SALMONELLA TYPHI H SLIDE

Determination of antibodies associated to salmonella Typhi H by means of coloured bacterial suspension on slide

TEST SUMMARY
Antibodies associated to Salmonella Typhi H 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.

- Salmonella Positive control: Solution of rabbit antisera that gives a clear agglutination with Salmonella 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

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” (GMP) 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</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Suspension</td>
<td>50 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
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 underlying 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>
<th>Contr. Susp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phys.</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>
<td>1 ml</td>
</tr>
<tr>
<td>Serum</td>
<td>100 µl</td>
<td>from 1</td>
<td>from 2</td>
<td>from 3</td>
<td>from 4</td>
<td>from 5</td>
<td>from 6</td>
<td>--</td>
</tr>
</tbody>
</table>

Discharge 1 ml from the last tube

<table>
<thead>
<tr>
<th>Variability</th>
<th>1 gt</th>
<th>1 gt</th>
<th>1 gt</th>
<th>1 gt</th>
<th>1 gt</th>
<th>1 gt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titre</td>
<td>1:25</td>
<td>1:40</td>
<td>1:80</td>
<td>1:160</td>
<td>1:320</td>
<td>1:640</td>
</tr>
</tbody>
</table>

Shake carefully the tubes. Incubate 24 hours at 37°C. Follow the illustrated modality in macro method to establish the titles.

RESULTS INTERPRETATION
The title of the serum examined is due to the most higher dilution in which is showed a feeble positivity. Use of control sera is recommended as reference; the positive control ought to show a partial or complete agglutination, instead the negative control ought to show no agglutination.

EXPECTED VALUES
Titres up to 1:40; have to be considered negative, and suspected from 1:80 to 1:160. Exceeded 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
- Flagellate agglutination is marked by rapid forming and easily separable.
- 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
Sensibility
The method sensibility decrease at low temperature. Better results will be obtained at higher temperature up to 10°C.

No prozone phenomenon were observed for concentrations studied up to a titre ≤ 1/4096.

Interference
No interference was observed by the presence of:
- hemoglobin bilirubin lipids < 1000 mg/dl
- rheumatic factor < 20 mg/dl
- < 1000 mg/dl
- < 300 lU/ml

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.