BRUCELLA BENGAL ROSE SLIDE TEST

For in Vitro diagnostics use

Determination of antibodies associated to Brucella Bengal Rose by means of coloured 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. Freeze for longer period at ~20°C, and keep at room temperature before the analysis. Do not freeze repeatedly. Samples with presence of fibrin should be centrifuged after use. Do not use highly hemolized or lipemic samples.

REAGENTS
Suspension: Coloured bacterial suspension, conservatives and stabilizers.
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

PRECAUTIONS
Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Mix with a stirrer and spread over the entire area enclosed by the ring. Shake for 4 minutes by rotating movement or with a mechanical shaker at 100 r.p.m. An excess of agitation time may cause false positive.

EXPECTED VALUES
Up to 25 IU/mL.

For infection diagnosis is distinctive the significative increasing of the title 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

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 title 1000 UI/mL.

Intefer
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.

NOTE
- Only for IVD use
- Code number
- Warning, read enclosed documents
- Biological risk

EDMA code 15 01 90 01

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