



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 07/10/2021

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	PCIII002		
MFG. DATE	2021-09		
EXP. DATE	2022-08		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIII-002

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	26.09 ± 0.71	ND
2	NG	29.91 ± 0.38	ND
3	Trich	28.39 ± 0.38	ND
4	HPV- <sub>HR</sub>	HP16: 27.54 ± 0.51 HP18: 28.99 ± 0.43	HP16:ND HP18: ND
5	GBS	28.14 ± 0.38	ND
6	Salmonella	29.50 ± 0.12	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

*for*  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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