



1801-01350-01 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 & 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 Montpellier SAS
Commercial name	POURQUIER®Rose Bengale Ag
Product reference	P00215
Batch number	419
Expiry date	30 October 2020
Description	Serological diagnosis of animal brucellosis by Rose Bengal Test (RBT). Vial of 10 mL.
Batch size	1400
Reference ANSES	D-17-4900/10312
Date of control	19 January 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 : 06-00215-02)

Control test	Criteria	Results
<b>Purity</b> (Gram staining)	Gram negative coccobacilli	<b>Passed</b>
<b>Antigen titration</b> BRU POS SE 01*	Positive at 1/45 dilution Negative at 1/55 dilution	<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>

<b>Conclusion</b>	<b>Passed</b>
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\* French National Standard equivalent to the OIEISS

Maisons-Alfort, 25 January 2018

UE / OIE / FAO Reference  
Laboratory for Brucellosis

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