



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date 09/11/2018

PRODUCT : Truenat™ MTB
LOT. NO. : TB078
MFG. DATE : 2018- 09
EXP. DATE : 2020- 08
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-TB-078a

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 CONTROLS			
Sr. No.		Test Lot (Ct Values)	
		MTB	IC
Specificity Tests		MTB	IC
Negative Control		ND	27.33
Positive Control		30.1	28.5
		29.67	28.2
		28.29	28.5
		28.56	28.75
		27.6	27.14
		30.14	28.33
		28.43	28.33
Standard deviation		± 0.99	± 0.52

*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

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Molbio Diagnostics Pvt. Ltd.

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

Works: Plot Nos. M 46-47, Phase III - B, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: 91 832 6624783/6682000 Fax: 91 832 2783139 E mail: admin@molbiodiagnostics.com

Office: No. UGO-7, Ground Floor, Ambrosia Residency, Cabesa, Alto Santacruz, Goa - 403 005. INDIA

Tel: 91 832 2458111/2458112 Email: sales@molbiodiagnostics.com

Website: www.molbiodiagnostics.com CIN: U33125GA2000PTC002909