**BRUCELLA ABORTUS SLIDE**

Determination of antibodies associated to Brucella Abortus infections by means of coloured bacterial suspension on slide

**TEST SUMMARY**

Antibodies associated to Brucella Abortus infections cause the agglutination of inactivate 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.

- **Positive control:** Solution of rabbit antisera that gives a clear agglutination with Brucella Suspension: conservative and stabilizer.
- **Negative control:** Non-reactive Proteinose 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 micropipette.
- 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>80 µl</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Positive control</td>
<td>50 µl</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Negative control</td>
<td>50 µl (1 gl)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Suspension</td>
<td>50 µl (1 gl)</td>
<td>50 µl (1 gl)</td>
<td>50 µl (1 gl)</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**

Agglutination into time established means positivity, an agglutination after three minutes means a feeble positivity.

If the sample is positive is opportune title the serum with macro or micro method.

**QUANTITATIVE PROCEDURE**

Is suggested the use of macro suspensions and furthermore micro suspensions which have buffers purposely studied to guarantee a certain analysis result. The analytical method is anyhow reported to establish the title with slide suspensions even if this technology has underlining limits.

<table>
<thead>
<tr>
<th>Tube</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiol</td>
<td>1.9 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
</tr>
<tr>
<td>Serum</td>
<td>100 µl</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
<td>1 ml</td>
</tr>
<tr>
<td>from</td>
<td>1</td>
<td>1 from</td>
<td>2</td>
<td>1 from</td>
<td>3</td>
<td>1 from</td>
<td>5</td>
</tr>
<tr>
<td>Discharge</td>
<td>1 ml from the last tube</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXPECTED VALUES**

Tittles up to 1:40; have to be considered negative, and suspected from 1:80 to 1:160. Exceded titles 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 ever used to distinguish an eventual agglutination of the bottom of reagent.

**TEST PERFORMANCE**

- **Sensitivity:** The method sensibility decrease at low temperature. Better results will be obtained at higher temperature up to 10°C.
- **Interference:** No interference was observed by the presence of:
  - hemoglobin < 1000 mg/dl
  - bilirubin < 20 mg/dl
  - lipids < 1000 mg/dl
  - rheumatic factor < 300 IU/ml

**WASTE DISPOSAL**

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

**REFERENCES**


**PACKAGING**

- **CODE AF-19**
  - Slide Suspension Brucella Abortus 1X 5 ml
  - Positive Control 1X 0.5 ml
  - Negative Control 1X 0.5 ml
  - Slide 2

**SYMBOLS**

- IVD: Only for IVD use
- Storage temperature interval
- Expiration date
- Lot: Lot of manufacturing
- Code number
- Read the directions

**MANUFACTURER**

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