



1806-00360-01 Report annex
Control Report
Batch control of a Rose Bengal 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® Rose Bengale Ag
Product reference	P00230
Batch number	424
Expiry date	30 October 2020
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 100 mL.
Batch size	400

Reference ANSES	D-18-2011/3399
Date of control	08 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) (<i>Current versions</i>)
Operating procedure	French standards AFNOR NF U 47-304 abrogated & U 47-003
Instructions for use	Satisfactory (version: 06-00215-03)

Control test	Criteria	Results
Purity (Gram staining)	Gram negative coccobacilli	Passed
Antigen titration BRU POS SE 01*	Positive at 1/45 dilution Negative at 1/55 dilution	Passed
Sensitivity 5 positive sera	Always positive	Passed
Specificity 5 negative sera	Always negative	Passed

Conclusion	Passed
-------------------	---------------

* French National Standard equivalent to the OIEISS

Maisons-Alfort, 08 June 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)

