



**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 Chlamydirose,  
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	SYNBIOTICS Europe
Commercial name	BENGATEST
Product reference	ABGT
Batch number	16ZBAB004
Expiry date	13 April 2020
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 10 mL.
Batch size	1828

Reference ANSES	D-16-4687/11439
Date of control	4 January 2017
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 47-310 & U 47-003
Instructions for use	Satisfactory (version : February 2013)

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>Failed</b> <b>Positive at 1/55</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>Failed</b>
-------------------	---------------

\* French National Standard equivalent to the OIEISS

Maisons-Alfort, 16 February 2017

Maryne Jaÿ  
Project manager  
UE / OIE / FAO Reference  
Laboratory for Brucellosis

This report applies only to the items submitted to control.  
Reproduction of this report is authorized in its integral form only.  
This report includes 0 annex (es)