



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date: 04/07/2019

PRODUCT :Truenat™ HBV
LOT. NO. : HB038
MFG. DATE : 2019- 06
EXP. DATE : 2021- 05
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-HB-038

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

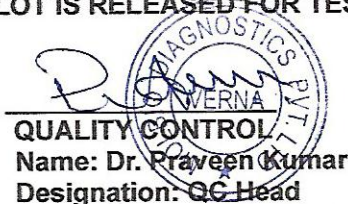
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos., 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance		
Sr. No.	CONTROLS	Test Lot (Ct Values)
Specificity Tests		HBV Control
Negative Control		ND 30.43
		ND 28.33
Positive Control		30.5 31.75
		31 29.8
		30.5 30.29
		29 31.47
		29.25 30.86
		31 31.67
		30 30.8
		29 31.14
Standard deviation		± 0.84 ± 0.68

*ND- Not detected

*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 RELEASED FOR TESTING PURPOSE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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