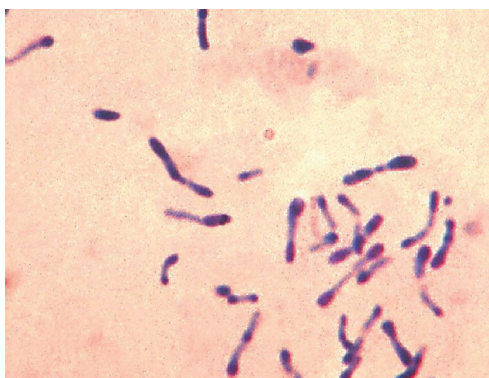


# SERION ELISA *classic* Diphtheria IgG

SERION ELISA *classic* Diphtheria IgG test is a quantitative immunoassay for the detection of human antibodies in serum or plasma directed against the diphtheria toxin. The SERION ELISA *classic* Diphtheria IgG is recommended for vaccination control and for the determination of the current individual immune status to prevent hyperimmune reactions.



Micrograph of *Corynebacterium diphtheriae* stained with methylenblue (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services).

## Pathogen

Diphtheria is caused by *Corynebacterium diphtheriae*, the toxin is responsible for pathogenicity.

## Disease

Diphtheria is a globally ubiquitous infectious disease, mainly transmitted by droplet infection and in rare cases by smear infection (skin diphtheria). The incubation time is usually two to five days, but may range up to eight days. Clinical symptoms of diphtheria in temperate zones mainly affect the respiratory tract. A primary infection can involve the tonsillar pharyngeal region or cause laryngeal, nasal or tracheobronchial primary infection sequentially. The most important complications are myocarditis and polyneuritis. In 5 to 25 % of cases the course of diphtheria is lethal due to respiratory obstruction or coronary failure.

In the Commonwealth of Independent States (CIS) regional epidemics have lead to an increase in diphtheria morbidity during the past 10 years, according to the WHO. As a consequence of extensive use of vaccination in western industrialized countries cases of this once common disease have declined considerably.

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In recent years a reduction in vaccine uptake has resulted in lower immunity prevalence against diphtheria. Consequently, success of vaccination control as well as immunity status determination in order to avoid hyper immune reactions is becoming increasingly important for routine laboratories.

The STIKO (Ständige Impfkommision on the Robert-Koch-Institute in Berlin) recommends a combined vaccine for the active immunisation of babies. The first immunisation takes place upon the completion of the second month of life; afterwards two further immunisations are made in an interval of 4 to 8 weeks. Booster shots should be made between the 12th and 18th month of life and also in the 5th to 6th and 11th to 18th year of life. For Diphtheria a booster immunization is then necessary after ten years.

## Diagnosis

For practical and economic reasons a passive hemagglutination test is used for the detection of diphtheria-antitoxin in human sera. It is specified in international units per milliliter (IU/ml). However, ELISA techniques have been increasingly utilized in recent years, because of increasing numbers of testings and their ability for automated processing. Adjusted to international reference sera, the specification of the SERION ELISA *classic* Diphtheria IgG is IU/ml.

## Validation of SERION ELISA *classic* Diphtheria IgG

The SERION ELISA *classic* Diphtheria IgG was evaluated with commercially available reference sera (source: Serolife, Frauenfeld/Switzerland) against the indirect hemagglutination assay (IHA) as well as with tissue culture methods (TC). The activity was indicated in IU/ml. The sensitivity and specificity can not be calculated since the test does not differentiate between positive and negative results. However, the assay supports a continuous quantitative evaluation of antibody activity.

## Precision

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

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV(%) (n=10)
negative	0,322	3,60	--	--
weak positive	0,690	3,90	0,816	4,60
positive	1,048	3,90	1,344	7,00

## Order Information

**SERION ELISA *classic* Diphtheria IgG**  
**Reference serum Diphtheria IgG**

**Order Nr.: ESR 130 G**  
**Order Nr.: BR 130 G**

Please visit our website [www.virion-serion.com](http://www.virion-serion.com) for more information on our SERION ELISA *classic* products.

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