FEVER MICRO TEST
FEVER KIT MINOR 6x10 ml

For in *Vitro* diagnostics use

Determination of antibodies associated with Salmonella or Brucella infections by coloured bacterial suspension in microplate

TEST SUMMARY

The Antibodies associated with Salmonella or Brucella infections cause agglutination of inactive bacteria present in suspension. The intravital colouring permits an easier reading of agglutination formation.

SAMPLES

Fresh clear serum. Stability 7 days at 2-8°C. Freeze for longer period at –20°C, and keep at room temperature before the analysis.
Do not freeze repeatedly.
Turbid samples have to be centrifuged.

REAGENTS

Suspension:	Coloured intravital inactive bacterial suspension; conservative and stabilizer.
Positive Control Salmonella:	Solution of rabbit antisera that gives a clear agglutination with Salmonella Suspension; conservative and stabilizer.
Positive Control Brucella:	Solution of rabbit antisera that gives a clear agglutination with Brucella Suspension; conservative and stabilizer.
Negative control:	Proteic bovine solution that doesn't react with suspension; conservative and stabilizer.

REAGENTS PREPARATION

The bacterial suspension must be resuspended with much care, shaking many times by inversion.
The Positive Control be diluted 1:10 with physiologic solution (100 µl + 900 µl).
Stability: the components of this kit will remain stable until the expiration date stated on the label stored at 2-8°C.
Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution. Automatic micropipette. Normal laboratory equipment.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SAMPLES PREPARATION

The serum must be diluted 1:10 with physiologic solution (100 µl of serum with 900 µl of physiologic).

PROCEDURE

In a microplate with "U" wells dilute the serum with physiologic solution as indicated in the following table.
Using the same pipette (inspiring and discharging many times) mix carefully content of the second well and transfer 100 µl in the following well etc.
Discharge 100 µl from last well (well n°9).

Well	1	2	3	//	9	Susp. Contr.	Contr. -	Contr. +
Physiolog	--	100 µl	100 µl	//	100 µl	100 µl	--	--
Diluted serum	100 µl	100 µl	100 µl from 2	//	100 µl from 8	--	--	--
Discharge 100 µl from well n°9								
Diluted Positive control	--	--	--	-	--	--	--	100 µl
Negative control	--	--	--	-	--	--	100 µl	--
Bacterial suspens.	100 µl	100 µl	100 µl	//	100 µl	100 µl	100 µl	100 µl
Titre	1/20	1/40	1/80	//	1/5120	--	--	--

Shake the plate by slow rotations for 20-30 sec.
Incubate at 37°C for 16-18 h or at 22°C for 2 days, to improve bottoms formation it is advisable put the plate in the fridge after the incubation for 2 hours.

RESULTS INTERPRETATION

A coloured bottom with a clear point shape, on the well bottom, indicates negativity.
An agglutinate that cover all the well bottom indicates a clear positivity, while, a no uniform agglutinate with a bottom in the centre, on the well bottom, indicate a feeble positivity.
The serum titre is given by a high dilution in which there is a feeble positivity.

DIAGNOSTIC VALUES

Somatic (O) and Brucella antigens.
Titers greater 1/80 indicates recent infection.

Flagellar Antigens (H).
Titers greater 1/160 indicates recent infection.

For infection diagnosis is distinctive the significative increasing of the title among examined samples from days distance.

NOTE

- The flagellar agglutination is characterized by rapid training and easy disintegration.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION/QUALITY CONTROL

Positive and Negative control sera should be always used to distinguish an eventual background's agglutination of reactive.

TEST PERFORMANCE

Sensitivity

In presence of high antibodies titres, phenomenon of prozone can happen, therefore positivity is absent for low dilutions also being present for higher dilutions.

Specificity

A comparison with an available commercial method gave following results on 50 samples compared, giving a specificity = 100%.

		TYPHI H MASCIA BRUNELLI		
		+	-	TOT.
COMPET.	+	17	0	17
	-	0	33	33
	TOT.	17	33	50

		TYPHI O MASCIA BRUNELLI		
		+	-	TOT.
COMPET.	+	16	0	16
	-	0	34	34
	TOT.	16	34	50

		P.TYPHI A TOTAL MASCIA BRUNELLI		
		+	-	TOT.
COMPETITORS	+ AH	8	0	8
	+ AO	9	0	9
	+ AH / AO	4	0	4
	-	0	29	29
	TOT.	21	29	50

		P.TYPHI B TOTAL MASCIA BRUNELLI		
		+	-	TOT.
COMPETITORS	+ BH	9	0	9
	+ BO	12	0	12
	+ BH / BO	3	0	3
	-	0	26	26
	TOT.	24	26	50

		P.TYPHI C TOTAL MASCIA BRUNELLI		
		+	-	TOT.
COMPETITORS	+ CH	12	0	12
	+ CO	7	0	7
	+ CH / CO	3	0	3
	-	0	28	28
	TOT.	22	28	50

		BRUCELLA TOTAL MASCIA BRUNELLI		
		+	-	TOT.
COMPETITORS	+ ABORTUS	12	0	12
	+ MELITENSIS	7	0	7
	+ ABORT./ MELITEN.	2	0	2
	-	0	29	29
	TOT.	21	29	50

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODICE XB105550

Salmonella typhi H	1 x 10 ml
Salmonella typhi O	1 x 10 ml
Salmonella paratyphi A total	1 x 10 ml
Salmonella paratyphi B total	1 x 10 ml
Salmonella paratyphi C total	1 x 10 ml
Brucella total	1 x 10 ml
Positive control Salmonella	1 x 0.5 ml
Positive control Brucella	1 x 0.5 ml
Negative control	1 x 0.5 ml
"U" bottom plate with 96 well	6

REFERENCES

Widal F. – Bull. Men. Soc. Med. Hop de Paris – 6; 26 (1986) Bergey's Manual of Determinative Bavteriology 8 Th Ed. Williams and Wilkins Co (1974) Weil E., Felix A.- Wein.Klin.Woch 29; 974 (1916) Gualtney J.B. e coll. – Microagglutination procedures for febrile agglutination tests-Applied microbiology-4; 635-640 Vol.22 (1971) Rose N.R., Friedman H.-Manual of clinical Immunology-American Society for Microbilogy, II ed.

SYMBOLS

IVD Per esclusivo uso diagnostico in vitro

LOT Lotto di fabbricazione

REF Codice di catalogo

Intervallo di temperatura per la conservazione

Data di scadenza (anno – mese)

Consultare i documenti allegati

Consultare le istruzioni operative

Rischio Biologico

CE IVD