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

TEST SUMMARY
Slide and tube agglutination test for the qualitative and semi-quantitative detection of antibodies associated to Salmonella Typhi H infections.

Samples containing the specific antibody cause the agglutination of inactivate bacteria present in suspension. The intravitral coloring allows an easier reading of the formation of the agglutinates.

High levels of agglutinating antibodies are indicative of infection by these microorganisms.

SAMPLES
Fresh clear serum. Stability 7 days at 2-8°C or 3 months at -30°C. Do not freeze repeatedly.

The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

Bring to room temperature before analysis.

REAGENTS
Suspension: Inactivated and intravitral colored bacterial suspension in glycine buffer pH 8.2; preservatives.

MATERIALS REQUIRED BUT NOT SUPPLIED
Saline Solution NaCl 9 g/L. Positive Control serum and Negative Control serum. Slide and stirrer. Automatically micropipette. Mechanical stirrer at 100 r.p.m. Incubator 37°C. Current laboratory instrumentation.

PRECAUTIONS
The reagent may contain non-reactive components and preservatives of various kinds. For precautionary purposes, however, contact with skin and ingestion should be avoided. Use the normal precautions for behavior in the laboratory.

REAGENTS PREPARATION
Reagents are ready to use. Bacterial suspension has to be carefully resuspended shaking it more times for inversion.

Bring to room temperature before analysis. Stability: until expiration date on label stored at 2-8°C. Do not freeze. Flagellar reaction (H) has a characteristic loose, flocculant agglutination.

Partial agglutination is a sign of positive reaction. The title of the serum examined is due to the most higher dilution in which is showed a feeble positivity.

REMARKS
For Flagellar Antigen (H) Titre ≥ 1/160 indicate a recent infection.

In case of a positive result with a low titre, it is significant for the diagnosis verify the increase of titre between samples taken at a distance of days. If the titre remains unchanged it may be a previous contact or previous vaccination. The level of “normal” agglutinins to these organisms varies in different countries and different communities. It is recommended that each laboratory establish its own reference range.

NOTE
- In some geographical areas with a high prevalence of febrile antibodies, it should be recommended to dilute the sample 1:4 with NaCl 9 g/L before to perform the assay.
- As with any diagnostic procedure, if the results are incompatible with the clinical presentation, the physician should evaluate the data obtained using this test by comparing them with other clinical information.
- For intra diagnostic use only.

CALIBRATION/QUALITY CONTROL
There is not any International Reference for the sensitivity standardization of these reagents. For this reason, LTA uses an internal control that contains animal serum with antibodies anti-Salmonellas, and titred with commercial reagents of certified quality.

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.

Controls should be used as described in procedures or even to be treated as samples (dilution, etc.).

The following controls are available on request:
BS00011 3 x 0.5 ml
Febrile Positive Control
BS00020 1 x 1 ml
Febrile Negative Control

TEST PERFORMANCE
Sensitivity
The method sensitivity 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 U/ml

Recent infection, immunodepression or antibiotic treatment 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 BS00110 Suspension S. typhi H slide 1 x 5 ml

REFERENCES

MANUFACTURER
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SYMBOLS

IVD: Only for IVD use
LOT: List of manufacturing
REF: Code number
ST: Storage temperature interval
D: Expiration date (year, month)
W: Warning, read enclosed documents
R: Read the directions
B: Biological risk

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