



SERION ELISA *classic*

Helicobacter pylori IgA/IgG/IgM

Intended use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Helicobacter pylori*
- Detection of different antibody classes facilitates the confirmation of contact with the pathogen and supports the categorization of the disease stage

Diagnostic Efficiency

The performance characteristics of the SERION ELISA *classic* Helicobacter pylori IgA, IgG and IgM immunoassays were assessed in individual studies each consisting of the analysis of more than 140 serum samples from blood donors and patients with suspected *Helicobacter pylori* infection. Commercially available ELISA test systems of leading European manufacturers were used as reference tests.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Helicobacter pylori IgA	>99 %	>99 %
SERION ELISA <i>classic</i> Helicobacter pylori IgG	96.6 %	>99 %
SERION ELISA <i>classic</i> Helicobacter pylori IgM	>99 %	79.7 %

Precision

SERION ELISA *classic* Helicobacter pylori IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.499	3.4	0.467	9.9
Serum 2	0.627	4.6	0.580	10.0
Serum 3	1.263	3.6	1.286	7.7

SERION ELISA *classic* *Helicobacter pylori* IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.442	4.5	0.423	13.8
Serum 2	1.513	2.4	1.514	11.0
Serum 3	1.615	3.1	1.599	9.8

Pathogen

More than 50% of the world's population harbor *Helicobacter pylori* in their upper gastrointestinal tract. As a consequence, infections with this spirally formed, gram-negative bacterium belong to the most frequently occurring chronic bacterial diseases.

Disease

80 to 90% of all gastritis cases are traceable to an *Helicobacter pylori* infection. The person-to-person transmission is still not fully elucidated, but oral-oral and faecal-oral route mechanisms are discussed. Diseases associated with *H. pylori* infections include *Ulcus duodeni*, *Ulcus ventriculi*, stomach cancer and the seldom occurring MALT (Mucosa Associated Lymphatic Tissue) lymphoma. Phenotypic differences between different *Helicobacter pylori* isolates are limited to their ability to express the vacuolating cytotoxin (VacA) and its associated gene prod-

SERION ELISA *classic* *Helicobacter pylori* IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.342	5.8	0.346	13.0
Serum 2	0.371	4.7	0.385	9.9
Serum 3	0.658	5.5	0.661	9.2

ucts (cytotoxin-associated genes; CagA). Due to phenotypic differences *Helicobacter pylori* isolates can be divided into virulent (type I) and non-virulent (type II) strains. Patients suffering from peptic or duodenal ulcers are more frequently infected with VacA and CagA producing *Helicobacter pylori* type I strains.

Diagnose

In the diagnosis of *H. pylori* infections, a distinction is made between non-invasive and invasive methods. Invasive procedures contain histology, urease rapid test and microbiological techniques such as cultivation and PCR. The C13-breath test, the *Helicobacter pylori* antigen detection in stool samples and serological antibody detection based on ELISA or immunoblot belong to the group of non-invasive methods. The detection of serum antibodies can be used for therapy control after eradication therapy.

Highlights

- Use of a *Helicobacter pylori* (type I) preparation for the detection of infections caused by *H. pylori* type I and less virulent and non VacA and CagA expressing *Helicobacter pylori* type II strains
- Demonstration of IgM antibodies for the sensitive detection of acute primary infections, primarily in children and young adolescents
- Demonstration of IgA und IgG antibodies for confirmation of acute and past infections
- Demonstration of IgG antibodies for immune status determination and for epidemiological studies
- Quantitative determination of IgA, IgG and IgM antibodies for disease stage characterization and therapy monitoring, particularly after eradication therapy

Product	Order No.
SERION ELISA <i>classic</i> <i>Helicobacter pylori</i> IgA	ESR118A
SERION ELISA <i>classic</i> <i>Helicobacter pylori</i> IgG	ESR118G
SERION ELISA <i>classic</i> <i>Helicobacter pylori</i> IgM	ESR118M

SERION ELISA *control*

Please visit our website for more information.

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