Molbio Diagnostics Limited
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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.	**I0010HL**
Mfg. Date	**2026-09**
Exp. Date	**2028-08**
Catalogue No./(Pack Size)	**601380005/(5T), 601380025/(25T)**
Storage condition	**2°C to 30°C**
Document ID	**COA/TN/I0010HL**
Date of Release	**11/11/2026**

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	22.26 ± 0.25
Positive Sample 1	21.27 ± 0.38	19.68 ± 0.27
Positive Sample 2	21.94 ± 0.66	19.82 ± 1.15
Positive Sample 3	23.70 ± 0.45	21.99 ± 0.27
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

for 11/11/26
Name: Dr. Praveen Kumar M.K.
Department: Quality Control
Designation: QC Head