Molbio Diagnostics Limited
(Formerly Molbio Diagnostics Private Limited)
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CERTIFICATE OF ANALYSIS

Product Name	Truenat® MTB
Generic Name	Chip-based Real Time PCR Test for *Mycobacterium tuberculosis*
Licence No.	MFG/IVD/2021/000071
Lot No.	V0548TB
Mfg. Date	2026-11
Exp. Date	2028-10
Catalogue No./ (Pack size)	601030005/(5T), 601030050/(50T)
Storage condition	2°C to 30°C
Document ID	COA/TN/V0548TB
Date of Release	09/11/2026

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Physical Verification data			
Sr. No.	**Components in each kit**	**Specification**	**Observation**
01	Number of pouches as per pack size	Should be present	Present
02	Pouch 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**	
	MTB	**Control**
Non Template Control	ND	ND
Negative Sample	ND	28.05 ± 0.45
Positive sample 1	25.35 ± 0.24	26.87 ± 0.19
Positive sample 2	28.02 ± 0.39	27.75 ± 0.24
Positive Sample 3	31.54 ± 0.48	27.19 ± 0.26
ND – Not detected, Ct- Cycle threshold		

Mfg- Manufacturing, Exp- Expiry, No.- Number, ID- Identification

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

09/11/26

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

MOLBIO DIAGNOSTICS LIMITED GOA

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