



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
LOT. NO. : TB081
MFG. DATE : 2018- 10
EXP. DATE : 2020- 09
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-TB-081a

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 | IC |
| Specificity Tests | | | |
| Negative Control | | ND | 28 |
| Positive Control | | 28 | 31 |
| | | 28.6 | 30.6 |
| | | 29.2 | 30.75 |
| | | 28.6 | 30.33 |
| Standard deviation | | ± 0.49 | ± 0.28 |

*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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