

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date: 05/04/2025**

**Document ID: COA/TN/02EBRa/20T**

<b>Product Name</b>	<b>Truenat<sup>®</sup> Brucella</b>
<b>Generic Name</b>	<b>Chip-based Real Time PCR Test for Brucellosis</b>
<b>Lot No.</b>	<b>02EBR</b>
<b>Set No.</b>	<b>a</b>
<b>Mfg. Date</b>	<b>2025-02</b>
<b>Exp. Date</b>	<b>2027-01</b>
<b>Pack Size</b>	<b>20T</b>
<b>Storage condition</b>	<b>2°C to 30°C</b>

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
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

<b>Performance testing data</b>		
<b>Samples</b>	<b>Ct Values</b>	
	<b>Brucella</b>	<b>Control</b>
<b>Non Template Control</b>	ND	ND
<b>Negative Sample</b>	ND	25.49 ± 0.49
<b>Positive sample 1</b>	24.45 ± 0.57	27.20 ± 0.47
<b>Positive sample 2</b>	27.57 ± 0.79	27.43 ± 0.19
<b>Positive Sample 3</b>	30.65 ± 0.65	24.35 ± 0.20

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**

