



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date: 05/07/2019

PRODUCT : Truenat™ MTB

LOT. NO. : TB103

MFG. DATE : 2019- 06

EXP. DATE : 2021- 05

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. No. : B-TB-103a

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos., 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance			
Sr. No.	CONTROLS	Test Lot (Ct Values)	
	<b>Specificity Tests</b>	<b>MTB</b>	<b>Control</b>
	<b>Negative Control</b>	ND	28.0
		ND	28.14
	<b>Positive Control</b>	29.13	27.0
		29.33	27.0
		29.57	27.33
		29.6	26.8
		29.5	26.6
		29.33	27.8
		29.8	29.6
		30.0	26.2
	<b>Standard deviation</b>	<b>+ 0.27</b>	<b>+ 1.04</b>

\*ND- Not detected

\*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 RELEASED FOR SALE

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

Page 1 of 1

Molbio Diagnostics Pvt. Ltd.

Regd. Office: H. No. 13, Sagar Society, Dona Paula, Panaji, North Goa 403 004. INDIA

Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com:

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO