SALMONELLA PARATYPHI A TOTAL SLIDE

Determination of antibodies associated to salmonella paraTyphi AH and paraTyphi AO 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 paraTyphi AH and paraTyphi AO 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 ~20°C. Do not freeze repeatedly. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples. Bring to room temperature before analysis.

REAGENTS
Suspension: Inactivated and intravital 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 Stablility: until expiration date on label stored at 2-8°C. Do not freeze.

PROCEDURE
SLIDE AGGLUTINATION (QUALITATIVE)
Reagents Sample Positive Control Negative Control Sample 50 µl 50 µl 50 µl Positive control 50 µl 50 µl 50 µl Negative control 50 µl (1 gtt) 50 µl (1 gtt) 50 µl (1 gtt) Suspension Mix using a disposable stirrer, spread homogeneously over the entire area enclosed by the ring and shake it with a rotary motion or with a mechanical stirrer at 80-100 rpm, for 1 minute.

SLIDE AGGLUTINATION (TITRATION)
Approximate Titre 1/20 1/40 1/80 1/160 1/320
Sample 80 µl 40 µl 20 µl 10 µl 5 µl
Suspension (1 gtt) (1 gtt) (1 gtt) (1 gtt) (1 gtt)
Mix using a disposable stirrer, spread homogeneously over the entire area enclosed by the ring and shake it with a rotary motion or with a mechanical stirrer at 80-100 rpm, for 1 minute.

TUBE AGGLUTINATION (semiquantitative)
Is suggested the use of LTA Macro suspensions and furthermore LTA Micro suspensions which have buffers purposely studied to guarantee a certain analysis result. The analytical method is anyhow reported to establish the titre with slide suspensions even if this technology has underlying limits.

NOTE
• In some geographical areas with a high prevalence of febrile antibodies, it is 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 in vitro 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.

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 ≤ 1000 mg/dl
- rheumatic factor ≤ 300 UI/ml
- Recent infection, immunodeficiency 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

CODICE 850460 Suspensions S. paratyphi A Total slide 1 x 5 ml

REFERENCES

MANUFACTURER
LTA s.r.l. - Via Milano 15/F 20060 Bussero (Milano) - ITALY tel. +39 02 95409034 fax. +39 02 95334185 e-mail. info@LTAAonline.it website. http://www.LTAAonline.it

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

Mod. 01.06 (ver. 3.0 - 02/05/2018)