



## recomLine Bordetella pertussis IgG recomLine Bordetella pertussis IgA

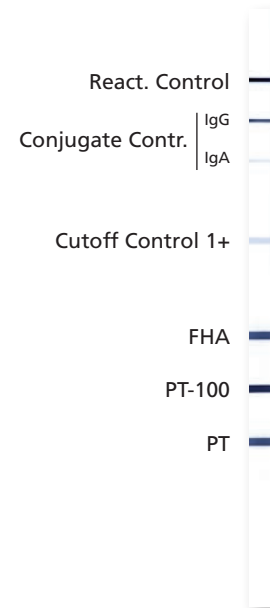
Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG or IgA antibodies against *Bordetella pertussis*

*Bordetella pertussis* is the main agent of the „whooping cough“, a disease often lasting for weeks til months. The passive immunoprotection transferred from mother to fetus is usually incomplete or inexistent. Therefore especially infants are imperiled by apnea (stop breathing) which can lead to death. Mild courses can be caused by related agents i.e. *B. parapertussis*. Several vaccinations are recommended especially for infants to provide at least some immunoprotection.

Besides the clinical diagnostics (long persisting cough with staccato cough attacks) the serological diagnostics is applied to determine the status of immunity (possibly after vaccination) and an acute infection. The new antigen PT-100 is used to standardize the *recomLine* Bordetella pertussis according to the WHO-standard and the guidelines of the German Robert-Koch-Institute. PT-100 detects an antibody titer  $\geq 100$  WHO units. A reactive PT-100 band corresponds with high probability to an acute infection when clinical symptoms appear (considering the vaccination management).

The *recomLine* Bordetella pertussis IgG, IgA uses the antigens pertussis toxin (PT), specific for *B. pertussis*, and filamentous haemagglutinin (FHA) which all representatives of *Bordetella* species have in common.

After screening by ELISA the *recomLine* Bordetella pertussis IgG, IgA can be used for clarification of borderline and positive ELISA-results and for the determination of the actual immune status.



### Product Advantages

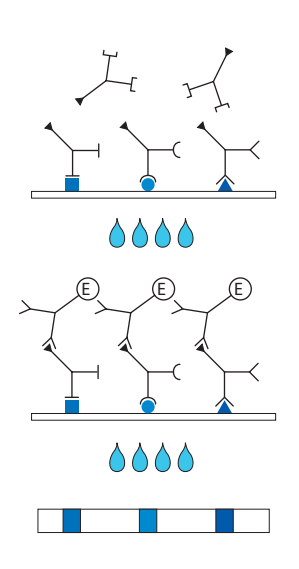
- Recombinant antigens
  - High sensitivity and specificity
  - Easy and clear interpretation due to easy to read bands
- PT-100 standardized by the WHO-Standard - hint for an acute infection
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recomScan* software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Separate detection of IgG and IgA antibodies - conjugate control on each strip
- Safe evaluation due to strip specific cutoff control
- CE label: The *recomLine* Bordetella tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

### Recombinant Bordetella Antigens

Antigen	Abbreviation	Molecular weight [kDa]
Filamentous haemagglutinin	FHA	35
Pertussis toxin*	PT-100, PT	28, 23, 22, 11.7, 9.3 (5 subunits)

\*Pertussis toxin is used in two different concentrations

## Test Principle and Procedure



- 1<sup>st</sup> Incubation** A test strip loaded with Bordetella antigens is incubated with diluted serum or plasma in a dish for **1 hour**.  
wash 3 times
- 2<sup>nd</sup> Incubation** Peroxidase conjugated anti-human antibodies (IgG and IgA specific) are added. Incubate for **45 minutes**.  
wash 3 times
- Color reaction** **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

## Evaluation

### Sensitivity and specificity

	Filamentous Haemagglutinin		Pertussis Toxin	
	IgG	IgA	IgG	IgA
Sensitivity	97,6 %	90,7 %	97,6 %	41,9 %
Specificity	100 %	100 %	100 %	100 %

### Samples from patients with acute pertussis infection

		FHA IgG	FHA IgA	PT100 IgG	PT IgA
		<i>recomLine Bordetella pertussis</i>	positive	42 (97,6 %)	39 (90,6 %)
	negative	1 (2,3 %)	4 (9,4 %)	1 (2,3 %)	25 (58,1 %)
	sum	43 (100 %)	43 (100 %)	43 (100 %)	43 (100 %)

### Samples strips from patients with acute pertussis infection

	Conjugate							
	Contr. IgG	Cutoff IgA	Control 1+	FHA	PT-100	PT		
IgG	+	+	+	2+	2+	3+	positive	Acute infection
IgA	+	+	+	2+	-	+	positive	

## Article-No

- 5772 ***recomLine Bordetella pertussis IgG***  
Reagents for 20 determinations
- 5773 ***recomLine Bordetella pertussis IgA***  
Reagents for 20 determinations
- 5770 ***recomLine Bordetella pertussis IgG***  
Reagents for 100 determinations
- 5779 ***recomLine Bordetella pertussis IgA***  
Reagents for 100 determinations

## Storage

At +2°C - +8°C