

SBio Brucella RB Test

Slide screening test for Brucella antibodies

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| REF | 90563005 |
| Pack | 5 ml |



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|-----------------------------------|---------------------------------|---|---|
| Store at 2-8°C | Manufacturer | <div>EC REP</div> Authorised Representative in the European Community | |
| Use by (Last day of stated month) | Consult Instructions for use | <div>IVD</div> In vitro Diagnostic Medical Device | This way up |
| Date of Manufacture | <div>REF</div> Catalogue Number | <div>LOT</div> Batch Number | <div>REAGENT</div> Description of reagent |

SUMMARY

Human Brucellosis (Diurnal, or undulant fever) is a common febrile illness caused by infection with bacteria of some of the *Brucella* species (*abortus/melitensis*). This undulant fever is associated with symptoms, which are often variable and non-specific with chills, fever, sweats, and anorexia. Specific antibodies to the *Brucella* species are detectable a few weeks after exposure and are of considerable importance in the diagnosis of Brucellosis.

REAGENT

The SBio Brucella RB Test 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.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE. Frozen reagents could change the functionality of the test.
2. The shelf life of the reagents is as per the expiry date mentioned on the reagent vial labels. Do not use beyond expiry date.
3. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Positive control, Isotonic saline, Glass slide with clear / white background, appropriate Pipettes / Micropipettes, Mixing sticks & a High intensity direct light source.

PRINCIPLE

The smooth, coloured, killed SBio Brucella RB Test antigen suspension is mixed with the patient serum. Specific antibodies to *Brucella* antigens if present in concentration ≥ 25 IU/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*.

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 IgM and IgG antibodies and very useful for the diagnosis of chronic individuals, which present a high level of IgG antibody.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use. Keep the reagent away from the direct sunlight.
2. The reagent contains 0.01% Thimerosal as preservative. Avoid contact with skin and mucosa. On disposal flush with large

quantities of water.

3. The 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 and negative controls.
4. Shake the reagent vials well before use to disperse the antigen suspension uniformly and improve test readability.
5. It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop.
6. Only a clean and dry glass slides must be used. Clean the glass slide with distilled water and dry.
7. SBio Brucella RB Test antigen suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded.
8. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

1. No special preparation of patient is required prior to sample collection by approved techniques. Do not use hemolysed serum samples.
2. Clean and dry glassware free from detergents must be used for sample collection.
3. Do not heat inactivate the serum.
4. Though freshly collected serum is preferred, samples can be stored at 2-8°C, for 24 hours, or frozen for 8 days should a delay in testing occur.

PROCEDURE

Bring all reagents to room temperature. The sensitivity of the test may be reduced at low temperatures.

Shake and mix the SBio Brucella RB Test antigen suspension well before dispensing.

SLIDE TEST METHOD

Qualitative method

1. Place one drop of Positive control (available as SBio Brucella Positive Control, REF 91020005) onto the reaction circle of glass slide.
2. Place 50 µl of saline onto the next reaction circle of the glass slide.
3. Place 50 µl of patient serum to be tested onto the next reaction circle.
4. Add one drop of well mixed SBio Brucella RB Test antigen suspension in each of the above circles containing positive control, isotonic saline and patient serum to be tested.
5. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
6. Gently rock the slide back and forth, observe for agglutination macroscopically at **four minutes** against a white background.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 0.9% normal saline solution.

- Place one drop of SBio Brucella RB Test antigen suspension to each circle.
- Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
- Gently rock the slide back and forth; observe for agglutination macroscopically at **four minutes** against a white background.

INTERPRETATION OF RESULTS

Qualitative method

Agglutination is a positive test result and indicates the presence of antibodies to *Brucella* in concentration ≥ 25 IU/mL in the patient serum. No agglutination is a negative test result and indicates absence of antibodies to *Brucella* in concentration ≤ 25 IU/mL in the patient serum.

Semi-quantitative method

Agglutination is a positive test result. The titre in 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.

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

PERFORMANCE CHARACTERISTICS

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

Specificity: 100%

REMARKS

- 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 SBio Brucella Abortus / Melitensis Test antigen suspensions by rapid slide test and confirmed by the tube test to determine the type of Brucella antibody detected.
- Agglutinins are found in high proportion of normal individuals and concentration less than 25 IU/mL are of doubtful significance. A rising titre is more significant than a single high titre.

- False positive reactions may occur in sera of patients infected with *Pasteurella tularensis* or vaccinated with *vibrio cholerae*.
- Cross-reactions between Brucella antigens and other organisms have been reported. These include *Yersinia enterocolitica*, *Escherichia coli* (0:157) and *Francisella tularensis*.
- False positive results are likely if the test is read more than four minutes after mixing on the slide test.
- Prozoning may sometimes be encountered in serum containing very high titres on slide test.
- 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.
- Since techniques and standardization vary from laboratory to laboratory on tube difference in titres can be expected.
- Use a separate disposable tip for each sample to prevent cross contamination.
- Turbid and contaminated sera should not be used for testing.
- After usage the antigen suspension should be immediately recapped and replaced at 2-8°C.
- Reagent vials that have leakage/ breakage problem should be discarded.
- Only qualified and well trained staff should use the reagents.
- It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
- The performance of the reagents should be validated periodically using known positive control. Good physiological saline may be used as a negative control.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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

 Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot No. Utility VIII, Phase III B, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:


Singapore Biosciences PTE Ltd.

11 Yishun Street 51, #04-23, The Criterion,
Singapore 767971

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

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