BRUCELLA BENGAL ROSE SLIDE

Determination of antibodies associated to Brucella by means of coloured with Bengal Rose bacterial suspension on slide

TEST SUMMARY
Specific IgG or IgM antibodies associated to Brucella infections cause the agglutination of inactivate bacteria present in suspension. The coloration allows an easy reading of agglutination. The reagent, because of its formulation in an acid buffer, is reactive with both IgG and IgM antibodies and very useful for the diagnosis of chronic individuals, which present a high level of IgG antibody, difficult to be detected by the reference tube method (Wright).

SAMPLES
Fresh clear serum. Stability 7 days at 2-8°C or 3 months at –20°C. Keep at room temperature before the analysis. Do not freeze repeatedly. Samples with presence of fibrin should be centrifuged before use. Do not use highly hemolized or lipemic samples.

REAGENTS
Suspension: Brucella abortus suspension in lactate buffer 1 mol/L, phenol 5 g/L, Rose Bengal, pH 3.6.

Brucella Positive control: Solution of rabbit antisera that gives a clear agglutination with Brucella Suspension; conservative and stabilizer.

Negative control: Non-reactive protein bovine solution with suspension, conservatives and stabilizers.

REAGENTS PREPARATION
Reagents are ready to use. Bacterial suspension has to be carefully resuspended shaking it more times for inversion. Stability: until expiration date on label stored at 2-8°C. Do not freeze.

MATERIALS REQUIRED BUT NOT SUPPLIED
Salin solution NaCl 9 g/L. Slide and stirrer. Current laboratory instrumentation.

PRECAUTIONS
Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general “Good Laboratory Practice” (GPL) guidelines.

QUALITATIVE PROCEDURE

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Sample</th>
<th>Positive control</th>
<th>Negative control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>50 µl</td>
<td>50 µl</td>
<td>50 µl</td>
</tr>
<tr>
<td>Brucella</td>
<td>50 µl</td>
<td>50 µl (1 gtt)</td>
<td>50 µl (1 gtt)</td>
</tr>
</tbody>
</table>

Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample. Place the slide on a mechanical rotator at 80-100 r.p.m. for 4 minutes. An excess of agitation time may cause false positive.

SEMI-QUANTITATIVE PROCEDURE
Make serial two fold dilutions of the sample in 9 g/L saline solution and proceed for each dilution as in the qualitative method.

RESULTS INTERPRETATION
Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates an antibody anti-Brucella concentration equal or greater than 25 IU/mL.

A homogeneous suspension without visible agglutination indicates negativity. The titre, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

The approximate antibody concentration in the patient sample is calculated as follows:

\[ 25 \times \text{anti-Brucella Titre} = \text{IU/mL} \]

REFERENCES

PACKAGING

| CODE BS00960 | Slide Suspension Brucella Rose 1 x 5 ml
| CODE BS00950 | Slide Suspension Brucella Rose 1 x 5 ml
| Brucella Positive control 0.5 ml | Negative control 0.5 ml
| CODE BS00955 | Slide Suspension Brucella Rose 6 x 5 ml
| Brucella Positive control 0.5 ml | Negative control 0.5 ml

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SYMBOLS

| IVD | Only for IVD use |
| Lot | Lot of manufacturing |
| REF | Code number |
| Storage temperature interval |
| Expiration date (year, month) |
| Warning, read enclosed documents |
| Biological risk |

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