



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 21/05/2022

Doc ID: COA/TN/HB047

BRAND NAME	Truenat <sup>®</sup> HBV		
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis B Virus		
LOT No.	HB047	CHIP LOT No.	HDLW404
MFG. DATE	2021-12	EXP. DATE	2023-11
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-HB-047R/f

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	30.0
Positive Control	28.13	28.67
	27.14	28.5
	28.0	29.11
	27.11	28.25
Average	27.59	28.63
Standard deviation	± 0.54	± 0.36

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

\*A deviation of  $\leq 1.5$  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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