



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 04/03/2024

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	PCIII015		
MFG. DATE	2024-02		
EXP. DATE	2025-01		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIII-015

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

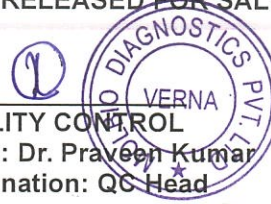
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat® test name	Positive control	Negative control
1	CT	27.92 ± 0.28	ND
2	NG	24.46 ± 0.22	ND
3	Trich	27.92 ± 0.55	ND
4	HPV-HR	HP16/31: 25.99 ± 0.15 HP18/45: 28.07 ± 0.59	HP16/31: ND HP18/45: ND
5	GBS	25.99 ± 0.15	ND
6	Salmonella	27.43 ± 0.38	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

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO