BioVendor Group CLIA

Gastrointestinal diseases

Coeliac disease
Chronic gastritis (*Helicobacter pylori*)

Diagnostic panel

CE IVD

The kits are CE-IVD certified and intended for professional use.

CLIA kits are optimized and validated for the determination of antibodies in human serum and plasma

Designed for the platform

Kleeya®

Coeliac sprue

Coeliac sprue (coeliac disease) is a common term for a cosmopolitan disease that occurs in people of all ages. It is a hereditary autoimmune disease caused by gluten intolerance. The main symptoms include inflammatory changes in the small intestine mucosa, diarrhoea, anaemia, weight loss and general disorders in somatic and psychic development.

If gluten is not completely and permanently removed from patient's food, their immune system becomes exhausted, the disease affects other organs and further autoimmune diseases and complications may develop, most of them being life-threatening.

Disease diagnostics

The diagnosis of the disease is based on clinical manifestation, enterobiopsy and laboratory tests. Detection of highly specific IgA and IgG antibodies to deamidated gliadin and transglutaminase is significant in the accurate diagnosis of coeliac disease and also for monitoring of the effects of gluten-free diet treatment.

Clinical applications

- Serological examination of patients suspected of coeliac disease, including patients with atypical symptoms
- Screening of individuals with (hereditary) increased risk of coeliac disease
- Monitoring of gluten-free diet in patients with coeliac disease
- Screening test for dermatitis herpetiformis

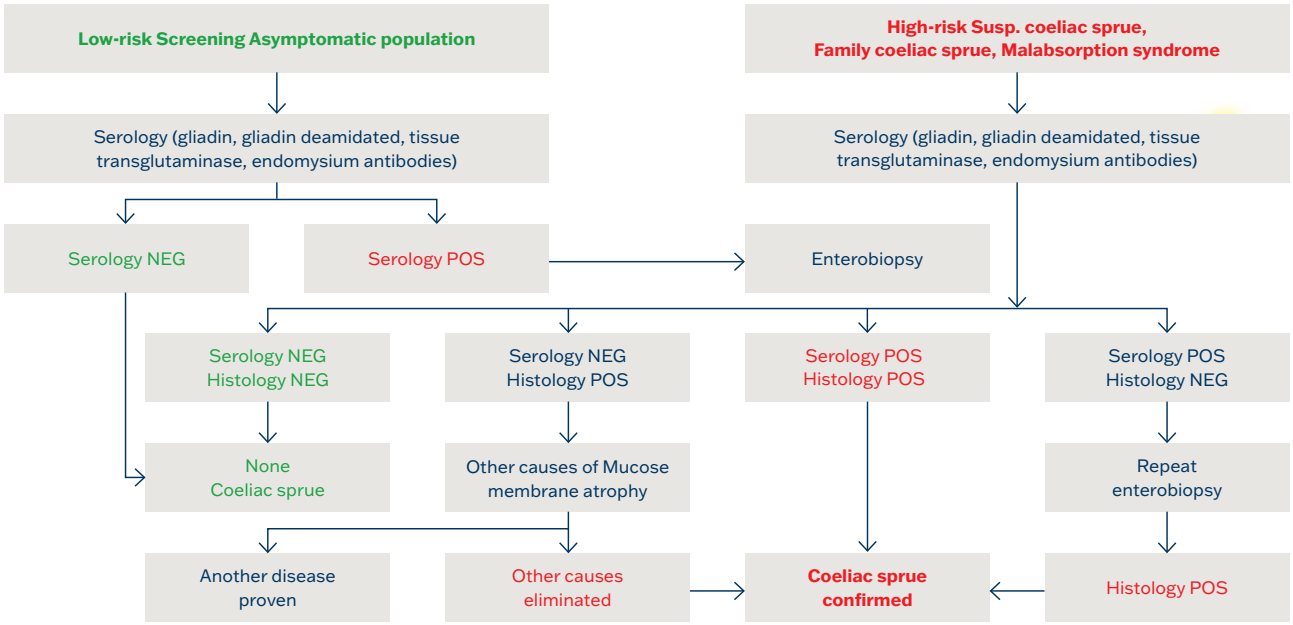
Antigens

CLIA Gliadin DA IgA, IgG	CLIA Transglutaminase IgA, IgG
Deamidated gliadin peptide DGPx1	Recombinant antigen (h-tTg)

Test characteristics

Kit	Calibration range	Diagnostic sensitivity	Diagnostic specificity
CLIA Gliadin DA IgA	5–200 U/ml	99,99 %	99, 99 %
CLIA Gliadin DA IgG	5–200 U/ml	99,99 %	99, 99 %
CLIA Transglutaminase IgA	5–200 U/ml	99,99 %	99, 99 %
CLIA Transglutaminase IgG	5–200 U/ml	99,99 %	99, 99 %

Recommended testing algorithm for coeliac disease



Helicobacter pylori

Helicobacter pylori belongs to the genus *Helicobacter*. Morphologically, it is a gram-negative, microaerophilic bacterium. It is found as a pathogen in patients with infection of the gastric mucosa, particularly in the area of pyloric antrum and duodenum. It is a causative agent of B-type chronic gastritis, which is linked to the development of gastric ulcers. In this case, *H. pylori* is detected in 100% of individuals. *H. pylori* infection is often associated with dyspepsia. Active chronic gastritis can further develop in the atrophy of stomach lining and increase the risk of gastric carcinoma.

H. pylori detection methods can be invasive or non-invasive. The most commonly used invasive methods are the rapid urease test and histological and cytological examination of bioptic sample of the gastric mucosa. Non-invasive techniques involve a breath test and serological methods (detection of IgM, IgA and IgG antibodies in the serum). Non-invasive tests are suitable for observation of treatment efficiency as well as for the determination of infection or reinfection status. Eradication of the microbial agent is followed by a decrease in the antibody level.

IgA antibodies are produced not only in the acute stage of the disease, but also in the case of chronic infection of gastric mucosa, along with IgG antibodies. An increased level of specific IgA antibodies is also described in patients with a risk of gastric carcinoma.

IgG antibodies indicate previous infection with *H. pylori*; however, they do not provide any evidence of active current infection. Seroconversion occurs approximately 2 months after primary infection.

Clinical applications

- Screening for acute or chronic *H. pylori* infection, or reactivation of infection
- Monitoring efficacy of treatment

Antigens

CLIA Helicobacter MONO IgA, IgG

Clinically significant *H. pylori* strain with high content of CagA (120 kDa) and VacA (87 kDa) proteins.

Test characteristics

Kit	Calibration range	Diasgnostic sensitivity	Diagnostic specificity
CLIA Helicobacter MONO IgA	10–320 U/ml	98,59 %	94,33 %
CLIA Helicobacter MONO IgG	10–640 U/ml	98,43 %	99,99 %

Interpretation of results

IgA

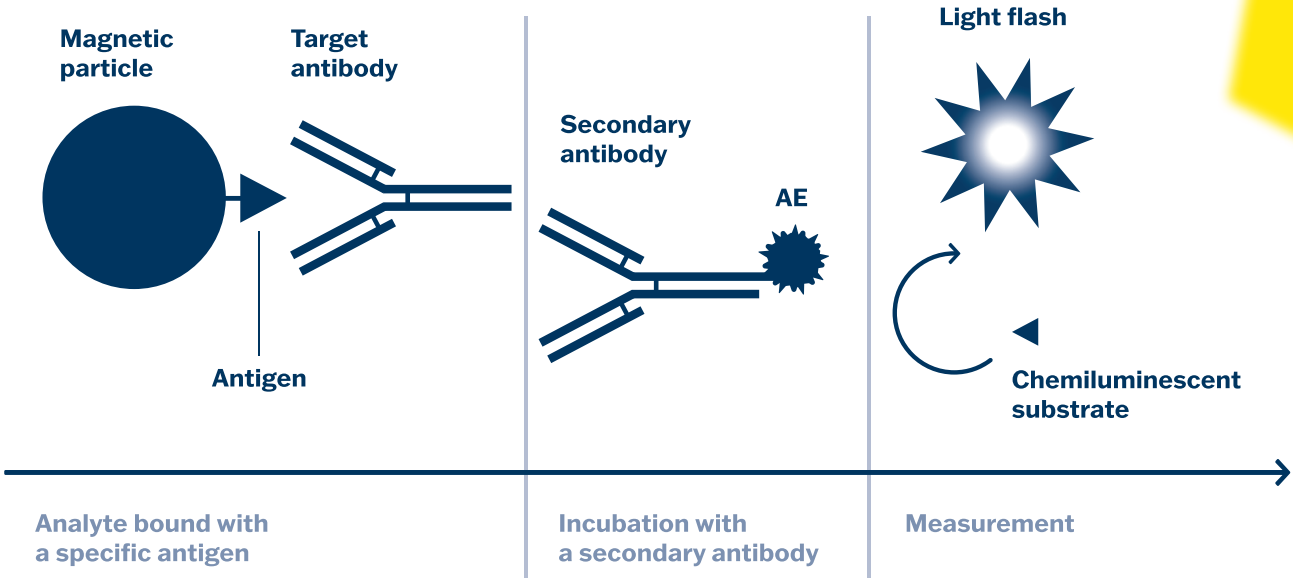
IgA antibodies are typically produced in the acute stage of the disease. However, both IgA and IgG antibodies can be detected in chronic gastric mucosal infection. Elevated antibody levels have also been reported in patients at risk for gastric cancer.

IgG

IgG antibodies indicate previous infection with *H. pylori*, not evidence of active infection. Seroconversion is usually observed 2 months after the primary infection. IgG antibody levels usually decline approximately 6 months after successful treatment and eradication of the infection.

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines magnetic particle-mediated antigen / antibody immunocomplex separation and flash chemiluminescence to achieve sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are used to determine specific antibodies in human serum or plasma on a KleeYa® analyzer. The results are reported in U/ml.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Ready-to-use reagents in the reaction cartridges
- Control sera available as independent sets
- Quantitative determination (U/ml)

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30 min)
- Wide measuring range
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

CLIA diagnostic kits are used to determine specific antibodies in human serum or plasma on a KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA Gliadin DA IgA	CL-GDA100	100
CLIA Gliadin DA IgG	CL-GDG100	100
CLIA Transglutaminase IgA	CL-tTA100	100
CLIA Transglutaminase IgG	CL-tTG100	100
CLIA Helicobacter MONO IgA	CL-HMA100	100
CLIA Helicobacter MONO IgG	CL-HMG100	100

Control sets

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA Gliadin DA IgA	CL-GDACON	2 x 20
Control set CLIA Gliadin DA IgG	CL-GDGCON	2 x 20
Control set CLIA Transglutaminase IgA	CL-tTACON	2 x 20
Control set CLIA Transglutaminase IgG	CL-tTGCON	2 x 20
Control set CLIA Helicobacter MONO IgA	CL-HMACON	2 x 20
Control set CLIA Helicobacter MONO IgG	CL-HMGCON	2 x 20

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