



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/TL/IVD/2019/000001

Date: 18-02-2020

BRAND NAME	Truenat™ HIV-1
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus
LOT No.	EHV27
MFG. DATE	2020-01
EXP. DATE	2021-12
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-EHV-27	

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	(Ct Values)	
	HIV-1	Control
Specificity Tests		
Negative Control	ND	29.4
Positive Control	31.17	29.4
	31.0	28.67
	30.8	28.67
	31.0	29.83
Standard deviation	± 0.15	± 0.57

*ND- Not detected, Ct- Cycle threshold, HIV-1- Human Immunodeficiency Virus type 1

*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 TESTING PURPOSE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head
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