



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 01/07/2022

Doc ID: COA/TN/HB049

BRAND NAME	Truenat [®] HBV		
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis B Virus		
LOT No.	HB049	CHIP LOT No.	HDLW430
MFG. DATE	2022-06	EXP. DATE	2024-05
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-HB-049a

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 dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HBV	Control
Negative Control	ND	31
	ND	31.4
Positive Control	28.29	30
	31.1	29.5
	30.4	29.25
	31	31
	29.22	31.33
	31.3	30.25
	29.14	30.5
	30.14	29.38
Average	30.21	30.16
Standard deviation	± 0.98	± 0.71

*ND- Not detected, Ct- Cycle threshold, HBV- Hepatitis B Virus

*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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