



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

Licence no.:MFG/IVD/2019/000003

Date: 09/05/2024

Document ID:COA/TN/HL026e/25T

Product Name	Truenat [®] HLA-B27
Generic Name	Chip-based Real Time PCR Test for HLA-B27
Lot No.	HL026
Set No.	e
Mfg. Date	2023-05
Exp. Date	2025-04
Pack Size	25T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

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	26.02 ± 0.34
Positive sample 1	21.77 ± 0.81	26.07 ± 0.50
Positive sample 2	23.70 ± 0.18	26.64 ± 0.37
Positive Sample 3	28.35 ± 0.83	24.84 ± 0.52

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0