



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date 01/12/2018

PRODUCT : Truenat™ MTB
LOT. NO. : TB082
MFG. DATE : 2018- 10
EXP. DATE : 2020- 09
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-TB-082a

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 contain 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)	
Specificity Tests		MTB	IC
Negative Control		ND	27
Positive Control		29.83	29.14
		31.38	29.33
		30.8	29.8
		30.8	30.5
		30.14	29.33
		31	29.67
		31.43	31.11
Standard deviation		± 0.60	± 0.72

*ND- Not detected

*A deviation of ≤ 1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCTS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE

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

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Molbio Diagnostics Pvt. Ltd.

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