

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

Licence No.:MFG/IVD/2019/000003

Date: 04/01/2025

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Product Name	Truenat [®] HLA-B27
Generic Name	Chip-based Real Time PCR Test for HLA-B27
Lot No.	HL030
Set No.	a
Mfg. Date	2024-07
Exp. Date	2026-06
Pack Size	20T
Storage condition	2°C to 30°C


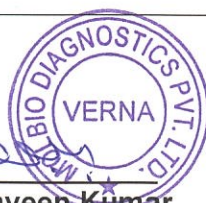
PRECAUTION: Refer Safety Data Sheet and Instructions for Use.-0-0

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	28.21± 0.44
Positive sample 1	23.06± 0.20	27.54± 0.51
Positive sample 2	26.20 ± 0.26	27.15 ± 0.10
Positive Sample 3	29.06 ± 0.33	25.81 ± 0.24
ND – Not detected, Ct- Cycle threshold		

*Mfg- Manufacturing, Exp- Expiry

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



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