The gram negative, spiral shaped bacterium Helicobacter pylori was described by Warren and Marschall in 1983. The connection between chronic type B gastritis and Helicobacter pylori has been well studied. In fact, there is a causal relation between Helicobacter pylori and almost all duodenal and stomach ulcers. Moreover, Helicobacter pylori is associated with an increased risk of gastric adenocarcinomas. Apart from strains of different virulence, host factors may also be responsible for this phenomenon.

An infection with Helicobacter pylori induces a specific immune response. As a rule, antibodies of the classes IgG and IgA can be detected. Only small amounts of IgM antibodies are identified. Indeed, there is a decrease in the antibody concentration after successful eradication through combined antibiotic therapy.

The eradication of Helicobacter pylori cures not only gastritis or peptic ulcer, but also low malignant gastric MALT lymphomas. Although peptic ulcers are also cured without eradication of Helicobacter pylori, there is a recurrence within one year in up to half of all the cases in the absence of permanent acid suppression treatment. The rate of recurrence is less than 5 % per year after successful microbial eradication.

In comparison with other immunological processes, such as ELISA or IFT, the immunoblot exhibits additional criteria with regard to sensitivity and specificity. Above all, reactivities with individual antigens can be detected. Antibodies against virulence factors like CagA, VacA or urease can be safely detected by using a toxin positive strain of Helicobacter pylori for antigen preparation.

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**Product Advantages**

- Easy test procedure; automation possible
- Unambiguous assignment of the antigen bands through kit-specific control strip
- Safe test interpretation through point evaluation
- Separate detection of IgG and IgA antibodies possible
- **Use of a cytotoxin-positive strain of Helicobacter pylori**, therefore:
  - Optimal presentation of serologically relevant pathogenicity factors
  - CagA, VacA and the urease subunits UreA and UreB are detectable
- CE label: The Immunoblot Helicobacter tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
**Test Principle and Procedure**

1st. Incubation: A test strip loaded with Helicobacter antigens is incubated with diluted serum or plasma in a dish for 1 h.

Wash 3 times

2nd. Incubation: Peroxidase conjugated anti-human antibodies (IgG or IgA specific) are added. Incubate for 45 min.

Wash 3 times

3rd. Incubation: 5 - 10 minutes after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

**Evaluation**

In a study carried out by Prof. N. Lehn at the Institute of Medical Microbiology, Immunology and Hygiene of the TU Munich, 99 sera were tested with Immunoblot Helicobacter IgG and IgA. The donors of these sera were exceptionally well characterized by means of histology and/or microbiology. The results are summarized in the following tables.

<table>
<thead>
<tr>
<th>IgG</th>
<th>Histology/Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunoblot Helicobacter</td>
<td>negative  positive total</td>
</tr>
<tr>
<td>negative</td>
<td>38       3       41</td>
</tr>
<tr>
<td>positive</td>
<td>2        56      58</td>
</tr>
<tr>
<td>total</td>
<td>40       59      99</td>
</tr>
</tbody>
</table>

Specificity 95 %
Sensitivity 95 %

<table>
<thead>
<tr>
<th>IgA</th>
<th>Histology/Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunoblot Helicobacter</td>
<td>negative  positive total</td>
</tr>
<tr>
<td>negative</td>
<td>36       21      57</td>
</tr>
<tr>
<td>positive</td>
<td>4        38      42</td>
</tr>
<tr>
<td>total</td>
<td>40       59      99</td>
</tr>
</tbody>
</table>

Specificity 90 %
Sensitivity 64 %

**Storage and Shelf Life**

At 4 °C 18 months from the time of production

**Commercial Product**

- Article No. 4702 Immunoblot Helicobacter IgG Reagents for 20 determinations
- Article No. 4703 Immunoblot Helicobacter IgA Reagents for 20 determinations