



## BRUCELLOSIS

### POSITIVE CONTROL

#### INTENDED USE

BRUCELLOSIS POSITIVE CONTROL can be used for validating the performance of BRUCEL<sup>®</sup>-A/BRUCEL<sup>®</sup>-M/BRUCEL<sup>®</sup>-RB antigen suspensions.

#### 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. 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<sup>®</sup> antigen suspensions.

#### REAGENT


The BRUCELLOSIS POSITIVE CONTROL contains ready to use standardized Goat antiserum with polyspecific antibodies having specific reactivity towards *Brucella abortus* & *Brucella melitensis* antigens and is useful in the validation of the performance of BRUCEL<sup>®</sup>-A/BRUCEL<sup>®</sup>-M/BRUCEL<sup>®</sup>-RB reagents.

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

#### REAGENT STORAGE AND STABILITY

1. Store the control reagent at 2-8°C. DO NOT FREEZE. Keep the control reagent away from direct sunlight.
2. The shelf life of the control reagent is as per the expiry date mentioned on the control vial label. Do not use beyond expiry date.
3. Once opened the shelf life of the control reagent is as described on its vial label provided it is not contaminated.

#### PRESENTATION

		0.5 ml	1 ml
<b>REF</b>		110200005	110200001
Control	+	0.5 ml	1 ml
PACKAGE INSERT		1 No.	1 No.

#### 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 BRUCELLOSIS 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 control reagent contains 0.1 % sodium azide 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. BRUCELLOSIS POSITIVE CONTROL is not from human source 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 BRUCELLOSIS POSITIVE CONTROL well before dispensing.

### Slide Test Method

1. Place one drop of BRUCellosis 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**.

### 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. 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. Control vials that have leakage/ breakage problem should be discarded.
5. Only qualified and well trained staff should use the controls.
6. The performance of the positive control should be validated periodically using BRUCEL antigen suspensions.

### PERFORMANCE CHARACTERISTICS

1. The positive control antisera should produce 1+ or greater agglutination in the slide at one minute when tested with the BRUCEL<sup>®</sup>-A/BRUCEL<sup>®</sup>-M/BRUCEL<sup>®</sup>-RB antigen suspensions.
2. Reproducibility of BRUCellosis 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, 14th Ed.: 473 – 478. (2). G. Galton, L. M. Jones, R. D. Angus, J. M. Verger, Techniques for the Brucellosis laboratory, INRA, Paris, 1988. (3). Data on file: Tulip Diagnostics (P) Ltd.

### SYMBOL KEYS

 Temperature limitation	 Manufacturer	 Contains sufficient for <n> tests
 Use by	 Consult Instructions for use	 This way up
 Date of Manufacture	 Catalogue Number	 Production Site
 Batch Number/ Lot Number	 <i>In vitro</i> Diagnostic Medical Device	 Positive control
 Authorised Representative in the European Community		



Manufactured by

**TULIP DIAGNOSTICS (P) LTD.**



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**Manufacturing Unit**

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