



SERION ELISA *classic*

Bordetella pertussis Toxin IgA/IgG

Intended Use

- Qualitative and quantitative detection of human IgA and IgG antibodies in serum or plasma directed against Pertussis Toxin
- Laboratory confirmation of infections with *Bordetella pertussis*
- Differential diagnosis of pneumonia in combination with the SERION ELISA *classic* Bordetella pertussis tests

Diagnostic Efficiency

In order to demonstrate the performance characteristics of the SERION ELISA *classic* Bordetella pertussis Toxin IgA test, a total of 113 sera, including 19 blood donor sera, 8 samples from a national quality assessment scheme, 84 internal control sera and the two WHO preparations 06/140 and 06/142 were tested in an internal study in comparison to commercially available ELISA and an immunoblot test.

The SERION ELISA *classic* Bordetella pertussis Toxin IgG test performance was evaluated in a study using 115 sera which included healthy blood donors from southern Germany as well as patients with suspected *Bordetella pertussis* infections and samples from a quality assessment scheme.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Bordetella pertussis Toxin IgA	> 99 %	> 99 %
SERION ELISA <i>classic</i> Bordetella pertussis Toxin IgG	> 99 %	98.6 %

Precision

SERION ELISA *classic* Bordetella pertussis Toxin IgA

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.309	9.1	0.412	12.1
Serum 2	0.997	3.6	0.991	6.5
Serum 3	1.549	2.1	1.623	7.0

SERION ELISA *classic* Bordetella pertussis Toxin IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.229	9.9	0.156	16.3
Serum 2	0.846	8.5	0.954	13.1
Serum 3	1.334	7.6	1.372	10.7

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. Often young children up to four years old are affected. The mortality in infected infants is particularly high. Although young people and adults usually do not get seriously ill, they may act as a source of infection for non-protected and at risk patients such as infants and old people. A significant virulence factor is Pertussis Toxin (PT), which is synthesized and secreted exclusively by *Bordetella pertussis*.

Disease

Progression of a typical whooping cough can be divided into three stages. After an incubation period of one to two weeks symptoms begin with the catarrhal phase, usually accompanied by a cough, rhinitis and conjunctivitis. Subsequently, the convulsive phase follows characterized by paroxysmal cough attacks combined with vomiting of viscid mucus, laryngospasm and bronchospasm, leading to cyanosis in the child. After four to six weeks attacks diminish and slowly subside in the decrementi phase.

Diagnosis

Recently, against the background of constantly increasing costs and performance pressures on diagnostic laboratories, efforts to establish a standardized interpretation of results from a single serum sample in cases of suspected *Bordetella pertussis* infection have come to the fore. The determination of IgG and IgA antibodies directed against Pertussis Toxin is of significant importance. Consequently, this antigen has been used for the development of SERION ELISA *classic* Bordetella pertussis Toxin IgG and IgA tests.

Highlights

- Use of Pertussis Toxins (PT) for the demonstration of IgA and IgG antibodies against *B. pertussis*
- Results of antibody activity are expressed in IU/ml referenced to the first international standard of the WHO
- Borderline regions in accordance with the recommendations of European reference centers for the standardized evaluation of single serum samples
- Excellent sensitivity and specificity values

Product	Order No.
SERION ELISA <i>classic</i> Bordetella pertussis Toxin IgA	ESR1201A
SERION ELISA <i>classic</i> Bordetella pertussis Toxin IgG	ESR1201G

SERION ELISA *control*

Please visit our website for more information.

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