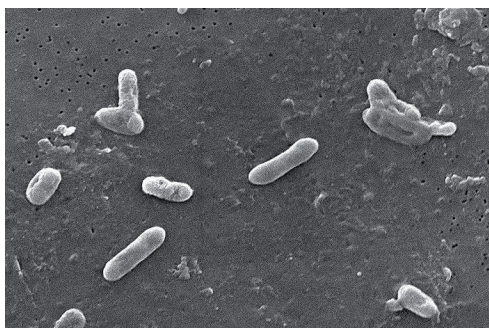


SERION ELISA *classic* Bordetella pertussis Toxin IgG

SERION ELISA *classic* Bordetella pertussis Toxin IgG test is a quantitative and qualitative immunoassay for the detection of human antibodies in serum or plasma directed against *Bordetella pertussis* Toxin. The assay is recommended for vaccination control and for differential diagnosis of pneumonia in combination with the SERION ELISA *classic* Bordetella pertussis IgA, IgG and IgM.



Electron micrograph of bacteria of genus *Bordetella* (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services).

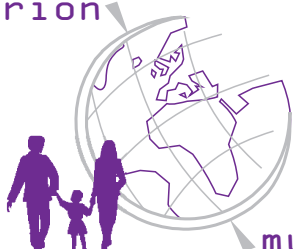
Pathogen

Bordetella pertussis is the pathogen responsible for whooping cough, a worldwide spread infectious disease that is transmitted from person to person by droplet infection. Particularly children up to four years old are affected and the mortality in infected infants is high. Although young people and adults usually do not get seriously ill, they are a risk as a source of infection for non protected and risk patients such as infants, old and ill people. Colonisation of the respiratory tract and establishment of infection are facilitated by the synergistic action of several virulence factors. A significant virulence factor is pertussis toxin (PT), which is synthesized and secreted exclusively by *Bordetella pertussis*.

Disease

Combined Diphtheria-, Tetanus-, and Bordetella pertussis-vaccination has been recommended for children at the age of 6 and younger by the German vaccination committee "STIKO" (Robert-Koch-Institut, Berlin) since 1991. Acellular vaccines with significantly increased compatibility compared to whole-cell vaccines were licensed in 1995. The acellular vaccines currently available contain one, two, three or five *B. pertussis* components. All manufacturers use PT. The bi-, tri-, and multi-valent vaccines contain amongst others FHA. Immunisation

serion



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is recommended for young people and adults with heart- and lung diseases, smokers, elderly people over 60 years of age, employees in child or nursing and other medical institutions.

Diagnosis

For the serological detection of *B. pertussis* specific antibodies the ELISA is the method of choice. IgM and IgG antibodies are detectable soon after vaccination. IgG antibodies are detectable in 90 % of cases after immunisation and may persist for several years or life long. The anti-*B. pertussis* toxin IgG titer is the most important marker for immunity. After vaccination IgA antibodies, which are an important diagnostic marker for acute infections, are produced in 20 to 40 % of cases only. IgA antibody response may be absent in infants younger than 6 months.

Validation of SERION ELISA *classic B. pertussis* Toxin IgG

For validation of SERION ELISA *classic Bordetella pertussis* Toxin IgG 92 serum samples from blood donors, children, patients with suspected infection and patients with a confirmed infection were analysed. The

results were compared with the test results of a leading European manufacturer.

Sensitivity and Specificity

| | | |
|---------------------------------------|-------------|-------------|
| SERION ELISA <i>classic</i> | Sensitivity | Specificity |
| <i>Bordetella pertussis</i> Toxin IgG | 97 % | > 99 % |

Sera classified as borderline were not included in the calculation.

Precision

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

SERION ELISA *classic Bordetella pertussis* Toxin IgG

| Sample | Mean value OD | Intraassay CV (%) (n=20) | Mean value OD | Interassay CV(%) (n=10) |
|---------------|---------------|--------------------------|---------------|-------------------------|
| negative | 0,229 | 9,9 | 0,156 | 16,3 |
| weak positive | 0,846 | 8,5 | 0,954 | 13,1 |
| positive | 1,334 | 7,6 | 1,372 | 10,7 |

Order Information

SERION ELISA *classic Bordetella pertussis* Toxin IgG

SERION ELISA *classic Bordetella pertussis* IgA

SERION ELISA *classic Bordetella pertussis* IgG

SERION ELISA *classic Bordetella pertussis* IgM

Reference serum *Bordetella pertussis* Toxin IgG

Reference serum *Bordetella pertussis* IgA

Reference serum *Bordetella pertussis* IgG

Reference serum *Bordetella pertussis* IgM

Order Nr.: ESR 1201 G

Order Nr.: ESR 120 A

Order Nr.: ESR 120 G

Order Nr.: ESR 120 M

Order Nr.: BR 1201 G

Order Nr.: BR 120 A

Order Nr.: BR 120 G

Order Nr.: BR 120 M

Please visit our website www.virion-serion.com for more information on our SERION ELISA *classic* products.

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