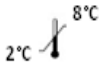
Atlas Medical CE

BRUCELLA (ROSE BENGAL) TEST

A rapid agglutination slide test for the detection of Brucella specific agglutinins

IVD *For In-Vitro Diagnostic and professional use only.*



Store at 2° to 8°C.

INTENDED USE

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

PRINCIPLE

In the course of human infection with any pathogenic microbiological agent, a variety of antibodies are formed. Among these antibodies are the agglutinins. An agglutinin when combined with homologous antigen (agglutinate) under the properly controlled conditions is capable of causing agglutination. A suspension of Brucella possessing active antigen will agglutinate when exposed to homologous Brucella antibody. This agglutination forms clumps of bacteria which become macroscopically visible.

The Rose Bengal stained Brucella antigen is used for the early detection of Brucella agglutinins (Brucella Abortus, Melitensis and Suis).

MATERIALS

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- **Rose Bengal Brucella Antigen:** *Brucella abortus* suspension, strain S99, in lactate buffer 1 mol/L, phenol 5 g/L, Rose Bengal, pH 3.6 .
- **Positive Control:** Animal serum, with an antibody anti- *Br.abortus* concentration 50 IU/mL. Preservative .
- **Negative Control:** Animal serum. Preservative.
- **White Glass slide.**
- **Stirring Sticks.**

Note: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTION

1. This reagent is for in vitro diagnostic and professional use.
2. Protective clothing should be worn when handling the reagents.
3. The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
4. Don't use these reagents if the label is not available or damaged.
5. Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
6. Test materials and samples should be discarded properly in a biohazard container.
7. Wash hands and the test table top with water and soap once the testing is done.
8. Don't use these reagents if the label is not available or damaged.
9. The test should be performed at room temperature in a well let area with very good visibility.
10. If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE

Brucella antigen and control anti-sera must be stored at 2-8°C.

SPECIMEN COLLECTION & PREPARATION

- Collect 5ml whole blood samples aseptically from the patient.
- Allow blood to clot and remove serum as soon as possible to prevent excess haemolysis.
- Store serum at 2-8°C until testing can be performed.

PRUCEDURE

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

1. 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.
2. 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 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. Bilirrubin interferes at 2.5 mg/dL. Other substances may interfere.

REFERENCES

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5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry