

Intended Use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum and plasma directed against human pathogenic *Brucella subspecies*
- · Determination of pathogen contact and categorization of the disease stage

Diagnostic Efficiency

To determine the performance characteristics of SERION ELISA *classic* IgG, IgM and IgA, a study utilizing 108 healthy blood donor sera, 132 sera from children (in-patients of a children's hospital), 44 sera from patients with other diseases as well as 27 patients with suspected Brucellosis were tested and compared with a commercially available ELISA test.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Brucella IgA	>99 %	99.7 %
SERION ELISA <i>classic</i> Brucella IgG	>99 %	99.3 %
SERION ELISA <i>classic</i> Brucella IgM	91.3 %	99.3 %

Precision

SERION ELISA classic Brucella IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.321	4.6	0.342	7.6
Serum 2	1.064	3.3	1.185	8.0
Serum 3	2.641	1.8	2.848	3.6

Flyer Brucella V6.20/11

SERION ELISA classic Brucella IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.754	2.6	0.768	3.7
Serum 2	1.408	1.2	1.438	3.7
Serum 3	1.536	2.3	1.638	3.6

SERION ELISA classic Brucella IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.862	3.5	0.801	3.1
Serum 2	1.319	3.3	1.380	4.2
Serum 3	2.398	1.9	2.443	2.2

Pathogen

Brucella ssp. are non-motile bacteria which live as intracellular parasites in a wide spectrum of hosts, particularily farm animals. Infections of humans are mainly caused by Brucella melitensis (Malta fever), Brucella abortus (Morbus Bang), Brucella suis and Brucella canis. The pathogen is transmitted by contact with infected animals, their excretions and by contaminated food.

Disease

The disease starts with moderate fever. During the acute stage of the disease, the fever rises in the evenings. Additionally, hepatomegaly, splenomegaly or swollen lymph nodes are characteristic symptoms. In *Brucella melitensis* and *Brucella suis* infections, undulating fever within afebrile intervals may manifest. Spontaneous healing as well as transition into a chronic stage with a wide spectrum of symptoms is possible. Multiple organs or organ systems, bones or joints can be affected during the chronic stage. Histologically, characteristic granulomas may be observed in infected tissues. Bacterial endocarditis might be fatal if it remains untreated. During the late stage of brucellosis, neurologic and even psychiatric manifestations might occur.

Diagnosis

Direct pathogen detection in culture systems can be performed with punctates from blood, bone marrow, synovia or urine. In this regard the special demands for nutrients have to be taken into account. More rapid results are obtained with serological methods such as agglutination tests. For differentiation between acute and chronic brucellosis, sensitive and specific ELISA test with separate detection of IqG, IqM and IqA antibodies are recommended.

Produkt	Bestell-Nr.
SERION ELISA <i>classic</i> Brucella IgA	ESR116A
SERION ELISA <i>classic</i> Brucella IgG	ESR116G
SERION ELISA <i>classic</i> Brucella IgM	ESR116M

SERION ELISA control

Please visit our website for more information.

Highlights

- Use of an extract from *Brucella abortus* with genus-specific antigens to allow demonstration of antibodies against human pathogenic *Brucella ssp.*
- Differentiation of acute and chronic brucellosis
- Quantification of antibody activities for therapy monitoring