



N° 1901-00959-01 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
Product reference	ABGT
Batch number	18ZBAB021
Expiry date	23 May 2022
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 10 mL
Batch size	900 vials

Reference ANSES	D-19-0019/0026
Date of control	09 January 2019
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 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, 09 January 2019

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