

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

Licence No.:MFG/IVD/2019/000003

Date: 02/02/2025

Document ID:COA/TN/HL033/20T

Product Name	Truenat [®] HLA-B27
Generic Name	Chip-based Real Time PCR Test for HLA-B27
Lot No.	HL033
Set No.	NA
Mfg. Date	2025-01
Exp. Date	2026-12
Pack Size	20T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.-0-0

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	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	
	HLA-B27	Control
Non Template Control	ND	ND
Negative Sample	ND	26.99 ± 0.18
Positive sample 1	23.04 ± 0.22	25.31 ± 0.15
Positive sample 2	24.76 ± 0.29	26.80 ± 0.38
Positive Sample 3	30.81 ± 1.30	24.69 ± 0.70

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

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

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

