

ROSE BENGAL
MonlabTest®



Qualitative determination of antibodies anti-Brucella

IVD Only for professional in vitro diagnostic use.
Store at 2 - 8°C.

PRINCIPLE OF THE METHOD

The Rose Bengal is a slide agglutination test for the qualitative and semi-quantitative detection of antibodies anti-Brucella in human and animal serum. 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).

REAGENTS

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

PRECAUTIONS

Phenol: Toxic (T) R24/25: Toxic in contact with skin and if swallowed. R34: Causes burns. S28.2: After contact with the skin, wash immediately with plenty of water. S45: In case of accident, seek medical advice immediately.

CALIBRATION

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

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 2-8°C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test. Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
Reagents deterioration: Presence of particles.

ADDITIONAL EQUIPMENT

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.

SAMPLES

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before use. Do not use highly hemolyzed 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. Mix the R. Bengal reagent vigorously or on a vortex mixer 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 two 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:

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

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 result different from the negative control result, will be considered as a 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), lipemia (10 g/L) and rheumatoid factors (300 IU/mL), do not interfere. Bilirubin interferes at 2.5 mg/dL. Other substances may interfere⁵.

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.











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

PACKAGING

Ref. MO-165016	100 test	: 5,0 mL Rose Bengal
		: 1 mL Control +
		: 1 mL Control -
		: 16 x 6 desposables slides

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer		For <i>in vitro</i> diagnostic use only
	Don't re-use		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
	Catalogue Code		Temperature limitation
	Lot Number		Use by

