IVD
Store at 2 - 8ºC.

Ref. 22202 ROSE BENGAL kit
50 t – 2,5 ml
pos. control 1 ml
neg. control 1 ml
8 x 6 disposable slides
Plastic stirrers

CYPRESS DIAGNOSTICS

CE

Rose Bengal

Slide agglutination

Qualitative determination of antibodies anti-Brucella

INTENDED USE

The Rose Bengal is a slide agglutination test for the qualitative and semi-quantitative detection of antibodies anti-Brucella in human serum.
For *in vitro* diagnostic use only.
For professional use only.

PRINCIPLE OF THE METHOD

The stained bacterial suspension agglutinates when mixed with samples containing specific IgG or IgM antibodies present in the patient sample.

CLINICAL SIGNIFICANCE

Brucella diagnostic may be assessed either by microorganism isolation in blood or stools, or by titration of specific antibodies in the patient serum. 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).
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REAGENTS

Rose Bengal	**Brucella abortus suspension, strain S99, in lactate buffer 1 mol/L, phenol 5 g/L, Rose Bengal, pH 3.6**
Control +	**Animal serum, with an antibody anti-Br. abortus concentration ≥ 50 IU/mL. Preservative.**
Control –	**Animal serum. Preservative**

CALIBRATION

The Rose Bengal sensitivity is calibrated against the 2º International Preparation of anti-*Brucella abortus* from NIBS (UK)(WHO).

PREPARATION

All the reagents are ready for use.

STORAGE AND STABILITY

All reagents are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Store the vials in vertical position. If the position is changed visible aggregates may be present in the vial or dropper. In this case, aspirate the reagent several times with the dropper or shake the vial vigorously or on a vortex mixer to dissolve the aggregates.
The reagent, once shaken, must be uniform without visible clumping.

ADDITIONAL EQUIPMENT, NOT INCLUDED

- **Mechanical rotator with adjustable speed at 80-100 r.p.m.**
- **Pipettes 50 µl**

SAMPLES

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged before use.
Do not use highly hemolized or lipemic samples.

PROCEDURE

Qualitative method

1. **Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.**
2. **Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.**
3. **Swirl the R. Bengal reagent gently before using and add one drop next to the sample to be tested.**
4. **Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.**
5. **Place the slide on a mechanical rotator at 80-100 r.p.m. for 4 minutes. False positive results could appear if the test is read later than four minutes.**

Semi-quantitative method

1. **Make serial two fold dilutions of the sample in 9 g/L saline solution.**
2. **Proceed for each dilution as in the qualitative method.**

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

CALCULATIONS

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

25 x anti-Brucella Titer = IU/mL

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
All results different from the negative control will be considered as positive.

REFERENCE VALUES

Up to 25 IU/mL.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. ***Analytical sensitivity*: 25 (± 5) IU/mL, under the described assay conditions**
2. ***Prozone effect*: No prozone effect was detected up to 1000 IU/mL.**
3. ***Diagnostic sensitivity:* 100 %.**
4. ***Diagnostic specificity:* 98 %.**

INTERFERENCES

Hemoglobin (10 g/L), lipids (10 g/L) and rheumatoid factors (300 IU/mL), do not interfere. Bilirrubin interferes at 2.5 mg/dL. Other substances may interfere.

BIBLIOGRAPHY

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4. **Comité mixto FAO/OMS de expertos en Brucelosis. WLD Health Org Tech Rep Ser (1958) 148 :1-60**
5. **Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press 1995**

05.2017, Rev. 7.0

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