



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 15/09/2021

Doc ID: COA/TN/ML014

| | |
|---------------------|---|
| BRAND NAME | Truenat [®] Malaria Pv/Pf |
| GENERIC NAME | Chip-based Real Time Duplex PCR Test for <i>Plasmodium vivax</i> and <i>Plasmodium falciparum</i> |
| LOT No. | ML014 |
| MFG. DATE | 2021-08 |
| EXP. DATE | 2023-07 |
| PACK SIZE | 5T, 20T, 50T |
| STORAGE | 2°C to 30°C |
| A.R. No. : B-ML-014 | |

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

| PERFORMANCE | | | |
|------------------------------|----------------------|--------|---------|
| CONTROLS | Test Lot (Ct Values) | | |
| Specificity Tests | Pv | Pf | Control |
| Negative Control | ND | ND | 29.5 |
| | ND | ND | 29.33 |
| Positive Control (Pv) | 26.8 | ND | 28.33 |
| | 26.6 | ND | 28.13 |
| Positive Control (Pf) | ND | 29.2 | 30.14 |
| | ND | 29.22 | 30.0 |
| Positive Control (Pv and Pf) | 29.6 | 29.8 | 29.8 |
| | 29.33 | 29.0 | 28.3 |
| | 28.57 | 28.44 | 28.29 |
| | 28.43 | 28.5 | 28.4 |
| Standard deviation | + 0.57 | + 0.62 | + 0.73 |

*ND- Not detected, Ct- Cycle threshold, Pv- *Plasmodium vivax*, Pf- *Plasmodium falciparum*

*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 QC APPROVED FOR SALE

QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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Molbio Diagnostics Private Limited

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