

MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

## CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 07/01/2022

|              |                                                                                                     |  |                       |
|--------------|-----------------------------------------------------------------------------------------------------|--|-----------------------|
| BRAND NAME   | Truenat® Positive Control Kit - Panel IV                                                            |  |                       |
| GENERIC NAME | Control Kit for Truenat® Chip-based micro PCR Tests: HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf |  |                       |
| LOT NO       | PCIV003                                                                                             |  |                       |
| MFG. DATE    | 2021-12                                                                                             |  |                       |
| EXP. DATE    | 2022-11                                                                                             |  |                       |
| PACK SIZE    | 08T                                                                                                 |  |                       |
| STORAGE      | 2°C to 40°C                                                                                         |  | A.R. No. : B-PCIV-003 |

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit                                                    | Specification | Observation |
|---------|---------------------------------------------------------------------------|---------------|-------------|
| 1       | Negative control                                                          | Present       | Present     |
| 2       | Positive control (08- strip tubes containing dried down positive control) | Present       | Present     |
| 3       | Package insert                                                            | Present       | Present     |

| Observation (Ct Value) |                    |                                    |                  |
|------------------------|--------------------|------------------------------------|------------------|
| Sr. No.                | Truenat® test name | Positive control                   | Negative control |
| 1                      | HAV                | 26.73± 0.3                         | ND               |
| 2                      | HEV                | 25.50 ± 0.2                        | ND               |
| 3                      | Rabies             | 28.13± 0.1                         | ND               |
| 4                      | LTS                | 27.71 ± 0.4                        | ND               |
| 5                      | Nipah              | 27.11± 0.6                         | ND               |
| 6                      | Malaria Pv/Pf      | Pv: 28.06 ± 0.1<br>Pf: 28.37 ± 0.5 | Pv: ND<br>Pf: ND |

\*ND- Not detected, Ct- Cycle threshold

\*A deviation of  $\leq 1.5$  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

Page 1 of 1

**Molbio Diagnostics Private Limited**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0

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