

MONOSCREEN^{Ab} ELISA - *Coxiella burnetii* - phase 1

BIOK404-Cox_Phase1_PP01_(EN)_V01
05/10/2022

Reference : BIO K 404

BRIEF OUTLOOK ON THE DISEASE

Q fever mainly affects humans, cattle, sheep and goats. The etiological agent, *Coxiella burnetii* is a Gram-negative intracellular bacterium which multiplies in the macrophage phagolysosomes. *Coxiella burnetii* can occur in two antigenic forms: a pathogenic phase I, isolated from infected animals or individuals, and an avirulent phase II, obtained in ovo or in vitro. There are 2 forms of infection, acute and chronic, which have different serological profiles: during the acute phase of the disease, titers of type IgG antibodies are high against phase II, while during the chronic phase of the disease, elevated levels of anti-phase I and II IgG antibodies are observed. In cows, sheep and goats, Q fever has mostly been associated with late abortions and reproductive disorders such as premature birth, dead or weakened fetuses, metritis, and infertility. Nevertheless, in a given species the serological responses or the isolation of the bacterium do not necessarily correlate with the expression of the clinical disease. Serological analyzes are appropriate for screening herds, but the interpretation at the individual level can be difficult.

INTENDED USE OF TEST



Serological diagnosis of Q fever



Characterized by official and self-checking methods according to the AFNOR NF U47-310 standard.



Appropriate tests for herd screening

	Results	Status
Bovine, caprine and ovine serum	S/P % < 40%	Negative
	$40\% \leq S/P \% \leq 60\%$	Doubtful
	S/P % > 60%	Positive
Bovine milk	S/P % < 50%	Negative
	E/P % $\geq 50\%$	Positive

«A multi-species and multi-matrix milk-oriented serological approach»

Why BIO K 404?

- A new simplified user manual
- Updated validation files
- Revised cut-offs
- 1X « ready to use » solutions



Indirect monowell test

Detection of antibodies against the pathogenic phase I of *Coxiella burnetii*



For bovine, caprine and ovine sera (1/100 dilution) and bovine milk (1/1 dilution)



G Protein conjugate

Reading Wavelength: 450nm

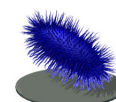
Incubation time : 2*1h + 10 min

Substrate : Single component TMB



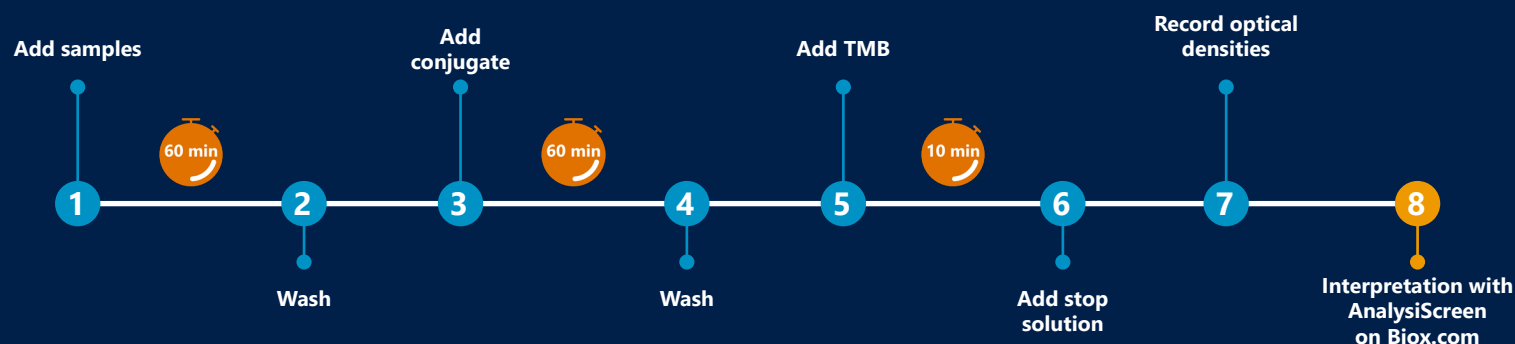
Protein G
labelled with
peroxidase

Serum
sample



Bacterium

BIO K 404-*Coxiella burnetii* _phase1 allows a fast and efficient detection.

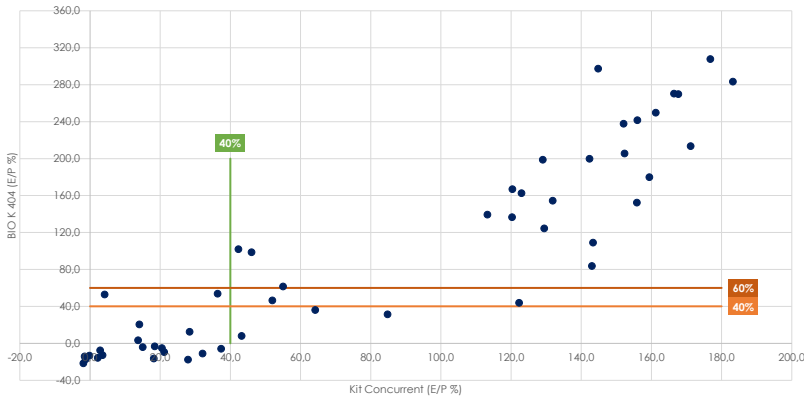


CORRELATION

Cohort A

A cohort is composed of serums of a panel of 50 goats from 10 Spanish farms was analyzed with Monoscreen AbELISA Coxiella Ph 1. The abortion rate for these farms was on average 6.5% in the year preceding the analysis with a maximum of 25% for one of the farms.

The cohort was analyzed with a competitor kit to compare the relative sensitivity and specificity of Monoscreen AbELISA Coxiella Ph 1 – BIO K 404.



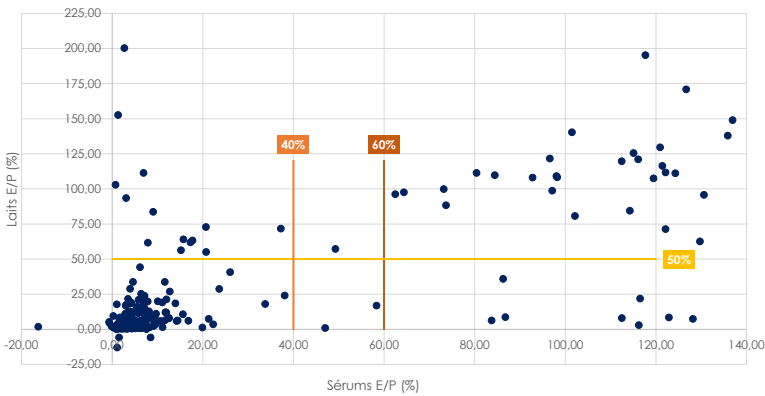
		Competitor		
		+	-	
Monoscreen™ AbELISA Coxiella Ph 1	+	27	3	30
	-	2	18	20
with a threshold of 40%		29	21	50

Se relative	93 %	VPP	90 %
Sp relative	86 %	VPN	90 %
Kappa	0,79	GOOD	

Cohort B

A cohort composed of 270 serums and 270 matched milks of adult cattle from 27 farms located in the Walloon region (Belgium) was analyzed with Monoscreen AbELISA Coxiella Ph 1. From each farm, 10 sera and 10 matched milks were collected.

The relative sensitivity and specificity calculations are good with the positive threshold above 50% for milks and a positive threshold above 40% for serums. This leads to the conclusion that there is a good correlation between the results obtained on the analyzes of milks or serums collected from the same animal.



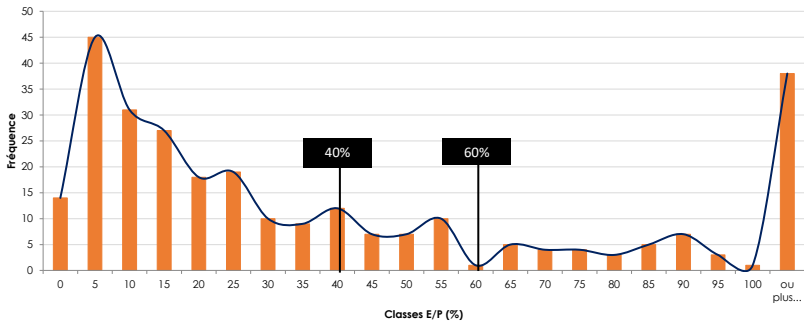
		Serum		with a threshold of 40%
		+	-	
Milk	+	30	14	44
	-	10	216	226
with a threshold of 50%		40	230	270

Se relative	75 %	VPP	65 %
Sp relative	94 %	VPN	96 %
Kappa	0,66	GOOD	

Cohort C

A cohort composed of serums of a panel of 280 sheep from 3 Spanish farms was analyzed with Monoscreen AbELISA Coxiella Ph 1. The abortion rate for these farms was on average 8% in the year preceding the analysis with a maximum of 20% for one of the farms.

The cohort made it possible to plot the frequency chart below. A negative threshold below 40%, an equivocal zone between 40 - 60% and a positive threshold above 60% could be determined.



TO ORDER :

Code	Description	Nb. of reactions
BIO K 404/2	Monoscreen™ AbELISA Coxiella burnetii _ phase 1	2 plates 192 tests



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Contact us

f.bernard@biox.com

+32 (0) 84 32 23 77

www.biox.com