



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/01/2021

BRAND NAME	Truenat™ HIV-1
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus
LOT No.	HV003
MFG. DATE	2020-12
EXP. DATE	2022-11
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HV-003	

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 dessicant 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)	
Specificity Tests	HIV-1	Control
Negative Control	ND	25.8
Positive Control	30.4	30.75
	31	30.14
	32	30.17
	31.4	31
Standard deviation	±0.67	± 0.42

*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 SALE


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

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