

FEVER SLIDE TEST BRUCELLA "BENGAL ROSE"

For *In Vitro* diagnostic use

Determination of antibodies associated to Brucella by means of coloured with Bengal Rose bacterial suspension on slide

TEST SUMMARY

Specific IgG or IgM antibodies associated to Brucella infections cause the agglutination of inactivate bacteria present in suspension. The coloration allows an easy reading of agglutination. The reagent, because of its formulation in an acid buffer, is reactive with both IgG and IgM antibodies and very useful for the diagnosis of chronic individuals, which present a high level of IgG antibody, difficult to be detected by the reference tube method (Wright).

SAMPLES

Fresh clear serum. Stability 7 days at 2-8°C or 3 months at -20°C. Keep at room temperature before the analysis. Do not freeze repeatedly. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

REAGENTS

Suspension: Brucella abortus suspension in lactate buffer 1 mol/L, phenol 5 g/L, Rose Bengal, pH 3.6.

Positive Control Brucella: Solution of rabbit antisera capable of giving a clear agglutination with Brucella bacterial suspensions; preservatives and stabilizers.

Negative Control: Bovine protein solution non-reactive with suspension; preservatives and stabilizers.

MATERIALS REQUIRED BUT NOT SUPPLIED

Saline Solution NaCl 9 g/L. Automatically micropipette. Mechanical stirrer at 100 r.p.m. Current laboratory instrumentation.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general "Good Laboratory Practice" (GPL) guidelines.

REAGENTS PREPARATION

Reagents are ready to use. Bacterial suspension has to be carefully resuspended shaking it more times for inversion. Stability: until expiration date on label stored at 2-8°C. Do not freeze.

QUALITATIVE PROCEDURE

Reagents	Sample	Positive Control	Negative Control
Sample	50 µl	--	--
Positive control	--	50 µl	--
Negative control	--	--	50 µl
Suspension	50 µl (1 gtt)	50 µl (1 gtt)	50 µl (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 4 minutes.** An excess of agitation time may cause false positive.

SEMI-QUANTITATIVE PROCEDURE

Make serial two fold dilutions of the sample in 9 g/L saline solution and proceed for each dilution as in the qualitative method.

RESULTS INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates an antibody anti-Brucella concentration equal or greater than 25 IU/mL.

A homogeneous suspension without visible agglutination indicates negativity.

The titre, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

The approximate antibody concentration in the patient sample is calculated as follows:

$$25 \times \text{anti-Brucella Titre} = \text{IU/mL}$$

REFERENCE VALUES

Up to 25 IU/ml.

For infection diagnosis is distinctive the significant increasing of the titre among examined samples from days distance.

Each laboratory should establish its own reference range.

NOTE

- As any diagnostic procedure, if the results are incompatible with clinical presentation, the physician should evaluated within a total clinical study.
- Only for IVD use.

CALIBRATION/QUALITY CONTROL

It is recommended to use control sera for reference: the positive control must show a partial or complete agglutination, while the negative control should show no agglutination.

Controls should be used as described in procedures or even to be treated as samples (dilution, ecc..).

TEST PERFORMANCE

Sensibility

The method sensibility decrease at low temperature. Better results will be obtained at higher temperature up to 10°C. The sensibility is 25 ± 5 UI/ml.

No prozone phenomenon were observed for concentrations of anti-brucella Abortus studied up to a titre 1000 UI/ml.

Interference

No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
lipids	≤ 1000 mg/dl
rheumatic factor	≤ 300 UI/ml

The Bilirubin interferer to concentration > 2,5 mg/dl.

Recent infection, immunodepression 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









CODE XC100852

Slide Suspension Brucella "Bengal Rose"	1 x 5 ml
Brucella Positive Control	0.5 ml
Negative Control	0.5 ml
Slide white ring	2
Stirrers	100

REFERENCES

- Edward J Young. Clinical Infectious Diseases 1995; 21: 283-290.
- Coulter JBS. Current Pediatrics 1996; 6: 25-29..
- David A et al. Currebt Opinion in Infectious Diseases 1994; 7: 616-623.
- David R et al Current Opinion in Infectious Diseases 1993; 6: 54-62.
- Bradley D Jones. Annu Rev Immunol 1996; 14: 533-61.

SYMBOLS

	Only for IVD use
	Lot
	Code number
	Storage temperature interval
	Expiration date
	Warning, read enclosed documents
	Read the directions
	Biological risk

EDMA CODE 14 02 03 01 00

