SALMONELLA PARATYPHI CH MACRO

Determination of antibodies associated with Salmonella ParaTyphi CH infections by coloured bacterial suspension in test-tube

TEST SUMMARY
The Antibodies associated with Salmonella ParaTyphi CH infections cause agglutination of inactive bacteria present in suspension. The intratidal colouring permits an easier reading of agglutination formation.

SAMPLES
Serum.
Stability 6 days at 4°C.

REAGENTS
Suspension: Coloured intratidal 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 inactive bacteria present in suspension. 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.

RESULTS INTERPRETATION
Shake before the 8th tube (suspension control) to can characterize the suspension, then shake tubes that contain the sample and value the precipitate’s appearance 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.

CALIBRATION/QUALITY CONTROL
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%.

COMPETITORS
<table>
<thead>
<tr>
<th>LTA srl</th>
<th>TOT.</th>
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<tr>
<td>+</td>
<td>13</td>
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<td></td>
<td>0</td>
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<td></td>
<td>37</td>
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WASTE DISPOSAL
Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING
CODE MA0700 S. Paratyphi CH macro suspension 1 x 20 ml
CODE MA0705 S. Paratyphi CH macro suspension 5 x 20 ml

REFERENCES
Rose N.R., Friedman H. – Manual of clinical Immunology – American Society for Microbiology, 2 ed.

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SYMBOLS

IVD Only for IVD use
LOT Lot of manufacturing
REF Code number
Storage temperature interval
Expiration date
Warning, read enclosed documents
Read the directions
Biological risk

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