



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date:13/10/2022
Doc ID: COA/TN/HL020b

BRAND NAME	Truenat [®] HLA-B27		
GENERIC NAME	Chip-based Real Time PCR Test for HLA-B27		
LOT No.	HL020	CHIP LOT NO.	HDLW479
MFG. DATE	2022-08	EXP. DATE	2024-07
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HL-020b

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	
	ND	23.4	
Positive Control	31	25	
	31.67	24.67	
	31.25	24.8	
	30	25	
Average	30.98	24.87	
Standard deviation	± 0.71	± 0.16	

*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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Molbio Diagnostics Private Limited

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