



SERION ELISA *classic* Tetanus IgG

Intended use

- Quantitative detection of human IgG antibodies in serum or plasma directed against tetanus toxin
- Vaccination control
- Determination of the current individual immune status to prevent hyperimmune reactions

Diagnostic Efficiency

The SERION ELISA *classic* Tetanus IgG was evaluated in an external study performed under the supervision of Prof. Dr. med. Kuhlmann at the Central Institute of Medical Services of the German Federal Armed Forces in Koblenz, Germany. Comparison of the measured antibody activities of 269 serum samples with the results of the in-house ELISA demonstrated excellent agreement with a high coefficient of correlation $r=0.94$. Sensitivity and specificity were not calculated since the test does not differentiate between positive and negative results, but supports a continuous quantitative evaluation of the IgG antibody activity.

Precision

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Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.089	5.8	0.102	8.9
Serum 2	0.952	2.8	1.059	2.8
Serum 3	2.629	1.6	2.767	3.6

Pathogen

Clostridium tetani is an ubiquitous, obligate anaerobic bacteria. The extremely resistant spores reach the ground through faeces and are able to survive for years. The pathogen enters the host by way of contaminated wounds. In the presence of nutrients and anaerobic conditions, spores will convert back to the vegetative form which then produce tetanospasmin, a very potent neurotoxin which causes an increase in neuromuscular stimulation.

Disease

After an incubation period of a few days up to several weeks, the disease begins with non-specific symptoms, primarily fatigue, followed by characteristic cramps which spread cranio-facial to caudal and may also affect the respiratory muscles. Patients are fully conscious during bouts of these extremely painful cramps which may be triggered by the slightest external stimuli. During the course of tetanospasmin poisoning, the patient may suffer from renal, cardiac and circulatory failure. Even with intensive care, over one third of patients die. The safest prophylaxis against tetanus is an active immunization with an effective tetanus toxoid vaccine. Side effects of immunization can occur after multiple vaccinations, varying from local and systemic allergic reactions to anaphylactic shock.

Diagnosis

To check for the individual's current immune status serological detection of antitoxin IgG antibodies by ELISA techniques are used. Uncertain immune status, possibly due to poor recollection or incomplete documentation, vaccination completions and immune depression, are all indications for performing a confirmatory ELISA to determine antibody levels. Serological investigation with the SERION ELISA *classic* Tetanus IgG test allows for the precise determination of IgG antibody activities expressed in International Units per milliliter (IU/mL) for direct demonstration of vaccination requirements.

Highlights

- Results expressed in IU/ml referenced to the international standard of the World Health Organization (WHO)
- Direct demonstration of vaccination requirements
- High precision and linearity within the wide measurement range from 0.05 to 5.0 IU/ml

Product	Order No.
SERION ELISA <i>classic</i> Tetanus IgG	ESR108G

SERION ELISA *control*

Please visit our website for more information.

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany

Tel. +49 931 3045 0 Fax +49 931 3045 100

Mail info@serion-diagnostics.de Web www.serion-diagnostics.de

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