



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 23-12-2019

BRAND NAME :	: Truenat™ HBV
GENERIC NAME :	: Chip-based Real Time PCR Test for Hepatitis B Virus
LOT No.	: HB040
MFG. DATE	: 2019- 12
EXP. DATE	: 2021- 11
PACK SIZE	: 5T, 20T
STORAGE	: 2°C to 30°C
	A.R. No. : B-HB-040b

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

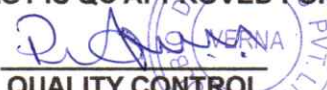
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HBV	Control
Negative Control	ND	28.2
Positive Control	30.17	29.88
	30.17	28.8
	30.8	29.2
	31.67	29.25
Standard deviation	± 0.71	± 0.44

*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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