

MONOSCREEN^{Ab} ELISA

Coxiella burnetii – phase I
ELISA Kit for serodiagnosis of Q Fever
Indirect test for blood sera, plasma and milk
Diagnostic test for cattle and small ruminants
Monowell
BIO K 404

Q fever affects human beings, cattle, sheep, and goats in particular. The aetiological agent, *Coxiella burnetii*, is a Gram-negative intracellular bacterium that multiplies in macrophage phagolysosomes. *Coxiella burnetii* can occur in two antigenic forms, namely, a pathogenic Phase I that is isolated from infected people or animals and an avirulent Phase II that is obtained in ovo or in vitro. The two forms of infection – acute and chronic – have different serological profiles. During the acute phase of the disease, the titres of IgG antibody against Phase II antigens are elevated, whereas during the chronic phase of the disease the titres of IgG antibody against Phase I and Phase II antigens are high. In cows, ewes, and goats Q fever is associated with late-term abortions and reproductive problems such as premature births, dead or weakened foetuses, metritis, and infertility. Nevertheless, the serological responses and isolation of the bacterium in a given species are not necessarily correlated with the disease's clinical expression. Serotests are appropriate for herd screening, but may be difficult to interpret for an individual subject.

Use of Kit

The kit is intended for the detection of *Coxiella burnetii* - phase I in blood sera, plasma and milk in cattle and small ruminants.

Reliability of results

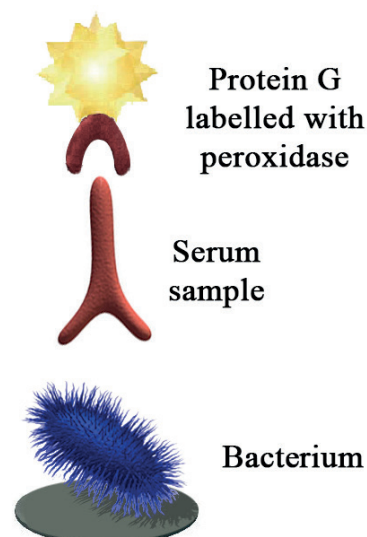
Phase I antigenic extract from *Coxiella burnetii* ensures an excellent specificity and very reliable results. The protein G used as conjugate detects most isotypes of mammals.

Ease of Use

Only a few steps are required
 Incubation at room temperature
 Results obtained in 140 minutes maximum

Test Procedure

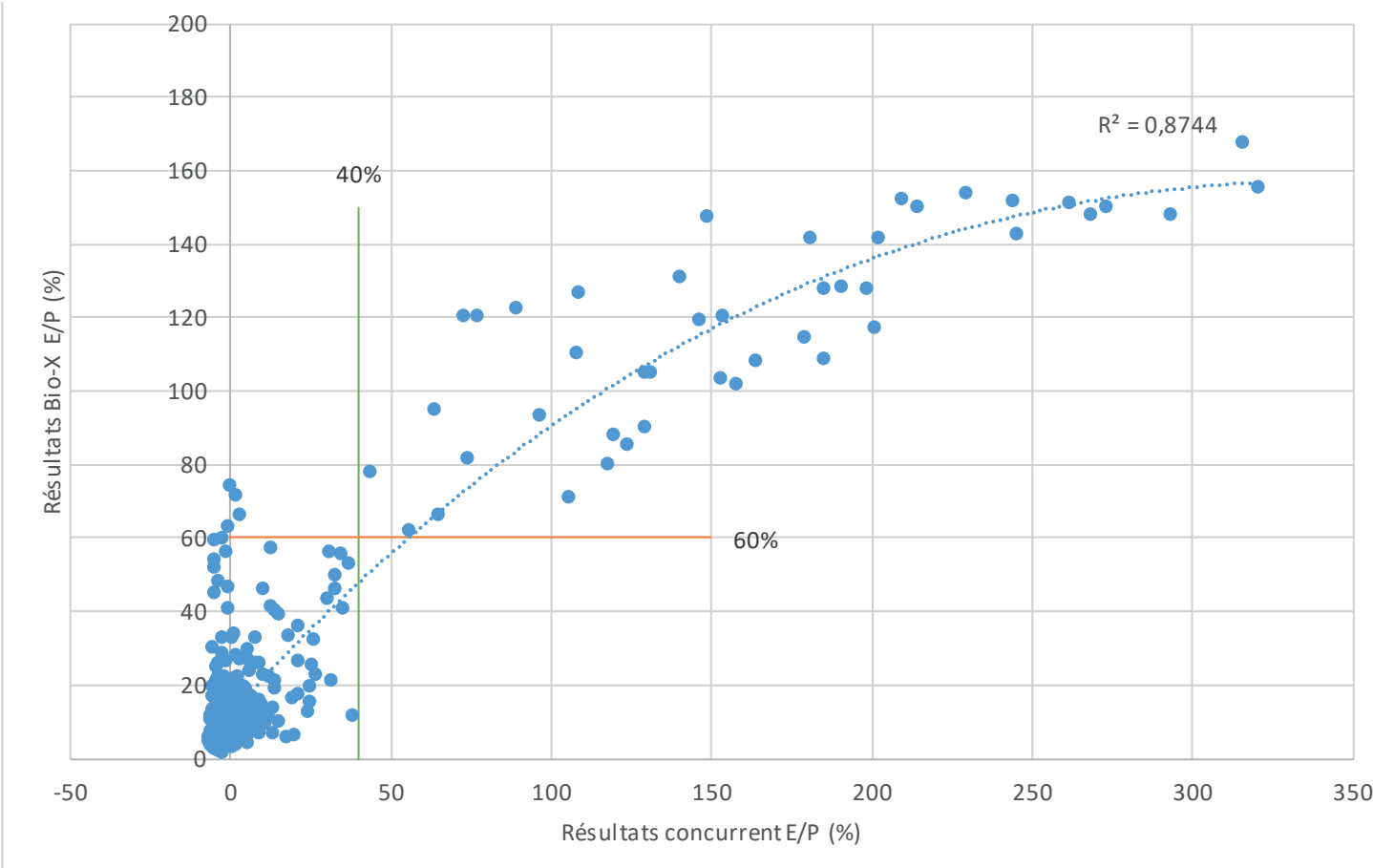
- 1- Phase I antigenic extract from *Coxiella burnetii* is fixed on the microplate.
- 2- Add samples and positive and negative controls.
 Incubate for 1 hour at 21°C+/-3°C
 Wash the plate
- 3- Add the conjugate
 Incubate for 1 hour at 21°C+/-3°C
 Wash the plate
- 4- Add TMB
 Wait 10 minutes
 Add the stop solution. Read at 450 nm





Result examples

439 blood sera were used to compare the BIO K 404 Monoscreen AbELISA Coxiella phase I and a competitor kit.
Results from these comparisons are shown on graph 1.
On the abscissa and ordinate axes, 100 indicates the value obtained with the reference positive serum of the kit (E/P).
Graph n°1



COXIELLA		COMPETITOR		
BIO X		+	-	
	+	44	5	49
	-	0	390	390
		44	395	439

RELATIVE SE	100,00 %	PPV	89,80 %
RELATIVE SP	98,73 %	PNV	100,00 %
KAPPA	0,94	EXCELLENT	

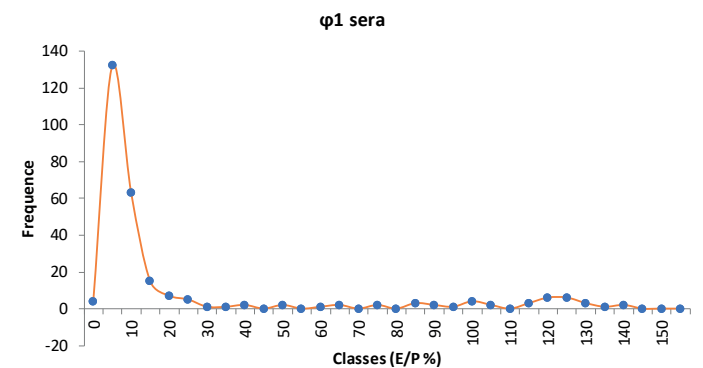
Agreement between the two tests : Kappa = 0,94
The agreement between the two tests is considered excellent.



Result examples

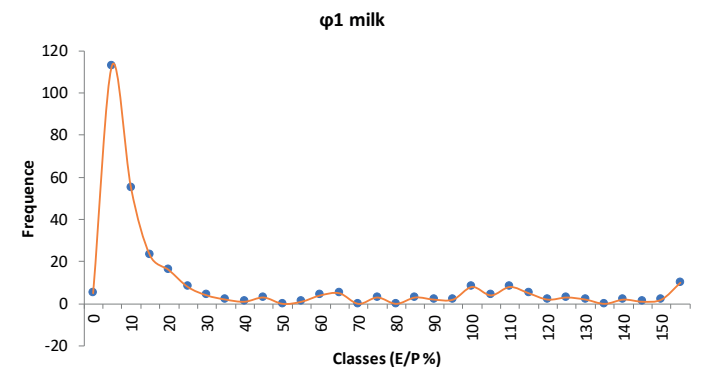
270 sera collected from adult cows were tested with the BIO K 404 kit. These samples come from 27 Belgian farms. The obtained optical densities were divided by the optical density provided by the reference serum of the kit (E/P). A frequency histogram was drawn for the blood sera (graph n°3).

Graph n° 3

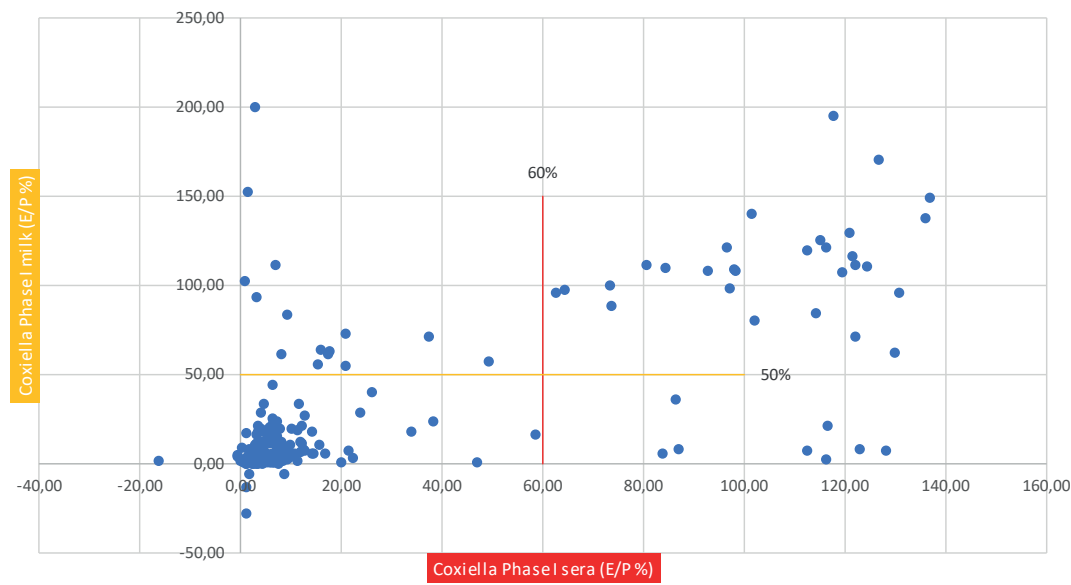


270 milk samples collected from adult cows were tested with the BIO K 404 kit. These samples come from 27 Belgian farms. The obtained optical densities were divided by the optical density provided by the reference serum of the kit (E/P). A frequency histogram was drawn for the milks (graph n°4).

Graph n° 4



Graph n° 5



COXIELLA		SERA		
MILKS		+	-	
	+	29	15	44
	-	8	218	226
		37	233	270

RELATIVE SE	78,38%	PPV	65,91 %
RELATIVE SP	93,56 %	PNV	96,46 %
KAPPA	0,67	GOOD	

Agreement between the two tests : Kappa = 0.67
The agreement between the two tests is considered good.

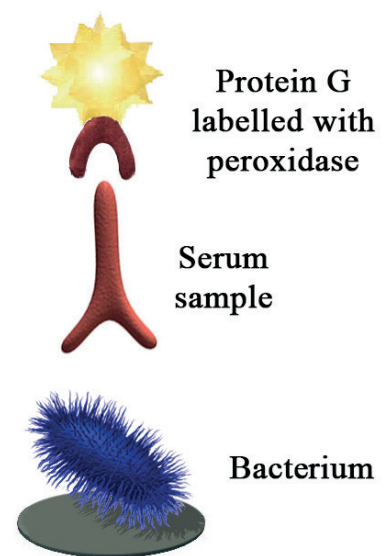


Composition of the kit

Monoscreen AbELISA Coxiella burnetii – phase I

	BIO K 404/2
Microplates	2 (96 tests)
Washing solution	1 X 100 ml (20 X)
Dilution buffer	1 X 50 ml (5 X)
Conjugate	1 X 0.5 ml (50 X)
Positive serum	1 X 0.5 ml (1 X)
Negative serum	1 X 0.5 ml (1 X)
Tracer	1 X 0.5 ml (1 X)
Single component TMB	1 X 25 ml (1 X)
Stopping solution	1 X 15 ml (1 X)

18 months stability between +2°C et + 8°C



Bio-X Diagnostics is ISO 9001:2008
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