



Control Report

Batch control of a Complement Fixation 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 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 France	
Commercial name	ANTIFIX	
Product reference	AATI	
Batch number	17ZBAA002	
Expiry date	10 February 2019	
Description	Serological diagnosis of animal brucellosis by Complement Fixation Test (CFT). Vial of 20 mL.	
Batch size	87	
Reference ANSES	D-17-4195/8077	
Date of control	09 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) (<i>Current versions</i>)	
Operating procedure	French standards AFNOR NF U 47-304 abrogated & U 47-004	
Instructions for use	Satisfactory (version : February 2013)	
Control test	Criteria	Results
Purity (Gram staining)	Gram negative coccobacilli	Passed
Antigen titration BRU POS SE 02*	50% haemolysis inhibition at the 1/200 dilution	Passed
Sensitivity 5 positive sera	Always positive	Passed
Specificity 5 negative sera	Always negative	Passed
Conclusion	Passed	

* French National Standard equivalent to the OIEISS

Maisons-Alfort, 17 January 2018

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UE / OIE / FAO Reference
Laboratory for Brucellosis

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