



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

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

Date:29/06/2022
Doc ID: COA/TN/HL019

BRAND NAME	Truenat [®] HLA-B27		
GENERIC NAME	Chip-based Real Time PCR Test for HLA-B27		
LOT No.	HL019	CHIP LOT NO.	HDLW429
MFG. DATE	2022-06	EXP. DATE	2024-05
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HL-019a

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	22.4
	ND	22.13
Positive Control	27.2	23.33
	27.25	23.33
	27.83	23.5
	27.33	24
	28.17	23.6
	28.3	24.33
	28.14	23.5
	28	23.5
Average	27.62	23.57
Standard deviation	± 0.46	± 0.30

*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
for Designation: QC Head
Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO