



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/11/2023

Doc ID: COA/TN/PCIII014

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	PCIII014		
MFG. DATE	2024-01		
EXP. DATE	2024-12		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIII-014

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	28.28± 0.13	ND
2	NG	27.21± 0.18	ND
3	Trich	27.28± 0.05	ND
4	HPV- _{HR}	HP16/31: 26.85± 0.02 HP18/45: 27.20± 0.11	HP16/31: ND HP18/45: ND
5	GBS	27.00± 0.80	ND
6	Salmonella	28.08± 0.18	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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