

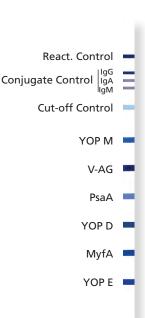


recomLine Yersinia IgG 2.0recomLine Yersinia IgA [IgM] 2.0

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG, IgM or IgA antibodies directed *Y. enterocolitica* and *Y. pseudotuberculosis*. Detection of species-specific IgG antibodies makes it possible to differentiate between *Y. enterocolitica* and *Y. pseudotuberculosis*.

The enteropathogenic Yersinia species, Yersinia enterocolitica and Yersinia pseudotuberculosis, have a global distribution and have become increasingly important in recent years. These pathogens are transmitted 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. With Y. pseudotuberculosis infection, mesenteric lymphadenitis with terminal ileitis can be observed clinically. Since it is difficult to distinguish this clinical picture 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.

For the *recom*Line Yersinia tests, plasmid-encoded virulence proteins localised on the cell surface (Yersinia outer proteins) and adhesins are produced recombinantly in order to differentiate serologically between the species *Y. enterocolitica* and *Y. pseudotuberculosis*. These proteins are only expressed by Yersinia strains that are pathogenic to humans. The *recom*Line Yersinia tests make it possible to detect 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.



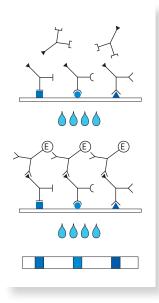
Product Advantages

- 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 LPS
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by recomScan software
- Test procedure and reagents identical in all MIKROGEN strip tests reagents exchangeable
- Separate detection of IgG, IgM and IgA antibodies can provide helpful evidence for the clarification of reactive arthritis and other symptoms
- CE label: The recomLine Yersinia tests 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 A test strip loaded with Yersinia 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, IgA

or IgM specific) are added. Incubate for 45 minutes.

wash 3 times

Color reaction 8 minutes after addition of the coloring solution, in-

soluble colored bands develop at the sites on the test

strips occupied by antibodies.

Evaluation

Diagnostic Sensitivity

recomLine Yersinia	Positive preliminary findings in two reference tests		
recomunie fersinia	lgG (n = 122)	lgA (n = 68)	lgM (n = 61)
negative	0	2	0
borderline	0	0	0
positive	122	66	61
Sensitivity	100 %	97 %	100 %

Diagnostic Specificity

recomLine Yersinia	Negative preliminary findings in two reference tests		
recomeine fersinia	lgG (n = 95)	lgA (n = 134)	lgM (n = 109)
negative	95	134	108
borderline	0	0	0
positive	0	0	1
Specificity	100 %	100 %	99 %

Differentiation between Y. enterocolitica and Y. pseudotuberculosis by detecting species-specific IgG antibodies

recomLine Yersinia	defined positive <i>Y. enterocolitica*</i> samples (n = 59)	defined positive <i>Y. pseudotuberculosis**</i> samples (n = 63)
positive for <i>Y. enterocolitica</i> (MyfA-Antigen)	41	0
positive for <i>Y. pseudotuberculosis</i> (PsaA-Antigen)	0	51
Differentiation possible in % of samples	69 %	81 %

Article-No		Storage
4672	recomLine Yersinia IgG 2.0 Reagents for 20 determinations	At +2°C - +8°C
4673	recomLine Yersinia IgA [IgM]* 2.0 Reagents for 20 determinations	
4676	<i>recom</i> Line Yersinia IgG 2.0 Reagents for 200 determinations	
4677	recomLine Yersinia IgA [IgM]* 2.0 Reagents for 200 determinations	
10015	Line - anti-Human IgM-Konjugat, 500 µl	
	* [] optional available as additional reagent	

^{*} Classified as Y. enterocolitica samples with a positive Widal test result
** Classified as Y. pseudotuberculosis samples with a positive culture and PCR results