



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

Licence no.: MFG/IVD/2021/000071

Date: 27/01/2024

Document ID: COA/TN/019TXa

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	019TX
Set No.	a
Mfg. Date	2024-01
Exp. Date	2025-12
Pack Size	5T, 25T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
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

Performance testing data				
Samples	Ct Values			Results
	Tm		Control	
	P2	P1		
Positive sample 1	65.81 ± 0.55	66.37 ± 0.40	70.47 ± 0.41	RIF Resistance detected
Positive sample 2	72.35 ± 0.47	67.07 ± 0.34	71.05 ± 0.74	RIF Resistance not detected
Positive sample 3	72.52 ± 0.36	66.46 ± 0.23	70.43 ± 0.42	RIF Resistance not detected
Tm- Melting temprature, Ct- Cycle threshold				
*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practice				

Tm- Melting temprature, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices, RIF-Rifampicin
Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.

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



Molbio Diagnostics Private Limited

FM/QT/219-01

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