SPECTRUM

The Creative Approach to Bioscience

Brucella A/M

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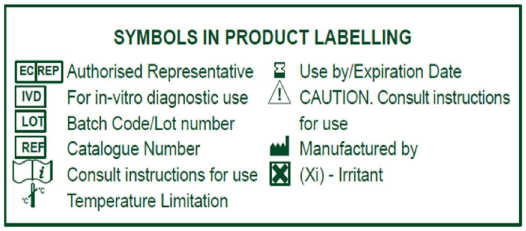

Intended Use

Spectrum Brucella reagent is intended for the detection of Anti-Brucella antibodies in human serum.

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-A / Brucella-M reagents contain ready to use standardized, killed, 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 reagents at 2 – 8^{o}C (Do not freeze).
2. The shelf life of reagent is as per the expiry date mentioned on the reagent vial labels.Open vial is stable for 6 months at the specified temperature. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

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 collection by approved techniques. Do not use haemolysed 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^{o}C for 24 hours or frozen for several days.

Materials provided with the kit

Stained Brucella-A / Brucella-M antigen suspension

Additional material required

Slide test method:
Stop watch, positive control, isotonic saline, glass slide with clear/white background, appropriate pipettes/micropipettes, mixing sticks and a high intensity direct light source.

Quantitative method:
Timer, test tubes (12 mm x 75 mm), appropriate pipettes/micropipettes, isotonic saline/0.25% phenol saline and incubator (37^{o}C).

Procedure

(a) Bring reagents to room temperature.
(b)Shake and mix Brucella antigen suspensions well before dispensing.
(c)The procedure for Brucella-A / Brucella-M is identical.

Slide test Method

1. Place one drop of positive control onto a reaction circle of the glass slide.
2. Place 80µl of saline onto the next reaction circle of the glass slide.
3. Place 80µl of patient serum to be tested onto each of the required number of reaction circle.
4. Add one drop of the appropriate Spectrum Brucella antigen suspension in each of the above circles. (containing positive control & saline and the patient 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, and observe for agglutination macroscopically at one minute against a white background.

Slide Semi-quantitative Method

1. Using a pipette place 80µl, 40µl, 20µl, 10µl and 5µl of patient serum to be tested on 5 different reaction circles on the glass slide. The corresponding titres obtained will be 1:20, 1:40, 1:80, 1:160 & 1:320 respectively.
2. Place one drop of appropriate Brucella antigen suspension to each circle.
3. Gently Rock the slide back and forth, and observe for agglutination macroscopically at one minute against a white background.

Tube-test procedure

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 of serum sample to be tested and mix well.
5. Transfer 1 ml of the diluted serum sample from tube No. 1 to tube No. 2 and mix well.
6. Transfer 1 ml of the diluted serum sample from tube No. 2 to tube No.3 and mix well.Continue this serial dilution till tube No.7 in each set.
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 negative control.
9. To all the tubes add one drop of appropriate Spectrum Brucella antigen suspensions and mix well.
10. Cover and incubate at 37^{o}C for 24 hours.
11. Observe for agglutination macroscopically in each tube of the dilution series.

Interpretation of the results

Slide screen 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.

Slide Semi-Quantitative method

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

Tube-test method

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

Note:Titers greater than 1/80 (Brucella Ag) indicate recent infection.

Remarks

1. Turbid and contaminated serum should not be used for testing.
2. In the semi quantitative test the reactions obtained are roughly equivalent to those which would occur in 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 titre.
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 slide test.
6. Its recommended that results of the tests should be correlated with clinical findings to reach the final diagnosis.
7. Prozoning may sometimes be encountered in serum containing very high titres on slide test.
8. Since techniques and standardization vary from lab to lab, one tube difference in tube titres can be expected.

Performance Characteristics

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

Warranty

This product is designed to perform as described on the label and package insert, the manufacturer disclaims any implied warranty of use and sale for any other purpose.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

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.

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