



## Anti-Bordetella pertussis Toxin ELISA (IgG)



- **Reliable antibody detection according to the guidelines of European reference centres**
- **Species-specific due to the use of purified pertussis toxin**
- **Quantification in IU/ml and interpretation with respect to 40 and 100 IU/ml cut-offs**

### Technical data

<b>Antigen</b>	Native highly purified Bordetella pertussis toxin (strain "Tohama")		
<b>Calibration</b>	Quantitative, in international units per millilitre (IU/ml); based on the first international standard of the WHO (WHO International Standard Pertussis Antiserum, human; 1 <sup>st</sup> IS NIBSC Code 06/140)		
	Calibration serum 1: 200 IU/ml	Calibration serum 3: 25 IU/ml	
	Calibration serum 2: 100 IU/ml	Calibration serum 4: 5 IU/ml	
<b>Sample dilution</b>	Serum or plasma, 1:101 in sample buffer		
<b>Reagents</b>	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits		
<b>Test procedure</b>	60 min (37°C) / 30 min / 15 min, room temperature, fully automatable		
<b>Measurement</b>	450 nm, reference wavelength between 620 nm and 650 nm		
<b>Test kit format</b>	96 break-off wells; kit includes all necessary reagents		
<b>Order number</b>	<b>EI 2050-9601 G</b>		

### Clinical significance

*Bordetella pertussis* is the causative agent of whooping cough, a disease with 3 stages: After an incubation time of about 7 to 14 days, the infection begins with an uncharacteristic catarrhal stage which lasts for about 1 to 2 weeks. Then the convulsive stage develops, lasting for 2 to 3 weeks with typical paroxysmal, staccato coughing attacks, frequently followed by stridor with possible vomiting. The coughing attacks frequently occur during the night. Following this is the decrement stage, which lasts for several weeks, with continual diminishment of coughing attacks. Complications such as secondary pneumonia or otitis media are possible, especially in children under the age of 2 years. An infection confers specific immunity, which reduces after several years. The clinical progression of whooping cough depends mainly on the production of the different virulence factors (adhesins and toxins), such as filamentous haemagglutinin (FHA) or pertussis toxin (PT).

### Diagnostic application

In the early stage of infection, cultivation of the pathogenic agent or detection of *Bordetella* DNA via PCR are possible. Around four weeks after the infection has started, the pathogen is generally not detectable any more in the respiratory tract. For this reason, serological diagnostics plays a major role. Pathogen-specific antibodies of classes IgA and IgG can be detected approximately from the stadium convulsivum. ELISAs based on pertussis toxin (PT) are recommended for the specific detection of antibodies against *Bordetella pertussis*, since they allow exclusion of a parapertussis infection and also quantification of the antibody titer in international units (IU/ml). The EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgG), however, is based on native, highly purified pertussis toxin, which is only produced by *B. pertussis*. Cross reactions with *B. parapertussis* can therefore be excluded. Increased anti-PT IgG titers ( $\geq 100$  IU/ml) are considered proof of an acute *B. pertussis* infection; titers  $> 40$  IU/ml should be investigated further. An immune response following vaccination cannot be distinguished from one following infection. Reliable interpretation of results after vaccination with acellular vaccines can only be achieved after around a year.



## Reproducibility

The reproducibility was investigated by determining the intra- and inter-assay coefficients of variation using three sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on four determinations performed in six different test runs.

Serum	Intra-assay variation, n = 20		Inter-assay variation, n = 4 x 6	
	Mean value (IU/ml)	CV (%)	Mean value (IU/ml)	CV (%)
1	33	3.3	113	6.9
2	115	2.6	29	5.5
3	77	1.8	75	5.4

## Reference range

Recent publications and guidelines recommend the following interpretations for evaluation of antibodies against Bordetella pertussis toxin of class IgG:

Anti-PT IgG  $\geq$  100 IU/ml: Indication of an acute infection with Bordetella pertussis or recent vaccination.

Anti-PT IgG < 40 IU/ml: No indication of an acute infection with Bordetella pertussis.

Anti-PT IgG  $\geq$  40 - < 100 IU/ml: Clarification by subsequent investigation or a second blood sample, collected after 7 to 10 days, is recommended.

## QA schemes

74 clinically characterised patient samples (INSTAND quality assessment, Germany; Labquality, Finland) were tested using the EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgG). The sensitivity was 97.8%, with a specificity of 100%. The results for three samples were in the borderline range. They were not included in the calculation.

EUROIMMUN Anti-Bordetella pertus- sis Toxin ELISA (IgG)	n = 74	INSTAND/LABQUALITY		
		positive	borderline	negative
positive		45	0	0
borderline		0	0	0
negative		1	3	25

## Specificity and sensitivity

92 patient sera serologically precharacterised using other commercial anti-Bordetella pertussis toxin ELISAs were analysed with the EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgG). The specificity with respect to the reference method was 95.5%, with a sensitivity of 100% (excluding borderline results).

EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgG)	n = 92	Other commercial ELISAs		
		positive	borderline	negative
positive		16	6	3
borderline		0	0	0
negative		0	3	64

## Cross reactivity

The quality of the antigen used in the ELISA guarantees a high specificity of the test. Sera from patients with infections caused by various infectious agents were analysed using the Anti-Bordetella pertussis Toxin ELISA (IgG).

Parameter	n	CR	Parameter	n	CR	Parameter	n	CR
Adenovirus	12	0%	Influenza virus A	12	0%	Parvovirus B19	12	0%
Chlamydia pneumoniae	12	0%	Influenza virus B	12	0%	RSV	12	0%
CMV	12	0%	Measles virus	12	0%	Rubella virus	12	0%
EBV-CA	12	0%	Mumps virus	12	0%	Toxoplasma gondii	12	0%
Helicobacter pylori	12	0%	Mycoplasma pneum.	12	0%	VZV	12	0%
HSV-1	12	0%	Parainfluenza Pool	12	0%	Yersinia enterocolitica	12	0%