Anti-Helicobacter pylori ELISA (IgG)

- **Serological detection of IgG antibodies against *Helicobacter pylori* antigens**
- **Non-invasive test to support the diagnosis of *H. pylori* infections**
- **Fully automated processing and evaluation possible**

Technical data

Antigen	The antigen used is the bacterial lysate of *H. pylori* strain "ATCC43504"
Calibration	Quantitative, in relative units per millilitre (RU/ml) Calibrator 1: 200 RU/ml Calibrator 2: 20 RU/ml Calibrator 3: 2 RU/ml Recommended upper threshold of the normal range (cut-off value): 20 RU/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, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	30 min / 30 min / 15 min (sample / conjugate / substrate incubation), room temperature, 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 2080-9601 G**

Clinical significance

Helicobacter pylori (*H. pylori*) is a gram-negative, spiral-shaped bacterium with unusually strong urea production. It colonises intercellularly on the luminal side of the epithelial cells of the stomach mucosa. It is the only human pathogenic species of the genus *Helicobacter* and is secreted in the faeces of infected humans and animals. The infectious disease has an average prevalence of around 50 % worldwide, with a significantly higher infection rate in developing countries than in industrialised countries. In Germany, around 33 million people are infected with *H. pylori*. Of these, around 10 to 20 % develop peptic ulcers. Antibodies against *H. pylori* occur in about 70 % of patients with chronic active gastritis and are associated with ulcer conditions in 60 to 90 % of all cases. Clinically, dyspepsia with upper abdominal complaints can occur, while histologically, surface gastritis and mucosal atrophy are observed. However, the majority of infections remain clinically asymptomatic. An *H. pylori* infection does not heal spontaneously, i.e. the infectious agent may rather persist for life.

Invasive methods for direct pathogen detection require gastroscopy and are stressful for the patient as well as costly. They should be used in clinically relevant indications (evidence of bleeding, weight loss) or unsuccessful antibiotic treatment, e.g. resulting from resistance. Non-invasive procedures are the method of choice for other patients with suspected *H. pylori* infection and for monitoring treatment.

After contact with *H. pylori*, antibodies of classes IgA, IgG and IgM can occur. **IgA** antibodies usually form locally after a few weeks and persist over a long period of time. However, they are not always detectable in the serum. Positive IgA results correlate with gastritis activity. **IgG** antibodies are frequently first detected after the IgM titer has declined and can persist for years. An increase in the IgG titer indicates an advanced infection. Elevated IgG antibody titers are considered a marker for chronic infection. **IgM** antibodies are already formed a few days after contact with *H. pylori*, but several weeks later, specific IgM is no longer detectable. The detection of specific IgA and IgG antibodies in patient serum using ELISA / IIFT is therefore an important and cost-saving initial examination. Confirmation and differentiation of borderline or positive ELISA / IIFT results using EUROLINE-WB support the diagnosis and provides additional information about the virulence of the pathogen.

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Detection limit

The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable antibody titer. The lower detection limit of the Anti-Helicobacter pylori ELISA (IgG) is 0.7 RU/ml.

Reference range

The anti-*H. pylori* antibody levels (IgG) were determined in a panel of 500 healthy blood donors using this ELISA. With a cut-off value of 20 RU/ml, 24.6 % of the blood donors were anti-*H. pylori* positive (IgG).

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation (CV) using three samples. 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		
Sample	**Mean value (RU/ml)**	**CV (%)**
1	144	3.2
2	179	3.2
3	207	3.1

Inter-assay variation, n = 4 x 6		
Sample	**Mean value (RU/ml)**	**CV (%)**
1	141	3.4
2	176	3.7
3	212	4.6

Sensitivity and specificity

59 clinically precharacterised patient samples from the quality assessment provider INSTAND e.V. were investigated using the EUROIMMUN Anti-Helicobacter pylori ELISA (IgG). The sensitivity and specificity amounted to 100 % each. Borderline results were not included in the calculation.

n = 59		Precharacterisation by INSTAND		
		positive	**borderline**	**negative**
EUROIMMUN Anti-Helicobacter pylori ELISA (IgG)	**positive**	35	2	0
	borderline	0	0	0
	negative	0	0	22

Cross reactivity

164 sera from patients with infections caused by different pathogens, such as various viruses, *Chlamydia pneumoniae* or *Toxoplasma gondii*, were investigated using the Anti-Helicobacter pylori ELISA (IgG). The test results obtained with the Anti-Helicobacter pylori ELISA (IgG) were negative for all samples.

Literature

1. Kist M et al. **S3 Guideline "Helicobacter pylori und gastroduodenale Ulkuskrankheit" – eine neue Herausforderung für die mikrobiologische Diagnostik.** Mikrobiologie 20: 41-46 (2010) [in German].
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4. Podbielski A, Abele-Horn M, Becker K, Herrmann M, Kniehl E, Mauch H, Rüssmann H (Hrsg.) **MiQ 35a.** Urban & Fischer, Munich 2016.

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