



**N° 1807-00662-01 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 Chlamydiose,  
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	ABGTC	
Batch number	18ZBAC006	
Expiry date	08 December 2021	
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 10 mL	
Batch size	185	
Reference ANSES	D-18-2535/4113	
Date of control	09 July 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) ( <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
<b>Purity</b> (Gram staining)	Gram negative coccobacilli	<b>Passed</b>
<b>Antigen titration</b> BRU POS SE 01*	Positive at 1/45 dilution Negative at 1/55 dilution	<b>Passed</b>
<b>Sensitivity</b> 5 positive sera	Always positive	<b>Passed</b>
<b>Specificity</b> 5 negative sera	Always negative	<b>Passed</b>

<b>Conclusion</b>	<b>Passed</b>
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\* French National Standard equivalent to the OIEISS

Maisons-Alfort, 12 July 2018

Acacia FERREIRA VICENTE  
UE / OIE / FAO Reference  
Laboratory for Brucellosis

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EU Reference Laboratory  
for Brucellosis

Laboratoire de Référence de l'UE  
pour la Brucellose



OIE/FAO Brucellosis Reference Laboratory

Laboratoire de Référence OIE/FAO  
pour la Brucellose

