Indications: Test system for the in vitro determination of antibodies against Helicobacter pylori in human serum or plasma for the diagnosis of the following diseases: chronic-active gastritis (of the antrum), ulcer ventriculi, ulcer duodeni.

Clinical significance: Helicobacter pylori is a gram-negative, spiral-shaped bacterium with unusually strong urease production. It colonises the luminal side of the epithelial cells of the stomach mucosa. H. pylori is the only human pathogenic type of the genus Helicobacter and is distributed worldwide. Humans and animals secrete the bacterium in their faeces. H. pylori is capable of surviving in water. With a prevalence of around 50% worldwide, H. pylori infection is one of the most common chronic bacterial infections. The infection level is much higher in developing countries than in industrial 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 can occur with corresponding upper abdominal complaints, while histologically, surface gastritis and mucosal atrophy are observed. However, the majority of infections remain clinically asymptomatic. H. pylori infections do not heal spontaneously. The pathogen can persist life long.

After contact with H. pylori, patients may exhibit antibodies of classes IgA, IgG and IgM against H. pylori in the serum. IgA antibodies usually form after a few weeks and remain detectable over a long time period. Positive IgA results correlate well with gastritis activity. However, these antibodies are formed locally and are not always detectable in the serum. IgG antibodies are frequently first detected after the IgM titer has declined and they can persist for years. An increase in the IgG titer indicates an advanced H. pylori infection. Elevated IgG antibody titers are considered a marker for chronic infection. IgM antibodies are formed a few days after contact with H. pylori. After a few weeks specific IgM is no longer detectable.

In therapy monitoring the determination of specific IgG antibodies against Helicobacter pylori is suitable for confirming eradication of the pathogen. A significant drop in the IgG antibody titer about 6 months after therapy is a sign of success.

Application of the Anti-Helicobacter pylori ELISA (IgA): Laboratory diagnostics for Helicobacter pylori infections can be divided into invasive methods (pathogen culture, histology, urease rapid test, PCR) and non-invasive methods (serological antibody determination, antigen detection in faeces, 13C urea breath test).

The invasive methods are stressful for patients and some are additionally costly. They should be used in cases of 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.

The detection of specific IgA and IgG antibodies in patient serum using ELISA/IIFT represents an important and cost-effective initial investigation. Confirmation and differentiation of borderline/positive ELISA/IIFT results using EUROLINE-WB (order no. DY 2080-####-1 IgA or IgG) supports the diagnosis and provides additional information about the virulence of the pathogen.
Test characteristics  
Anti-Helicobacter pylori ELISA (IgA)

Reproducibility: The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation (CV) using three sera. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on four measurements repeated in six different test runs.

Prevalence: 500 sera from healthy blood donors\(^1\) and 88 sera from healthy children\(^2\) (age: <10 years) were investigated using the EUROIMMUN Anti-H. pylori ELISA (IgA). The prevalences given in the table were obtained (cut-off ratio: 1.0).

Agreement with quality assessment data: 51 serologically precharacterised sera\(^3\) were investigated using the EUROIMMUN Anti-H. pylori ELISA (IgA). There was a 95% agreement between the ELISA results and the quality assessment target results (borderline sera excluded).

Technical data:

- **Antigen**: The antigen source is a bacterial lysate from the Helicobacter pylori strain "ATCC43504".
- **Calibration**: Semiquantitative. Calculation of a ratio from the extinction of the sample and the extinction of the calibrator.
- **Result interpretation**: Ratio <0.8: negative  
  Ratio ≥0.8 to <1.1: borderline  
  Ratio ≥1.1: positive
- **Sample dilution**: Serum or plasma; 1:101 in sample buffer.
- **Reagents**: Ready for use. Exception: wash buffer (10x). Colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits.
- **Test procedure**: 30min / 30min / 15min. Room temperature. Fully automatable.
- **Measurement**: 450 nm. Reference wavelength between 620 nm and 650 nm.
- **Kit format**: 96 break-off wells. Kit includes all necessary reagents.
- **Order no.**: EI 2080-9601 A

<table>
<thead>
<tr>
<th>Panel</th>
<th>n</th>
<th>Target results from QA institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donors</td>
<td>500</td>
<td>pos.</td>
</tr>
<tr>
<td>Healthy children ≤3 years old</td>
<td>25</td>
<td>pos.</td>
</tr>
<tr>
<td>Healthy children 4–10 years old</td>
<td>88</td>
<td>neg.</td>
</tr>
</tbody>
</table>

These sera also demonstrated IgG antibodies.

\(^1\) University Clinic of Schleswig-Holstein, Campus Luebeck, Germany; \(^2\) Origin of sera: Germany; \(^3\) INSTAND e.V.: Society for Promotion of Quality Assurance in the Medical Laboratories, Duesseldorf, Germany.