

Rose Bengal Brucella Antigen

REF: 711 001 50 test
 REF: 711 002 100 test
 REF: 711 003 100 test + Positive Control
 REF: 711 004 100 test + Positive Control + Negative Control

Intended Use

Spectrum Diagnostics Brucella Rose Bengal reagent is intended for the early detection of Brucella specific agglutinins (Brucella Abortus, Melitensis and Suis).

Background

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. On exposure the body responds to this antigenic stimulation by producing specific antibodies whose titres 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 titre of antibodies can be obtained by using specific Spectrum Brucella antigen suspensions.

Assay Principle

The smooth, killed stained Brucella antigen suspensions are mixed with the patient's serum. Specific antibodies to Brucella antigens if present in the patient serum will react with the antigen suspension to produce an agglutination reaction. No agglutination indicates the absence of specific antibodies to Brucella antigens.

Reagent

Spectrum Brucella Rose Bengal reagent contains ready to use standardized, killed, stained, smooth specific antigen suspensions of Brucella having specific reactivity towards antibodies to Brucella Antigens.

Reagent Storage and Stability

1. Store the reagents at 2 – 8°C (Do not freeze).
2. The shelf life of reagent is as per the expiry date mentioned on the reagent vial labels. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance. Once opened, the reagent is stable for 6 months at 2 - 8°C if contamination is avoided.

Note

1. In-vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagent contains 0.01% thimerosal as preservative. Avoid contact with skin and mucosa. On disposal flush with plenty of water.

Specimen Collection and Storage

1. No special preparation of the patient is required prior to sample samples.
2. Clean and dry glassware free from detergents must be used for sample collection.
3. Don't heat inactive the serum.
4. Freshly collected serum is preferable, store samples at 2 – 8°C for 24 hours or frozen for several days.

Materials provided with the kit

1. Rose Bengal Brucella Antigen Suspension.
2. Positive Control (REF: 711 003).

SYMBOLS IN PRODUCT LABELLING		
	Authorised Representative	
	For in-vitro diagnostic use	
	Batch Code/Lot number	
	Catalogue Number	
	Consult instructions for use	
	Temperature Limitation	

3. Positive Control + Negative Control (REF: 711 004)

Additional material required

Slide test method:

Stop watch, positive control, isotonic saline, and glass slide with clear/white background, appropriate pipettes/Micropipettes, mixing sticks & a high intensity direct light source.

Procedure

1. Allow reagents and serum samples to reach room temperature before use.
2. Shake the antigen bottle gently to insure a uniform suspension.
3. Place one drop (40µl) serum sample to the selected ring of the slide.
4. Place one drop of the Rose Bengal antigen to serum sample.
5. Mix serum sample with Rose Bengal antigen using Stirring stick.
6. Repeat these steps using the positive and negative controls instead of serum sample.
7. Gently rock the slide for 2 minutes (automatic rotator can also be used).
8. Observe for agglutination after 2 minutes from beginning of shaking.

Interpretation of the results

Agglutination is a positive test result and indicates the presence of specific antibodies to Brucella in the patient serum.

No agglutination is a negative test result and indicates absence of specific antibodies to Brucella in the patient serum.

Limitations

1. Agglutinins are not always produced in bacterial infections.
2. Cross reactions may occur in certain pathologies. For instance, Tularemia infections may produce agglutinins to Brucella antigens.
3. Vaccinations may produce cross reacting antibodies.

Performance Characteristics

All the performance characteristics are found in the corresponding Technical Report and available on request

References

1. J. G. Collee, J.P. Duguid, A G Fraser. Practical Medical Microbiology, 13 th Ed: 525-530.
2. G.Galton, L.M.Jones, R.D.Angus, J.M.Verger. techniques for the Brucellosis laboratory, © INRA, Paris, 1988.
3. Felix A., (1942), Brit. Med. J., 11, 597.
4. Rose, J.E., Roepke, M.H., Am. J. Vet. Res. 18, 550-555 (1957).

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
711 001	50 test
711 002	100 test
711 003	100 test + Positive Control
711 004	100 test + Positive Control + Negative Control