

**N° 1808-00018-01 Report Annex
Control Report**
**Batch control of a Seroagglutination 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 France (SYNBIOTICS Europe)	
Commercial name	Antigen SAW	
Product reference	ASAW	
Batch number	18ZBAI002	
Expiry date	08 june 2021	
Description	Serological diagnosis of animal brucellosis by Seroagglutination Test (SAT). Vial of 100 mL.	
Batch size	50	
Reference ANSES	D-18-2587/4142	
Date of control	31 july 2018	
Standard references	Annex C of 64/432/EC directive and OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Chapt. 2.4.3) (<i>Current versions</i>)	
Operating procedure	French standards AFNOR NF U 47-304 abrogated & U 47-021	
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% agglutination at the 1/650 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, 01 august 2018


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UE / OIE / FAO Reference
Laboratory for Brucellosis

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des Brucelloses Animales
National Reference Laboratory
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Laboratoire de Référence de l'UE
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