



1801-01352-01 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 & 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)

Version 4_2014-01

Supplier / Manufacturer	ZOETIS
Commercial name	BENGATEST litre
Product reference	ABGT
Batch number	17ZBAC003
Expiry date	02 May 2021
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 100 mL.
Batch size	182

Reference ANSES	D-17-5025/10482
Date of control	19 January 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 : 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, 25 January 2018

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Laboratory for Brucellosis

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