



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

Licence No.: MFG/IVD/2019/000003

Date: 27/07/2023

Document ID: COA/TN/HL026a

| | |
|-------------------|---|
| Product Name | Truenat® HLA-B27 |
| Generic Name | Chip-based Real Time PCR Test for HLA-B27 |
| Lot No. | HL026 |
| Set No. | a |
| Mfg. Date | 2023-05 |
| Exp. Date | 2025-04 |
| Pack Size | 5T, 20T, 25T |
| Storage condition | 2°C to 30°C |


PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

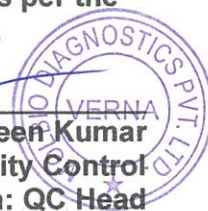
| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|-------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present | Present |
| 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 | 24.24 ± 0.24 |
| Positive sample 1 | 22.00 ± 0.86 | 26.62 ± 0.35 |
| Positive sample 2 | 26.14 ± 0.73 | 28.22 ± 0.67 |
| Positive Sample 3 | 28.46 ± 0.45 | 25.40 ± 0.15 |
| 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.

For 
Name : Dr. Praveen Kumar
Department: Quality Control
Designation: QC Head



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