QUADRAPED™

BRUCEL- RB

SLIDE SCREENING TEST FOR *BRUCELLA* ANTIBODIES IN ANIMAL SERUM

INTENDED USE

QUADRAPED™ Brucel-RB is a rapid slide agglutination test for screening of antibodies to Brucella in animal serum including cattle, sheep, goats, swine and dogs.

SUMMARY

Brucellosis (Diurnal, or undulant fever) is a common febrile illness caused by infection with bacteria of some of the Brucella species (abortus / melitensis / ovis / suis / canis). 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. Infection with Brucella species can cause abortion, birth of stillborn or weak calves, retained placenta, reduced milk production in female animals and orchitis, epididymitis, infertility, reduced libido in male animals. Infected cattle usually abort only once but can still shed the organism in amniotic fluid and milk at subsequent calvings. This is significant because the bacteria are highly contagious to humans, who can contract the disease through contact with these fluids or by consuming unpasteurized milk from infected animals. This chronic shedding is a key reason why controlling brucellosis in livestock is critical for public health.

REAGENT

QUADRAPED™ 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

QUADRAPED™ Brucel-RB

∑	100 Tests
REF	105960100

Kit Contents

Brucel-RB Reagent	5 ml
Positive Control	0.5 ml
Negative Control	0.5 ml
Glass Slide	1 No.
Mixing Sticks	100 Nos. (4 ladders, each with 25 detachable mixing sticks)
Sample droppers	100 Nos. (2 pouches, each with 50 disposable sample droppers)
Pack Insert	1 No.

ADDITIONAL MATERIAL REQUIRED

Stop watch, variable micropipette, Isotonic saline and a High intensity direct light source.

PRINCIPLE

The smooth, coloured, killed **QUADRAPED™** Brucel-RB antigen suspension is mixed with the 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 cases 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). **QUADRAPED™** 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 animal 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^{0}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 **QUADRAPED™** Brucel-RB antigen suspension well before dispensing.

SLIDE SCREEN METHOD

Qualitative method

1. Dispense one drop of Positive control onto the 1st reaction circle of glass slide.
2. Using a micropipette, dispense 50 µl of isotonic saline onto the 2nd reaction circle of the glass slide.
3. Using a sample dropper provided, dispense one drop (50 µl) of animal serum to be tested onto the 3rd reaction circle.
4. Next add one drop of well mixed **QUADRAPED™** Brucel-RB antigen suspension into each of the above reaction circles containing positive control, isotonic saline and animal serum.
5. Detach 3 mixing sticks from the ladder, Mix contents of each circle uniformly with separate mixing sticks.
6. 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.

PERFORMANCE CHARACTERISTICS

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

REMARKS

(1). False positive results are likely if the test is read more than four minutes after mixing on the slide test. (2). Prozoning may sometimes be encountered in serum containing very high titres on slide test. (3). 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. (4). Use a separate disposable tip or sample dropper for each sample to prevent cross contamination. (5). Turbid and contaminated sera should not be used for testing. (6). After usage the antigen suspension should be immediately recapped and replaced at 2-8^{0}C. (7). Reagent vials that have leakage/ breakage problem should be discarded. (8). Only qualified and well trained staff should use the reagents. (9). It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis. (10).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). Textbook of Veterinary Microbiology by Prof. S.N. Sharma & Dr. S.C. Adlakha. (4). Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

8°C 2°C Temperature limitation	Manufacturer	Σ Contains sufficient for <n> tests	LOT Batch Number/ Lot Number	Date of Manufacture
Use by	Consult Instructions for use	This way up	IVD *In vitro* Diagnostic Medical Device	REF Catalogue Number

Manufactured by

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