BRUCELLA TOTAL MACRO

Determination of antibodies associated with Brucella infections by coloured bacterial suspension in test-tube

**TEST SUMMARY**
The Antibodies associated with Brucella infections cause agglutination of inactive bacteria present in suspension. The intravitral colouring permits an easier reading of agglutination formation.

**SAMPLES**
Serum:
Stability 6 days at 4°C.

**REAGENTS**
Suspension: Coloured intravitral inactive bacterial suspension; conservative and stabilizer.

**REAGENTS PREPARATION**
Reagents are ready for the use. The bacterial suspension must be resuspended with much care, shaking many times by inversion. Stability: the components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

**MATERIAL REQUIRED BUT NOT SUPPLIED**

**PRECAUTIONS**
Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

**PROCEDURE**
In a 8 tubes serie (12 x 100 mm) dilute the serum in the first 7 with physiologic solution as indicated in the following table. Using the same pipette (inspiring and discharging many times) mix carefully content of the second tube and transfer 500 µl in the following tube etc. Discharge 500 µl from last tube (tube n°7).

<table>
<thead>
<tr>
<th>Test tubes</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>...</th>
<th>7</th>
<th>Serum Conc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiologic Sample</td>
<td>900 µl</td>
<td>500 µl</td>
<td>500 µl</td>
<td>...</td>
<td>500 µl</td>
<td>500 µl</td>
</tr>
<tr>
<td>Sample</td>
<td>100 µl</td>
<td>500 µl</td>
<td>500 µl</td>
<td>...</td>
<td>500 µl</td>
<td>500 µl</td>
</tr>
</tbody>
</table>

Discharge 500 µl from last test tube

Discharge 500 µl from last test tube

Bacterial suspension

<table>
<thead>
<tr>
<th>500 µl</th>
<th>500 µl</th>
<th>500 µl</th>
<th>...</th>
<th>500 µl</th>
<th>500 µl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube</td>
<td>1.20</td>
<td>1.40</td>
<td>1.80</td>
<td>...</td>
<td>1.2800</td>
</tr>
</tbody>
</table>

Shake tubes by a sweet movement. Incube at 37°C for 16-18 h or at 22°C for 2 days.

Shake before the 8th tube (suspension control) to can characterize the suspension, then shake tubes that contain the sample and value the precipitate’s behaviour as regards that of suspension’s control. The negativity is given by absence of agglutinates (the same behaviour as regards that suspension’s control), positivity shows, on the contrary, the presence of agglutinates always as bigger as the positivity is greater.

The agglutination of somatic component has an uncother appearance and persists also after the shaking, while the ciliary component has a flaky appearance and tends to dissolve by shaking.

The serum titre is given by a higher dilution in which there is a feeble positivity.

**DIAGNOSTIC VALUES**
Titres until 1:40 are considered negative; from 1:80 to 1:160 are suspect, and from 1:320 are positive. It is a distinctive sign for the infection diagnosis the significant increase of titre between examined samples after some days.

**NOTES**
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.
- It’s advisable the execution of a quality internal control. In order to do this, are available by request the following control sera.
- BS00011 3 x 0,5 ml
- Positive Control Salmonella, Brucella, Proteus

**TEST PERFORMANCE**
Sensitivity
In presence of high antibodies titres, phenomenon of prozone can happen, therefore positivity is absent for low dilutions also being present for higher dilutions.

Specificity
A comparison with an available commercial method gave following results on 50 samples compared, giving a specificity = 100%.

**REFERENCES**
Rose N.R., Friedman H. – Manual of clinical Immunology – American Society for Microbiology, II ed.

**MATERIALS**
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**SYMBOLES**
- IVD Only for IVD use
- LOT Lot of manufacturing
- REF Code number
- Storage temperature interval
- EXPIRATION Expiration date
- WARNING Warning, read enclosed documents
- READ Read the directions
- BIOLOGICAL Biological risk

**BIODATA**
Mod. 01.06 (ver. 2.2 - 29/10/2007)

**COMPETITIONS**
<table>
<thead>
<tr>
<th>LTA srl</th>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>POSITIVE ABORTUS</td>
<td>12</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>POSITIVE MELITENESIS</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>POSITIVE ABORTUS &amp; MELITENESIS</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>0</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>TOTAL</td>
<td>21</td>
<td>29</td>
<td>50</td>
</tr>
</tbody>
</table>

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

**PACKAGING**
**CODE MA00900**
Brucella Total macro suspension 1 x 20 ml
**CODE MA00905**
Brucella Total macro suspension 5 x 20 ml

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