: 30/10/2026
Document ID: COA/TN/I0002LM

Product Name	**Truenat® M.Leprae**
Generic Name	**Chip-based Real Time PCR Test for *Mycobacterium leprae***
Lot No.	**I0002LM**
Set No.	**NA**
Mfg. Date	**2025-03**
Exp. Date	**2027-02**
Pack Size	**5T, 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 DNase and RNase free filter barrier microtip	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	30.24 ± 0.51
Positive Sample 1	23.39 ± 0.48	27.93 ± 0.44
Positive Sample 2	26.79 ± 0.40	28.83 ± 0.39
Positive Sample 3	30.73 ± 0.26	26.67 ± 0.52
ND – Not detected, Ct- Cycle threshold		

Mfg- Manufacturing, Exp- Expiry

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

MOLBIO DIAGNOSTICS LIMITED GOA

for

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