

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

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

**Date: 27/12/2025**

**Document ID: COA/TN/236TX**

<b>Product Name</b>	Truenat® MTB-RIF Dx
<b>Generic Name</b>	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
<b>Lot No.</b>	236TX
<b>Set No.</b>	NA
<b>Mfg. Date</b>	2025-12
<b>Exp. Date</b>	2027-11
<b>Pack Size</b>	5T, 20T
<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>Results</b>	
	<b>Tm</b>		<b>Control</b>		
	<b>P2</b>	<b>P1</b>			
<b>Positive sample 1</b>	66.84 ± 0.39	66.67 ± 0.33	70.78 ± 0.41	RIF Resistance detected	
<b>Positive sample 2</b>	72.77 ± 0.35	66.94 ± 0.37	70.98 ± 0.45	RIF Resistance not detected	
<b>Positive sample 3</b>	72.43 ± 0.20	66.93 ± 0.18	70.29 ± 0.21	RIF Resistance not detected	

Tm- Melting temperature, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

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

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FM/QT/219-03

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