



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 71 (IgA), 163 (IgG) or 184 (IgM) 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 classic <i>Helicobacter pylori</i> IgA	ESR118A
SERION ELISA classic <i>Helicobacter pylori</i> IgG	ESR118G
SERION ELISA classic <i>Helicobacter pylori</i> IgM	ESR118M

SERION ELISA control

Please visit our website for more information.

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