



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

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

Date: 10/11/2020

| | |
|---------------------|--|
| BRAND NAME | Truenat™ MTB-RIF Dx |
| GENERIC NAME | Chip-based Real Time PCR Test for Rifampicin resistant <i>Mycobacterium tuberculosis</i> |
| LOT No. | TX043 |
| MFG. DATE | 2020-10 |
| EXP. DATE | 2022-09 |
| PACK SIZE | 5T, 20T |
| STORAGE | 2°C to 30°C |
| A.R. No. : B-TX-043 | |


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 dessicant 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 | 66.1 | 65.45 | 70.29 | RIF RESISTANCE DETECTED |
| | 66.15 | 65.13 | 70.59 | RIF RESISTANCE DETECTED |
| Sample 2 | 65.85 | 71.41 | 71.19 | RIF RESISTANCE NOT DETECTED |
| | 66.58 | 72.03 | 69.92 | RIF RESISTANCE NOT DETECTED |
| | 66.24 | 71.61 | 70.96 | 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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