

**Laboratoire de Santé Animale**

**Unité Zoonoses Bactériennes**

*Laboratoire National de Référence pour la Brucellose, les Mycobactérioses, la Tularémie, le Charbon bactérien, la Morve et pour la Chlamydie aviaire*

*Brucellosis, Mycobacterioses, Tulareamia, Anthrax, Glanders and Avian Chlamydiosis French Reference Laboratory*

*Laboratoire de Référence OMSA (OIE) pour la Brucellose, les Chlamydioses aviaire et abortive, la Morve et la Tuberculose bovine*

*Brucellosis, Avian Chlamydiosis, Enzootic Abortion in ewe, Glanders and bovine Tuberculosis WOA (OIE) Reference Laboratory*

*Laboratoire Communautaire de Référence pour la Brucellose et la Morve*

*EU Community Reference Laboratory for Brucellosis and Glanders*

Version 1\_2024-01

Supplier / Manufacturer	Innovatives Diagnostics (ID-Vet)
Commercial name	ID Screen Bovine Brucellosis Indirect
Product reference	BRUS
Batch number	P76
Expiry date	01/2027
Description	Serological diagnosis of bovine brucellosis by indirect ELISA. Individual serum or pool of 10 sera.
Batch size	1000 plates

Reference ANSES	D : 25-0145/0152
Date of control	05/02/2025
Standard references	Regulation (EU) 2017/625 and WOA (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Chapt. 3.1.4.) (Current versions)
Operating procedure	French standard AFNOR XP U 47-310 & NF U 47-019
Instructions for use	Satisfactory (version : 0215)

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 OIE ELISA<sub>SPSS</sub>

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