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CERTIFICATE OF ANALYSIS

Product Name	**Truenat® HLA-B27**
Generic Name	**Chip-based Real Time PCR Test for HLA-B27**
Licence No.	**MFG/IVD/2025/000148**
Lot No.	**I0009HL**
Mfg. Date	**2026-09**
Exp. Date	**2028-08**
Catalogue No./(Pack Size)	**601380005/(5T), 601380020/ (20T), 601380025/(25T), 601380050/(50T)**
Storage condition	**2°C to 30°C**
Document ID	**COA/TN/I0009HL**
Date of Release	**07/11/2026**

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Physical verification data			
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 DNase and RNase free filter barrier microtip	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	19.83 ± 0.20
Positive Sample 1	21.14 ± 0.65	19.85 ± 0.62
Positive Sample 2	22.25 ± 0.41	19.41 ± 0.52
Positive Sample 3	23.56 ± 0.65	21.83 ± 0.21
ND - Not detected, Ct- Cycle threshold		

Mfg- Manufacturing, Exp- Expiry, No.- Number, ID- Identification

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

MOLBIO DIAGNOSTICS LIMITED GOA

11/11/26

for **Name: Dr. Praveen Kumar M.K.**
Department: Quality Control
Designation: QC Head