



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 26/12/2020

<b>BRAND NAME</b>	Truenat™ HBV
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for Hepatitis B Virus
<b>LOT No.</b>	HB043
<b>MFG. DATE</b>	2020-08
<b>EXP. DATE</b>	2022-07
<b>PACK SIZE</b>	5T, 20T
<b>STORAGE</b>	2°C to 30°C
	<b>A.R. No.: B-HB-043</b>

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

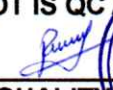

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HBV	Control
	ND	30.57
Positive Control	28.33	29.57
	27.8	30
	30	29.33
	30	31.17
Standard deviation	± 1.13	± 0.81

\*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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