



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/IVD/2019/000018

Date: 22/02/2020

BRAND 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.	HP007
MFG. DATE	2020-01
EXP. DATE	2021-12
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-HP-007	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance			
CONTROLS	Test Lot (Ct Values)		
	HPV 16/31	HPV 18/45	Control
Specificity Tests			
Negative Control	ND	ND	32
Positive Control (HPV 16/31)	27.67	ND	33.8
Positive Control (HPV18/45)	ND	28.43	33.5
Positive Control (HPV 16/31 and HPV 18/45)	29.11	29.6	34.2
	28.64	30.63	34
Standard deviation	0.33	0.72	0.14

*ND- Not detected, Ct- Cycle threshold, HPV- Human Papillomavirus

*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 QC APPROVED FOR SALE

QUALITY CONTROL

Name: Dr. Praveen Kumar
Designation: QC Head

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