Yersinia sp.

Immunoenzymatic kits for the diagnostics of Yersinia infections

ELISA, **IMMUNOBLOT**, and **MICROBLOT-ARRAY** kits are optimized and validated for detection of specific IgA, IgG, and IgM antibodies in human serum or plasma

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Yersinia are pathogenic gram-negative bacteria of the Enterobacteriaceae family and their representatives Y. enterocolitica and Y. pseudotuberculosis are known as human enteropathogens. The carriers are latently infected warm-blooded animals.

The infection occurs orally after the ingestion of contaminated water or food.

The clinical signs of *Y. enterocolitica* and *Y. pseudotuberculosis* infection are very similar. Differences are mostly observed in intestinal complaints, pseudoappendicitis and sepsis. The most widespread Y. enterocolitica causes diarrhoea in humans, accompanied by diarrhoea of the small intestine, colon or appendix. It can also cause joint inflammation and enlargement of the lymph nodes. Complications such as acute reactive arthritis, erythema nodosum, acute glomerulonephritis and myocarditis may develop during the infection.

Arthritis can sometimes develop into a chronic and incurable form. Reactive arthritis is often associated with erythema nodosum, especially in women. Skin symptoms appear about 1–6 weeks after the infection. In some cases, Y. enterocolitica may also persist for years in the intestinal mucosa and in the lymphatic tissues.

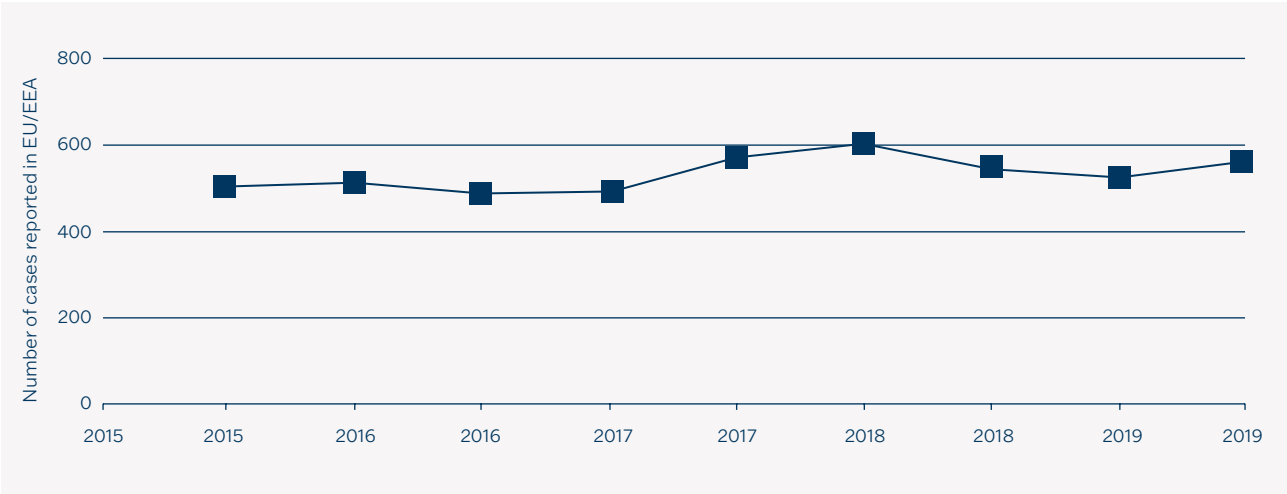
Antibody Response

IgA, IgG and IgM antibodies can be detected in the initial phase after contact with virulent Yersinia factors. IgA and IgM titres will decrease after several months.

IgG class antibodies persist longer and can be detected in serum for longer than one year. In chronic forms of the disease and immunopathological complications, the decrease in IgA antibodies may be slower and they may completely disappear only after several years. IgG antibodies may persist in some cases throughout the live.

Prevalence

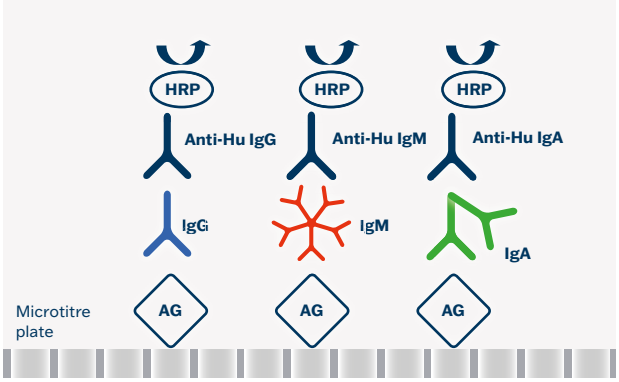
Yersinosis is the third most common bacterial food disease after salmonellosis and campylobacteriosis, and the fourth the most common zoonosis in many European countries. The highest rates were reported by Finland, Lithuania and Czechia (ECDC 2021).



ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

Mixture of highly specific recombinant antigens.

Clinical Application

- Screening tests for detection of yersinia infection in humans
- Diagnositics of the disease phase by significant increase or decrease of antibodies

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF and calibrators included
- Semiquantitative evaluation of results (Index of Positivity) or quantitative evaluation of results (IU/ml)

Advantages

- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Identical assay procedure
- Short total assay time
- Ready for automation
- Customer support

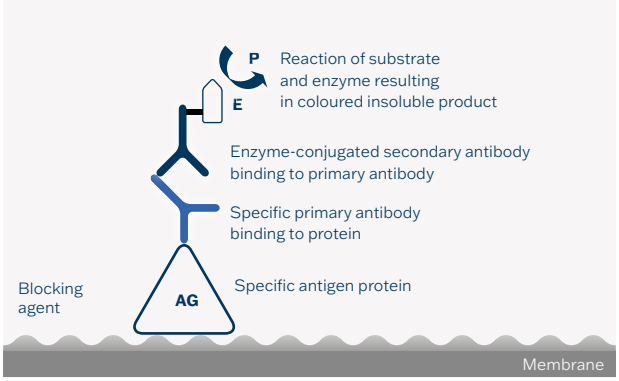
Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
EIA Yersinia IgA	90.0%	99.9%
EIA Yersinia IgG	94.2%	90.0%
EIA Yersinia IgM	90.0%	95.0%

IMMUNOBLOT

Test Principle

Recombinant antigens are transferred to a nitrocellulose membrane using a micro-dispensing method.

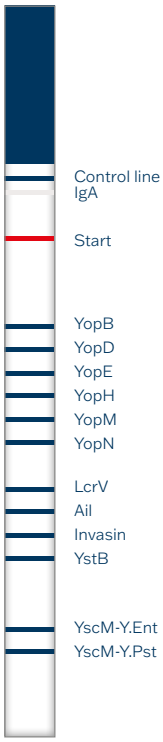


Clinical Application

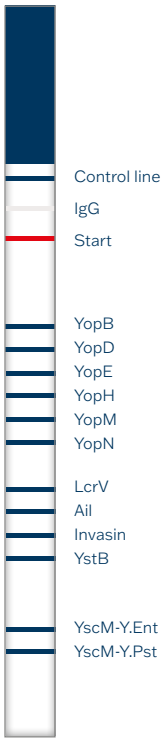
- Detailed determination for the presence of *anti-Yersinia* sp. specific antibodies
- Confirmation of ambiguous results
- Confirmation for ELISA tests

Antigens

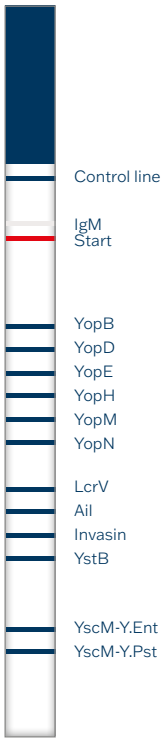
BLOT-LINE Yersinia IgA



BLOT-LINE Yersinia IgG



BLOT-LINE Yersinia IgM



YopB – Yersinia outer protein, transmembrane protein
YopD – Yersinia outer protein, transmembrane protein
YopE – Yersinia outer protein
YopH – Yersinia outer protein
YopM – Yersinia outer protein
YopN – Yersinia outer protein
LcrV – Low calcium response Virulence, important for YopD a YopB secretion
Ail – Attachment-invasion locus protein early phase, involved in the adhesion and invasion process, and allows yersinia to survive outside the host cell, a significant virulence factor
Invasin – surface adhesin that binds to β1 integrins on the surface of target cells and is important particularly in the first stage of infection, a virulence factor
YstB – heat-stable enterotoxin B, responsible for the virulence and pathogenicity of *Y. Enterocolitica* strains, biotype 1A
YscM-Y.ent – Yop proteins translocation protein M (specific for *Y. enterocolitica*)
YscM-Y.pst – Yop proteins translocation protein M (specific for *Y. pseudotuberculosis*)

Summary Protocol

Step		Test steps
	1.	Pipette Universal solution 2.5 ml
	2.	Strips soaking 10 min. at room temperature – Shaker
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (30 µl + 1.5 ml)
	5.	Pipette Controls and diluted samples 1.5 ml
	6.	Incubate 30 min. at room temperature – Shaker
	7.	Aspirate samples and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	8.	Pipette Conjugate 1.5 ml
	9.	Incubate 30 min. at room temperature – Shaker
	10.	Aspirate Conjugate and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	11.	Pipette Substrate solution (BCIP/NBT) 1.5 ml
	12.	Incubate 15 min. at room temperature – Shaker
	13.	Aspirate Substrate solution and wash strips with 2 ml of distilled water 2-times for 5 min. – Shaker
	14.	Sticking and evaluation of strips

User Comfort

- Ready-to-use components
- Colour-coded strips
- Positive and Negative controls
- Interchangeable components
- Control line is present on the strip
- Possibility of software evaluation

Advantages

- Identical assay procedure
- Easy interpretation and reproducibility of results
- Sophisticated evaluation software
- High diagnostic efficiency
- Ready for automation
- Customer support

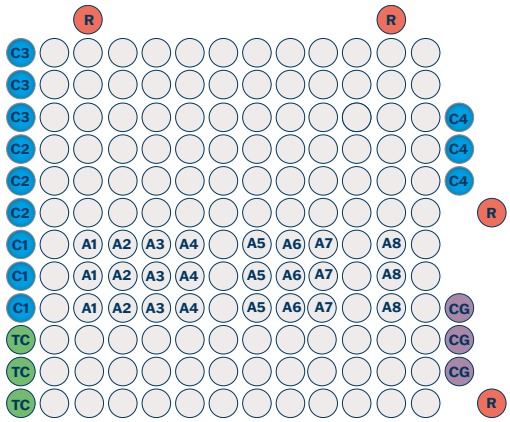
Test Characteristics

Pathogen	Diagnostic Sensitivity	Diagnostic Specificity
BLOT-LINE Yersinia IgA	94.2%	93.9%
BLOT-LINE Yersinia IgG	97.8%	93.9%
BLOT-LINE Yersinia IgM	90.0%	95.5%

IMMUNOBLOT

MICROBLOT-ARRAY

Distribution of Antigens and Control Spots



Description of antigens

A1 – YopB
A2 – YopD
A3 – YopM
A4 – YopN
A5 – LcrV
A6 – Ail
A7 – Invasin
A8 – YscM

Description of control spots

R – Reference
TC – Test control
CA – Conjugate control IgA
CG – Conjugate control IgG
C1 – Calibration 1
C2 – Calibration 2
C3 – Calibration 3
C4 – Calibration 4

Protocol Summary

Step		Test steps
	1.	Pipette Universal solution 150 µl
	2.	Strips soaking 10 min. at room temperature
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (10 µl + 500 µl)
	5.	Pipette Controls and diluted samples 100 µl
	6.	Incubate 30 min. at room temperature
	7.	Quick wash using the Universal Solution*
	8.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	9.	Pipette Conjugate 100 µl
	10.	Incubate 30 min. at room temperature
	11.	Quick wash using the Universal Solution*
	12.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	13.	Pipette Substrate solution (BCIP/NBT) 100 µl
	14.	Incubate 15 min. at room temperature
	15.	Quick wash using the distilled water*
	16.	Aspirate Substrate solution and wash strips with 200 µl of distilled water 2-times for 5 min.
	17.	Dry and evaluate strips

* In case of using the washer fill the wells up to the rim and aspirate immediately after filling the last well.

User Comfort

- Low sample consumption
- Antigens spotted in triplicate – minimizing statistical variation
- Possibility of automatic processing and results evaluation
- Parallel testing of multiple markers simultaneously
- High sensitivity and specificity

Microblot-Array

Test Characteristics

Pathogen	Diagnostic Sensitivity	Diagnostic Specificity
Microblot-Array Yersinia IgA	95.1%	99.9%
Microblot-Array Yersinia IgG	95.5%	99.9%

Interpretation of Results

IgG	IgA	IgM	Interpretation
–	–	–	Negative result.
–	– / +	+	Eventual incipient infection. In order to confirm the results it is necessary to repeat the tests.
+	–	–	Persistent IgG antibodies after previous infection.
+	border line/low +	–	Previous infection. Beginning of reinfection.
+	++	–	On-going infection. (IgM not necessarily produced) Repeated infection. Chronic infection. (Chronicity confirmed by tests repeated after the 1st and 3rd months; occurrence of clinical symptoms)
+	+	+	On-going infection

Ordering Information

ELISA

Cat. No.	Product	No. of Wells
YeA096	EIA Yersinia IgA	96
YeG096	EIA Yersinia IgG	96
YeM096	EIA Yersinia IgM	96
SK-YeA096	SmartEIA Yersinia IgA	96
SK-YeG096	SmartEIA Yersinia IgG	96
SK-YeM096	SmartEIA Yersinia IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyser

IMMUNOBLOT

Cat. No.	Product	No. of Tests
YAL020	BLOT-LINE Yersinia IgA	20
YGL020	BLOT-LINE Yersinia IgG	20
YML020	BLOT-LINE Yersinia IgM	20
BD-YAL020	BlueBLOT-LINE Yersinia IgA	24
BD-YGL020	BlueBLOT-LINE Yersinia IgG	24
SwIm03	Immunoblot Software	1

The BlueBLOT-LINE kits are designed for automatic processing using BlueDiver® analyser

MICROBLOT-ARRAY

Cat. No.	Product	No. of Tests
YAMA048	Microblot-Array Yersinia IgA	48
YGMA048	Microblot-Array Yersinia IgG	48

TestLine®

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CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.