

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

**Licence No.: MFG/IVD/2019/000018**
**Date: 08/01/2026**
**Document ID:COA/TN/TB446**

<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>	TB446
<b>Set No.</b>	NA
<b>Mfg. Date</b>	2025-12
<b>Exp. Date</b>	2027-11
<b>Pack Size</b>	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	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

<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	28.04 ± 0.26
<b>Positive sample 1</b>	22.33 ± 0.29	27.35 ± 0.07
<b>Positive sample 2</b>	26.16 ± 0.08	27.24 ± 0.95
<b>Positive Sample 3</b>	30.98 ± 0.75	27.13 ± 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.**

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