BRUCELLA BENGAL ROSE SLIDE

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

TEST SUMMARY
Antibodies associated to Brucella Bengal Rose infections cause the agglutination of inactive bacteria present in suspension. The coloration allows an easy reading of agglutination.

SAMPLES
Fresh clear serum. Stability 7 days at 2-8°C. Freeze for longer period at –20°C, and keep at room temperature before the analysis. Do not freeze repeatedly. Turbid samples have to be centrifuged.

REAGENTS
Suspension: Coloured bacterial suspension, conservatives and stabilizers.
Brucella
Positive control: Solution of rabbit antisera that gives a clear agglutination with Brucella Suspension; conservative and stabilizer.
Negative control: Non-reactive Proteinous 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
Physiological solution. Slide and stirrer. Automatic 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>80 µl</td>
<td>50 µl</td>
<td>50 µl</td>
</tr>
<tr>
<td>Positive control</td>
<td>80 µl + 1/320</td>
<td>50 µl + 1/640</td>
<td>50 µl + 1/1280</td>
</tr>
<tr>
<td>Negative control</td>
<td>80 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
</tr>
</tbody>
</table>

Mix with a stirrer and spread over the entire area enclosed by the ring. Shake for one minute by rotating movement or with a mechanical shaker at 100 r.p.m.

RESULTS INTERPRETATION

The title of the serum examined is due to the most higher dilution in which is showed a clear positivity.

EXPECTED VALUES
Tities up to 1:40; have to be considered negative, and suspected from 1:80 to 1:160. Exceeded titiles to 1:160 show a recent infection.

For infection diagnosis is distinctive the significative increasing of the title among examined samples from days distance.

NOTE
• If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
• Only for IVD use.

CALIBRATION/QUALITY CONTROL
Controls, eventually supplied in the kit, ought to be used ever used to distinguish an eventual agglutination of the bottom of reagent.

Controls should be used as described in procedures or even to be treated as samples (dilution, ecc.).

TEST PERFORMANCE

Sensibility
The method sensibility decrease at low temperature. Better results will be obtained at higher temperature up to 10°C.

The sensibility 100 UI/ml.

No prozone phenomenon were observed for concentrations of anti-brucella Abortus studied up to a title 1000 UI/ml.

Interference
No interference was observed by the presence of:

- hemoglobin ≤ 1000 mg/dl
- lipids ≤ 1000 mg/dl
- rheumatic factor ≤ 300 UI/ml

The Bilirubin interferer to concentration > 2.5 mg/dl.

Recent infection ad immunodepression can do false negativity.

WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.