



N° 1809-00656-01 Report annex
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

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

*Animal Anthrax, Brucellosis,
Chlamydiosis, Glanders,
Tuberculosis & Tularemia*
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)*

Version 4_2014-01

Supplier / Manufacturer ZOETIS
Commercial name BENGATEST
Product reference ABGT
Batch number 18ZBAB016
Expiry date 23 february 2022
Description Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT).
Vial of 10 mL
Batch size 800

Reference ANSES D-18-3930/6058
Date of control 19 september 2018
Standard references Annex C of 64/432/EC directive and OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Chapt. 2.1.4) (Current versions)
Operating procedure French standards AFNOR NF U 47-304 abrogated & U 47-003
Instructions for use Satisfactory (version : April 2017)

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, 19 september 2018

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UE / OIE / FAO Reference
Laboratory for Brucellosis

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