



SERION ELISA *classic*

# Bordetella pertussis IgA/IgG/IgM

## Intended Use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Bordetella pertussis* and *Bordetella parapertussis*
- Laboratory confirmation of whooping cough
- Differential detection of individual antibody classes supports the categorisation of the disease stage

## Diagnostic Efficiency

The performance characteristics of the SERION ELISA *classic* Bordetella pertussis IgA (IgG) tests were assessed by the analysis of 72 (69) specimens including serum samples from patients with suspected infection of *Bordetella pertussis* or *Bordetella parapertussis*, from healthy blood donors, samples from German EQAS as well as the two international standard preparations of the World Health Organization 06/140 and 06/142. Three ELISA and an

immunoblot of leading European manufacturers were used as references. The evaluation of SERION ELISA *classic* Bordetella pertussis IgM test was performed in an internal study with 144 serum samples in comparison to two reference assays from other manufacturers.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Bordetella pertussis IgA	> 99 %	> 99 %
SERION ELISA <i>classic</i> Bordetella pertussis IgG	> 99 %	> 99 %
SERION ELISA <i>classic</i> Bordetella pertussis IgM	88.9 %	> 99 %

## Precision

### SERION ELISA *classic* Bordetella pertussis IgA

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.480	7.9	0.563	7.4
Serum 2	1.827	4.1	2.022	3.6
Serum 3	2.008	6.0	2.177	4.2

## SERION ELISA *classic* Bordetella pertussis IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.397	5.4	0.446	12.4
Serum 2	1.133	3.4	1.188	7.3
Serum 3	1.786	1.6	1.806	4.4

## SERION ELISA *classic* Bordetella pertussis IgM

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.512	5.5	0.479	9.6
Serum 2	0.551	4.6	0.516	14.2
Serum 3	0.984	4.8	0.962	15.9

### Pathogen

*Bordetella pertussis* and *Bordetella parapertussis* are pathogens 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. Colonization of the respiratory tract and establishment of infection are facilitated by the synergistic action of several virulence factors.

### 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 decremendi phase.

Product	Order No.
SERION ELISA <i>classic</i> Bordetella pertussis IgA	ESR120A
SERION ELISA <i>classic</i> Bordetella pertussis IgG	ESR120G
SERION ELISA <i>classic</i> Bordetella pertussis IgM	ESR120M

### SERION ELISA *control*

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### Diagnosis

The ELISA technique is the most commonly chosen method for *B. pertussis* and *B. parapertussis* specific antibody determination in serodiagnosis and complements direct antigen detection. In over 90% of cases the IgG and IgA antibody responses are directed against the immunogens PT and FHA. Therefore, the SERION ELISA *classic* Bordetella pertussis IgG and IgA tests are based on antigen mixtures of PT and FHA. For the detection of IgM antibodies cellular bound lipopolysaccharid has outstanding diagnostic properties. Consequently, a whole-cell antigen preparation of *B. pertussis* is used in the SERION ELISA *classic* Bordetella pertussis IgM.

## Highlights

- Sensitive demonstration of IgM antibodies for diagnosis of acute primary infections, particularly in children
- Detection of IgA and IgG antibodies for laboratory confirmation of whooping cough as well as for differential diagnosis in case of atypical pneumonia
- Detection of *Bordetella parapertussis* mediated infections (ca. 15% of all cases of whooping cough)
- Results of IgA and IgG antibody activity are expressed in IU/ml referenced to the first international standard of the WHO

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