



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 28/06/2023

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	PCIII011		
MFG. DATE	2023-06		
EXP. DATE	2024-05		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIII-011

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	27.07 ± 0.28	ND
2	NG	26.98 ± 0.14	ND
3	Trich	27.30 ± 0.26	ND
4	HPV- _{HR}	HP16/31: 27.42 ± 0.24 HP18/45: 27.39 ± 0.01	HP16/31: ND HP18/45: ND
5	GBS	28.64 ± 0.23	ND
6	Salmonella	26.55 ± 0.24	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

Page 1 of 1

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO