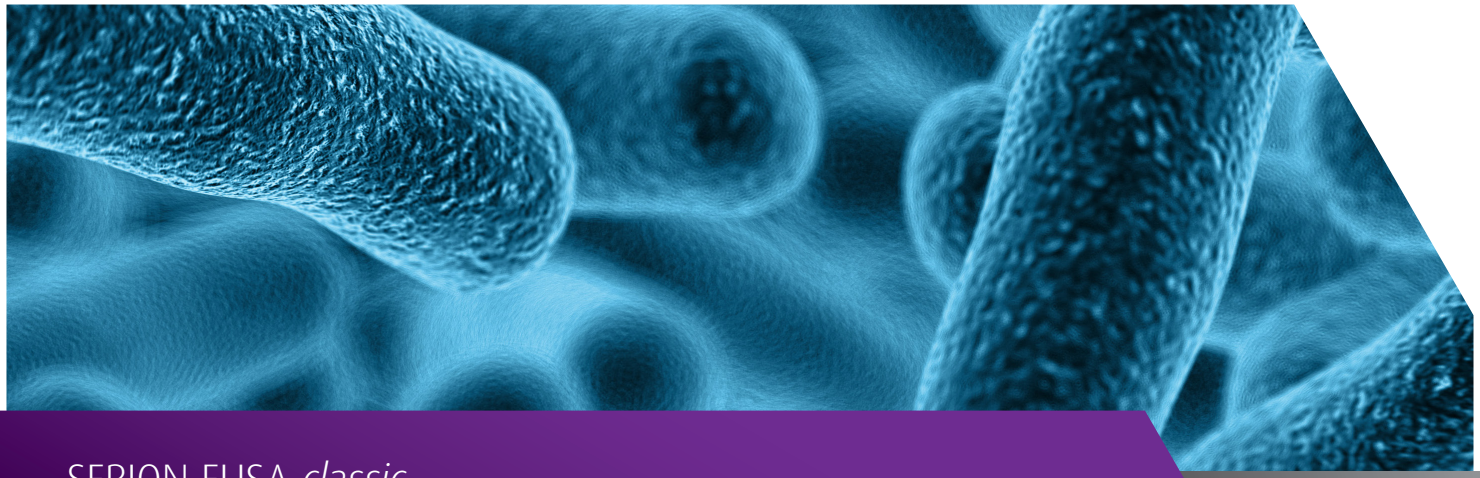

SERION ELISA *classic*

Coxiella burnetii IgA/IgG/IgM

Intended Use

- Qualitative and quantitative (ESR1312G) detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Coxiella burnetii* in phase 1 or phase 2
- Detection of IgM antibodies directed against *Coxiella burnetii* (Phase II) supports in the diagnosis acute infections
- Demonstration of *Coxiella burnetii* (Phase 2) IgG specific antibodies supports the differential diagnosis of infections of the respiratory tract, especially atypical pneumonia.
- Detection of antibodies directed against *Coxiella burnetii* (Phase 1) supports in the diagnosis of chronic Q-fever.

Diagnostic Efficiency

The performance characteristics of the SERION ELISA *classic* Coxiella burnetii Phase 2 IgG test was determined with 77 sera from blood donors and from patients with suspected Q fever. For the SERION ELISA *classic* Coxiella burnetii Phase 2 IgM test 273 sera from blood donors and patients with suspected Q fever infection were tested against a commercially available test. The performance characteristics of the SERION ELISA *classic* Coxiella burnetii Phase 1 IgA and IgG test were evaluated with 54 serum samples from patients with suspected Q fever infection and 105 sera from blood donors in comparison to the complement fixation test (CFT). Since the CFT does not allow for the detection of IgA antibodies, the evaluation was performed with the assumption that the generation of IgA antibodies occurs in parallel with the formation of complement binding antibodies following the course of an infection.

Product	Sensitivity	Specificity
SERION ELISA *classic* Coxiella burnetii Phase 2 IgG	92.5 %	>99 %
SERION ELISA *classic* Coxiella burnetii Phase 2 IgM	94.4 %	99.3 %
SERION ELISA *classic* Coxiella burnetii Phase 1 IgA / IgG	94.2 %	96.2 %

Precision

SERION ELISA *classic* Coxiella burnetii Phase 2 IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.116	3.6	0.127	12.2
Serum 2	1.490	2.5	1.552	6.3
Serum 3	1.865	3.0	1.912	7.0

SERION ELISA *classic* Coxiella burnetii Phase 2 IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.060	6.2	0.087	10.4
Serum 2	1.529	2.7	1.632	4.5
Serum 3	1.695	1.7	1.773	5.0

SERION ELISA *classic* Coxiella burnetii Phase 1 IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.153	6.0	0.156	16.3
Serum 2	0.814	6.8	0.721	9.1
Serum 3	1.696	4.1	1.512	6.3

SERION ELISA *classic* Coxiella burnetii Phase 1 IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.188	3.2	0.207	13.0
Serum 2	0.363	2.6	0.366	8.2
Serum 3	0.788	3.1	0.852	4.5

Pathogen

Coxiella burnetii is a gram-negative, aerobic coccobacillus of the *Coxiellaceae* family. The causative agent of the so called Q fever is extremely infectious and very resistant to environmental factors.

Disease

Approximately half of infected individuals exhibit no clinical symptoms. The most common manifestation following an incubation period of two to three weeks, are mild flulike symptoms with abrupt onset of fever, malaise, severe headache, myalgia, loss of appetite, dry cough, chest pain and chill, more seldom accompanied by gastrointestinal symptoms such as nausea, vomiting and diarrhea. During its course, the disease can progress to an atypical pneumonia, which may result in a life-threatening acute respiratory distress syndrome (ARDS). More seldom, Q fever presents as granulomatous hepatitis with inflammation of the liver. In rare cases, the disease takes a chronic course and presents as an inflammation of the inner lining of the heart muscle (endocarditis) or of the heart sac (pericarditis), which is usually fatal if untreated.

Product	Order No.
SERION ELISA *classic* Coxiella burnetii Phase 2 IgG	ESR1312G
SERION ELISA *classic* Coxiella burnetii Phase 2 IgM	ESR1312M
SERION ELISA *classic* Coxiella burnetii Phase 1 IgA	ESR1311A
SERION ELISA *classic* Coxiella burnetii Phase 1 IgG	ESR1311G

SERION ELISA *control*

Please visit our website for more information.

Diagnose

The diagnosis of Q fever is performed by the demonstration of specific antibodies directed against *Coxiella burnetii*. Due to variations in the lipopolysaccharide (LPS) structure on the surface of the pathogen, as the disease enters the chronic state, a serological differentiation of acute from chronic infections is possible. Due to the high sensitivity and specificity, the use of ELISA immunoassays is recommended by the World Health Organization (WHO). Following the regular course of an acute primary infection, specific IgM and IgG antibodies directed against the immunogenic phase 2 antigens can be demonstrated. IgG antibodies directed against phase 2 antigens often persist over several years. In the lead-up to a chronic infection, IgG and IgA antibodies directed against the phase 1 antigens appear, which are of diagnostic value particularly for the diagnosis of Q fever endocarditis.

Highlights

- Demonstration of phase-specific antibodies according to the recommendations of the WHO
- Detection of all relevant immunoglobulin classes
- Differentiation of acute, recent and chronic infections
- Quantification of IgG antibody activity directed against phase 2 antigen, starting in the clinically negative measurement range, for the analysis of paired sera for disease stage monitoring and therapy control

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Flyer Coxiella burnetii V7.20/11