



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/11/2023

| | | | |
|--------------|---|----------|---------------|
| BRAND NAME | Truenat [®] Positive Control Kit - Panel III | | |
| GENERIC NAME | Control Kit for Truenat [®] Chip-based micro PCR Tests: CT, NG, Trich, HPV- _{HR} , GBS and Salmonella | | |
| LOT NO | PCIII013 | | |
| MFG. DATE | 2023-11 | | |
| EXP. DATE | 2024-10 | | |
| PACK SIZE | 08T | | |
| STORAGE | 2°C to 40°C | A.R. No. | : B-PCIII-013 |

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 | CT | 27.11 ± 0.35 | ND |
| 2 | NG | 28.03 ± 0.29 | ND |
| 3 | Trich | 28.34 ± 0.09 | ND |
| 4 | HPV- _{HR} | HP16/31: 27.90 ± 0.20 HP18/45: 27.15 ± 0.82 | HP16/31: ND HP18/45: ND |
| 5 | GBS | 29.50 ± 0.27 | ND |
| 6 | Salmonella | 27.95 ± 0.45 | ND |

*ND- Not detected, Ct- Cycle threshold

*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 RELEASED FOR SALE

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

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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0