



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date 30/10/2018

PRODUCT : Truenat™ MTB Plus

LOT. NO. : TP009

MFG. DATE : 2018- 10

EXP. DATE : 2020- 09

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. NO. : B-TP-009a

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	29.33
Positive Control		28.75	31.29
		28.67	34.17
		29.33	31.14
		29	31.4
Standard deviation		+ 0.30	+ 1.45
MTP11		28.33	30
TB076		30.5	31.2

*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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