



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**Mfg. Lic. No.: MFG/IVD/2019/000018**

**Date: 22/10/2020**

<b>BRAND NAME</b>	Truenat™ MTB	
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i>	
<b>LOT No.</b>	TB127	
<b>MFG. DATE</b>	2020-10	
<b>EXP. DATE</b>	2022-09	
<b>PACK SIZE</b>	5T, 20T, 50T	
<b>STORAGE</b>	2°C to 30°C	<b>A.R. No. : B-TB-127</b>

**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>
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

<b>PERFORMANCE</b>		
<b>CONTROLS</b>	<b>(Ct Values)</b>	
<b>Specificity Tests</b>	<b>MTB</b>	<b>Control</b>
<b>Negative Control</b>	ND	29
	ND	28
<b>Positive Control</b>	30.27	26.67
	31.2	28.2
	29.75	27.75
	31.8	27.67
	30.29	27.33
	30.4	27.5
	29.6	28.33
	29.6	27.2
<b>Standard deviation</b>	± 0.79	± 0.54

\*ND- Not detected, Ct- Cycle threshold, MTB- *Mycobacterium tuberculosis*

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

**MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR SALE**

  
  
**QUALITY CONTROL**  
**Name: Dr. Praveen Kumar**  
**Designation: QC Head**

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## **Molbio Diagnostics Private Limited**

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