



N° 1805-00666-01 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 Chlamydie,
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	IDEXX Montpellier SAS
Commercial name	Pourquier® Brucellosis SAW Ag
Product reference	P00110
Batch number	421
Expiry date	12 may 2021
Description	Serological diagnosis of animal brucellosis by Seroagglutination Test (SAT). Vial of 100 mL.
Batch size	180

Reference ANSES	D-18-0559/1029
Date of control	23 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) (Current versions)
Operating procedure	French standards AFNOR U 47-310 & U 47-021
Instructions for use	Satisfactory version : 06-00110-05

Control test	Criteria	Results
Purity (Gram staining)	Gram negative coccobacilli	Passed
Antigen titration BRU POS SE 02*	50% agglutination at the 1/600 dilution	Passed
Sensitivity 5 positive sera	Always positive	Passed
Specificity 5 negative sera	Always negative	Passed

Conclusion	Passed
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* French National Standard equivalent to the OIEISS

Maisons-Alfort, 5th of June 2018

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Laboratory for Brucellosis

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