



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date 13/07/2019

PRODUCT : Truenat™ MTB Plus

LOT. NO. : TP013

MFG. DATE : 2019- 07

EXP. DATE : 2021- 06

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. No. : B-TP-013a

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)	
		MTB	Control
Specificity Tests			
Negative Control		ND	33.6
Positive Control		29.17	32.33
		29.33	32.4
		30.83	32.75
		29.4	33.13
Standard deviation		± 0.77	± 0.37

\*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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