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CERTIFICATE OF ANALYSIS

Product Name	Truenat® HBV
Generic Name	Chip-based Real Time PCR Test for Hepatitis B Virus
Licence No.	MFG/IVD/2021/000071
Lot No.	V0042HB
Mfg. Date	2026-07
Exp. Date	2028-06
Catalogue No./ (Pack size)	601090025/(25T)
Storage condition	2ºC to 30ºC
Document ID	COA/TN/V0042HB/25T
Date of Release	06/11/2026

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Physical Verification data			
Sr. No.	**Components in each kit**	**Specification**	**Observation**
01	Number of pouches as per pack size	Should be present	Present
02	Pouch Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 DNase and RNase free filter barrier microtip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data		
Samples	**Ct Values**	
	HBV	**Control**
Non Template Control	ND	ND
Negative Sample	ND	28.41 ± 0.10
Positive sample 1	24.37 ± 0.22	28.08 ± 0.39
Positive sample 2	28.24 ± 0.26	28.80 ± 0.27
Positive Sample 3	30.60 ± 0.66	26.56 ± 0.37
ND – Not detected, Ct- Cycle threshold		

Mfg- Manufacturing, Exp- Expiry, No.- Number, ID- Identification

The lot is tested and verified as per QC standards and is approved.

MOLBIO DIAGNOSTICS LIMITED GOA

Name: Dr. Praveen Kumar
Department: Quality Control
For **Designation:** QC Head

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