



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company  
CERTIFICATE OF ANALYSIS

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

Date: 15/08/2020

|              |                                                                                          |
|--------------|------------------------------------------------------------------------------------------|
| BRAND NAME   | Truenat™ MTB-RIF Dx                                                                      |
| GENERIC NAME | Chip-based Real Time PCR Test for Rifampicin resistant <i>Mycobacterium tuberculosis</i> |
| LOT No.      | TX040                                                                                    |
| MFG. DATE    | 2020-07                                                                                  |
| EXP. DATE    | 2022-06                                                                                  |
| PACK SIZE    | 5T, 20T                                                                                  |
| STORAGE      | 2°C to 30°C                                                                              |
|              | A.R. No. : B-TX-040                                                                      |

PRECAUTION: Refer Safety Data Sheet and 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 no, 20 no.  | Pass        |
| 2       | Colour of desiccant pouch                                                       | Blue          | Pass        |
| 3       | Package insert                                                                  | 01 no.        | Pass        |

| PERFORMANCE       |       |       |         |                             |
|-------------------|-------|-------|---------|-----------------------------|
| Specificity Tests | Tm    |       | Control | Result                      |
|                   | P1    | P2    |         |                             |
| Sample 1          | 66.26 | 64.99 | 71.31   | RIF RESISTANCE DETECTED     |
|                   | 66.49 | 65.59 | 70.5    | RIF RESISTANCE DETECTED     |
|                   | 66.07 | 65.61 | 71.01   | RIF RESISTANCE DETECTED     |
|                   | 65.96 | 65.31 | 71.08   | RIF RESISTANCE DETECTED     |
| Sample 2          | 67.12 | 71.25 | 72.35   | RIF RESISTANCE NOT DETECTED |
|                   | 66.91 | 71.8  | 72.44   | RIF RESISTANCE NOT DETECTED |
|                   | 67.02 | 71.86 | 72.77   | RIF RESISTANCE NOT DETECTED |
|                   | 67    | 71.99 | 72.14   | RIF RESISTANCE NOT DETECTED |
|                   | 67.21 | 72.17 | 72.44   | RIF RESISTANCE NOT DETECTED |
|                   | 66.68 | 71.55 | 71.72   | RIF RESISTANCE NOT DETECTED |

\*Tm-Melting temperature, RIF-Rifampicin

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE

QUALITY CONTROL  
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Designation: QC Head

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## Molbio Diagnostics Private Limited

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