CE

BRUCEL® - RB

Improved Sensitivity 25IU/mL

SLIDE SCREENING TEST FOR *BRUCELLA* ANTIBODIES

INTENDED USE
BRUCEL®-RB is a rapid slide agglutination test for screening of antibodies to *Brucella* in human and animal serum.

SUMMARY
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. Information regarding the titre of antibodies can be obtained by using specific BRUCEL®-A/BRUCEL®-M antigen suspension.

REAGENT
The BRUCEL®-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

REAGENT STORAGE AND STABILITY
(1). Store the reagent at 2-8°C. DO NOT FREEZE. Frozen reagents could change the functionality of the test. Keep the reagents away from direct sunlight. (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.

PRESENTATION

	5ml
REF	105630005
Reagent	BRUCEL®-RB
PACKAGE INSERT	1

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 BRUCEL®-RB antigen suspension is mixed with the patient or animal serum. Specific antibodies to *Brucella* antigens if present in concentration ≥ 25IU/mL in the 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 diagnosis may be assessed either by microorganism isolation in blood or stools, or by titration of specific antibodies in the 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 reagents away from 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). BRUCEL®-RB 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 BRUCEL®-RB antigen suspension well before dispensing.

SLIDE TEST METHOD
Qualitative method
1. Place one drop of Positive control (available as BRUCELLOSIS POSITIVE CONTROL, REF 110200005 and 110200001) 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 serum to be tested onto the next reaction circle.
4. Add one drop of well mixed BRUCEL®-RB antigen suspension in each of the above circles containing positive control, isotonic saline and 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.
2. Place one drop of BRUCEL®-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.

INTERPRETATION OF RESULTS

Qualitative method

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

25 x anti-Brucella titre = IU/mL

PERFORMANCE CHARACTERISTICS

Analytical sensitivity: 25 (±5) IU/mL, under described assay conditions. **Specificity:** 100%

REMARKS

(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 BRUCEL®-A and BRUCEL®-M antigen suspensions by rapid slide test and confirmed by the tube test to determine the type of *Brucella* antibody detected. (2). 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. (3). False positive reactions may occur in sera of patients infected with *Pasteurella tularensis* or vaccinated with *vibrio cholerae*. (4). Cross-reactions between *Brucella* antigens and other organisms have been reported. These include *Yersinia enterolitica, Escherichia coli* (0:157) and *Francisella tularensis*. (5). False positive results are likely if the test is read more than four minutes after mixing on the slide test. (6). Prozoning may sometimes be encountered in serum containing very high titres on slide test. (7). 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. (8). Since techniques and standardization vary from laboratory to laboratory on tube difference in titres can be expected. (9). Use a separate disposable tip for each sample to prevent cross contamination. (10). Turbid and contaminated sera should not be used for testing. (11). After usage the antigen suspension should be immediately recapped and replaced at 2-8°C. (12). Reagent vials that have leakage/ breakage problem should be discarded. (13). Only qualified and well trained staff should use the reagents. (14). It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis. (15). 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

(1). J. G. Collee, J. P. Duguid, A. G. Fraser, Practical Medical Microbiology, 14th Ed.: 473-478. (2). G. Galton, L. M. Jones, R. D. Angus, J. M. Verger, Techniques for the brucellosis laboratory, © INRA, Paris, 1988. (3).Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	Contains sufficient for <n> tests
Use by	Consult Instructions for use	This way up
Date of Manufacture	REF Catalogue Number	PS Production Site
LOT Batch Number/ Lot Number	IVD *In vitro* Diagnostic Medical Device	EC REP Authorised Representative in the European Community

Manufactured by

TULIP DIAGNOSTICS (P) LTD.

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EC REP

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0563/0917/VER-04