



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date: 20/11/2019

PRODUCT : Truenat™ MTB Plus
LOT. NO. : TP015
MFG. DATE : 2019- 11
EXP. DATE : 2021- 10
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. No. : B-TP-015a

PRECAUTION: Refer Safety Data Sheet and 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)	
	Specificity Tests	MTB	Control
	Negative Control	ND	31.17
		ND	31.33
	Positive Control	27.8	31.0
		27.6	32.6
		28.17	32.83
		28.0	31.0
		29.0	31.33
		27.5	32.17
		27.8	31.17
		28.4	31.2
	Standard deviation	+ 0.49	+ 0.75

*ND- Not detected

*A deviation of ≤ 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 & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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

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

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