



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 13/06/2022

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	PCIII006		
MFG. DATE	2022-05		
EXP. DATE	2023-04		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIII-006

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	26.15 ± 0.45	ND
2	NG	27.19 ± 0.66	ND
3	Trich	28.37 ± 0.54	ND
4	HPV- _{HR}	HP16:26.98 ± 0.58 HP18:27.14 ± 0.25	HP16:ND HP18: ND
5	GBS	28.77 ± 1.36	ND
6	Salmonella	25.85 ± 0.14	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
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Designation: QC Head
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Molbio Diagnostics Private Limited

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