

# BRUCELLA BENGAL ROSE SLIDE

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.

Samples with presence of fibrin should be centrifuged before use. 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.

Brucella Positive control: Solution of rabbit antisera that gives a clear agglutination with Brucella Suspension; conservative and stabilizer.

Negative control: Non-reactive protein bovine solution with suspension, conservatives and stabilizers.

## 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.

## MATERIALS REQUIRED BUT NOT SUPPLIED

Salin solution NaCl 9 g/L. Slide and stirrer. Automatical micropipette. 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.

## QUALITATIVE PROCEDURE

Reagents	Sample	Positive control	Negative control
Serum	50 µl	--	--
Positive control	--	50 µl	--
Negative control	--	--	50 µl
Suspension	50 µl (1 gtt)	50 µl (1 gtt)	50 µl (1 gtt)

Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample. Place the slide on a mechanical rotator at 80-100 r.p.m. 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 significative 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 ad immunodepression 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 BS00960

Slide Suspension Brucella Bengal Rose 1 x 5 ml

### CODE BS00950

Slide Suspension Brucella Bengal Rose 1 x 5 ml

Brucella Positive control 0.5 ml

Negative control 0.5 ml

### CODE BS00955

Slide Suspension Brucella Bengal Rose 6 x 5 ml

Brucella Positive control 0.5 ml

Negative control 0.5 ml









## REFERENCES

- Young E J. Clinical Infectious Diseases 1995; 21: 283-290.
- Alton GC. Techniques for Brucellosis Laboratory INRA Paris, 1988.
- Ariza J. Current Opinion in Infectious Diseases 1996; 9: 126-131.
- Comité mixto FAO/OMS de expertos en Brucellosis. WLD Health Org Tech Rep Ser 1958; 148: 1-60.
- Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

## MANUFACTURER

LTA s.r.l.  
Via Milano 15/F  
20060 Bussero (Milan) ITALY  
Tel: +39 02 95409034  
Fax: +39 02 95334185  
e-mail: info@LTAonline.it  
Website: http://www.LTAonline.it

## SYMBOLS

-  Only for IVD use
-  Lot of manufacturing
-  Code number
-  Storage temperature interval
-  Expiration date (year, month)
-  Warning, read enclosed documents
-  Read the directions
-  Biological risk

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