



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/05/2023

BRAND NAME	Truenat <sup>®</sup> Positive Control Kit - Panel III		
GENERIC NAME	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: CT, NG, Trich, HPV- <sub>HR</sub> , GBS and Salmonella		
LOT NO	PCIII010		
MFG. DATE	2023-05		
EXP. DATE	2024-04		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIII-010

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 <sup>®</sup> test name	Positive control	Negative control
1	CT	27.92 ± 0.72	ND
2	NG	27.33 ± 0.31	ND
3	Trich	26.81 ± 0.42	ND
4	HPV- <sub>HR</sub>	HP16/31: 26.23 ± 0.22 HP18/45: 27.41 ± 0.39	HP16/31: ND HP18/45: ND
5	GBS	28.31 ± 0.10	ND
6	Salmonella	28.54 ± 0.18	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  
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Molbio Diagnostics Private Limited

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