

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:25/07/2022
Doc ID: COA/TN/TX075d

| | | | |
|---------------------|--|---------------------|----------------------------|
| BRAND NAME | Truenat [®] MTB-RIF Dx | | |
| GENERIC NAME | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> | | |
| LOT No. | TX075 | CHIP LOT NO. | HDLW442 |
| MFG. DATE | 2022-03 | EXP. DATE | 2024-02 |
| PACK SIZE | 5T, 20T, 25T, 50T | | |
| STORAGE | 2°C to 30°C | | A.R. No.: B-TX-075d |


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, 25 no 50 no. | Pass |
| 2 | Colour of dessicant pouch | Orange | Pass |
| 3 | Package insert | 01 no. | Pass |

| PERFORMANCE | | | | |
|-------------------|-------|-------|---------|-----------------------------|
| Specificity Tests | Tm | | Control | Result |
| | P1 | P2 | | |
| Sample 1 | 66.65 | 67.07 | 70.36 | RIF RESISTANCE DETECTED |
| | 66.66 | 67.03 | 70.82 | RIF RESISTANCE DETECTED |
| | 66.52 | 67.12 | 70.63 | RIF RESISTANCE DETECTED |
| | 66.8 | 67.12 | 70.26 | RIF RESISTANCE DETECTED |
| Sample 2 | 66.86 | 72.24 | 70.43 | RIF RESISTANCE NOT DETECTED |
| | 67 | 72.36 | 69.94 | RIF RESISTANCE NOT DETECTED |
| | 66.96 | 72.33 | 69.78 | RIF RESISTANCE NOT DETECTED |
| | 67.05 | 72.4 | 69.92 | RIF RESISTANCE NOT DETECTED |
| | 67.07 | 67.07 | 69.5 | RIF RESISTANCE NOT DETECTED |
| | 66.61 | 66.61 | 70.38 | 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

For 
QUALITY CONTROL
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