



**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	P04130-10
Batch number	8020
Expiry date	19 January 2020
Description	Serological diagnosis of bovine brucellosis by indirect ELISA. Individual sera or pools of 10 sera.
Batch size	300 kits of 10 plates

Reference ANSES	D-18-380/624
Date of control	26 February 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, 05 March 2018

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UE / OIE / FAO Reference
Laboratory for Brucellosis

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