SBio Brucella Positive Control

Polyspecific serum control reactive with Brucella antigens.

REF	91020005
Pack	0.5 ml

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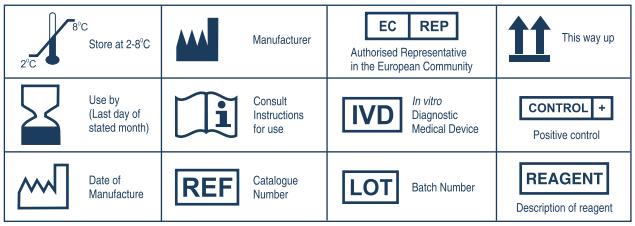

SUMMARY

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 Brucel antigen suspensions.

The performance of the SBio Brucella Abortus / Melitensis / RB antigen suspensions can be validated with the help of SBio Brucella Positive Control.

REAGENT

The SBio Brucella Positive Control contains ready to use standarized Goat antiserum with polyspecific antibodies having specific reactivity towards *Brucella abortus* & *Brucella* melitensis antigens and is useful in the validation of the performance of SBio Brucella Abortus / Melitensis / RB reagents.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.

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 bottle label. 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.

ADDITIONAL MATERIAL REQUIRED

Stop-watch, Isotonic saline, Glass slide with clear/white background, appropriate Pipettes/Micropipettes, Mixing sticks & a High intensity direct light source.

PRINCIPLE

The SBio Brucella Positive Control is mixed with the *Brucella* antigen suspensions to be tested and allowed to react. Specific reactivity of *Brucella* antigens if present in the antigen suspensions will produce an agglutination reaction. No agglutination indicates the deterioration of the performance of antigen suspensions.

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 large quantities of water.
3. The Positive control can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the Positive control be verified with the known Brucella antigen suspensions.
4. Only a clean and dry glass slides / tubes must be used. Clean the glass slides / tubes with distilled water and dry.
5. SBio Brucella Positive Control is not from human sources hence contamination due to HBsAg and HIV is practically excluded.
6. Do not use damaged or leaking reagents.

PROCEDURE

1. Bring all reagents to room temperature.
2. Shake and mix the SBio Brucella Positive Control well before dispensing.

Slide Test Method

1. Place one drop of SBio Brucella Positive Control onto the reaction circle of glass slide.
2. Place ~ 80 µl of saline onto the next reaction circle of the glass slide.
3. Add one drop of test reagent (Brucella antigen suspensions) in each of the above circles.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Gently rock the slide back and forth, observe for agglutination macroscopically **at one minute** against a white background.

INTERPRETATION OF RESULTS

Slide test method

Agglutination is a positive test result and indicates that the *Brucella* antigen reagents are performing satisfactorily.

No agglutination is a negative test result and indicates the deterioration of *Brucella* antigen reagents.

REMARKS

1. Since techniques and standardization vary from laboratory to laboratory on tube difference in titres can be expected.
2. Turbid and contaminated controls should not be used for testing.
3. After usage the control should be immediately recapped and replaced at 2-8°C.
4. Reagent vials that have leakage/ breakage problem should be discarded.
5. Only qualified and well trained staff should use the reagents.
6. The performance of the positive control should be validated periodically using SBio Brucella antigen suspensions.

PERFORMANCE CHARACTERISTICS

1. The positive control antisera should produce 1+ or greater agglutination at 1: 80 titre in the slide and tube test when tested with the SBio Brucella Abortus / Melitensis / RB antigen suspensions.
2. The negative control should show no agglutination with any of the SBio Brucella Abortus / Melitensis / RB antigen suspensions.

3. Reproducibility of SBio Brucella Positive Control is 100% (+/- one double dilution).

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, 13th Ed.: 525 – 530.
2. G. Galton, L. M. Jones, R. D. Angus, J. M. Verger, Techniques for the Brucellosis laboratory, INRA, Paris, 1988.

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EC REP

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