

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

**Licence No.: MFG/IVD/2021/000071**

**Date: 10/02/2026**

**Document ID:COA/TN/V0011TB**

<b>Product Name</b>	Truenat® MTB
<b>Generic Name</b>	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>
<b>Lot No.</b>	V0011TB
<b>Set No.</b>	NA
<b>Mfg. Date</b>	2026-02
<b>Exp. Date</b>	2028-01
<b>Pack Size</b>	5T, 50T
<b>Storage condition</b>	2°C to 30°C

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

<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
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 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

<b>Performance testing data</b>		
<b>Samples</b>	<b>Ct Values</b>	
	<b>MTB</b>	<b>Control</b>
<b>Non Template Control</b>	ND	ND
<b>Negative Sample</b>	ND	26.30 ± 0.28
<b>Positive sample 1</b>	23.74 ± 0.21	28.67 ± 0.14
<b>Positive sample 2</b>	27.35 ± 0.28	27.18 ± 0.17
<b>Positive Sample 3</b>	31.22 ± 0.60	26.82 ± 0.29

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  
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 Designation: QC Head

