

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

Licence No.:MFG/IVD/2019/000003

Date: 11/02/2025

Document ID:COA/TN/HL034/20T

| | |
|-------------------|---|
| Product Name | Truenat [®] HLA-B27 |
| Generic Name | Chip-based Real Time PCR Test for HLA-B27 |
| Lot No. | HL034 |
| 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.

| 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 | 27.00 ± 0.33 |
| Positive sample 1 | 23.63 ± 0.22 | 25.47 ± 0.23 |
| Positive sample 2 | 25.28 ± 0.31 | 26.87 ± 0.39 |
| Positive Sample 3 | 30.68 ± 0.89 | 25.16 ± 0.13 |

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 Kuntar
Department: Quality Control
Designation: QC Head

