



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 25/10/2021

Doc. ID: COA/TN/HV008

BRAND NAME	Truenat® HIV-1
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus
LOT No.	HV008
MFG. DATE	2021-04
EXP. DATE	2023-03
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HV-008	

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, 50 no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HIV-1	Control
Negative Control	ND	31.14
Positive Control	29.33	26.8
	29.33	27.6
	30	28
	29.8	27.8
Standard deviation	±0.34	± 0.53

*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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