



**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 & Tularemia
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 Laboratories
Commercial name	IDEXX Brucellosis Serum
Product reference	P04130-2
Batch number	8007
Expiry date	19 January 2020
Description	Serological diagnosis of bovine brucellosis by indirect ELISA. Individual sera or pools of 10 sera.
Batch size	238 kits of 2 plates

Reference ANSES	D-18-460/836
Date of control	7 March 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 standard AFNOR NF U 47-310
Instructions for use	Satisfactory (version : 06-04130-14)

Control test	Criteria	Results
Criteria for test validity	OD pos > 0.350 OD pos / OD neg > 3	Passed
Detectability BRU POS SE 03*	Positive at 1/16 dilution	Passed
Lower limit of detection BRU POS SE 03*	Negative at 1/64 dilution	Passed
Repeatability Positive serum (<i>close to cut-off</i>)	CV<10%	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 OIEELIS_{spSS}

Maisons-Alfort, 15 March 2018

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UE / OIE / FAO Reference
Laboratory for Brucellosis

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