Anti-Bordetella pertussis Toxin ELISA (IgA)

- **Specific for Bordetella pertussis: exclusion of B. parapertussis infections**
- **Useful in problematic cases with anti-pertussis toxin IgG titers in the range of ≥ 40 to < 100 IU/ml**
- **Efficient automation solutions**

Technical data

Antigen	Native highly purified Bordetella pertussis toxin (strain "Tohama")
Calibration	Quantitative, in international units per millilitre (IU/ml); based on the first international standard of the WHO (WHO International Standard Pertussis Antiserum, human, 1st IS NIBSC Code 06/140) Calibration serum 1: 50 IU/ml Calibration serum 3: 10 IU/ml Calibration serum 2: 25 IU/ml Calibration serum 4: 2 IU/ml
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	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
Test procedure	60 min (37 °C) / 30 min / 15 min, room temperature, fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Order number	**EI 2050-9601 A**

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 decrimenti 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 (IgA), 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. Detection of anti-PT IgA is particularly useful for diagnosis in problematic cases with anti-PT IgG titers of 40 to 100 IU/ml. 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.

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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.

	Intra-assay variation, n = 20		Inter-assay variation, n = 4 x 6	
Serum	Mean value (IU/ml)	CV (%)	Mean value (IU/ml)	CV (%)
1	13	2.9	38	4.7
2	34	3.6	17	5.5
3	15	3.8	14	9.8

Reference range

No standardised reference values have been described for the evaluation of antibodies against Bordetella pertussis toxin of class IgA. In literature, the lower detection limit of 12 IU/ml is recommended for the interpretation of anti-PT IgA antibodies (Riffelmann et al. J. Clin. Microbiol. Vol. 48, 2010):

Anti-PT IgA > 12 IU/ml: Indication of an acute infection with Bordetella pertussis or recent vaccination.

Anti-PT IgA < 12 IU/ml: No indication of an acute infection with Bordetella pertussis

Specificity and sensitivity

77 clinically characterised patient samples (INSTAND quality assessment, Germany; Labquality, Finland) were tested using the EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgA). The sensitivity was 97.4 %, with a specificity of 100 %. Borderline results were not included in the calculation.

n = 77		INSTAND/LABQUALITY		
		positive	borderline	negative
EUROIMMUN Anti-Bordetella pertussis Toxin ELISA (IgA)	positive	37	0	0
	borderline	0	1	0
	negative	1	0	38

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 (IgA).

Parameter	n	CR	Parameter	n	CR	Parameter	n	CR
Adenovirus	10	0 %	**Helicobacter pylori**	10	0 %	**Parainfluenza virus Pool**	10	0 %
Bordetella FHA	10	0 %	**HSV Pool**	10	0 %	**RSV**	10	0 %
Brucella abortus	10	0 %	**Influenza virus A**	10	0 %	**Toxoplasma gondii**	10	0 %
Chlamydia pneumoniae	10	0 %	**Influenza virus B**	10	0 %	**VZV**	10	0 %
Chlamydia trachomatis	10	0 %	**Legionella pneumoniae**	10	0 %	**Yersinia enterocolitica**	10	0 %
EBV-CA	10	0 %	**Mycoplasma pneumoniae**	10	0 %			

Literature references

1. Guiso N, et al. **What to do and what not to do in serological diagnosis of pertussis: recommendations from the EU reference laboratories.** EUR J Clin Microbiol Infect Dis (2010)
2. Riffelmann M, et al. **Performance of commercial enzyme-linked immunosorbent assay for detection of antibodies to Bordetella pertussis.** J Clin Microbiol 48(2010) 4459-4463

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