



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:23/09/2022
Doc ID: COA/TN/HV015a

BRAND NAME	Truenat [®] HIV-1		
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus		
LOT No.	HV015	CHIP LOT NO.	HDLW463
MFG. DATE	2022-09	EXP. DATE	2024-08
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HV-015a

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,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HIV-1	Control
Negative Control	ND	27.5
Positive Control	31.29	30.83
	31	30.89
	31.14	31
	30.75	30.5
Average	31.05	30.81
Standard deviation	±0.23	± 0.22

*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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