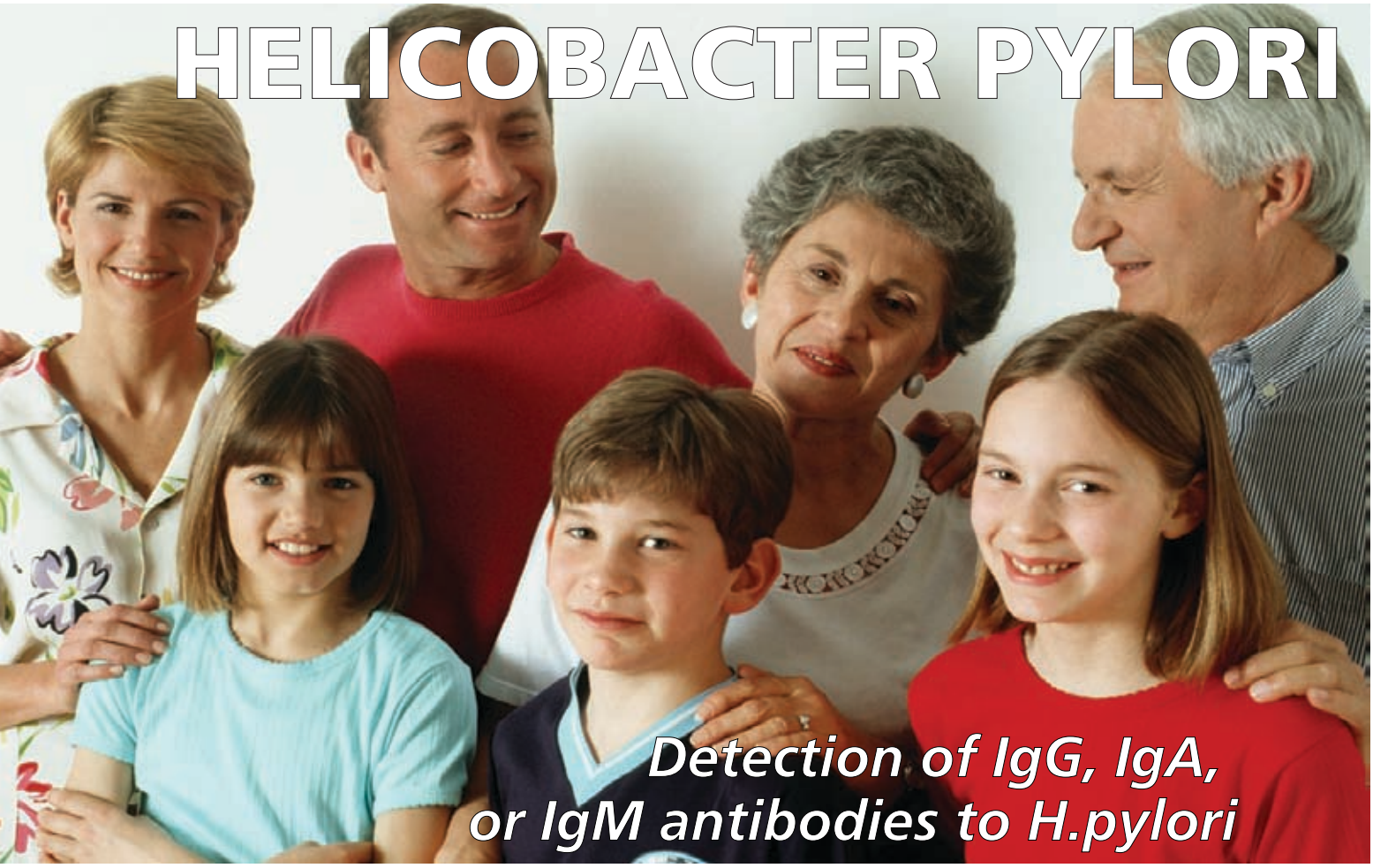
GAP®-IgG
GAP®-IgM
GAP®-IgA
FDA CLEARED (IgG)



Helicobacter Pylori: The GAP® tests offer proven performance with excellent sensitivity and specificity in independent studies

Comprehensive assay range:

- GAP®-IgG: IgG Antibodies to H. pylori
- GAP®-IgA: IgA Antibodies to H. pylori
- GAP®-IgM: IgM Antibodies to H. pylori

Simple
Same procedure for all kits. One sample dilution for all procedures.

Unique
4-point calibration curve

Flexible
Performs in manual or fully automated systems

Accurate
Excellent and extensive patient sample correlation vs. gold standard

Quick
1 hour 40 minute total incubation time

BIOMERICA

INTENDED USE

GAP® microwell ELISA kits measure the levels of IgG, IgA and IgM antibodies to Helicobacter pylori (H. pylori) in serum or plasma. Numerous studies have found a correlation between H. pylori infection to peptic ulcers, gastric lesions, chronic gastritis, and gastric cancer.

GAP®-IgG test kit is intended for *in vitro* determination of the levels of IgG antibodies to H. pylori.
GAP®-IgM test kit is intended for *in vitro* determination of the levels of IgM antibodies to H. pylori.
GAP®-IgA test kit is intended for *in vitro* determination of the levels of IgA antibodies to H. pylori.

BACKGROUND

Helicobacter pylori has been found in biopsy samples from gastric epithelium from patients showing active type B gastritis.[1,2,3,4,5] Although the route of infection is unknown, reports have shown that *H. pylori* infection is associated with chronic gastritis.[6,7] A correlation has been found between the presence of *H. pylori* and gastric lesions in some cases of duodenal ulcers.[8] Complete resolution of gastritis after eradication of the organism has also been reported.[9]

H. pylori is a gram negative, curved, spiral-shaped rod, 0.2 - 0.8 µ in width by 0.5 - 5.0 µ in length. It colonizes the deep portion of the mucous gel layer and the apical surface of the gastric mucosal epithelial cells. It may also be located in the junction between adjacent mucosal epithelial cells.

The presence of *H. pylori* can be detected by both invasive and non-invasive methods. Invasive methods include testing biopsy specimens by culture, histology, and rapid urease. Due to the patchy distribution of *H. pylori* in tissue, false negative results are common. Non-invasive procedures include serum tests for antibodies against H. pylori and the urea breath test which utilizes radiolabelled urea.

PERFORMANCE

Assay Time: 1hr. 40 min.
Result Type: Quantitative (international); Qualitative (USA only)

GAP® -IgG ELISA

Biopsy[1]	Positive (+)	Equiv. (±)	Negative (-)	Total
+	172	0	1	173
-	6	11[2]	87	104
			Total Samples	277

Relative Accuracy = 97.4%
Relative Specificity = 93.5%
Relative Sensitivity = 99.4%

(1) By histological techniques (culture or urease on the biopsy samples).
(2) Equivocal results have not been considered in the calculations for percent accuracy and percent specificity. Equivocal results (± values) are considered negative in the GAP-IgG ELISA procedure.

PUBLISHED CLINICAL STUDIES USING GAP®

Publication	Sensitivity	Specificity
Euro J Gastro Hepatol	96%	80.5%
Gastroenterol Clin Biol	90%	90%
J. Medicine & Pharm	93%	97%
Euro J Clin Micro Infect Dis	95%	91%
Research Forum Digest Dis	95%	83%
Euro J Cancer Prevention	93%	76%

Eradication of Helicobacter pylori infection *Hepatogastroenterology* 2003 Jan-Feb
Of the 4 kits in the study (GAP®-IgG, Hel-P™, Helico-G™, and HM-CAP™), the GAP®-IgG kit was able to detect whether or not *H. pylori* was eradicated in shortest time period (100% uniformity ratio at 3 months).

CONCLUSIONS: monitoring serum IgG levels after treatment may provide an early indicator of the efficacy of therapy in eradicating *H. pylori* infection. Additionally, the serum IgG level can provide evidence of infection in chronic gastritis patients even when the biopsy specimens are negative by microbiological and/or histological tests.

ORDERING

Catalog No.	Description
7004	GAP®-IgG *H.pylori* ELISA kit - Quantitative (Int'l); Qualitative (USA) (96 tests)
7006	GAP®-IgM *H.pylori* ELISA kit - Quantitative (Int'l); Qualitative (USA) (96 tests)
7008	GAP®-IgA *H.pylori* ELISA kit - Quantitative (Int'l); Qualitative (USA) (96 tests)

CE and EN ISO 13485:2003 Compliant

BIOMERICA

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