



GENESIS

Instructions For Use

Brucella-RB (Agglutination Method)

Product	Cat no.	TEST
Brucella - RB	5103 101	100 TEST
Brucella – RB (With Controls)	5103 102	100 TEST

INTENDED USE

Brucella -RB Reagent (rapid slide agglutination tes) is intended 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 BRUCELLA-A/BRUCELLA-M antigen suspension.

REAGENT

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):-

	Reagents:-
1	Brucella -RB
2	Negative Control
3	Positive Control

REAGENT STORAGE AND STABILITY

- 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.
- The shelf life of the reagents is as per the expiry date mentioned on the reagent vial labels. Do not use beyond expiry date.

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 BRUCELLA-RB antigen suspension is mixed with the patient or animal serum. Specific antibodies to *Brucella* antigens if present in concentration 25 IU/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*.

SAMPLE COLLECTION AND STORAGE

- No special preparation of patient is required prior to sample collection by approved techniques. Do not use hemolysed serum samples.
- Clean and dry glassware free from detergents must be used for sample collection.
- Do not heat inactivate the serum.
- 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 BRUCELLA-RB antigen suspension well before dispensing.

Symbols in Product Labeling			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		Temperature Limit
	Consult instructions for use		

SLIDE TEST METHOD

Qualitative method

- Place one drop of Positive control
- Place 50 µl of saline onto the next reaction circle of the glass slide.
- Place 50 µl of serum to be tested onto the next reaction circle.
- Add one drop of well mixed BRUCELLA-RB antigen suspension in each of the above circles containing positive control, isotonic saline and serum to be tested.
- 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.

Semi-quantitative method

- Make serial two fold dilutions of the sample in 0.9% normal saline solution.
- Place one drop of BRUCELLA-RB 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 serum. No agglutination is a negative test result and indicates absence of antibodies to Brucella in concentration ≤ 25 IU/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.
 $25 \times \text{anti-Brucella titre} = \text{IU/mL}$

PERFORMANCE CHARACTERISTICS

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

BIBLIOGRAPHY

- J. G. Collee, J. P. Duguid, A. G. Fraser, Practical Medical Microbiology, 14th Ed.: 473-478.
- G. Galton, L. M. Jones, R. D. Angus, J. M. Verger, Techniques for the brucellosis laboratory, © INRA, Paris, 1988.

