



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 29/08/2019

PRODUCT : Truenat™ MTB Plus

LOT. NO. : TP014

MFG. DATE : 2019- 08

EXP. DATE : 2021- 07

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. No. : B-TP-014a

**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)	
	<b>Specificity Tests</b>	<b>MTB</b>	<b>Control</b>
	<b>Negative Control</b>	ND	29.4
		ND	30.75
	<b>Positive Control</b>	29.17	28.0
		28.8	27.4
		28.6	28.13
		30.75	27.31
		30.5	28.6
		30.0	28.13
		29.14	28.5
		28.8	28.5
	<b>Standard deviation</b>	<b>+ 0.83</b>	<b>+ 0.49</b>

\*ND- Not detected

\*A deviation of  $\leq 1.5$  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**

For  
  
QUALITY CONTROL

Name: Dr. Praveen Kumar  
Designation: QC Head

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