

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence no.: MFG/TL/IVD/2022/000402

Date: 14/05/2025

Document ID: COA/TN/03EBRa/20T

| | |
|-------------------|-----------------------------------------------|
| Product Name | Truenat [®] Brucella |
| Generic Name | Chip-based Real Time PCR Test for Brucellosis |
| Lot No. | 03EBR |
| Set No. | a |
| Mfg. Date | 2025-03 |
| Exp. Date | 2027-02 |
| 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 | Pouch 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 | |
| | Brucella | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 26.43 ± 0.39 |
| Positive sample 1 | 23.60 ± 1.44 | 26.68 ± 0.34 |
| Positive sample 2 | 27.76 ± 0.70 | 27.59 ± 0.97 |
| Positive Sample 3 | 29.42 ± 0.31 | 25.32 ± 0.29 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

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

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

