Efficient screening test for the detection of anti-Brucella antibodies in bovines

- Broad antigen spectrum for high sensitivity
- Efficient automation solutions available

Technical data

- **Antigen**: Suitable components of Brucella, native
- **Calibration**:
  - Semiquantitative: Calculation of a ratio from the extinction of the sample and the extinction of the calibrator
- **Result interpretation**: EUROIMMUN recommends interpreting results as follows:
  - Ratio < 0.8: negative
  - Ratio \( \geq 0.8 \) to < 1.1: borderline
  - Ratio \( \geq 1.1 \): positive
- **Sample dilution**: Bovine serum or plasma, 1:101 in sample buffer
- **Reagents**: Ready for use, with the exception of the wash buffer (10 x), colour-coded solutions
- **Test procedure**: 30 min (37°C) / 30 min (37°C) / 15 min (room temperature), fully automatable
- **Measurement**: 450 nm, reference wavelength between 620 nm and 650 nm
- **Test kit format**: 96 break-off wells; kit includes all necessary reagents
- **Order number**: EI 2189-9601 GB

Clinical significance

Brucellosis is a long known zoonotic disease in humans and animals which is caused by gram-negative bacteria of the Brucella genus. Brucella is classified as risk group III by the WHO. Various species of Brucella were isolated from bovines, with Brucella abortus being identified as the most frequent cause of bovine brucellosis. If cattle are held in direct vicinity of small ruminants such as sheep or goat, infections with Brucella melitensis may also occur. Dogs and cats can also be vectors of Brucella. Bovine brucellosis should generally be considered as a herd problem. Transmission of the pathogen can be oral, but also venereal, congenital or perinatal.

Infections in non-pregnant cows usually proceed asymptptomatically, whereas in pregnant cows the following symptoms or sequelae are observed: late abortion, retained placenta, subclinical mastitis, sterility and, in rare cases, tendinitis and joint inflammation. Male animals experience orchitis and epididymitis. Brucella is excreted by infected animals via milk and uterine secretion and can therefore also be transmitted to humans, thus becoming a severe health problem. Human brucellosis is considered as the most widely distributed zoonosis, with 500,000 new infections per year.

The economic loss from abortion, decreased milk production and infertility, and the transmission of the disease to other species, including humans, is significant. In most countries brucellosis is under control. Some countries such as northern and central Europe, Canada, Japan, Australia and New Zealand are considered as brucellosis-free. In structurally weak regions, however, the disease is often unknown or disregarded, particularly with respect to the transmission via dairy and meat products.

There are various studies about vaccinations and eradication strategies for brucellosis in bovines. However, the optimal vaccine has not yet been found. Drawbacks of currently used vaccines are, for instance, a potential infection risk for humans, the triggering of abortions in pregnant animals and the interference with diagnostic assays. Besides vaccination, eradication strategies also include hygiene instructions, the so-called “test and slaughter policy” and continuous monitoring.
Reliable diagnosis can only be achieved by direct detection of Brucella in the affected tissue, e.g. from the placenta or lymph nodes. This procedure, however, is complicated, and also constitutes a potential infection risk for the laboratory staff. For this reason, various serological test systems for the detection of antibodies against Brucella have been developed, including the complement fixation test (CFT) and Rose Bengal test (RBT). But these tests are time-consuming and limited with respect to sensitivity and standardisation. The CFT, for instance, is recommended by the OIE (Office International des Epizooties; World Organisation for Animal Health) for monitoring of the international cattle trade, despite disadvantages with respect to performance, expenditure of time and standardisation. The RBT can only be used for monitoring in Brucella-free regions. The OIE names various serological tests for the detection of bovine antibodies against Brucella, including the above-mentioned CFT and RBT, as well as ELISA and fluorescence polarisation. However, the Organisation also points out that none of these tests is suited for all epidemiological situations and that a positive result should always be verified using a confirmatory test.

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using three samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on four determinations performed in six different test runs.

The sensitivity and specificity was determined by investigating 45 samples from cattle. The results were then compared with those of a commercially available multi-species ELISA for the detection of antibodies against Brucella. The tested samples encompassed also international standard sera of the Animal and Plant Health Agency (APHA, an international reference laboratory for brucellosis, recognised by FAO/OIE/WHO). The sensitivity and specificity of the Anti-Brucella ELISA Bovine (IgG) were 100%. Borderline results were not included in the calculation.

The reproducibility and sensitivity and specificity are presented in the following tables:

<table>
<thead>
<tr>
<th>Serum</th>
<th>Intra-assay variation, n = 20</th>
<th>Inter-assay variation, n = 4 x 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean value (ratio) CV (%)</td>
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</tr>
<tr>
<td>1</td>
<td>1.7 2.9</td>
<td>1.9 5.3</td>
</tr>
<tr>
<td>2</td>
<td>1.8 3.4</td>
<td>2.1 10.4</td>
</tr>
<tr>
<td>3</td>
<td>2.8 5.2</td>
<td>3.3 11.4</td>
</tr>
</tbody>
</table>

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<tr>
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<th>n = 45</th>
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<tbody>
<tr>
<td>positive</td>
<td>7</td>
</tr>
<tr>
<td>borderline</td>
<td>2</td>
</tr>
<tr>
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<td>0</td>
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Literature