

SALMONELLA PARATYPHI CH SLIDE

Determination of antibodies associated to salmonella paraTyphi CH by means of coloured bacterial suspension on slide

TEST SUMMARY

Antibodies associated to Salmonella paraTyphi CH 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.

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. Automatically 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

| Reagents | Sample | Positive control | Negative control |
|---------------------------------|----------------|------------------|------------------|
| Serum | 80 µl | -- | -- |
| Positive control (Not supplied) | -- | 50 µl | -- |
| Negative control (Not supplied) | -- | -- | 50 µl |
| Suspension | 50 µl (1 drop) | 50 µl (1 drop) | 50 µl (1 drop) |

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. If the sample is positive is opportune title the serum with macro or micro method. Smooth suspension with no visible agglutination is negative.

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.

| Tube | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Contr. Sosp. |
|---|--------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| Physiol. | 1.9 ml | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml | 1 ml |
| Serum | 100 µl | 1 ml from 1 | 1 ml from 2 | 1 ml from 3 | 1 ml from 4 | 1 ml from 5 | 1 ml from 6 | -- |
| Discharge 1 ml from the last tube | | | | | | | | |
| Bacterial Susp. | 1 gt | 1 gt | 1 gt | 1 gt | 1 gt | 1 gt | 1 gt | 1 gt |
| Title | 1/20 | 1/40 | 1/80 | 1/160 | 1/320 | 1/640 | 1/1280 | -- |
| Shake carefully the tubes. Incubate 24 hours at 37°C. | | | | | | | | |

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

Titers greater 1/160 indicates 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 should be ever used to distinguish an eventual agglutination of the bottom of reagent. The following controls are available on request:

BS00011 3 x 0.5 ml
FebriLe Positive Control
(0.5 ml Salmonella, 0.5 ml Brucella, 0.5 ml Proteus)

BS00020 1 x 1 ml
FebriLe Negative Control

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.

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

Interference

No interference was observed by the presence of:

| | |
|------------------|--------------|
| hemoglobin | ≤ 1000 mg/dl |
| bilirubin | ≤ 20 mg/dl |
| lipids | ≤ 1000 mg/dl |
| rheumatic factor | ≤ 300 UI/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.

PACKAGING

CODE BS00710

Slide Suspension S. paratyphi CH 1 x 5 ml

REFERENCES

Edward J Young. Clinical Infectious Diseases 1995; 21: 283-290.
David A et al. Current Opinion in Infectious Diseases 1994; 7: 616-623.
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Chart H. Serodiag Immunother Infect Diseases 1995; 7: 34-39.
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Bradley D Jones. Annu Rev Immunol 1996; 14: 533-561.

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SYMBOLS

-  Only for IVD use
-  Lot of manufacturing
-  Code number
-  Storage temperature interval
-  Expiration date (year, month)
-  Warning, read enclosed documents
-  Read the directions
-  Biological risk

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