Product Data for Gastric Ulcers Prevention Test

- an immunochromatographic assay for qualitative determination of antibodies to Helicobacter pylori in whole blood

Introduction
Test principle
Interpretation
Limitation

Performance
Sensitivity
Specificity and cross-reactions

Correlation
Gastric Ulcers Prevention Test vs. EIA
Gastric Ulcers Prevention Test vs. HUT-Test vs. Histology

Real Time Stability Data

References

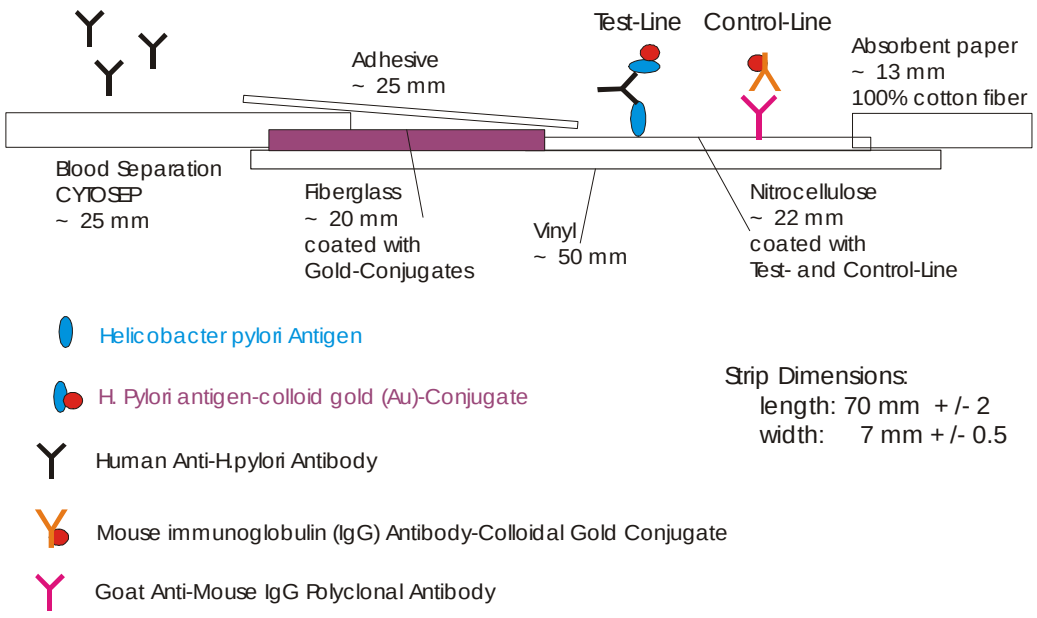
PRINCIPLE OF THE TEST:

The Gastric Ulcers Prevention Test Whole Blood Test is a qualitative determination of Helicobacter pylori antibodies in whole blood. It incorporates multilayer filtration and sandwich immunoassay systems in a single module, allowing both the pretreatment of whole blood sample and the immunochromatographic detection assay to be performed in one step.

Once applied to the sample well (S1), blood undergoes vertical capillary filtration through the porous filtration system. The blood cells are retained in the top layers while the liquid phase (plasma) reaches the bottom membrane layer. The buffer, when applied to the buffer well (S2), flows along the bottom membrane layer, mixes with plasma and migrates horizontally along the test membrane. If antibody against H.pylori is present in the sample, labeled antigen-dye conjugate binds to it, forming an antigen-antibody-dye complex.

This complex is then captured by the antigen immobilized in the Test Zone of the membrane, producing a visible purple color band on the membrane. Another independent colored conjugate is captured by a immunochemical reaction in the Control Zone of the membrane, producing a control band as a marker of proper test performance.

Detection Limit:	20 U H.pylori Ab / ml (in-house STANDARD – see below)
Incubation Time:	RESULTS 10 MINUTES AFTER APPLICATION OF BUFFER
Active Ingredients:	Bovine Serum Albumin
	Goat Anti-(Mouse IgG) Polyclonal Antibody
	H.pylori Antigen
	H.pylori Antigen Colloidal Gold Conjugate
	Mouse IgG-Colloidal Gold Conjugate
Puffer:	Sodium Azide
	Sodium Dibasic Phosphate
	Sodium Chloride
	Polyoxyethylenesorbitan Monolaurate
	Casein from Bovine Milk



Strip Dimensions:
length: 70 mm + /- 2
width: 7 mm + /- 0.5

ASSAY PROCEDURE:
Given in instructions.

INTERPRETATION OF RESULTS:
Samples are recorded as positive if two purple color bands appear in the test zone of the cassette.
Specimens that give only one color band in the test zone of the cassette should be recorded as negative.
The absence of a purple color band in the test zone, or its discoloration after the test procedure, indicates, that the correct test procedure was not followed.

LIMITATIONS:
The test is limited to the detection of antibody against H.pylori in whole blood.
The test allows to detect anti-H.pylori antibody as a general indication of H.pylori infection. It does not allow to differentiate between different types of the infection (current, ongoing, etc.).

Performance Study:

Sensitivity

The test sensitivity of Gastric Ulcers Prevention Test to H. Pylori antibody solutions was studied by testing different lots of each device. Ten tests of each lot were tested with each standard solution. Numbers of negative (-), weak positive (~+), and positive (+) results yielded are shown in table below:

H. pylori Ab *	**LotI**			**LotII**			**LotIII**			**Comment**
	-	~+	+	-	~+	+	-	~+	+	
0,0	10	0	0	10	0	0	10	0	0	Neg
20,0	0	0	10	0	0	10	0	0	10	Pos
40,0	0	0	10	0	0	10	0	0	10	Pos
80,0	0	0	10	0	0	10	0	0	10	Pos
160	0	0	10	0	0	10	0	0	10	Pos
320	0	0	10	0	0	10	0	0	10	Pos
	0	0	10	0	0	10	0	0	10	Pos

*: (u/ml = units/ml) referenced to the following ELISA test kit:
BIOMERICA cat# 7004-H
Biomerica, Inc.
1533 Monrovia Avenue
Newport Beach, CA 92663
Tel. (949) 645-2111
Fax (949) 722-6674
Web Site: http://www.biomerica.com
E-Mail: info@biomerica.com

Conclusions:
The minimum detectable concentration of anti-H.pylori antibody solution is 20,0 u/ml. The test is capable of qualitative testing anti-H.pylori antibodies at a concentration of 20,0 u/ml – 320 u/ml.

Specificity and Cross Reactivity:

The specificity of Gastric Ulcers Prevention Test immunochromatographic test was determined as described:
First, cross reactivity in H. pylori free serum was assessed, and second interference was measured in normal serum containing anti H. pylori Ab.
Serum with triglycerides, AFP, hemolized specimens with hemoglobin, and hormones such as FSH, TSH, human chorionic gonadotropin, LH and prolactin and IgE were analyzed and did not show interference or cross reactivity with the test:

Substance	Conc.	H.pylori Conc. u/ml, A)	Test result A)	H.pylori Conc. U/ml, B)	Test result B)
TSH	40 µIU/ml	20 and 80	+	0	-
Ferritin	1000 ng/ml	20 and 80	+	0	-
Hemoglobin	1000 mg/dl	20 and 80	+	0	-
IgE	1000 IU/ml	20 and 80	+	0	-
FSH	100 mIU/ml	20 and 80	+	0	-
hCG	200 mIU/ml	20 and 80	+	0	-
AFP	320 ng/ml	20 and 80	+	0	-
Prolactin	200 ng/ml	20 and 80	+	0	-
LH	200 mIU/ml	20 and 80	+	0	-
Triglycerides	1000 mg/dl	20 and 80	+	0	-

Correlation Studies:

A

To confirm the sensitivity and specificity of Gastric Ulcers Prevention Test a correlation study with a total number of 300 patient serum and plasma samples was performed, with patients including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients.
Results:
The Gastric Ulcers Prevention Test assay and a quantitative EIA were tested on all specimens. Of these, 116 were confirmed H. pylori positive and 184 were confirmed H. pylori negative using the enzyme immunoassay. 2 Samples tested negative with Gastric Ulcers Prevention Test and positive with the EIA. In addition, 7 samples tested negative with the EIA and positive with Gastric Ulcers Prevention Test. The results are shown below:

	Gastric Ulcers Prevention Test Positive	Gastric Ulcers Prevention Test Negative
EIA Positive (116)	114	2
EIA Negative (184)	7	177

The 7 negative H. pylori antibody results which initially tested positive with Gastric Ulcers Prevention Test were re-tested by EIA: all samples were weak positive. Therefore the following conclusions can be drawn:

Sensitivity: (114/116) @ 98,27 %
Specificity: (177/184) @ 96,20 %

B

A further study with 304 patients was conducted to compare Gastric Ulcers Prevention Test to the HUT-Test and to histology as a reference method (see attached abstract).

The following results were yielded:

		+	-	Total
Histology +	Gastric Ulcers Prevention Test	118	14	132
	HUT-Test	110	22	132
Histology -	Gastric Ulcers Prevention Test	9	163	172
	HUT-Test	4	168	172
			Sum	304

The sensitivity is the estimate of the percent of true positives for the Gastric Ulcers Prevention Test, that is, the percent of the positive reference results which are positive by the Gastric Ulcers Prevention Test test.

The specificity is the percent of true negatives for the Gastric Ulcers Prevention Test, that is, the percent of the negative reference results which are negative by the Gastric Ulcers Prevention Test test.

From this study the sensitivity is calculated as follows:
118/132 * 100 = 89,39 %
95% confidence interval: 82,8% to 94,1%
The HUT-Test shows a sensitivity of 110/132 * 100 = 83,3% (95% confidence interval: 75,9% to 89,3%)

The specificity is calculated as follows:
163/172 * 100 = 94,77%
95% confidence interval: 90,3% to 97,6 %
The HUT-Test shows a specificity of 168/172 * 100 = 97,76% (95% confidence interval: 94,2% to 99,4%) in this study.

Real Time Stability Test Results for Gastric Ulcers Prevention Test, stored at 15°C – 28°C Tested over 20 months

LOT 1:

Sample	No	Real Time (Months)																				
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Neg. control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20 U / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

LOT2

Sample	No	Real Time (Months)																				
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Neg. control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20 U / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

LOT3

Sample	No	Real Time (Months)																				
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Neg. control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20 U / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

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