



**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,
Chlamydia, 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 5_2014-01

Supplier / Manufacturer	IDEXX Laboratories
Commercial name	IDEXX Brucellosis Milk
Product reference	P04210
Batch number	8002
Expiry date	05 June 2020
Description	Serological diagnosis of bovine brucellosis in bulk milk by indirect ELISA.
Batch size	100 kits of 2 plates & 201 kits of 10 plates
Reference ANSES	D-18-2508/4082
Date of control	28 June 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 : 06-04210-13)

Control test	Criteria	Results
Criteria for test validity	OD Pos \geq 0.4 OD pos / OD neg \geq 3	Passed
Detectability BRU POS SE 03*	Positive at 1/125** dilution	Passed
Lower limit of detection BRU POS SE 03*	No requirement	Dilution (\leq): 1/500**
Repeatability Positive serum (close to cut-off)	CV < 10%	Passed
Sensitivity 5 positive sera	Always positive	Passed
Specificity 4 negative milk samples & negative serum	Always negative	Passed

Conclusion Passed

* French National Standard equivalent to the OIEELIS_{SPSS}

** Before further 1/10 dilution in negative milk

Maisons-Alfort, 12 July 2018

Acacia FERREIRA VICENTE
UE / OIE / FAO Reference
Laboratory for Brucellosis

This report applies only to the items submitted to control.
Reproduction of this report is authorized in its integral form only.
This report includes 0 annex (es)

