FEBRILE ANTIGENS – STAINED ANTIGEN SUSPENSIONS

CAT NO	DESCRIPTION	PACK SIZE
FEBBAB1	Brucella abortus – Stained antigen suspension	10x5ml
FEBBME1	Brucella melitensis – Stained antigen suspension	10x5ml
FEBO191	Proteus OX19 – Stained antigen suspension	10x5ml
FEBOX21	Proteus OX2 – Stained antigen suspension	10x5ml
FEBOXK1	Proteus OXK – Stained antigen suspension	10x5ml
FEBAGK1	Febrile Antigen Kit – Stained Salmonella antigens without controls	8x5ml
FEBAGK2	Febrile Antigen Kit – Stained Salmonella antigens with controls	8x5ml / 2x1ml
FEBPAH1	Salmonella paratyphi A-H – Stained antigen suspension	10x5ml
FEBPAO1	Salmonella paratyphi A-O – Stained antigen suspension	10x5ml
FEBPBH1	Salmonella paratyphi B-H – Stained antigen suspension	10x5ml
FEBPBO1	Salmonella paratyphi B-O – Stained antigen suspension	10x5ml
FEBPCH1	Salmonella paratyphi C-H – Stained antigen suspension	10x5ml
FEBPCO1	Salmonella paratyphi C-O – Stained antigen suspension	10x5ml
FEBSTH1	Salmonella typhi H – Stained antigen suspension	10x5ml
FEBSTO1	Salmonella typhi O – Stained antigen suspension	10x5ml

Intended Use:

Stain antigen suspension reagents for Salmonella, Brucella and Proteus are intended to be used in the qualitative detection and semi quantitation of antibodies against febrile infections such as salmonellosis and brucellosis in human serum. This reagent is for In vitro diagnostic use by trained professionals only.

Summary and Principle:

Stained antigen suspensions, somatic (stained blue) and flagellar (stained red) are mixed with test samples. Visible agglutination occurs in the presence of antibodies specific to the antigen being tested.

Reagent Composition:

Febrile Reagents	**Stained and killed suspension of bacterial antigens in a buffered solution**
	Preservatives 0.095%

Precautions:

- Reagents do not contain dangerous substances as defined by the current UK chemicals regulations.
- All reagents should, however, be treated as potential biohazards in use and disposal. Wear full personal protective equipment.
- Do not ingest the reagent.
- The reagent contains sodium azide as a preservative which may be toxic. It also may react with lead and copper plumbing to form highly explosive salts. On disposal flush with large quantities of water.

Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2 - 8°C.
Store reagent tightly capped at 2 - 8°C. Protect reagents from light. Do not freeze. Do not expose the reagents to excessive temperatures.
Wash test slides thoroughly before use as traces of detergents or prior samples may affect results. Used cards must be immersed in a disinfectant solution.
The reaction circles must be scrubbed with a non-abrasive material to ensure removal of possible adhering particles.
Thoroughly rinse in purified water then allow reaction cards to dry.
Spray cards with a 70% alcohol solution. Use after alcohol evaporates.

Specimen Collection:

Use fresh clear serum collected by standard venepuncture technique. Samples that cannot be tested immediately can be stored at 2 - 8°C for a period of 48 hours. For longer term storage keep serum samples at -20°C for up to 6 weeks. Do not use contaminated, haemolysed or lipemic samples for testing as these may interfere in the assay.
Before use, bring all samples to room temperature (+25°C). Mix well and use.

Procedure:

Slide test

1. Using a graduated pipette add the following amounts of serum to consecutive circles on a slide for each dilution under test. (0.08ml, 0.04ml, 0.02ml, 0.01ml and 0.005ml)
2. Thoroughly resuspend the antigen and add 1 drop to the appropriate circle on the slide.
3. Mix the drops and spread to cover the entire test circle.
4. Gently and evenly, rock and rotate the test slide for 1 minute whilst examining the test slide for agglutination.
5. Results obtained correspond to tube agglutination titres of 1:20, 1:40, 1:80, 1:160 and 1:320 respectively.
6. It is advisable to confirm a slide titration by the tube technique.
7. Any sample showing agglutination should be tested in the tube agglutination test.

Tube agglutination test:

1. Prepare a rack of 10 tubes. Add 1.9ml of saline in tube 1 and 1 ml of saline to all the other tubes.
2. Add 0.1ml of patient serum to tube 1 and mix.
3. Withdraw 1ml from tube 1 and transfer to tube 2, mix well. Continue serial doubling dilutions in this way until tube 9. Discard 1ml of the mixture from tube 9 to equalise volume.
4. Add 1 drop of thoroughly resuspended antigen suspensions to each tube in the rack. Do not dilute the suspensions for use. Tubes 1-9 now contain serum diluted 1/20 to 1/5120. Tube 10 contains only saline and antigen and is the antigen control.
5. Mix well and incubate as follows and examine for agglutination.
   O titrations 50°C for 4 hours
   H titrations 50°C for 2 hours
   Brucella titrations 37°C for 24 hours
   Proteus titrations 50°C for 4 hours

The antigen control should not show any agglutination.

Results:

Examine the test slide under a strong light source after 1 minute. Quality controls or known level value samples should be tested with each test run. A negative Quality Control must give a negative result after 1 minute. A positive Quality Control should give a positive result at a titre of ½ +/- one double dilution after 1 minute.
For unknown samples, agglutination of the antigen reagent indicates the presence of antibody.
The titre is taken as the highest dilution tube showing visible agglutination. Titres in excess of 1/80 are probably significant. A comparison between samples taken 10-14 days apart may be of more value in acute illness, with a rise in titre indicating a current infection rather than residual antibody from previous infection or immunisation.

Notes:

1. Use a separate disposable tip for each sample to prevent cross contamination.
2. Replace caps on all reagents immediately after use.
3. Prior to the start of the assay bring all reagents to room temperature (20 - 25°C). Gently mix all reagents by gentle inversion or swirling.
4. The assay results from the test should not be the sole criteria for diagnosis of febrile infection, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Do not use damaged or contaminated kit components.

Expected values and sensitivity:

The generally accepted performance characteristics of this type of test is 70% sensitivity and specificity.
Reproducibility of the assay is 100% (+/- one double dilution).

References:

1. Freter, R. Man of Clin Immunol. 2nd Ed ASM Washington DC, 1980; 453-460
2. Weil E and Felix A. Wein Klin. 1916; 29: 974.
3. Cruikshank R. Med Mic 1the Ed, 907.
4. Protell RL et al. Anti-Salmonella agglutins in chronic active liver disease. Lancet ii 330.
5 Robertson L et al. Serum antibody response in acute brucellosis. J Hyg, 1975; 74: 23.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

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