

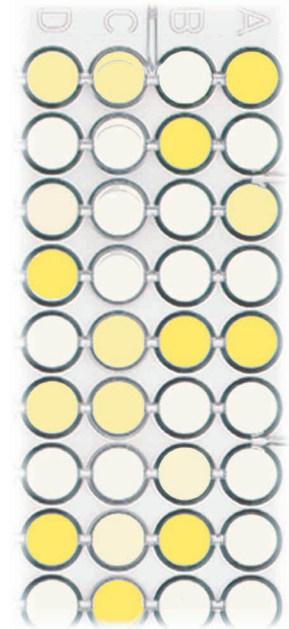
recomWell Helicobacter IgG recomWell Helicobacter IgA

Enzyme immunoassay with recombinant antigens for the detection of IgG and IgA antibodies against *Helicobacter pylori* in serum or plasma.

The gram-negative, spiral-shaped bacterium *Helicobacter pylori* was described by Warren and Marshall 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.

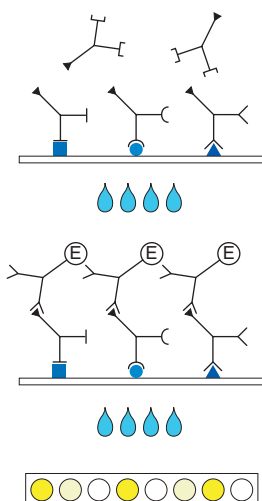
The eradication of *Helicobacter pylori* cures not only gastritis or peptic ulcer, but also low-malignant gastric MALT lymphomas. Although peptic ulcers are also cured without eradication of *Helicobacter pylori*, there is a recurrence within one year in up to half of all the cases in the absence of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



■ Test Principle and Procedure

Indirect sandwich test.

Recombinant antigens are bound to the solid phase.



1st Incubation: Add patient samples diluted 1:101 (sample: 10 μ l of serum or plasma), incubate for **1 h** at **37 °C**.

Wash 4 times

2nd Incubation: Add peroxidase conjugated anti-human IgG or IgA antibodies (conjugate), incubate for **30 min** at **37 °C**

Wash 4 times

Color reaction: Add ready-to-use TMB solution and incubate for **30 min** at room temperature. Stop the substrate reaction with H_3PO_4 and measure the extinction at 450 nm.

■ Product Advantages

- **Recombinant antigens**, therefore
 - Highest sensitivity and specificity
 - No cross reactions
 - Excellent discrimination between negative and positive results
- Separate detection of IgG and IgA antibodies
- Easy to quantify
- Easy test procedure; automation possible
- Break-a-parts: single sample examination possible
- **Use of recombinant CagA. Therefore detection of infection with virulent type I strains possible**
- CE label: The *recomWell* Helicobacter tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

■ Evaluation

Specificity: Negative sera/blood donors

n = 141	IgG test
Negative	87
Positive or equivocal	54
Confirmed by western blot	51
Prevalence	36 %
Specificity	98 %

Sensitivity: Clinically defined sera (histology/culture)

	Number	IgG test
Gastritis	38	97 %
Carcinoma	14	100 %

Accuracy

Intra assay	IgG/IgA	VC < 7 %
Inter assay	IgG/IgA	VC < 10 %

■ Storage and Shelf Life

At 4 °C 12 months from the date of production

■ Commercial Product

Article No. 4704 **recomWell Helicobacter IgG**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)

Article No. 4705 **recomWell Helicobacter IgA**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)