



MOLBIO DIAGNOSTICS PRIVATE LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2019/000018

Date: 10/01/2024

Document ID: COA/TN/HP021b

Product Name	Truenat® HPV-HR
Generic Name	Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16,31 and 18,45
Lot No.	HP021
Set No.	b
Mfg. Date	2023-04
Exp. Date	2025-03
Pack Size	5T, 25T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data			
Samples	Ct Values		
	HPV 18/45	HPV 16/31	Control
Non Template Control	ND	ND	ND
Negative Sample	ND	ND	29.90 ± 0.39
Positive sample 1	ND	28.28 ± 0.26	28.73 ± 0.39
Positive sample 2	27.33 ± 0.10	ND	27.46 ± 0.43
Positive Sample 3	28.96 ± 0.73	28.96 ± 1.00	27.65 ± 1.06
ND – Not detected, Ct- Cycle threshold			

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.


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Molbio Diagnostics Private Limited

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