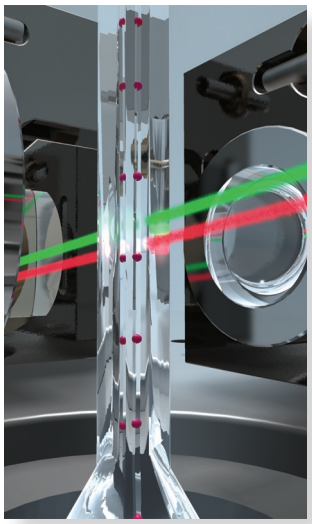
MIKROGEN DIAGNOSTIK

NEW

*recom*Bead Yersinia IgG
*recom*Bead Yersinia IgA [IgM]

Fluorescence based particle immunoassay using recombinant antigens for the detection of IgG, IgA or IgM antibodies against *Y. enterocolitica* and *Y. pseudotuberculosis*. By determination of species specific IgG antibodies, a differentiation between *Y. enterocolitica* and *Y. pseudotuberculosis* is possible.



The enteropathogenic Yersinia species, *Yersinia enterocolitica* and *Yersinia pseudotuberculosis*, have a global distribution. Transmissions occur orally either in food (especially meat) or in contaminated water. Typical symptoms of an acute *Y. enterocolitica* infection are watery, sometimes bloody diarrhoea with abdominal pain, vomiting and fever. A *Y. pseudotuberculosis* infection is difficult to distinguish from appendicitis, it is also referred to as "pseudoappendicitis". Post infectious complications such as reactive arthritis, erythema nodosum and other rheumatic diseases can occur, especially with HLA-B27 carriers. High and persistent IgA titres against Yersinia antigens are characteristic of these patients.

The modern Luminex® multiplex technology integrates the advantages from ELISA and strip assays: Quantitative detection of antibodies against individual antigens. Genetically engineered virulence factors and adhesins are used for the multiplex *recom*Bead Yersinia test systems. These proteins are expressed only by Yersinia strains that are pathogenic for humans. The *recom*Bead Yersinia test systems allow the serologic differentiation of species, as well as the determination of long past Yersinia infections and are thus ideally suited for identification of Yersinia-induced immunopathological complications and chronic yersiniosis. Detection of IgG and IgA antibodies can be a very useful diagnostic tool if Yersinia-induced arthritis is suspected.

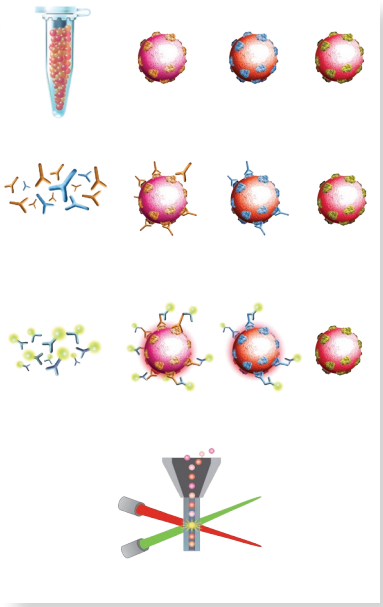
Product Advantages

- Use of recombinant Yersinia antigens
  - ➢ Identification of all pathogenic Yersinia by means of Yersinia outer proteins (YOPs)
  - ➢ Serological differentiation of *Y. enterocolitica* and *Y. pseudotuberculosis* infections is possible for the first time with the use of new species-specific Yersinia antigens (PsaA, MyfA)
  - ➢ No cross reactions with Brucella and other pathogens, as well as no interference caused by LP
- Automated interpretation with feasible connection with LIMS
- Integration of advantages from ELISA and confirmation assay: Quantitative detection of antibodies against individual antigens
- Ideal screening or confirmation assay for high sample throughput
- Very high measuring accuracy and very good reproducibility of test results, therefore reliable testing of follow-up samples
- Integrated controls - no additional control samples necessary
- Small sample volume (10 µl)
- Combination of all Mikrogen *recom*Bead test systems on one plate due to unified processing and exchangeable reagents
- CE label: The *recom*Bead Yersinia test systems meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Yersinia antigens used

Antigen	Description
YOP M	Yersinia outer protein
V-AG	Yersinia virulence factor
PsaA	Adhesin (specific for *Y. pseudotuberculosis*)
YOP D	Yersinia outer protein
MyfA	Adhesin (specific for *Y. enterocolitica*)
YOP E	Yersinia outer protein

Test Principle and Procedure



1st Incubation Microspheres coated with Yersinia specific antigens are incubated with diluted serum or plasma for **60 min**.

wash 3 times

2nd Incubation Phycoerythrin marked anti-human antibodies (IgG, IgA or IgM specific) are added. Incubate for **30 min**.

Aspirate and add system fluid

Measurement Either with Luminex® 100™ or Luminex® 200™ system

Evaluation

Diagnostic Sensitivity

*recom*Bead Yersinia	Positive findings in two reference test systems		
	IgG (n = 122)	IgA (n = 71)	IgM (n = 61)
negative	0	5	3
borderline	0	0	0
positive	122	66	58
Sensitivity	100 %	93,0 %	95,1 %

Diagnostic Specificity

*recom*Bead Yersinia	Negative findings in two reference test systems		
	IgG (n = 99)	IgA (n = 149)	IgM (n = 108)
negative	98	149	107
borderline	0	0	0
positive	1	0	1
Specificity	99,0 %	100 %	99,1 %

Differentiation between *Y. enterocolitica* and *Y. pseudotuberculosis* by detection of species specific IgG antibodies

*recom*Bead Yersinia	defined positive *Y. enterocolitica** samples (n = 59)	defined positive *Y. pseudotuberculosis*** samples (n = 63)
positive for *Y. enterocolitica* (MyfA antigen)	41	0
positive for *Y. pseudotuberculosis* (PsaA antigen)	0	48
Differentiation possible in % of samples	69,5 %	76,2 %

* Classified as Y. enterocolitica samples by positive Widal test result
** Classified as Y. pseudotuberculosis samples by positive culture and PCR result

Article-No

4652	***recom*Bead Yersinia IgG** Reagents for 96 determinations
4653	***recom*Bead Yersinia IgA [IgM]*** Reagents for 96 determinations
11015	**Anti-Human Conjugate IgM** 5,5 ml for 96 determinations

* [] optional available as additional reagent

Storage and Shelf Life

At +2°C - +8°C
6 months from the date of production

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