



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/08/2023

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	PCIII012		
MFG. DATE	2023-08		
EXP. DATE	2024-07		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIII-012

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	26.54 ± 0.68	ND
2	NG	27.30 ± 0.43	ND
3	Trich	27.90 ± 0.46	ND
4	HPV- _{HR}	HP16/31: 26.60 ± 0.58 HP18/45: 27.51 ± 0.31	HP16/31: ND HP18/45: ND
5	GBS	28.26 ± 0.56	ND
6	Salmonella	27.89 ± 0.29	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

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