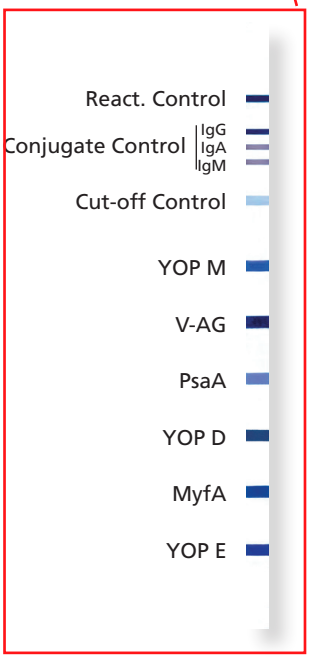
MIKROGEN DIAGNOSTIK

24.recomLine Yersinia IgG 2.0 yra reagentų rinkinys skirtas įersinijozės antikūnų tyrimams IB metodu. Nustatomi Yersinia spp., Yersinia entrocolytica ir Yersinia pseudotuberculosis vienoje juostelėje.

*recom*Line Yersinia IgG 2.0
*recom*Line 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

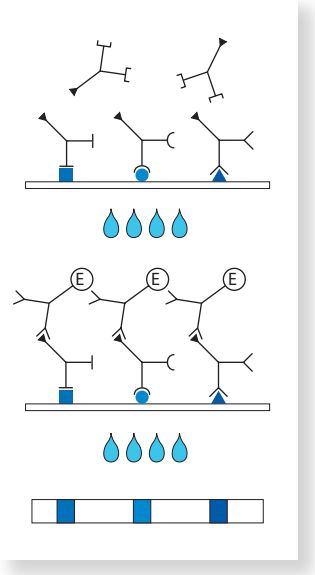
- **Use of recombinant Yersinia antigens**
  - **Identification of all pathogenic Yersinia by means of Yersinia outer proteins (YOPs)**
  - **Serological differentiation of *Y. enterocolitica* and *Y. pseudotuberculosis* infections is possible for the first time with the use of new species-specific Yersinia 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 *recom*Scan 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 *recom*Line Yersinia tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

24. Galimybė atlikti tyrimus ir juos įvertinti pusiauautomatine Dynablot įranga, tyrimai yra validuoti ant siūlomos sistemos (tas pats gamintojas).

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, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Diagnostic Sensitivity

*recom*Line Yersinia	Positive preliminary findings in two reference tests		
	IgG (n = 122)	IgA (n = 68)	IgM (n = 61)
negative	0	2	0
borderline	0	0	0
positive	122	66	61
Sensitivity	100 %	97 %	100 %

Diagnostic Specificity

*recom*Line Yersinia	Negative preliminary findings in two reference tests		
	IgG (n = 95)	IgA (n = 134)	IgM (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

*recom*Line 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	51
Differentiation possible in % of samples	69 %	81 %

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

Article-No

4672 ***recom*Line Yersinia IgG 2.0**
Reagents for 20 determinations

4673 ***recom*Line Yersinia IgA [IgM]* 2.0**
Reagents for 20 determinations

4676 ***recom*Line Yersinia IgG 2.0**
Reagents for 200 determinations

4677 ***recom*Line Yersinia IgA [IgM]* 2.0**
Reagents for 200 determinations

10015 **Line - anti-Human IgM-Konjugat**, 500 µl

* [] optional available as additional reagent

Pakuotės po 20 vnt.

Storage

At +2°C - +8°C

IVD

Instructions for use (English)

1 Purpose

*recom*Line Yersinia IgG, IgA [IgM] is an immunoassay for the qualitative determination of IgG, IgA and IgM antibodies to Yersinia enterocolitica and Yersinia pseudotuberculosis in human serum or plasma.

2 Intended use

*recom*Line Yersinia IgG, IgA [IgM] can be used as a screening or confirmatory test.
*recom*Line Yersinia IgG, IgA [IgM] is a line immunoassay. In contrast to ELISAs, this testing principle allows the separate lining up of individual antigens and thus the determination of specific antibodies to individual Yersinia enterocolitica and Yersinia pseudotuberculosis antigens. The test uses recombinantly produced antigens: Yersinia Outer Proteins (YOP-M, YOP-D, YOP-E), V-AG, PsaA and MyfA. Through the use of species-specific antigens, such as PsaA (specific to Y. pseudotuberculosis) and MyfA (specific to Y. enterocolitica), it is also possible to distinguish between Y. enterocolitica and Y. pseudotuberculosis infections.

3 Test principle

Highly purified recombinant Yersinia antigens are fixed on nitrocellulose membrane strips.

1. The test strips are incubated with the diluted serum or plasma sample, and the specific antibodies bind to the pathogen antigens on the test strips.
2. Unbound antibodies are then flushed away.
3. In a second step, the strips are incubated with anti-human immunoglobulin antibodies (IgG, IgA and/or IgM), which are coupled to horseradish peroxidise (HRP).
4. Unbound conjugate antibodies are then flushed away.
5. Specifically bound antibodies are detected with a staining reaction catalysed by the peroxidase. If an antigen-antibody reaction has taken place, a dark band will appear on the strip at the corresponding point.

There are control bands at the upper end of the test strips:

a) Reaction control is located below the strip number, and needs to show a reaction for each serum/plasma sample.
b) The conjugate controls (IgG, IgA, IgM) are used for the inspection of the antibody class detected. If, for example, the test strip is used for the detection of IgG antibodies, the IgG conjugate will show this clearly on the band.
c) "Cut-off control": The intensity of this band allows the assessment of the reactivity of each antigen band (see 9.2. Evaluation).

4 Reagents

4.1 Package contents

The reagents in one package are sufficient for 20 (200) tests.

Each test kit contains:

WASHBUF A 10 X	**100 ml (10x100 ml)** Wash Buffer A (**10-fold concentration**) Contains phosphate buffer, NaCl, KCl, detergent, preservative: MIT (0.1%) and Oxypyrion (0.2%)
SUBS TMB	**40 ml (10x40 ml)** Chromogenic substrate Tetramethylbenzidin (**TMB, ready-to-use**)
MILKPOW	**5 g (10x5 g)** skimmed milk powder
INSTRU	**1** Instructions for use
EVALFORM	**1 (10)** Evaluation form

4.1.1 *recomLine Yersinia IgG*

In addition to the components listed in 4.1, each test kit contains:

TESTSTR	**2 (20)** tubes, each with 10 numbered test strips
CONJ IgG	**500 µl (10x 500 µl)** anti-human IgG conjugate **(100-fold concentration, green cap)** From rabbit, contains NaN3 (<0.1%), MIT (<0.1%) and chlorazetamide (<0.1%)

4.1.2 *recomLine Yersinia IgA*

In addition to the components listed in 4.1, each test kit contains:

TESTSTR	**2 (20)** tubes, each with 10 numbered test strips
CONJ IgA	**500 µl (10x500 µl)** anti-human IgA conjugate **(100-fold concentration, colourless cap)** From rabbit, contains NaN3 (<0.1%), MIT (<0.1%) and chlorazetamide (<0.1%)

Also available for the determination of IgM antibodies is *recom*Line Yersinia IgA:

CONJ IgM Art. No. 10015	**500 µl** anti-human IgM conjugate **(100-fold concentration, purple cap)** From rabbit, contains NaN_3 (<0.1%), MIT (<0.1%) and chlorazetamide (<0.1%)

4.2 Materials required but not supplied

- Incubation trays (can be ordered from MIKROGEN)
- Deionised water (high quality)
- Plastic forceps
- Horizontal shaker
- Vortex mixer or other rotators
- Vacuum pump or similar device
- Volumetric cylinders, 50 ml and 1000 ml
- Micropipettes with disposable tips, 20 µl and 1000 µl
- 10 ml pipette or dispenser
- Timer
- Absorbent paper towels
- Disposable protective gloves
- Waste container for bio-hazardous materials

5 Shelf life and handling

- Store reagents at +2 to +8°C before and after use, **do not freeze**.
- Leave all ingredients at room temperature (+18 to +25°C) for at least 30 minutes before starting the test. The test procedure is carried out at room temperature.
- Washing Buffer, Milk Powder, Dilution Buffer, Conjugate and TMB can be interchanged between the different *recom*Line and *recom*Blot test systems, if these components carry the same symbols. Consider the shelf life of these components.
- Mix the concentrated reagents and samples thoroughly before use. Avoid a build up of foam.
- Only open the tube containing the test strip immediately before use to avoid condensation. Leave unused strips in the tube and store at +2 to +8°C (reseal tube tightly to prevent test strips from absorbing moisture before the test!).
- The strips are marked with the serial number, as well as the test code.
- The packages bear an expiration date. After this has been reached, no guarantee of quality can be offered.
- Protect the kit components from direct sunlight throughout the entire test procedure. The substrate solution (TMB) is especially sensitive to light.
- The test should only be carried out by trained and authorised personnel.
- In case of significant changes to the product or the regulations for use by the user, the application may lie outside the purpose indicated by MIKROGEN.
- Cross-contamination of patient samples or conjugates can lead to inaccurate test results. Add patient samples, test strips and conjugate solution carefully. Make sure that incubation solutions do not flow over into other wells. Carefully remove liquids.
- The strips must be completely wetted and immersed throughout the entire procedure.
- Automation is possible; further information can be obtained from MIKROGEN.

6 Warnings and precautions

- For *in vitro* diagnostic use only
- All blood products must be treated as potentially infectious.
- The test strips were manufactured with inactivated whole cell lysates and / or recombinant produced bacterial, viral or parasitic antigens.

- After the addition of patient or control specimens the strip material must be considered infectious and treated as such.
- Suitable disposable gloves must be worn throughout the entire test procedure.
- The reagents contain the antimicrobial agents and preservatives sodium azide, MIT (methylisothiazolone), oxypyrion and chloroacetamide and hydrogen peroxide. Avoid contact with the skin or mucous membrane. Sodium azide can form an explosive azide upon contact with heavy metals such as copper and lead azide.
- All siphoned liquids must be collected. All collection containers must contain suitable disinfectants for the inactivation of human pathogens. All reagents and materials contaminated with potentially infectious samples must be treated with disinfectants or disposed of according to your hygiene regulations. The concentrations and incubation periods stated by the manufacturer must be observed.
- Use incubation trays only once.
- Handle strips carefully using plastic forceps.
- Do not substitute or mix the reagents with reagents from other manufacturers.
- Carefully read the instructions for use prior to the test and then follow the individual steps indicated. Deviation from the test protocol provided in the instructions for use can lead to erroneous results.

7 Sampling and preparation of reagents

7.1 Samples

The sample can be serum or plasma (citrate, EDTA, heparin, CPD), which needs to be separated from the blood clot as soon as possible after sampling so as to avoid haemolysis. Avoid microbial contamination of the samples. Insoluble substances must be removed from the sample prior to incubation.
The use of heat-inactivated, icteric, haemolytic, lipaemic or turbid samples is not recommended.
Caution!
If tests are not carried out immediately, samples can be stored for up to 2 weeks at +2 to +8°C. More extended storage of the samples is possible at -20°C or lower. Repeated freezing and thawing of samples is not recommended due to the risk of producing inaccurate results. Avoid more than 3 cycles of freezing and thawing

7.2 Preparation of solutions

7.2.1 *Preparation of ready-to-use wash buffer A*
This buffer is required for sample and conjugate dilutions, as well as for the washing stages.
Prior to dilution, the volume of wash buffer A must be determined for the corresponding number of tests.
First of all, the skimmed milk powder is dissolved in wash buffer A concentrate and then deionised water is added to bring the solution up to the final volume (dilution: 1 + 9). The quantities required for a defined number of test strips need to be calculated using the following formulae (device-specific dead volume has not been taken into account):

Reagent	Formula	Example: 5 strips
Skimmed milk powder [g]	= number of strips x 0.1	0.5 g
Wash buffer A concentrate [ml]	= number of strips x 2	10 ml
Deionised water [ml]	= number of strips x 18	90 ml
Ready-to-use wash buffer A [ml]	= number of strips x 20	100 ml

Ready-to-use wash buffer A can be stored for 4 weeks at +2°C to +8°C. The ready-to-use wash buffer A is odourless and slightly turbid.

7.2.2 *Preparation of conjugate solutions*
The conjugate solution must be prepared just before use. It is not possible to store the ready-to-use conjugate solution.
One part of conjugate concentrate is diluted with 100 parts of ready-to-use wash buffer A (1 + 100).

The quantities required for a defined number of test strips are to be calculated according to the following formula:

Reagent	Formula	Example: 5 strips
Conjugate concentrate [µl]	= number of strips x 20	100 µl
Ready-to-use wash buffer A [ml]	= number of strips x 2	10 ml

The conjugate quantities are calculated without dead volume. Depending on handling (manual or on a device), please mix additional conjugate for 1 to 3 strips.

8 Test procedure

No.	Execution	Note
1	Subject all reagents for at least 30 minutes to 18-25°C (room temperature) before beginning the test.	The test procedure is carried out at room temperature.
2	Prepare test strips Place the strips in **2 ml** of ready-to-use **wash buffer A**.	Do not touch the strips with bare hands - use tweezers instead. The strip number points upward. Place each strip in a separate well in the incubation tray (see 4.2).The strips must be completely immersed.
3 a) b)	Incubation of samples **20 µl** of undiluted sample (human serum or plasma) is pipetted on to the test strip for each incubation mixture. (Dilution 1 + 100) Incubate for **1 hour** while gently shaking.	 Pipette the sample at one end of the immersed strip in the wash buffer A and mix as quickly as possible by carefully shaking the tray. Cover the incubation tray with plastic cover and place in the shaker.
4 a) b) c)	Washing Carefully remove the plastic cover from the incubation trays. Gently siphon the serum dilution from the individual wells. Pipette **2 ml** of ready-for-use **wash buffer A** into each well, wash for 5 minutes while gently shaking and then siphon off the wash buffer A.	Carry out washing stages 8.4a-8.4c three times in all. Avoid cross-contamination. The manufacturer's instructions must be observed during automatic processing.
5	Incubation with conjugate Add **2 ml** of ready-to-use **conjugate solution** and incubate for **45 minutes** while shaking gently.	Cover the incubation tray with plastic cover and place in the shaker.
6	Washing see 8.4	Carry out the washing stages three times in all (see 8.4a-8.4c).
7	Substrate reaction Add **1.5 ml** of ready-to-use **substrate solution** and incubate for **8 minutes** while shaking gently.	
8	Stopping the reaction Remove the substrate solution. Wash at least three times **briefly** with **deionised water**.	
9	Drying the strips Dry the strip between 2 layers of absorbent paper for **2 hours** prior to analysis.	Carefully remove strips from water using plastic forceps. Store strip away from light.
Caution! **Incubation solutions must not flow into other wells. Splashing must be avoided especially when opening and closing the lid.**		

9 Results

Caution:
Please read the information on interpretation below, before using automated interpretation.

9.1 Validation – Quality Control

An analysis of the test can be carried out if the following criteria have been fulfilled:
1. Reaction control band (top line) with clearly visible stain, dark band
2. Antibody class (second, third and fourth bands): the IgG, IgA and/or IgM conjugate control band must show clearly visible staining.
3. Cut-off control (fourth band): weak, but visible staining

9.2 Evaluation

The test strips can be analysed visually or by using a computer - by making use of the test strip analysis software *recom*Scan. The *recom*Scan software has been designed to support the evaluation of test strips. Further information and related instructions for computer-assisted analysis are available on request from MIKROGEN. The following instructions relate to visual analysis.

9.2.1 *Assessment of band intensity*

1. Enter the date, batch number and detected antibody class to the attached evaluation form.
2. Enter the sample identification numbers in the evaluation sheet.
3. Now stick the corresponding test strip onto the appropriate fields on the evaluation form using a glue stick. Align the test strip with the reaction control bands along the marked lines. Then use a transparent adhesive tape to attach the test strip to the left of the marked lines (do not tape over the reaction control band!). Sticking the entire test strip down flat using glue or tape can lead to changes in colour.
4. Then identify the bands of the developed test strip using the printed control strip of the evaluation sheet for comparison purposes and enter them to the evaluation sheet. For each corresponding immunoglobulin class, assess separately the intensity of the bands occurring on the basis of Table 1.

Table 1: Assessment of band intensity in relation to the cut-off band

Stain intensity of the bands	Assessment
No reaction	-
Very low intensity (lower than cut-off band)	+/-
Low intensity (equivalent to cut-off band)	+
Strong intensity (stronger than cut-off band)	++
Very strong intensity	+++

9.3 Interpretation of test results

The test result is determined by adding the point values in Table 2 of the individual bands reactive ≥ cut-off (i.e. with a minimum grade of +). The resulting total is entered in the column with the sigma (summation) symbol.

The positive, unknown or negative assessment of the sample can then be directly determined using Table 3 and entered in the assessment column of the evaluation sheet.

Table 2: Antigen points' rating

Antigen	Points
Yop M	1
V-AG	1
PsaA	1
Yop D	3
MyfA	1
Yop E	1

Table 3: Test Interpretation

Points' total	Assessment
0-1	negative
2	inconclusive
≥ 3	positive

Species are differentiated by antigens PsaA and MyfA, but only with positive test results (see tables 3 and 4), and only in the IgG.

Table 4: Differentiation

Differentiation	Criteria
Y. pseudotuberculosis	• Test result is positive and • PsaA reacts ≥ cut-off and • MyfA reacts < cut-off
Y. enterocolitica	• Test result is positive and • MyfA reacts ≥ cut-off and • PsaA reacts < cut-off
differentiation not possible	• Test result is positive and • and none of the criteria for y. pseudotuberculosis or y. enterocolitica apply

10 Limitations of the method - restrictions

- Serological test results must always be considered in the context of other medical assessments of the patient. The therapeutic consequences of the serological findings must always be taken in context with the clinical data.
- After fresh infections, IgM and IgA antibodies disappear within three to six months. IgG antibodies persist for years. In chronic yersiniosis and with immunopathological complications, IgG reactivity and IgA titre are present for many years. When evaluating IgA reactivity, it is important to also include the results of the IgG determination and possibly also of the IgM determination.
- Samples with inconclusive results should be followed up after 3-5 weeks, subject to the clinical situation.
- Isolated IgA-positive results require careful interpretation. They may indicate a fresh infection or long-term persistent antibodies.
- The typical serological image of a Yersinia-induced reactive arthritis is the high IgG and IgA titre along with weak or missing IgM antibody reactivity.
- Dark test strips: Some patient samples can produce dark, uniform or patterned staining across the entire nitrocellulose strip. Various factors in each patient serum are responsible for this. The evaluation of these strips is usually only partly feasible. Thus, "inverse" bands (white bands on dark background), for example, should be evaluated as negative. The respective serum should always be examined using other serological methods.

11 Test performance

11.1 Diagnostic sensitivity

	Earlier positive findings in two reference tests		
***recom*Line Yersinia**	**IgG (n=122)**	**IgA (n=68)**	**IgM (n=61)**
negative	0	2	0
borderline	0	0	0
positive	122	66	61
sensitivity	100%	97%	100%

11.2 Differentiation between Y. enterocolitica and Y. pseudotuberculosis through determination of species-specific IgG antibodies

***recom*Line Yersinia**	**Yersinia enterocolitica* (n=59)**	**Yersinia pseudotuberculosis ** (n=63)**
positive for Y. enterocolitica (MyfA antigen)	41	0
positive for Y. pseudotuberculosis (PsaA antigen)	0	51
Differentiation possible in % of the samples	**69%**	**81%**

* Classification as Y. enterocolitica samples with positive Widal test result
* Classification as Y. pseudotuberculosis samples with positive culture and PCR results

11.3 Diagnostic specificity

	Earlier negative findings in two reference tests		
***recom*Line Yersinia**	**IgG (n=95)**	**IgA (n=134)**	**IgM (n=109)**
negative	95	134	108
borderline	0	0	0
positive	0	0	1
Specificity	100%	100%	99%

11.4 Detection rate

***recom*Line Yersinia**	**n**	**IgG positive**	**IgA-positive**	**IgM positive**
Blood donor serums	114	47 (41,2%)	13 (11,4%)	2 (1,8%)

Differentiation of IgG positive samples (n = 47):
7/47 were linked to a Y. enterocolitica infection
4/47 were linked to a Y. pseudotuberculosis infection
Differentiation was not possible for the remainder of the samples, since these blood samples – mostly infections from the distant past – only showed YOP D reactivity.

11.5 Analytical specificity

Analytical specificity is defined as the capacity of the test to precisely determine the analytes in the presence of potential interference factors in the sample matrix or cross-reactions with potentially interfering antibodies.
a) Interferences: Control studies on potentially interfering factors have shown that anticoagulants (sodium citrate, EDTA, heparin, CPD), haemolysis, lipaemia or bilirubinaemia or cycles of freezing and thawing do not affect the performance of the test.
b) Cross-reactions: The potential interference of antibodies with other organisms (Treponema sp.) has been investigated in control studies. Also tested were conditions caused by atypical activity of the immune system (antinuclear autoimmune antibodies, rheumatoid factor, pregnancy, fresh herpes simplex infection). There was no evidence of cross-reactions.

12 Literature

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3. Larsen J. H. et al. The determination of specific IgA-Antibodies to Yersinia Enterocolitica and their role in enteric infections and their complications. Acta Pathol Microbiol Immunol Scand B. 1985, 93(5):331-9
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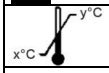
9. Jalava K, et al. An outbreak of gastrointestinal illness and erythema nodosum from grated carrots contaminated with Yersinia pseudotuberculosis. J Infect Dis 2006, 94(9):1209-16

Further Information on Yersinia diagnostics is available on request.

13 Explanation of symbols

	Content is sufficient for <n> applications Number of applications
WASHBUF A 10 X	Wash Buffer A (**10 times concentration**)
SUBS TMB	Chromogenic substrate Tetramethylbenzidin
MILKPOW	Skimmed milk powder
TESTSTR	Test strips
CONJ IgG	Anti-human IgG conjugate
ADD	Additional reagent, available on request
CONJ IgA	Anti-human IgA conjugate
CONJ IgM	Anti-human IgM conjugate
EVALFORM	Evaluation form
INSTRU	Instructions for use
	See instructions for use
CONT	Contents, includes
IVD	In vitro test
LOT	Batch/version number
	Do not freeze
REF	Order number
	Use by Expiry date
	Store at x°C to y°C
	Manufacturer

14 Manufacturer and version information

***recom*Line Yersinia IgG 2.0** ***recom*Line Yersinia IgA [IgM] 2.0**	Item no. **4672 (4676)** Item no. **4673 (4677)**
Instructions for use valid from	GARLYE010EN 2023-03

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GARLYE010

Additional confirmation for legacy devices

as

Annex to the Declaration of Conformity according to the Directive 98/79/EC
on *in vitro* diagnostic medical devices

	Mikrogen GmbH Anna-Sigmund-Straße 10 82061 Neuried Deutschland
SRN	DE-MF-000027747

We declare under our sole responsibility that the products listed below (Legacy Devices) comply with all applicable requirements of article 110(3) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

Product information			
Name	REF	Packaging unit	Kind of product
recomLine Yersinia IgG 2.0	4672	20 Det.	Kit
recomLine Yersinia IgA [IgM] 2.0	4673	20 Det.	Kit
recomLine Yersinia IgG 2.0	4676	200 Det.	Bulk
recomLine Yersinia IgA [IgM] 2.0	4677	200 Det.	Bulk

Directive 98/79/EC (IVDD)

Classification according to Directive 98/79/EC

List A, Annex II ☐ List B, Annex II ☐ Other products ☒

Conformity Assessment Procedure according to Directive 98/79/EG

☐ List A, according to annex IV	EU-Certificate number:	
	Notified Body:	mdc medical device certification GmbH
	Notified Body Identification:	0483
☐ List B, according to annex IV	EU-Certificate number:	
	Notified Body:	mdc medical device certification GmbH
	Notified Body Identification:	0483
☒ Other products	---	

Regulation (EU) 2017/746 (IVDR)

Classification according to Regulation (EU) 2017/746 (IVDR), Annex VIII

B ☒ C ☐ D ☐

Legal basis

Article 110(3) Regulation (EU) 2017/746 (Legacy Device)

The period of validity of the declaration of conformity results from the transition periods according to article 110(3) of Regulation (EU) 2017/746.

On behalf of MIKROGEN GmbH, Managing Director Dr. Erwin Soutschek:

i.V. Micheline Weigend	Neuried	2024-09-18
Signature	Issued in	Date

Dr. Micheline Weigend	QMB
Name	Function

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DICLARATIONE DE CONFORMITA / DECLARATION OF CONFORMITY

Name und Adresse der Firma

Nom et adresse de léntreprise
Nome e indirizzo della ditta
Name and address of the firm

MIKROGEN GmbH
Floriansbogen 2-4
82061 Neuried

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsibilité que
Dichiariamo sooto propria responsibilitá che
We declare on our own responsibility that

die in Anhang I aufgelisteten Medizinprodukte für die In-vitro-Diagnostika
les dispositif médical de diagnostique in vitro et les composantes listé en annexe I.
ils dispositivos medico-diagnostico in vitro e les components listata en l´appendice I
the in vitro diagnostic medical devices and components listed in Annex I

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entsprechen, die anwendbar sind.
remplit toutes les exigences de la directive aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.
soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.
meet all the provisions of the directive on diagnostic medical devices 98/79/EC which apply to it.

Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG, siehe Anhang I
Classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE en annexe I
Classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE listata en l´appendice I
Classification according to the directive on in vitro diagnostic medical devices 98/79/EC listed in Annex I

Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente

Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués

Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati

Applied common technical specifications, harmonised standards, national standards or other normative documents

siehe Liste externer Dokumente (Liste 0501)

Konformitätsbewertungsverfahren
Procédure d´evaluation de la conformité
Procedimento di valutazione della conformità
Conformity assessment procedure

Klassifizierung gemäß Anhang I dieser Konformitätserklärung

Benannte Stelle (falls zutreffend)
Notified body (if applicable)
Organisme notifié (le cas échéant)
Organo notificato (se il caso)

-

Bei relevanten Änderungen an den in Anhang I genannten In-vitro-Diagnostika verliert diese Konformitätserklärung ihre Gültigkeit.

Ort, Datum: Neuried, den 25.5.2022
lieu, date / luogo, data / place, date

Name, Unterschrift, Funktion: Micheline Weigend, i.V. Michi Wein, QMB
name, signature et fonction / nome, firma e funzione / nom, signature and function

ANHANG I / ANNEX I

Dieser Anhang erklärt, dass die folgenden Produkte in der oben zitierten Konformitätserklärung enthalten sind /
This appendix declares the products included in the above referenced Declaration of Conformity

Produkte mit Konformitätsbewertungsverfahren gemäß / *Products with Conformity Assessment Procedure according to:*

Klasse gem. 98/79/EG / *Class acc. to 98/79/EC*	KBV gem. 98/79/EG / *Conformity assessment*
Sonstige Produkte / *Other products*	Anhang III / Annex III

- **Produkte/ *Products***

Produkt-Kennzeichnung (Etikett) / Product Identification (label)	Art. Nr. / Art. No.	VPE / *Packaging Unit*	Version	*Produkt-Art / *Kind of Product*
recomLine Yersinia IgG 2.0	4672	20 Best. / *Det.*	04	Kit
recomLine Yersinia IgA [IgM] 2.0	4673	20 Best. / *Det.*	04	Kit
recomLine Yersinia IgG 2.0	4676	200 Best. / *Det.*	04	Großpackung / *Bulk pack*
recomLine Yersinia IgA [IgM] 2.0	4677	200 Best. / *Det.*	04	Großpackung / *Bulk pack*

*Kit, Einzelreagenz, Großpackung / *Kit, Single Reagent, Bulk Pack*

- **Test-spezifische Komponenten / Test-specific Components**

Produkt-Kennzeichnung (Etikett) / *Product Identification (label)*	Art. Nr. / *Art. No..*	VPE / *Packaging unit*	Anz. VE / *No. of packaging units*	Separates In-Verkehr-bringen von Produkt-Chargen-Komponenten: / *Separate Placing on the market of product batch components* JA / *Yes*, NEIN / *NO*
Kit recomLine Yersinia IgG 2.0				
recomLine Yersinia IgG 2.0 TESTSTR	18420	2x10	1	JA
Kit recomLine Yersinia IgA [IgM] 2.0				
recomLine Yersinia IgA [IgM] 2.0 TESTSTR	18432	2x10	1	JA
Großpackung /Bulk pack recomLine Yersinia IgG 2.0				
recomLine Yersinia IgG 2.0 TESTSTR	18420	2x10	10	JA
Großpackung /Bulk pack recomLine Yersinia IgA [IgM] 2.0				
recomLine Yersinia IgA [IgM] 2.0 TESTSTR	18432	2x10	10	JA

Erläuterung der Symbole / *Explanation of Symbols*

TESTSTR	Teststreifen