



**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 Laboratories  
Commercial name IDEXX Brucellosis Serum  
Product reference P04130-10  
Batch number 8094  
Expiry date 14 september 2020  
Description Serological diagnosis of bovine brucellosis by indirect ELISA. Individual sera or pools of 10 sera.  
Batch size 243 kits of 10 plates

Reference ANSES D-18-4340/6782  
Date of control 09 october 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.) (Current versions)  
Operating procedure French standard AFNOR NF U 47-310  
Instructions for use Satisfactory (version : 06-04130-14)

Control test	Criteria	Results
<b>Criteria for test validity</b>	OD pos > 0.350 OD pos / OD neg > 3	<b>Passed</b>
<b>Detectability</b> BRU POS SE 03*	Positive at 1/16 dilution	<b>Passed</b>
<b>Lower limit of detection</b> BRU POS SE 03*	Negative at 1/64 dilution	<b>Passed</b>
<b>Repeatability</b> Positive serum (close to cut-off)	CV<10%	<b>Passed</b>
<b>Sensitivity</b> 5 positive sera	Always positive	<b>Passed</b>
<b>Specificity</b> 5 negative sera	Always negative	<b>Passed</b>

**Conclusion Passed**

\* French National Standard equivalent to the OIEELIS<sub>SPSS</sub>

Maisons-Alfort, 17 October 2018

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UE / OIE / FAO Reference  
Laboratory for Brucellosis

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