Febrile Antigen Kit (Slide Test)

IVD CE

Colored bacterial suspensions for rapid slide test of bacterial specific antibodies

Instructions for Use (IFU)

ORDERING INFORMATIONS

Code	Suspension	Composition
REF CSI087309	Febrile Antigen Kit	n° 7 vials x 3 ml
REF CSI087401	TR *Brucella*	n° 1 vial x 6 ml
REF CSI087411	TR *Brucella abortus*	n° 1 vial x 6 ml
REF CSI087412	TR *Brucella melitensis*	n° 1 vial x 6 ml
REF CSI087402	TR *Salmonella typhi* O	n° 1 vial x 6 ml
REF CSI087403	TR *Salmonella typhi* H	n° 1 vial x 6 ml
REF CSI087416	TR *Salmonella typhi* tot	n° 1 vial x 6 ml
REF CSI087407	TR *Salmonella paratyphi* AO	n° 1 vial x 6 ml
REF CSI087408	TR *Salmonella paratyphi* AH	n° 1 vial x 6 ml
REF CSI087413	TR *Salmonella paratyphi* A tot	n° 1 vial x 6 ml
REF CSI087405	TR *Salmonella paratyphi* BO	n° 1 vial x 6 ml
REF CSI087406	TR *Salmonella paratyphi* BH	n° 1 vial x 6 ml
REF CSI087414	TR *Salmonella paratyphi* B tot	n° 1 vial x 6 ml
REF CSI087409	TR *Salmonella paratyphi* CO	n° 1 vial x 6 ml
REF CSI087410	TR *Salmonella paratyphi* CH	n° 1 vial x 6 ml
REF CSI087415	TR *Salmonella paratyphi* C tot	n° 1 vial x 6 ml
REF CSI087387	TR Positive Control	n° 1 vial x 2 ml
REF CSI087388	TR Negative Control	n° 1 vial x 2 ml
REF CSI087389	TR Positive Control Plus	n° 1 vial x 2 ml

INTENDED USE

In vitro diagnostic medical device for the rapid slide screening of antibodies specific for Salmonella e Brucella. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

The serological diagnosis of infectious diseases characterized by persistent fever is based on the agglutination reaction that occurs between the antigen and specific antibodies present in the patient serum. Grumbaum and Widal firstly introduced the immunology applications in laboratory practice. Their method became universally known as "Widal test" and quantitatively determines antibodies (agglutinins) in the sera of patients with typhoid fever. In addition, the use of serological tests has become common even for the use in the diagnosis of brucellosis both in humans and animals.

PRINCIPLE

When serum containing specific agglutinins reacts with homologous antigen under optimized conditions, it is able to cause a visible agglutination. The agglutination level depends on the antigen and antibody concentration, saline composition of the fluid and temperature.

Storage and Stability

= **Storage Temperature 2-8 °C**

Maintained at 2-8°C, avoiding direct light, reactive are stable until the expiry date printed on the label. Do not freeze. Avoid microbial contamination

Stability tests repeated on three different batches confirmed a validity for almost 36 months if stored 2-8°C. Slight variations in composition from batch to batch do not affect test result.

KIT COMPONENTS

All concentrations refer to ready to use reagents.

Kits for single antigens

Suspensions: 1 vl x 6 mL of dyed and inactivated bacterial suspension (the name is reported on the vial label)
Sodium azide 0,9 g/l

Multiple Kit (REF CSI087370)

Suspension *Brucella*

Suspension Salmonella typhi O

Suspension Salmonella typhi H

Suspension Salmonella paratyphi AO

Suspension Salmonella paratyphi AH

Suspension Salmonella paratyphi BO

Suspension Salmonella paratyphi BH

Each vial contains 1x3 mL of dyed and inctivated bacterial suspension

Positive Control

1x2 mL, polyvalent positive serum, ready to use.
Contains Sodium Azide 0,9 g/L as preservative.

Negative Control

1x2 mL, negative serum, ready to use.
Contains Sodium Azide 0,9 g/L as preservative.

Separately are also available:

Ref. C18087300 Slides white background Package with 50 slides with 6 circles.

Warning: products that contain Sodium azide can react with lead and copper to form explosive metal azides deposits. To eliminate dilute with large amounts of water.

Other materials required but not supplied:

- Physiological Saline
- Automatic Pipettes (variable volumes)
- Serologic tubes

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials. Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV, and antibodies to HIV (1/2). However, handle cautiously as potentially infectious (Biosafety Level 2)
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.
10. Laboratory standards for protection against infection shall be used.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality control

Kit suspensions must be analyzed with positive and negative control sera. Absence of reactions, respectively positive and negative indicates alteration of suspensions and/or controls.

REAGENT PREPARATION

Reactives and control sera, brought to room temperature, are ready to use. Mix gently suspension to obtain an homogeneous solution. After opening the reagents are stable if maintained as indicated in “Storage and Stability”.

SPECIMEN COLLECTION AND PRESERVATION

Non inactivated serum must be used. The specimen must be clear, free of visible fat, excessive hemolysis, or bacterial contamination. If serum specimens are not to be tested within the day od collection, they should be stored at 2-8°C.

PROCEDURES

Reagents and materials must be brought to room temperature before use. Shake the antigen bottles thoroughly until a homogeneous suspension is obtained.

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Instructions for Use (IFU)

Screening test
Distribute on the circle of the slide 50µl of serum and 50 µl of each bacterial suspension, mix well and rotate the slide for 2 minutes (respect the indicated times). Use a new stirrer for each antigen.
Positive Reaction : Presence of visible agglutination
Negative Reaction: Absence of visible agglutination

Semi - quantitative test
Distribute respectively 0,08, 0,04, 0,02, 0,01, and 0,005 mL of serum in different circles of a clean and dried slide. Add a drop of antigen to be tested, near each drop of serum previously distributed. Mix well all the samples starting from that containing mL 0,005 of serum. Rotate the slide (manually or mechanically) for **2 minutes.**
Observe the presence (+) or absence (-) of visible di agglutination under a good light source. Strictly follow the suggested time.

Results
Screening test
Observe for the positive or negative reaction.
Febrile positive control serum must show a positive reaction (full agglutination) within the advisable time.
Febrile Negative Control serum must show a negative reaction (no agglutination) within the advisable time.
Otherwise the test has to be consider invalid.

Semi-quantitative test
Reading scheme:

Full agglutination (100%)	=	++++
Agglutination up to 75%	=	+++
Agglutination up to 50%	=	++
Agglutination up to 25%	=	+
Weak agglutination	=	±
No agglutination	=	-

mL serum	Corresponding dilution
0,08	1:20
0,04	1:40
0,02	1:80
0,01	1:160
0,005	1:320

The titer is definied as reciprocal of higest dilution of serum showing agglutinated bacteria.
The **Febrile positive serum** control should present an agglutination of approximately 50% (++) at least up to dilution 1:80, within the indicated reaction time.
The **negative control** should present a negative reaction (absence of agglutination) within the indicated reaction time.
Otherwise the test must be considered null and void.

Warning
The positive results obtained with the slide test can be further confirmed with the quantitative test tube (From Ref. CSI087201 a Ref. CSI087219) or microplates (Ref. CSI087228 to Ref. CSI087314).
Significant titers can be obtained in patients with an history of typhoid vaccination.
Sera of patients positive for influence can show an aspecific agglutination in presence of Salmonella O group D antigens.
Brucella antigens can give aspecific reactions in subjects vaccinated for Cholera.
Sera form drug addicts or individuals suffering from chronic liver diseases may present Non specific reactions.
Prozona reactions are possible, especially with Brucella antigens. In this case (negative reactions at low dilutions) it is important to verify the presence of agglutination at higher dilutions.
The Rapid slide test, despite being a valuable help for the diagnosis of febrile infections, can't be considered a substitute of classical researches based on bacterial isolation and identification.

Normal values
Titers between 1:40 and 1:80 are to be considered suspect; for the diagnosis of disease a titer greater than 1:80 is necessary. Individual immunological response against bacterial agents can be influenced by multiple factors.

Validation test
Specificity
Tests carried out with three different lots of bacterial suspensions of *Salmonella typhi* and *paratyphi* A, B, C ant. "O", "H" and Brucella on samples of human negative serum have given repeatedly negative results.

Precision
Test of repeatability (within run) and reproducibility (between run) carried out with three different lots of bacterial suspension of *Salmonella typhi e paratyphi* A, B, C ant. "O", "H", "O+H" and Brucella on normal human samples and animal samples, at a known titer, have given the expected results.

Stability
Stability tests, in real time, was carried out on three different lots of each bacterial suspension have confirmed the functionality of the reagent for at least 36 mesi at 2-8°C.

Limits of the method
Especially with the Brucella suspension if aggregates are observed at low dilutions, the higher dilutions must be examined carefully to highlight any agglutination (at least to the dilution 1:640). Serum agglutination tests apparently negative, may be due to an excess of antibodies, which at low dilutions, prevents the agglutination (prozone effect) . In case of not significant positivity, the addition of serum anti - human Ig may reveal the presence of incomplete antibodies (Coombs test) present particularly in the case of chronic disease. As with all serological procedures, a single antibody determination should not be used for diagnosis. The significance of antibody present in a single serum cannot beyond providing evidence of prior exposure to etiologic agent.
For a correct diagnosis it is necessary to observe a significant increase of titer between samples collected 10-14 days apart.

Bibliography

1. **Castaneda M.R**. Bull. WHO • 9: 399, 1953.
2. **Sonnerwirth A.C.** 1970, in: Gradwohl's Clinical Laboratory Methods and Diagnosis • 7th ed., p. 1482, The CV Mosby Co., St. Louis.

Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
F	06/2023	Edit titles: Technical Data Sheet /IFU and Recommended Use / Intended use and IVDR compliance

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