



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/09/2022
Doc ID: COA/TN/HB051a

BRAND NAME	Truenat [®] HBV		
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis B Virus		
LOT No.	HB051	CHIP LOT No.	HDLW465
MFG. DATE	2022-09	EXP. DATE	2024-08
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-HB-051a

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	27.8
	ND	28.14
Positive Control	29.55	25.14
	29.67	25.2
	31	25.2
	29.33	25.5
	29.67	25.4
	30.88	25.4
	30.44	27
	30.71	25.25
Average	30.16	25.51
Standard deviation	± 0.67	± 0.61

*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

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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