

Increased
sensitivity
by use of P39

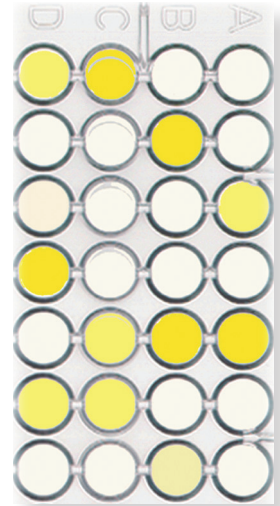
recomWell Campylobacter IgG recomWell Campylobacter IgA

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.

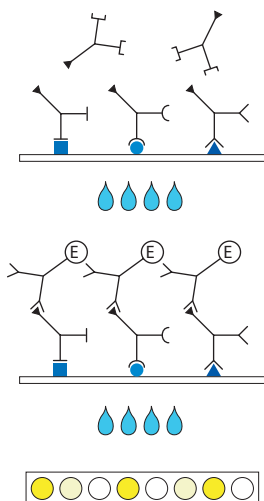
recomWell Campylobacter is a quantitative in vitro test for the detection and safe identification of IgG or IgA antibodies against specific antigens of *Campylobacter jejuni* and *Campylobacter coli*. In cases of previous or persistent *Campylobacter* infection with primary diagnosis based on stool sample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



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 possible
- Identical procedure for IgG and IgA determination
- Easy to quantify
- Easy test procedure; automation possible
- Test procedure and reagents identical in all MIKROGEN ELISA - reagents exchangeable
- Break-a-parts: single simple 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.

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 µl 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, incubate **30 min at 37 °C**.

wash 4 times

Color reaction Add ready-to-use TMB solution and incubate **30 min** at room temperature. **Stop the substrate solution with H₃PO₄** and measure the extinction at 450 nm.

Evaluation

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

Sensitivity

<i>recomWell Campylobacter IgG/IgA</i>	Number	positive or equivocal	
		IgG	IgA
<i>C. jejuni</i> , <i>C. coli</i> positive stool culture *	310	86 %	40 %
GBS samples with unclarified aetiology **	30	23 %	13 %
ReA samples with unclarified aetiology ***	38	37 %	16 %
Blood donors	200	16 %	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. (Testet with *recomLine Campylobacter* without P39).

*** 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.

Article-No.

6204 ***recomWell Campylobacter IgG***
Reagents for 96 determinations

6205 ***recomWell Campylobacter IgA***
Reagents for 96 determinations

Storage

+2°C - +8°C