



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 21/05/2020

BRAND NAME	Truenat™ HBV	
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis B Virus	
LOT No.	HB041	
MFG. DATE	2020-04	
EXP. DATE	2022-03	
PACK SIZE	5T, 20T	
STORAGE	2°C to 30°C	A.R. No.: B-HB-041

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

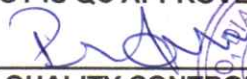
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass


PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HBV	Control
Negative Control	ND	27.67
Positive Control	28.38	29.33
	28	28.75
	29	29.8
	29	29.8
Standard deviation	± 0.49	± 0.49

*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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