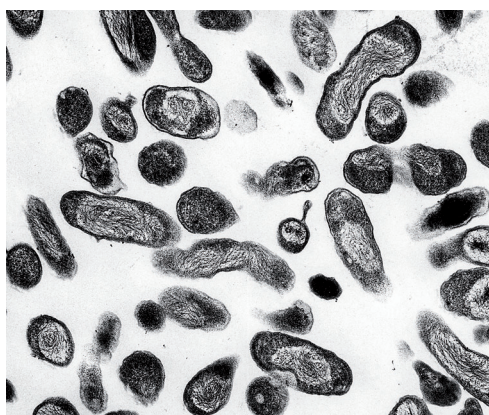


SERION ELISA *classic*

Coxiella burnetii IgG / IgM

SERION ELISA *classic* Coxiella burnetii tests are quantitative (Phase II IgG) and qualitative (Phase I IgG, IgA and Phase II IgM) immunoassays for the detection of human antibodies in serum or plasma directed against *Coxiella burnetii*. SERION ELISA *classic* Coxiella burnetii IgM is recommended for the detection of acute infections, while SERION ELISA *classic* Coxiella burnetii (Phase II) IgG supports the differential diagnosis of infections of the respiratory tract, especially atypical pneumonia. SERION ELISA *classic* Coxiella burnetii (Phase I) tests are recommended for the diagnosis of chronic Q-fever.



Electron micrograph of the Rickettsie *Coxiella burnetii* (Source: National Institutes of Health, United States Department of Health and Human Services).

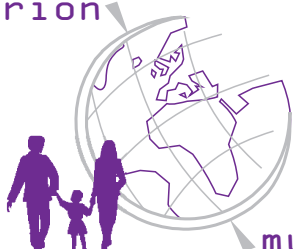
Pathogen

Q-fever is a zoonosis with global distribution. The pathogen responsible is the rickettsia *Coxiella burnetii*, a small, gram-negative, obligate intracellular bacterium. Bacteria multiply in the digestive system of ticks (*Dermacentor marginatus* in Germany) and in the trophoblasts of the placenta in the secondary host. Accordingly, tick faeces and the afterbirth of infected mammals (predominantly sheep) are highly infectious.

Disease

The incubation time is two to four weeks. The frequency of clinical evidence of infection is 30 to 50 %, the remaining being subclinical or with uncharacteristic general symptoms. Influenza-like symptoms are often evident. In about 50 % of cases an atypical, interstitial pneumonia develops. In some cases the acute progression can be complicated by meningoencephalitis, myoditis or pericarditis. If not treated the pathogen persists in a variety of organs, leading to chronic infection which often presents as an endocarditis and/or granulomatous hepatitis. About 65 % of chronic Q-fever cases are fatal.

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Following primary infection specific IgM and IgG antibodies directed against the phase 2 antigen are detected after two weeks and two months, respectively. Anti-phase 2 IgM antibodies can be detected up to three months after infection, whereas IgG antibodies often persist over a period of about five years. In the lead up to chronic infection, IgG and IgA antibodies directed against the phase 1 antigen appear. These are of diagnostic value for Q-fever endocarditis.

Diagnosis

Due to the lack of characteristic clinical symptoms of acute and chronic Q fever infection, diagnosis is based on serological evidence. The use of ELISA is recommended by the WHO due to its high sensitivities and specificities and the possibility to perform a differential analysis of the antibody response.

Validation of SERION ELISA *classic* Coxiella burnetii

The SERION ELISA *classic* Coxiella burnetii (II) IgG was evaluated by the analysis of 414 serum samples from blood donors and pregnant women and 97 serum samples from patients with clinically and serologically (IFT) identified Q-Fever. For the validation of the SERION ELISA *classic* Coxiella burnetii (II) IgM 149 serum samples from blood donors and 114 serum samples from patients with suspected Q-Fever were analysed in comparison to the assay of a leading manufacturer.

Sera classified as borderline were not included in the calculation.

Sensitivity and Specificity

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Coxiella burnetii (II) IgG	93,4 %	98,5 %
Coxiella burnetii (II) IgM	94,4 %	> 99 %

Precision

The intra- and interserial precisions were determined by the analysis of serum samples of different reactivities.

SERION ELISA *classic* Coxiella burnetii (II) IgG

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak positive	0,661	5,7	0,669	15,0
positive	1,058	5,3	1,074	11,3
strong positive	2,353	3,7	2,231	4,0

SERION ELISA *classic* Coxiella burnetii (II) IgM

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,218	5,1	0,221	10,4
weak positive	0,403	6,3	0,415	5,5
positive	0,808	4,6	0,900	11,5

Order Information

SERION ELISA *classic* Coxiella burnetii (II) IgG

Order Nr.: ESR 1312 G

SERION ELISA *classic* Coxiella burnetii (II) IgM

Order Nr.: ESR 1312 M

SERION ELISA *classic* Coxiella burnetii (I) IgA

Order Nr.: ESR 1311 A

SERION ELISA *classic* Coxiella burnetii (I) IgG

Order Nr.: ESR 1311 G

Reference serum Coxiella burnetii (II) IgG

Order Nr.: BR 1312 G

Reference serum Coxiella burnetii (II) IgM

Order Nr.: BR 1312 M

Please visit our website www.virion-serion.com for more information on our SERION ELISA *classic* products.

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