

**MOLBIO DIAGNOSTICS LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 15/10/2025  
Doc ID: COA/TN/PCII026

|              |                                                                                                                                  |  |                      |
|--------------|----------------------------------------------------------------------------------------------------------------------------------|--|----------------------|
| BRAND NAME   | Truenat <sup>®</sup> Positive Control Kit - Panel II                                                                             |  |                      |
| GENERIC NAME | Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: HBV, HCV, HIV-1, HLA-B27, Dengue, Chikungunya and Influenza A/B |  |                      |
| LOT NO       | PCII026                                                                                                                          |  |                      |
| MFG. DATE    | 2025-10                                                                                                                          |  |                      |
| EXP. DATE    | 2026-09                                                                                                                          |  |                      |
| PACK SIZE    | 08T                                                                                                                              |  |                      |
| STORAGE      | 2°C to 40°C                                                                                                                      |  | A.R. No.: B-PCII-026 |

**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 <sup>®</sup> test name | Positive control                                         | Negative control                     |
| 1                      | HBV                            | 28.68 ± 0.47                                             | ND                                   |
| 2                      | HCV                            | 27.76 ± 0.32                                             | ND                                   |
| 3                      | HIV-1                          | 28.90 ± 0.21                                             | ND                                   |
| 4                      | HLA-B27                        | 28.12 ± 0.94                                             | ND                                   |
| 5                      | Dengue/<br>Chikungunya         | Dengue : 27.40 ± 0.43<br>Chikungunya : 27.14 ± 0.25      | Dengue : ND<br>Chikungunya : ND      |
| 6                      | Influenza A/B                  | Influenza A : 26.95 ± 0.39<br>Influenza B : 28.19 ± 0.43 | Influenza A : ND<br>Influenza B : 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 MK  
Designation: QC Head

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