BRUCELLA – A / BRUCELLA – M

INTENDED USE

Vitro rapid slide test for the qualitative and semi-quantitative determination of specific antibodies present in serum against Brucella Abortus.

METHOD

Slide agglutination test.

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 Tulip Brucel antigen suspensions.

ASSAY PRINCIPLE

The smooth, attenuated 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.

REAGENTS

Vitro Brucella-A / Brucella-M reagents contain ready to use standardized, attenuated, stained, smooth specific antigen suspensions of Brucella having specific reactivity towards antibodies to *Brucella abortus* (Brucella-A), and *Brucella melitensis* (Brucella–M).

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagents 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.

SPECIMEN

1. No special preparation of the patient is required prior to sample collection by approved techniques. Do not use hemolyzed samples.
2. Clean and dry glassware free from detergents must be used for sample collection.
3. Do not heat inactivate the serum.
4. Athough freshly collected serum is preferable, store samples at 2-8°C in case of delay in testing, for up to 72 hours.

PROCEDURE

1. Bring all reagents to room temperature. Shake and mix Vitro Brucella antigen suspensions well before dispensing.

The procedure for Brucella-A and Brucella-M is identical.

SLIDE TEST METHOD

Qualitative method

2. Place one drop of Positive control (available as Brucella Positive control) onto the reaction circle of glass slide.
3. Place 80 µl of isotonic saline onto the next reaction circle of the glass slide.
4. Place 80 µl of patient serum to be tested onto the next reaction circle.
5. Add one drop of appropriate Brucella antigen suspensions in each of the above circles (Containing positive control, saline, and the patient serum to be tested).
6. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
7. Gently rock the slide back and forth, observe for agglutination macroscopically **at one minute** against a white background.

Semi-quantitative method

1. Using a pipette place 80 µl, 40 µl, 20 µl, 10 µl and 5 µl of patient serum to be tested on 5 different circles on the glass slide. The corresponding titres obtained will be 1:20, 1:40, 1:80, 1:160, and 1:320 respectively.
2. Place one drop of appropriate Brucel antigen suspensions 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 one minute** against a white background.

TUBE TEST METHOD

1. Take 8 Test tubes and label them 1 to 8.
2. Pipette 1.9 ml of isotonic saline or preferably 0.25% phenol saline to tube No.1
3. To each of the remaining tubes (2-7) add 1.0 ml of isotonic saline or preferably 0.25% phenol saline.
4. To the tube No. 1 add 0.1 ml of serum sample to be tested. Mix well.
5. Transfer 1.0 ml of the diluted serum from tube No.1 to tube No.2 and mix well.
6. Transfer 1.0 ml of the diluted serum from tube No.2 to tube No. 3 and mix well. Continue this serial dilution till tube No. 7.
7. Discard 1.0 ml of the diluted serum from tube No. 7.
8. Pipette 1.0 ml of isotonic saline in tube No. 8, which serves as a negative control.
9. To all the tubes add 1 drop of appropriate Brucel antigen suspensions and mix well.
10. Cover the tubes and incubate at 37°C for 24 hours.
11. Observe for agglutination macroscopically in each tube of the dilution series.

INTERPRETATION OF RESULTS

SLIDE TEST METHOD

Qualitative method

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.

Semi-Quantitative method

Agglutination is a positive test result. The titer of patient serum corresponds to the visible agglutination in the test circle with the minimum amount of serum sample.

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TUBE TEST METHOD

The titer of the patient serum is the reciprocal of the last dilution of the serum sample that gives a granular agglutination. In negative reaction, the appearance of the suspension remains unchanged, which shows a typical swirl when the tube is flicked.

PROCEDURAL NOTES

1. Turbid and contaminated serum should not be used for testing.
2. In the semiquantitative test the reactions obtained are roughly equivalent to those which would occur in a tube test.
3. Agglutinins are found in high proportion of normal individuals and titres less than 1:80 are of doubtful significance. A rising titre is more significant than a single high titer.
4. False positive reactions may occur in sera of patients infected with *Pasteurella tularensis* or vaccinated with *Vibrio cholerae*.
5. False positive results are likely if the test is read more than one minute after mixing on the slide test.
6. It is recommended that results of the test should be correlated with the clinical findings to arrive at the final diagnosis.
7. Prozoning may sometimes be encountered in serum containing very high titers on slide test.
8. Since techniques and standardization vary from laboratory to laboratory one tube difference in titers can be expected.

WARNING & PRECAUTION

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 large quantities of water.

BIBLIOGRAPHY

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

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	Product	SIZE
5101	Brucella Abortus	1 X 5 ml
5111	Brucella melitensis	1 X 5 ml

Manufactured in Egypt by:
Vitro Scient
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