

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date:06/06/2022

Doc ID: COA/TN/HL018

BRAND NAME	Truenat [®] HLA-B27		
GENERIC NAME	Chip-based Real Time PCR Test for HLA-B27		
LOT No.	HL018	CHIP LOT NO.	HDLW412
MFG. DATE	2022-05	EXP. DATE	2024-04
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-HL-018a

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 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HLA	Conrol
Negative Control	ND	21
Positive Control	29.46	22.6
	27.5	23.17
	27.5	22.75
	28.75	23.6
Average	28.3	23.03
Standard deviation	± 0.97	± 0.45

*ND- Not detected, Ct- Cycle threshold, HLA- HLA-B27

*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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