

# MONOSCREEN<sup>Ab</sup> ELISA - *Besnoitia besnoiti*

BIOK466-Besnoitia besnoiti\_PP01\_(EN)\_V02  
23/01/2024

Reference : BIO K 466



French NRL  
approval for  
individual  
and pool

## BRIEF OUTLOOK ON THE DISEASE

*Besnoitia besnoiti* is an intracellular protozoan strictly responsible for bovine Besnoitiosis, often called «cattle anasarca». The disease mainly affects young cattle. Besnoitiosis is epizootic in the south of France, but it is now widespread in Africa, Asia and southwestern Europe. Given global warming and animal transfers, the disease is gradually moving north (first cases in Belgium in 2021, for example). The preferred route of transmission is transcutaneous, by biting insects (tabanids, stomoxes).

During the infection, an incubation phase of 3 to 6 days is followed by **3 successive clinical stages**:

- **A febrile stage** of 3 to 7 days; the multiplication of tachyzoites in the endothelial cells of blood vessels causes hyperthermia in the animal.
- **A second phase** of 1 to 2 weeks; bradyzoite cysts generate subcutaneous edema.
- **A chronic phase** lasting several months, characterized by alopecia and scleroderma. The skin then becomes clearly thickened and wrinkled, and parasitic cysts are seen on the conjunctiva and sclera. This final phase generally leads to the death of the animal or to its euthanasia.

Bio-X Diagnostics was a pioneer in developing a PCR method which has the advantage of detecting infected animals in the very early febrile phase, by detecting tachyzoites in blood monocytes. A new diagnostic phase is now made possible for the detection of antibodies specific to *Besnoitia besnoiti* in individual and pool by the ELISA blocking test developed according to ANSES specifications..

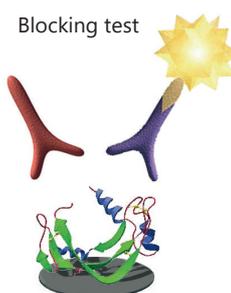
## « A specific and sensitive serological approach »

### AIM OF TEST

-  Rapid and effective detection of specific *Besnoitia besnoiti* antibodies (IgM, IgG)
-  Monitoring of control and treatment strategies of bovine besnoitiosis
-  Identical cut-offs for mixed and individual assays demonstrating the **high sensitivity and specificity of the test**

### SPECIFICITY OF THE TEST

-  **BIO K 466 - MonoScreen AbELISA - *Besnoitia Besnoiti***  
Blocking monowell ELISA test  
Coating : culture lysate of *Besnoitia besnoiti*
-  Sample: serum  
Dilution 1/2
-  G Protein conjugate  
Reading Wavelength: 450nm  
Incubation time : 2h30 + 10 min  
Substrate : Single component TMB



### BIO K 466: MonoScreen AbELISA - *Besnoitia Besnoiti* Simplified protocol



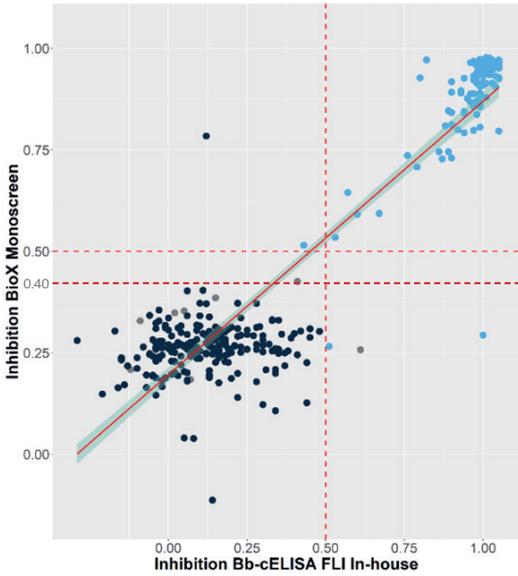


# EXTERNAL EVALUATION OF THE TEST

"Validation of a commercial version of a competitive enzyme linked immunosorbent assay for the detection of antibodies to *Besnoitia besnoiti*."

Gereon Schares (FLI), Andrea Barwald, Marie-Astrid Vernet, Frédéric Bernard, Béatrice Blanchard, Philippe Coppe.

A total of 305 bovine sera has been collected from German herds infected by *B. besnoiti*, *Neospora caninum* or *Sarcocystis spp.* Sera had been characterized by reference serological tests (immunoblot, immunofluorescence test and FLI indirect ELISA).



Correlation of the inhibition values obtained in the Monoscreen AbELISA *Besnoitia besnoiti* (BIO K 466) and the Bb-cELISA (FLI in-house) including *Besnoitia besnoiti* reference positive (blue), reference negative (black) samples and reference negative samples but with positive immunofluorescence test titer (grey).

On a qualified panel of 305 sera, the BIO K 466 shows an **estimated diagnostic sensitivity of 97,9 %** and a **diagnostic specificity of 99,5 %** relative to reference (see table below). A direct comparison of the results revealed an almost perfect agreement between the results of the in-house Bb-cELISA and the commercialized version (Kappa 0.98; 95% CI: 0.95-1). The positive-negative test result of both tests largely agreed with only five sera of a total number of 305 showing divergent results (see figure on the left).

Herd (number of herds)	Status	Number (additional information)	Sensitivity	Specificity
Besnoitiosis herds (n=2)	Besnoitia-positive	95 (positive IFAT* titer)	97.9% [91,9% - 99,6%]	99.5% [96,9% - 100%]
	Besnoitia-negative	9 (positive IFAT titer)		
Neosporosis herd (n=1)	Neospora-positive	97 (including 6 with abortion)		
	Neospora-negative	4		
Sarcocystis herd (n=1)	NA**	100		

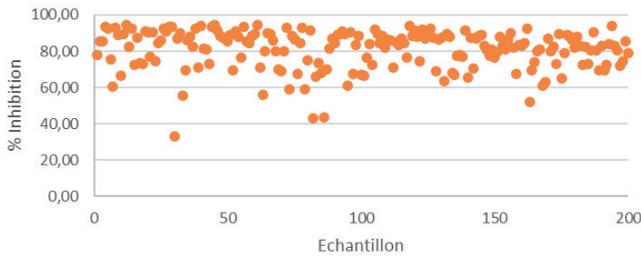
\*IFAT, immunofluorescence test, \*\* Sarcocystis spp. status unknown, frequent cases of eosinophilic myositis were recorded for this herd at slaughter



## VALIDATION IN POOL ACCORDING TO ANSES SPECIFICATIONS

### Diagnostic sensitivity in pool of 10

Diagnostic sensitivity  
BIO K 466  
Pool of 10



#### 99,5% of positive pools with a cut-off of 40%

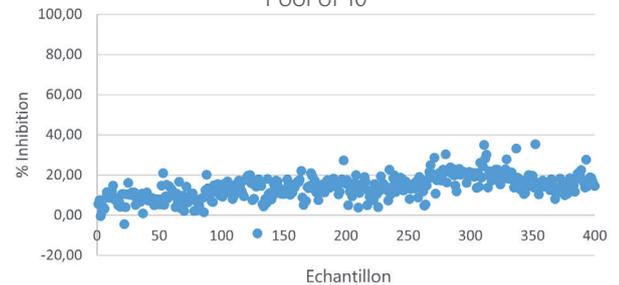
Serums analytically and epidemiologically qualified from infested animals from 12 herds geographically representative of the national territory were tested in **201 pools of 10**.

### Validation on the LOD in 10 replicates at 1/10th

On two different plates, all samples were found to be positive with a CV of 5,61%.

### Diagnostic specificity in pool of 10

Diagnostic specificity  
BIO K 466  
Pool of 10



**100% of negative pools on 400 pools of 10 with a cut-off of 40%** (Serums from several herds from European countries that have not recorded an outbreak of *Besnoitiosis*).

« MONOSCREEN™ AbELISA *Besnoitia besnoiti* presents a remarkable sensitivity and specificity, with the same cut-off in individual and pool analysis. »

### TO ORDER :

Code	Description	Nb. of reactions
BIO K 466/2	Monoscreen™ AbELISA <i>Besnoitia besnoiti</i>	2 plates / 192 tests
ADI451-100	ADIAVET™ <i>Besnoitia</i> Real Time	100 R

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