



Control Report

Batch control of a Rose Bengal Test Antigen (Animal brucellosis serology)

**French Agency for Food,
Environmental &
Occupational Health
Safety**

Maisons-Alfort

**LABORATOIRE DE SANTE
ANIMALE**

ANIMAL HEALTH LABORATORY

Unité Zoonoses Bactériennes
Bacterial Zoonoses Unit

Centre National de
Référence des *Brucella*

*National Reference Centre
for Human Brucellosis*

Laboratoire National de
Référence pour la
Brucellose, la Chlamydieuse,
la Fièvre Charbonneuse, la
Morve, la Tuberculose & la
Tularémie animales

*Animal Anthrax, Brucellosis,
Chlamydiosis, Glanders,
Tuberculosis & Tularaemia
National Reference
Laboratory*

Laboratoire de Référence
O.I.E. / FAO
pour la Brucellose,
la Paratuberculose et
la Tuberculose bovine

*OIE /FAO
Reference Laboratory
for Brucellosis,
Bovine Paratuberculosis
and Tuberculosis*

Laboratoire de Référence de
l'UE pour la Brucellose

*EU Reference Laboratory for
Brucellosis*

Laboratoire de Référence de
l'UE pour les Maladies
Equines (Morve)

*EU Reference Laboratory for
Equine Diseases (Glanders)*

Supplier / Manufacturer	SYNBIOTICS Europe
Commercial name	BENGATEST
Product reference	ABGT
Batch number	16ZBAB003
Expiry date	23 March 2020
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 10 mL.
Batch size	2127
Reference ANSES	D-16-4323/10784
Date of control	18 November 2016
Standard references	Annex C of 64/432/EC directive and OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Chapt. 2.1.4) (<i>Current versions</i>)
Operating procedure	French standards AFNOR NF U 47-304 & U 47-003
Instructions for use	Satisfactory (version : February 2013)

Control test	Criteria	Results
Purity (Gram staining)	Gram negative coccobacilli	Passed
Antigen titration BRU POS SE 01*	Positive at 1/45 dilution Negative at 1/55 dilution	Passed
Sensitivity 5 positive sera	Always positive	Passed
Specificity 5 negative sera	Always negative	Passed

Conclusion	Passed
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* French National Standard equivalent to the OIEISS

Maisons-Alfort, 18 November 2016

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Laboratory for Brucellosis

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