ARENA
BioScien

Block 5, Street 9 inside The Ismailia free zone. Ismailia- Egypt
Post Code-41511
Tel.-Fax: +202 21813500/ +202 21813600
Mob.: +2 01211550941/ +2 01119225860
E-mail: sales@arenabioscientific.com
Website: www.arenabioscien.com

BRUCELLA RB

Diagnostic reagent set **(Slide and Tube Tests)** for the in-vitro qualitative screening and semi-quantitative determination of Brucella antibodies present in infected human serum manually.

REF: BS.1/BRB1.100.0100 100 tests for Brucella-RB

CLINICAL SIGNIFICANCE

Human Brucellosis (DiurnaL or undulant faver) is a common febrile illness caused by infection with bacteria of some of the Brucella species (abortus, melitensis). This undeulant fever is associated with symptoms which are often variable and non-specific with chills, fever, sweats and anorexia. On exposure the body responds to this antigenic stimulation by producing specific antibodies whose titers rise slowly at early stages and then increases. Specific antibodies to the Brucella species are detectable a few weeks after exposure and are of considerable importance in the diagnosis of Brucellosis. Information regarding the titer of antibodies can be obtained by using specific ***BioScien*** Brucella antigen suspension.

METHOD PRINCIPLE

The smooth, coloured, killed BRUCELLA -RB antigen suspension is mixed with the patient serum. Specific antibodies to Brucella antigens if present in concentration > 25IU/mL in the patient serum will react with the antigen suspension to produce an agglutination reaction. No agglutination indicates the absence of detectable levels of specific antibodies to Brucella.

REAGENT COMPOSITION

The BRUCELLA -RB reagent contains smooth, killed buffered suspensions of Brucella abortus strain 99, coloured with rose bengal, standardized against the 2nd International preparation of anti-Brucella abortus from NIBS (UK) (WHO).
Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent (R) contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Brucella reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien *Brucella* reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration

The ***BioScien*** *Brucella* reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive controls.

SPECIMEN COLLECTION AND PRESERVATION

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8°C in case of delay in testing up to 24 hours or frozen for 8 days.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Physiological saline (as negative control)

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix antigens well before dispensing

Qualitative procedure

1. Identify each reaction circle of the slide test to make one positive control for each type, one negative control and the desired number of samples respectively.
2. Place one drop of positive control reagents, 50 µl of physiological saline and 50 µl of patient's serum to be tested onto each reaction circles.
3. Add one drop of Brucella RB antigen suspension to the reaction circles containing positive controls, physiological saline and patient's serum.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination macroscopically at four minutes.

Semi-quantitative method

1. Make serial two-fold dilutions of the sample in 0.9% normal saline solution.
2. Place one drop of BRUCELLA -RB antigen suspension to each circle.
3. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
4. Gently rock the slide back and forth; observe for agglutination macroscopically at four minutes against a white background.

READING AND INTERPRETATION

Qualitative procedure	
Positive	Agglutination is a positive test result and indicates the presence of antibodies to Brucella in concentration 25 IU/mL in the patient serum.
Negative	No agglutination as indication for the absence of Brucella antibody in the patient's serum.
Semi-Quantitative procedure	
Titre	The titer of the patient serum corresponds to the visible agglutination in the test circle with the smallest amount of serum sample.

The approximate antibody concentration in the patient sample is calculated as follows.
25 x anti-Brucella titer= IU/mL

QUALITY CONTROL

The positive controls may included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed, the reagent should not be used. For more information, please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of Brucella antigen suspensions is 100% (+/- one double dilution).

Analytical sensitivity: 25 (±5) IU/mL, under described assay conditions.

Diagnostic specificity: 100 %.

LIMITATIONS OF PROCEDURE

1. Both Brucella abortus and Brucella melitensis share a common Brucella antigen. A sample giving a positive result with the Rose Bengal reagent should be tested using Brucella-A and Brucella-M antigen suspensions by rapid slide test and confirmed by the tube test to determine the type of Brucella antibody detected. The higher titer detected determines the specific type of Brucella antibodies present.
2. In the semiquantitative test the reactions obtained are roughly equivalent to those, which would occur in a tube test.
3. Agglutinins are found in high proportion of normal individuals and concentration less than 25 IU/mL are of doubtful significance. Arising titer is more significant than a single high titer.
4. False positive reactions may occur in sera of patients infected with Pasteurella tularensis or vaccinated with vibrio cholerae.
5. Cross-reactions between Brucella antigens and other organisms have been reported. These include Yersinia enterolitica, Escherichia coli (0:157) and Francisella tularensis.
6. False positive results are likely if the test is read more than four minutes after mixing on the slide test.
7. Prozoning may sometimes be encountered in serum containing very high titers on slide test.
8. Serological findings are not intended as a substitute for culture. An appropriate attempt should be made to recover and identify the etiologic organisms through various culture and biochemical tests.
9. Since techniques and standardization vary from laboratory to laboratory in tube, difference in titers can be expected.
10. Use a separate disposable tip for each sample to prevent cross contamination.
11. Turbid and contaminated sera should not be used for testing.
12. After usage the antigen suspension should be immediately recapped and replaced at 2-8 C.
13. Vials that have leakage/ breakage problem should be discarded.
14. Only qualified and well-trained staff should use the reagents.
15. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
16. The performance of the reagents should be validated periodically using known positive control. Good physiological saline may be used as a negative control.

REFERENCES

1. J. G. Collee, J. P. Duguid, A. G. Fraser, Practical Medical Microbiology, 13th Ed.: 525 – 530.
2. G. Galton, L. M. Jones, R. D.angus, J. M. Verger, Techniques for the brucellosis laboratory, ©INRA, Paris, 1988.

SYMBOLS IN PRODUCT LABELLING	
IVD For in-vitro diagnostic use	Number of <n> test in the pack
LOT Batch Code/Lot number	Caution
REF Catalogue Number	Do not use if package is damaged
Temperature Limitation	Consult Instruction for use
Expiration Date	
Manufactured by	

EC REP

Medical Device Safety Service
MDSS GmbH
Schiffgr aben 41
30175 Hannover, Germany

CE