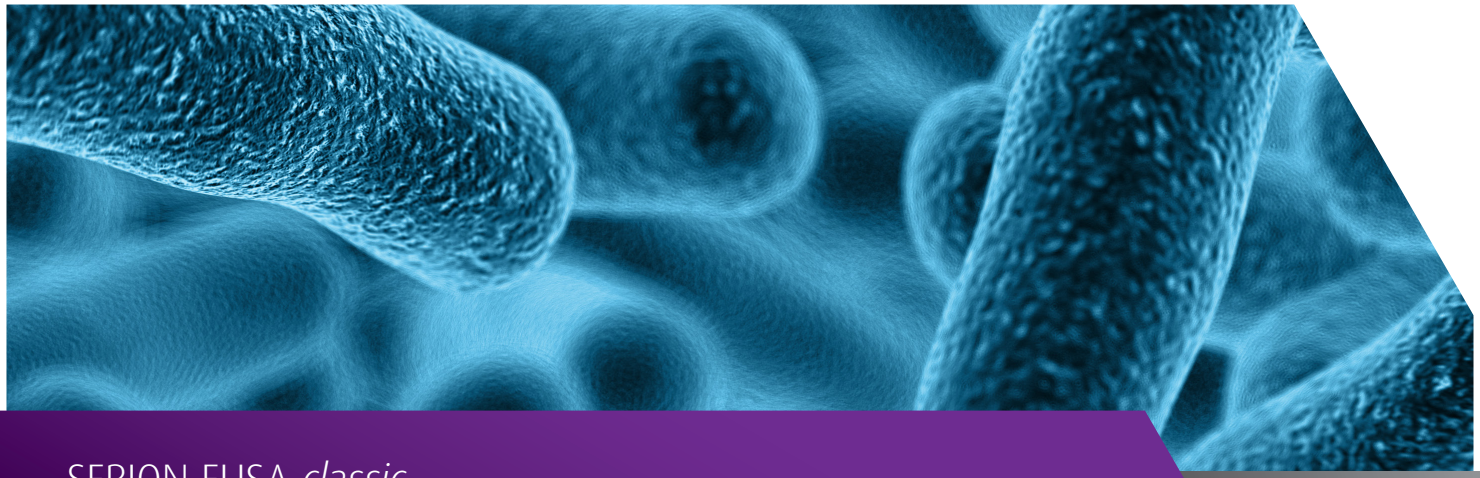

SERION ELISA *classic*

Diphtherie IgG

Intended use

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

Diagnostic Efficiency

The diagnostic efficiency of the SERION ELISA *classic* Diphtheria IgG test was verified by analysis of 28 samples derived from interlaboratory tests and provided by INSTAND e.V. between 2005 and 2012. Comparison of the measured antibody activities of the samples with the target values demonstrated excellent agreement with a high coefficient of correlation r=0.98. As the test is intended for immune status control and therefore no positive and negative evaluation is performed, a cut-off of 0.1 U/mL is set (> 0.1 U/mL => positive) to determine sensitivity and specificity.

Product	Sensitivity	Specificity
SERION ELISA *classic* Diphtherie IgG	96.3 %	98.8 %

Precision

SERION ELISA *classic* Diptherie IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	1.239	0.7	1.375	1.8
Serum 2	0.198	1.2	0.217	2.1
Serum 3	0.464	1.3	0.518	2.6
Serum 4	0.980	1.3	1.063	1.6

Pathogen

Diphtheria is caused by *Corynebacterium diphtheriae*. The diphtheria toxin is responsible for pathogenicity.

Disease

Diphtheria is a globally distributed infectious disease, that is mainly transmitted by droplet infection and in rare cases by smear infection. The incubation time is usually two to five days. In temperate climate zones, clinical symptoms of diphtheria mainly affect the respiratory tract. A primary infection can involve the tonsillar pharyngeal region or cause laryngeal, nasal or tracheobronchial primary infection in sequential order. The most important complications are myocarditis and polyneuritis. In 5 to 25 % of cases, diphtheria can take a lethal course due to respiratory obstruction or coronary failure.

As a consequence of extensive immunization programs, cases of this once common disease have declined considerably. Nevertheless, an inreasing number of regional epidemics occur in countries with low vaccination coverage.

Diagnose

For practical and economic reasons a passive hemagglutination test was used for the detection of diphtheria antitoxin in human serum samples. It is specified in international units per milliliter (IU/ml). However, ELISA techniques have been increasingly utilized in recent years, due to the possibility of standardization and the ability for automated processing. Adjusted to international reference preparations, the IgG antibody activity measured by the SERION ELISA *classic* Diphtheria IgG test is expressed in IU/ml.

The control of vaccination success as well as the determination of the immune status prior to immunization in order to prevent hyperimmune reactions plays an increasing role in routine laboratories. In recent years, different studies reported a high rate of unimmunized individuals among the adult population. The serological demonstration of the anti-diphtheria toxin IgG antibody activity provides a basis for the necessity of vaccination.

Highlights

- Results expressed in IU/ml referenced to the international standard of the WHO
- Direct demonstration of vaccination requirements
- High precision and linearity within the wide measurement range from 0.05 to 2.0 IU/ml

Product	Order No.
SERION ELISA *classic* Diphterie IgG	ESR130G

SERION ELISA *control*
Please visit our website for more information.

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