MIKROGEN
D I A G N O S T I K

NEW

Automatische
Streifen-
Auswertung

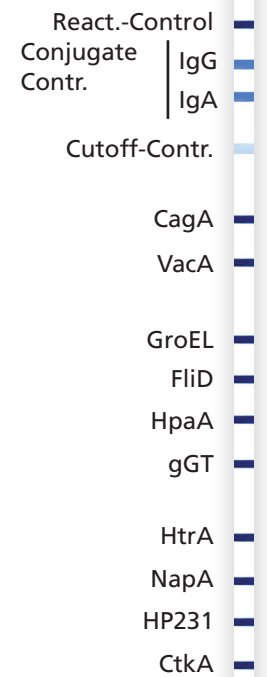## *recom*Line Helicobacter IgG 2.0
*recom*Line Helicobacter IgA 2.0

Line immunoassay using recombinant antigens for the detection and differentiation of IgG and
IgA antibodies against Helicobacter pylori type I and type II

The gram-negative, microaerophilic bacterium was described in 1983 by Warren and Marshall.
It colonises the human stomach and is able to persist there in the long term.

Approx. 50% of all humans worldwide are infected with Helicobacter pylori. While all those
infected develop a chronic inflammation of the gastric mucosa, this leads to complaint sym-
ptoms only in a part of the patients. The Helicobacter pylori infection is believed to be linked to
various gastric disorders, such as gastric ulcers, gastric adenocarcinomas and MALT lymphomas.
As for its cause, host-related factors (social factors as well as nutritional and environmental
factors) are, besides various virulent strains, also named as causal factors.

The *recom*Line Helicobacter 2.0 detects antibodies against ten selected Helicobacter pylori
antigens. The detection of antibodies against the two most important virulence factors, CagA
and VacA, is of high diagnostic significance. These two virulence factors markedly increase
the risk of premalignant changes, gastric carcinoma, MALT lymphoma and ulcer. The humoral
immune response to the biomarkers GroEL, HtrA, NapA, HP231 and CtkA is associated with a
severe course of disease.

The *recom*Line Helicobacter 2.0 is the first serological test to present this selection of diagnosti-
cally relevant Helicobacter pylori markers.

React.-Control
Conjugate
Contr.
IgG
IgA
Cutoff-Contr.

CagA
VacA

GroEL
FliD
HpaA
gGT

HtrA
NapA
HP231
CtkA

Product advantages

Reliable diagnostics:
- Excellent correlation with the gold standard of Helicobacter pylori diagnostics –
  culture and histology
- Sensitivity: > 99% IgG-positive results in patients who are positive according to the gold standard
- Specificity: 100% IgG- and IgA-negative results in patients who are negative according to the gold
  standard
- Safe evaluation due to strip specific controls (reaction, cut-off and conjugate control)
- Take advantage of serology – anytime reliable results even with low bacterial load
- CE label: The *recom*Line Helicobacter 2.0 tests meet the high standard of the EC directive 98/79/EC on in
  vitro diagnostic medical devices

Meaningful diagnostics:
- Identification of highly virulent Helicobacter pylori type I infections by means of CagA
- Detection of antibodies against ten relevant biomarkers and virulence factors associated with severe
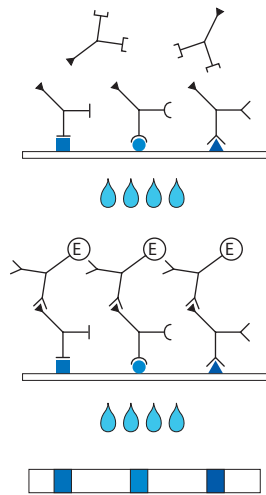 courses of disease

Fast and easy diagnostics:
- Fast and easy to use due to automation and software based evaluation
- Test procedure and reagents identical in all MIKROGEN line assays – reagents exchangeable

Recombinant Helicobacter pylori Antigens

Anti-gen	Description	Virulence factor	Specific for type I / type II	Anti-gen	Description	Virulence factor	Specific for type I / type II
CagA	Cytotoxin-associated gene A	✓	Type I	gGT	gamma-Glutamyl Transpept-idase	✓	Type I / Type II
VacA	Vacuolating cytotoxin A	✓	Type I / Type II	HtrA	High temperature requirement serine protease A	–	Type I / Type II
GroEL	Chaperone	–	Type I / Type II	NapA	Neutrophil activating protein	✓	Type I / Type II
FliD	Flagella hook associated protein	–	Type I / Type II	HP231	Oxidoreductase	–	Type I / Type II
HpaA	Neuraminyllactose-binding hemagglutinin, Adhesin	✓	Type I / Type II	CtkA	Serin/Threonin Kinase	✓	Type I / Type II

Test Principle and Procedure

1st Incubation	A test strip loaded with Helicobacter pylori antigens is incubated with diluted serum or plasma in a dish for **1 hour**.	
	wash 3 times	
2nd Incubation	Peroxidase conjugated anti-human antibodies (IgG or IgA specific) are added. Incubate for **45 minutes**.	
	wash 3 times	
Color reaction	**8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.	

Evaluation

Diagnostic Sensitivity

*recom*Line Helicobacter 2.0	Histology/culture positive samples (n=139)	
	IgG	IgA
negative	1	51
borderline	0	0
positive	138	88
sensitivity	99,3%	63,3%

Diagnostic Specificity

*recom*Line Helicobacter 2.0	Histology/culture negative samples (n=97)	
	IgG	IgA
negative	97	97
borderline	0	0
positive	0	0
specificity	100 %	100 %

Examples: IgG analysis of clinically defined patient samples

Helicobacter pylori positive / premalignant changes (int. metaplasia, atrophy)

	∑ Sum of points
positive (HP Type I)	21
positive (HP Type I)	20
positive (HP Type I)	15
positive (HP Type I)	20

Helicobacter pylori positive / simple gastritis

	∑ Sum of points
positive (HP Type II)	9
positive (HP Type II)	11
positive (HP Type I)	18
positive (HP Type I)	15

Article No.

4774	***recom*Line Helicobacter IgG 2.0** Reagents for 20 determinations
4775	***recom*Line Helicobacter IgA 2.0** Reagents for 20 determinations

Storage

+2°C - +8°C