

NEW

## recomLine Campylobacter IgG

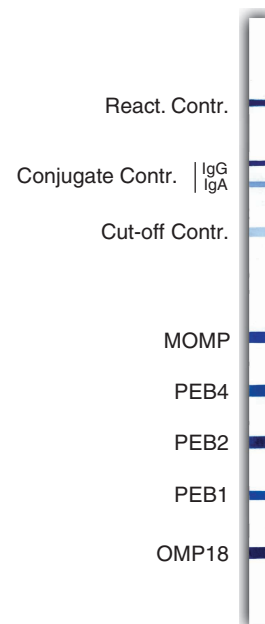
## recomLine Campylobacter IgA

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG and IgA antibodies against *Campylobacter jejuni* and *Campylobacter coli*

The genus *Campylobacter* comprises gram-negative, spiral-shaped, microaerophilic, mesophilic to thermophilic bacteria with bipolar flagella. Human *Campylobacter* infections are mainly food associated intestinal infections with world-wide incidence. Contaminated and insufficient cooked foods or drinking water in tropical countries are the main sources of infection. The pathogen reservoir is mainly the intestinal tract of warm-blooded wild, domestic and pet animals. Intestinal *Campylobacter* infections are the second most frequent enteric bacterial infections reported in Germany after enteric Salmonellosis, whereas unreported cases not reflected in the statistics probably outnumber reported cases many times over.

*Campylobacter jejuni* is much more frequent, accounting for over 90% of cases as compared to *Campylobacter coli* at approx. 9%. Besides nearly asymptomatic (clinically inapparent) courses, infected persons suffer from painful gastrointestinal symptoms with sometimes bloody diarrhoea, fever, meningism and myalgias. In rare cases sequelae like postinfectious Reactive Arthritis or Guillain-Barré Syndrome may develop with onset a few weeks after the primary infection.

*recomLine Campylobacter* is a qualitative in-vitro test for the detection of IgG and IgA antibodies against immunodominant antigens of *Campylobacter jejuni* and *Campylobacter coli*. In cases of previous or persistent *Campylobacter* infection with primary diagnosis based on stool sample culturing, *recomLine Campylobacter* provides for identification of specific *Campylobacter* antibodies by means of separate lineups of different antigens produced by recombinant engineering for the purpose of clarifying postinfection complications.



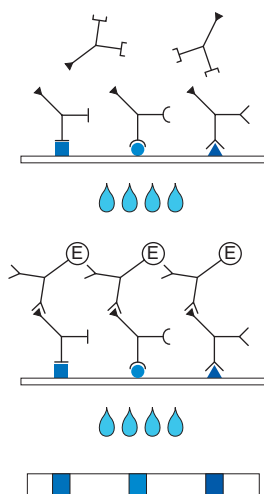
### Product advantages

- **Recombinant antigens**, therefore:
  - High sensitivity and specificity
  - Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Test procedure is identical to other MIKROGEN strip tests
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG and IgA antibodies possible
- CE label: The *recomLine Campylobacter* tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

### Related recombinant Campylobacter antigens

Recombinant Antigen	Abbreviation	Size of rec. Antigens [kDa]
Major outer membrane protein	MOMP	46
Cytoplasmic protein	PEB4	31
Periplasmic protein	PEB2	27
Periplasmic protein	PEB1	28
Outer membrane protein	OMP18	18

## ■ Testprinciple and Procedure



**1<sup>st</sup> Incubation:** A test strip loaded with Campylobacter antigens is incubated with diluted serum or plasma in a dish for **60 min.**

*wash 3 times*

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

*wash 3 times*

**3<sup>rd</sup> 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

Patient samples from different sources were tested to assess the performance capability of *recomLine* Campylobacter IgG/IgA. Additional data on the frequency of positive reactivity for the individual recombinant antigens are listed.

<i>recomLine</i> Campylobacter IgG	n	Frequencies of the recombinant antigens (%)					IgG positive
		MOMP	PEB4	PEB2	PEB1	OMP18	
<i>C. jejuni, C. coli</i> positive stool culture *	100	9	30	4	9	70	76%
GBS samples with unclarified aetiology **	30	13	13	10	7	10	20%
ReA samples with unclarified aetiology ***	60	0	17	8	2	12	23%
Blood donors	130	5	4	2	2	13	14%

<i>recomLine</i> Campylobacter IgA	n	Frequencies of the recombinant antigens (%)					IgA positive
		MOMP	PEB4	PEB2	PEB1	OMP18	
<i>C. jejuni, C. coli</i> positive stool culture *	100	3	4	0	2	21	22%
GBS samples with unclarified aetiology **	30	7	7	0	0	3	10%
ReA samples with unclarified aetiology ***	60	2	7	0	2	2	8%
Blood donors	130	1	1	0	0	1	1,5%

\* Samples from patients with positive Campylobacter stool cultures (*C. jejuni, C. coli*). Blood samples were taken 0 to 40 days after the stool diagnostics, the beginning of the disease was unknown.

\*\* Samples from patients with suspected Guillain-Barré-Syndrom (GBS) unclarified aetiology. No data on previous illnesses involving diarrhoea were known.

\*\*\* Samples from patients with suspected Reactive Arthritis (ReA) unclarified aetiology. No data on previous illnesses involving diarrhoea were known.

## ■ Storage and Shelf life

At 4 °C, 12 months from the time of production

## ■ Commercial Product

Article No. 6272 ***recomLine* Campylobacter IgG**  
Reagents for 25 determinations

Article No. 6273 ***recomLine* Campylobacter IgA**  
Reagents for 25 determinations