Antígenos Febriles

Reagents for the determination of specific antibodies to Salmonella and Brucella

SUMMARY

Salmonellae are considered enteric pathogenic agent. Contaminated foods and water are transmission sources. The disease may appear as gastroenteritis, septicemia with lesions affecting different organs or typhoid fever.
Brucellosis symptoms are mostly anorexia, fever, weakness and chills. Some important bone and neuropsychiatric complications may subsequently appear.
Even though pathogenic agent isolation is the definitive method for etiology confirmation of these diseases, it has some difficulties since it is often used in late periods of the disease and after an antibiotic therapy. Thus, early detection of specific antibodies that appear during the course of each one of these pathologies is of prime diagnostic significance. Isolated tests are worthless, being necessary two or more serial tests to pinpoint changes in antibodies' titer.

PRINCIPLE

Patient's serum reacts with specific antigens, present in the suspensions of dead Salmonella or Brucella. If sample contains matching antibodies, a macroscopically visible agglutination will appear.

PROVIDED REAGENTS

Antígenos Febriles Salmonella: suspension in saline solution with the corresponding preservatives, containing the following bacterial antigens:
- Paratyphoid A antigens (Salmonella, a flagellar antigen).
- Paratyphoid B antigens (Salmonella, b flagellar antigen).
- Typhoid H antigens (Salmonella, d flagellar antigen).
- Typhoid O antigens (Salmonella, D somatic antigen).

Antígenos Febriles Brucella: suspension of bacterial antigens (Brucella abortus, strain 1119-3) in saline solution with the corresponding preservatives. The celular concentration of the antigens is between 4 and 6%. The bacteria used are in the plain phase.

Antígenos Febriles Controles:
- Positive Control: dilution of inactivated human positive serum.
- Negative Control: dilution of human negative serum.

NON-PROVIDED REAGENTS

Saline Solution.

INSTRUCTIONS FOR USE

Reagents are ready to use. Bring to room temperature and shake vigorously before use.

WARNINGS

Reagents are for "in vitro" diagnostic use.
The controls have been tested for HIV, HCV and HBV and found non-reactive. However, they should be handled as infective material.
Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents are stable at 2-10°C until the expiration date stated on the box. Do not freeze.

INSTABILITY OR DETERIORATION OF REAGENTS

Any bacterial contamination of the reagents may cause deterioration. Discard in such case.

SAMPLE

Serum
a) Collection: obtain clear serum under sterile conditions. Do not heat inactivate sample, since antibodies are thermolabile.
b) Additives: not required.
c) Known interfering substances: both visible hemolysis and chylomicrons can yield non-specific reactions.
d) Stability and storage instructions: samples can be stored at 2-10°C for up to 7 days.

REQUIRED MATERIAL (non-provided)

- Glass slide
- Micropipettes
- Hemolysis tubes
- Rod
- Watch or timer

PROCEDURE

I- RAPID SLIDE TEST

Place one drop (50 ul) of serum on the slide and add one drop (50 ul) of the antigen suspension. Mix and shake the slide in circles for 2 minutes. Observe the presence or absence of agglutination, using an indirect light source against a dark ground.

II- RAPID SLIDE TITRATION

1) Use a glass slide divided in sectors of approximately 4 cm^2.

2) With adequate micropipettes place 80 ul, 40 ul, 20 ul, 10 ul and 5 ul of limpid serum on each sector. Repeat this procedure for both a Positive and a Negative Control.
3) Add one drop of homogenized antigen to every drop of serum.
4) Mix sample and antigen with the rod spreading over an area of approximately 2 cm diameter. Use a different rod for each dilution, (the same rod can be used if the mixing starts from the sample with a higher dilution).
5) Shake the slide for 2 minutes in circles.
6) Observe agglutination using an indirect light source against a dark ground.

INTERPRETATION OF RESULTS
4+: all microorganisms agglutinate.
3+: approximately 75% agglutination.
2+: approximately 50% agglutination.
1+: approximately 25% agglutination.
Negative: no agglutination is observed.

Procedure I: it only indicates positive or negative results.
Procedure II: titer will be considered as the last dilution showing 50% agglutination (++).
The results obtained in the plate titration are similar to the ones of the tube test described in Bennet, C.W. (see References), considering the following dilutions:

Serum Volume (ml)	Approx. Dilution in tube test
0.08	1:20
0.04	1:40
0.02	1:80
0.01	1:160
0.005	1:320

QUALITY CONTROL METHOD
Antígenos Febriles Controles.

REFERENCE VALUES
Generally, titers of 1:40 or 1:80 may suspect disease. Only titers above 1:80 can be considered as a diagnostic evidence of disease. Titers over 1:320 are conclusive.

PROCEDURE LIMITATIONS
See Known Interfering Substances under SAMPLE.
Significant titers may be obtained from individuals immunized with typhoid vaccines. Non-specific cross-reactions with Salmonella O group D antigens may be observed in sera from patients suffering from influenza.
Non-specific reactions have also been reported on patients with active chronic hepatic disease and narcotic users.
Brucella antigens may produce cross-reactions in individuals vaccinated against cholera.

PERFORMANCE
Antígenos Febriles Salmonella: the following results were obtained in a study performed on 191 samples, compared with another reference method of similar principle:

Salmonella Paratyphoid A:
Sensitivity: 94.1%
Specificity: 98.8%

Salmonella Paratyphoid B:
Sensitivity: 89.3%
Specificity: 100%

Salmonella Typhoid H:
Sensitivity: 86.2%
Specificity: 99.3%

Salmonella Typhoid O:
Sensitivity: 95%
Specificity: 99.1%

Antígenos Febriles Brucella: the following results were obtained in a study performed on 191 samples, compared with another reference method of similar principle:
Sensitivity: 100%
Specificity: 100%

WIENER LAB. PROVIDES
Antígenos Febriles Salmonella (Cat. Nº: 1863151)
Paratyphoid A: 1 x 5 ml
Paratyphoid B: 1 x 5 ml
Typhoid H: 1 x 5 ml
Typhoid O: 1 x 5 ml

Antígenos Febriles Brucella (Cat. Nº: 1503151)
Brucella Abortus: 1 x 5 ml

Antígenos Febriles Controles (Cat. Nº: 1933151)
Positive Control: 1 x 2 ml
Negative Control: 1 x 2 ml

REFERENCES
- Widal, F. - Bull. Soc. Med. Hop. de Paris 13 (1896).
- Bennet, T. Clinical Serology, pág. 145, Charles Thomas Co. (1964).
- Huddleson, J.B. - J. Infect. Dis. 42:242 (1928).

Symbols

The following symbols are used in packaging for Wiener lab. diagnostic reagent kits.

CE — This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

EC REP — Authorized representative in the European Community

IVD — "In vitro" diagnostic medical device

Σ — Conteins sufficient for <n> tests

Use by

Temperature limitation (store at)

Do not freeze

Biological risks

Volume after reconstitution

Cont. — Contents

LOT — Batch code

Manufactured by:

Xn — Harmful

Corrosive / Caustic

Xi — Irritant

Consult instructions for use

Calibr. — Calibrator

CONTROL — Control

CONTROL + — Positive Control

CONTROL − — Negative Control

REF — Catalog number

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 - Rosario - Argentina
http://www.wiener-lab.com.ar
Dir. Téc.: Viviana E. Cétola
Biochemist
A.N.M.A.T. Registered product
Disp. Nº: 1889/89 - 4957/00-153/05
(Controles)
1889/89 - 4957/00-153/05-1733/13
(Brucella-Salmonella)

Wiener lab.

2000 Rosario - Argentina

UR130715