

**NEW**
**ELISA**

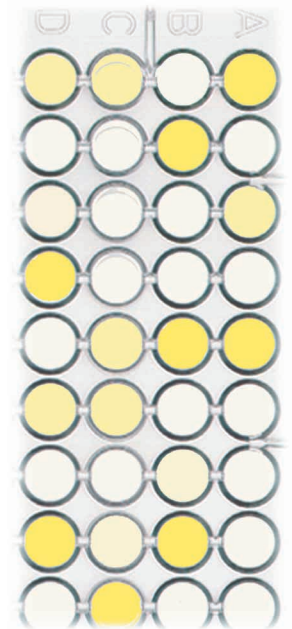
## recomWell Campylobacter IgG recomWell Campylobacter IgA

Enzyme 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-Syndrom may develop with onset a few weeks after the primary infection.

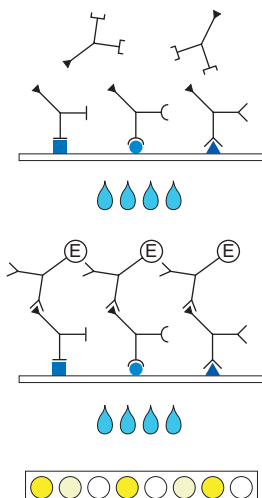
*recomWell Campylobacter* is a quantitative in vitro test for the detection and safe identification of IgG or IgA antibodies against specific antigens of *Campylobacter jejuni* and *Campylobacter coli*. In cases of previous or persistent *Campylobacter* infection with primary diagnosis based on stool sample culturing, *recomWell Campylobacter*, as a screening test, provides for identification of specific *Campylobacter* antibodies for the purpose of clarifying postinfection complications.



### ■ Test Principle and Procedure

Indirect sandwich test.

Recombinant antigens are bound to the solid phase.



**1<sup>st</sup> Incubation:** Add patient samples diluted 1:101 (sample: 10 µl of serum or plasma), incubate for **1 h** at **37 °C**.

*Wash 4 times*

**2<sup>nd</sup> 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
  - High sensitivity and specificity
  - Excellent discrimination between negative and positive results
  - Immunodominant antigens of *Campylobacter jejuni* and *Campylobacter coli*
- Separate detection of IgG and IgA antibodies
- Identical procedure for IgG and IgA determination
- Test procedure is identical to other MIKROGEN ELISA tests
- Easy test procedure; automation possible
- Easy to quantify
- Break-a-part: single sample examination possible
- CE label: The *recomWell* Campylobacter tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

## ■ Evaluation

Patient samples from different sources were tested to assess the performance capability of *recomWell* Campylobacter.

<i>recomWell</i> Campylobacter IgG/IgA	number	positive or equivocal	
		IgG	IgA
<i>C. jejuni</i> , <i>C. coli</i> positive stool culture *	292	73%	24%
GBS samples with unclarified aetiology **	30	23%	13%
ReA samples with unclarified aetiology ***	38	18%	11%
Blood donors	220	19%	3%

\* Samples from patients with positive Campylobacter stool cultures (*C. jejuni*, *C. coli*). Blood samples were taken 0 to 81 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.

Potentially falsifying sera of patients (n=100) infected by *Yersinia enterocolitica*/Y. *pseudotuberculosis*, *Helicobacter pylori*, *Borrelia burgdorferi*, *Parvovirus B19* and *Toxoplasma gondii* did not show a higher number of increased Campylobacter antibody titers.

## ■ Storage and Shelf Life

At 4 °C 12 months from the date of production

## ■ Commercial Product

Article No. 6204 ***recomWell* Campylobacter IgG**  
Reagents for 96 determinations  
(Mikrotiter plates: 12 x 8 wells)

Article No. 6205 ***recomWell* Campylobacter IgA**  
Reagents for 96 determinations  
(Mikrotiter plates: 12 x 8 wells)

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