

MONOSCREEN^{Ab} ELISA - Brucellosis

BIOK140-Brucella_PP01_(EN)_V01
31/07/2025

Reference: BIO K 140

BRIEF OUTLOOK ON THE DISEASE

Brucellosis is a disease caused by the pathogen *Brucella sp.*. It is a bacterium of the order Rhizobiales. Animal brucellosis affects **cattle, sheep, pigs and goats**. It causes reproductive disorders (the *Brucella* bacterium multiplies in the placenta and fetus, resulting in spontaneous abortion).

The animal reservoir consists of numerous terrestrial animals.

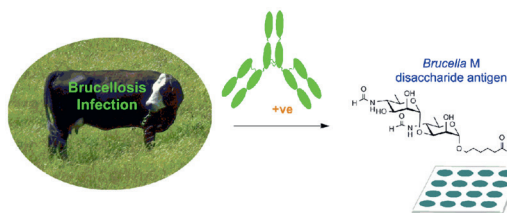
The mains species of *Brucella* are:

- ***Brucella melitensis*** main causative agent [*B. melitensis* biotype 3: 90,7% of identified strains]: ovine, caprine (Mediterranean Basin, Middle East).
- ***Brucella abortus*** : cattle (ubiquitous).
- ***Brucella suis*** : pigs (America, Asia, Oceania).

Bovine brucellosis (bB) is a global zoonosis primarily caused by *Brucella abortus*, a facultative intracellular pathogen mainly associated with cattle, its natural or primary host.

In cattle, the clinical presentation of bB is varied and non-pathognomonic. The isolation and identification of *Brucella sp.* is considered the standard diagnostic method of reference; a positive test result allows for an unequivocal diagnosis of brucellosis.




Bio-X Diagnostics is a pioneer in developing an immunodiagnostic method using synthetic antigens to improve the serological diagnosis of brucellosis. A new diagnostic phase is now possible for the detection of *Brucella*-specific serum antibodies in individuals and in mixtures using the indirect ELISA test developed in accordance with ANSES specifications.



Bundle and McGiven 2017 Brucellosis Improved Diagnostics and Vaccine Insights from Synthetic Glycans

« A specific and sensitive serological approach that limits the risk of false positives. »


AIM OF THE TEST


-  Rapid and effective detection of antibodies against *Brucella sp.* in bovine and small ruminants sera.
-  Monitoring strategies for the detection and control of bovine brucellosis.
-  Different cut-off values depending on pooled and individual analyses, in line with the high performances of sensitivity and specificity of the test.

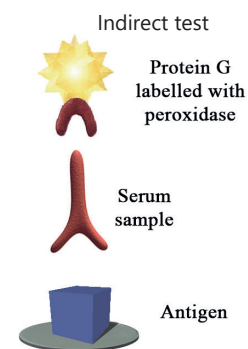
SPECIFICITY OF THE TEST

BIO K 140 - MonoScreen AbELISA - *Brucella*

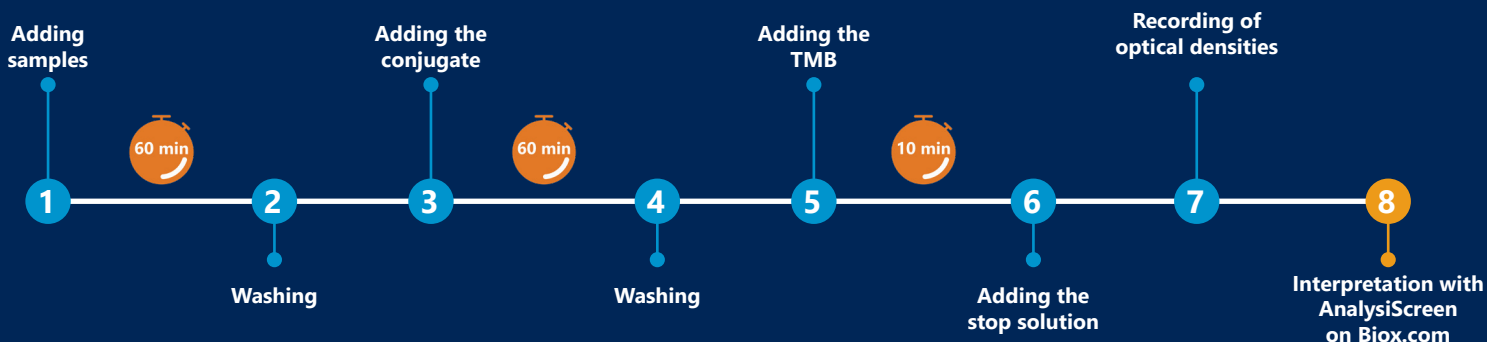
Indirect monowell ELISA test
Coating: synthetic *Brucella* antigen

 Sample: serum
Dilution 1/100

 Use of a conjugate, G protein coupled to peroxidase
Reading at 450 nm
Incubation time: 2h30 + 10 min
Substrate: single component TMB



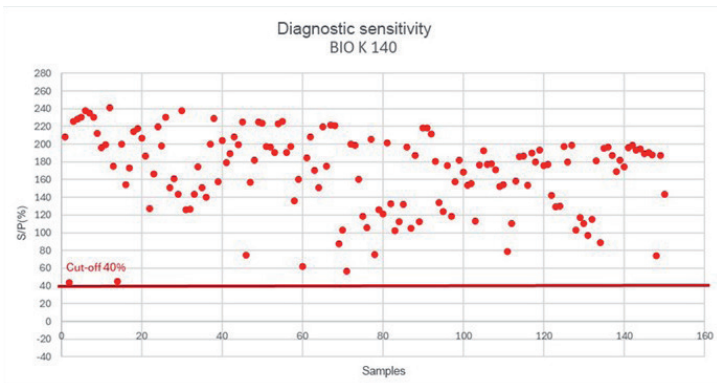
BIO K 140: MonoScreen AbELISA - *Brucella* Simplified protocol



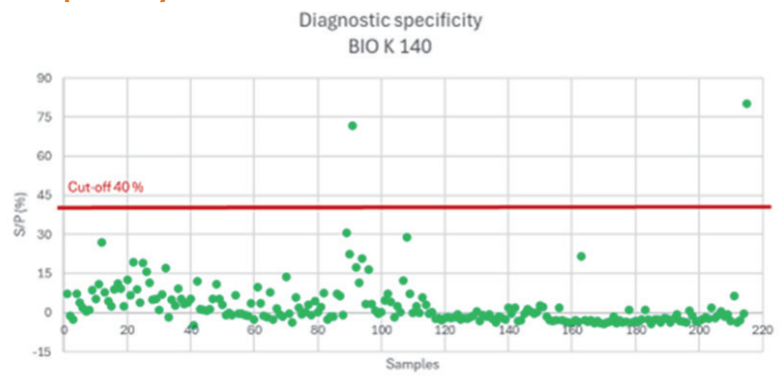


VALIDATION IN INDIVIDUAL SERUM

Sensitivity in individual serum



Specificity in individual serum

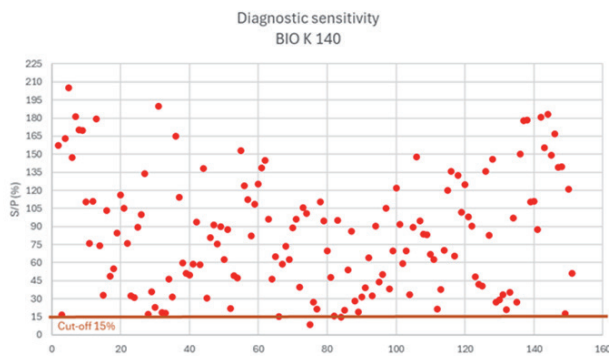


One hundred and fifty sera from animals diagnosed as *Brucella*-positive and 215 sera from animals diagnosed as *Brucella*-negative were tested. On a qualified panel of 365 sera, BIO K 140 showed an **estimated diagnostic sensitivity of 100 %** and a **diagnostic specificity of 99 %**.



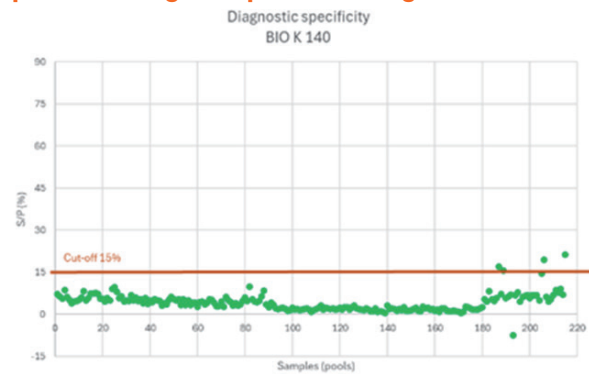
VALIDATION IN POOL

Diagnostic sensitivity in pool of 10



98,7% positive mixtures out of 150 mixtures of 10 (with a cut-off of 15%)

Spécificité diagnostique en mélange de 10



98,1% negative mixtures out of 215 mixtures of 10 (with a cut-off of 15%)

Selection of the cut-off point for interpreting results

| | Results | Status |
|-------------------|------------|----------|
| Individual sample | %S/P < 40% | Negative |
| | %S/P ≥ 40% | Positive |
| Pool of 10 | %S/P < 15% | Negative |
| | %S/P ≥ 15% | Positive |

- ✓ No cross-reactivity with pathogens other than *Brucella* causing abortions (*Neospora caninum*, *BVDV*, *Coxiella burnetii*, *Besnoitia besnoiti*).
- ✓ Seropositive samples detected at 100% individually
- ✓ On three different plates, all samples tested positive with a low CV of 6.02%.
- ✓ An interlaboratory test demonstrates good interlaboratory reliability (CV < 15%).

« MONOSCREEN™ AbELISA *Brucella* offers remarkable sensitivity and specificity and is one of the most specific methods for detecting *Brucella* infections.»

TO ORDER :

| Code | Description | Nb. of reactions |
|-------------|-------------------------------------|----------------------|
| BIO K 140/2 | Monoscreen™ AbELISA <i>Brucella</i> | 2 plates / 192 tests |
| BIO K 140/5 | | 5 plates / 480 tests |



Smart solutions for sharp decisions

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