

**1805-00381-01 Report Annex**  
**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*

Laboratoire National de  
Référence pour la  
Brucellose, la Chlamydiose,  
la Fièvre Charbonnueuse, 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	ID.vet
Commercial name	Brucellosis Antigen for CFT
Product reference	AG-BRU
Batch number	006
Expiry date	march 2020
Description	Serological diagnosis of animal brucellosis by Complement Fixation Test (CFT). Vial of 5 mL.
Batch size	20
Reference ANSES	D-18-1102/3088
Date of control	15 may 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 & U 47-004
Instructions for use	Satisfactory (version : 0512)
<b>Control test</b>	<b>Criteria</b>
<b>Purity</b> (Gram staining)	Gram negative coccobacilli
<b>Antigen titration</b> BRU POS SE 02*	50% haemolysis inhibition at the 1/200 dilution
<b>Sensitivity</b> 5 positive sera	Always positive
<b>Specificity</b> 5 negative sera	Always negative
<b>Conclusion</b>	<b>Passed</b>

\* French National Standard equivalent to the OIEISS

Maisons-Alfort, 23 may 2018.



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des Brucelloses Animales  
*National Reference Laboratory  
for Animal Brucellosis*

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for Brucellosis  
Laboratoire de Référence de l'UE  
pour la Brucellose



OIE/FAO Brucellosis Reference Laboratory  
Laboratoire de Référence OIE/FAO  
pour la Brucellose

