Anti-Bordetella FHA ELISA (IgA)

- **Reliable diagnosis of infections with Bordetella pertussis and Bordetella parapertussis**
- **Useful in problematic cases with anti-pertussis toxin IgG titers ranging from ≥40 to <100 IU/ml**
- **Efficient automation solutions**

Technical data

Antigen	Native, highly purified Bordetella FHA
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 (room temperature) / 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 no.	**EI 2050-9601-3 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, 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 from around the stadium convulsivum. The EUROIMMUN Anti-Bordetella FHA ELISA (IgA) is based on highly purified native Bordetella FHA, with which both B. pertussis and B. parapertussis infections can be detected sensitively. Test systems based on a mixture of PT and FHA antigens are not recommended by international reference laboratories. Quantification is performed in international units (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.

EUROIMMUN Medizinische Labordiagnostika AG · Seekamp 31 · 23560 Lübeck (Germany) · Phone: +49 451 2032-0 · www.euroimmun.com

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 3 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

	Intra-assay variation, n = 20			Inter-assay variation, n = 4 x 6	
No.	Mean value (IU/ml)	CV (%)	No.	Mean value (IU/ml)	CV (%)
1	17	3.3	4	0.6	6.0
2	14	3.4	5	1.0	9.7
3	12	5.5	6	2.0	3.6

Reference range

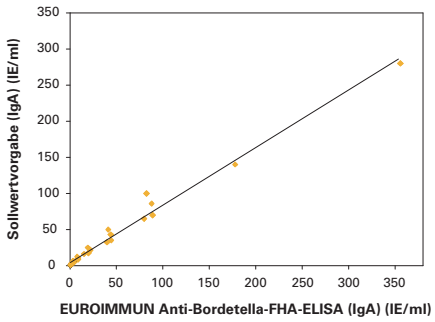
In literature, the following age-dependent reference ranges are recommended for the evaluation of class IgA antibodies against Bordetella pertussis toxin:

Antibodies	Age-dependent reference range in IU/ml			
	< 1 year	1 – 4 years	5 – 10 years	from 11 years
Anti-FHA IgA	< 2	< 2	< 18	< 42

Correlation with target values of international reference sera

Four reference sera* were tested for anti-Bordetella FHA IgA antibodies in various concentrations using the Anti-Bordetella FHA ELISA (IgA). The linear regression analysis yielded a correlation coefficient of $r^2 = 0.99$.

* 1st serum: WHO international standard (lot 06/140), 2nd serum: WHO reference serum (lot 06/142), 3rd serum: FDA US reference serum lots 3&4, 4th serum: FDA US reference serum lot 5



Cross reactivity

159 sera from patients with different infectious diseases (positive IgA results) and without previous Bordetella pertussis infection or vaccination were investigated with the EUROIMMUN-Anti-Bordetella pertussis FHA ELISA (IgA). No cross reactions (CR) were found.

Parameter	n	CR	Parameter	n	CR	Parameter	n	CR
Adenoviruses	10	0%	HSV pool	10	0%	Parainfluenza pool	10	0%
Brucella abortus	9	0%	Influenza virus A	10	0%	RSV	10	0%
Chlamydia pneumoniae	10	0%	Influenza virus B	10	0%	Toxoplasma gondii	10	0%
Chlamydia trachomatis	10	0%	Legionella pneum.	10	0%	VZV	10	0%
EBV-CA	10	0%	Mycoplasma pneum.	10	0%	Yersinia enterocolitica	10	0%
Helicobacter pylori	10	0%						

Literature

1. Cherry JD. **Immunity to Pertussis.** CID 77 (2004) 1278-1279.
2. Munoz FM. **Pertussis in infants, children and adolescents: diagnosis, treatment and prevention.** Semin Pediatr Infect Dis 17(2006) 14-19
3. Riffelmann M, et al. **Performance of commercial enzyme-linked immunosorbent assays for detection of antibodies to Bordetella pertussis.** J Clin Mircobiol (2010) 4459-4463.
4. Wellinghausen et al. **Immunological methods for the detection of infectious diseases. Part I.** 2016. MiQ 35a.
5. Guiso et al. **What to do and what not to do in serological diagnosis of pertussis: recommendations from EU reference laboratories.** Eur J Clin Microbiol Infect Dis. 2011;30(3):307-12.
6. Cherry et al. **Clinical Definitions of Pertussis: Summary of a Global Pertussis Initiative Roundtable Meeting, February 2011.** Clin Infect Dis. 2012; 54(12): 1756–1764.
7. Riffelmann et al. **Performance of Commercial Enzyme-Linked Immunosorbent Assays for Detection of Antibodies to Bordetella pertussis.** J Clin Microbiol. 2010; 48(12): 4459–4463.

EUROIMMUN Medizinische Labordiagnostika AG · Seekamp 31 · 23560 Lübeck (Germany) · Phone: +49 451 2032-0 · www.euroimmun.com
EI_2050_D_UK_D05 09/2019