Diamedix®
A Subsidiary of ERBA Diagnostics, Inc.

H. pylori IgG

Enzyme Immunoassay Test Kit
For *In Vitro* Diagnostic Use
Catalog No. 720-130 – 96 Tests

SUMMARY OF PROCEDURE

1. Prepare 1:21 dilutions of samples in Sample Diluent. Mix well.
2. Add 100 µl of diluted samples into the antigen wells. Reserve one well for reagent blank (100 µl of Sample Diluent).
3. Incubate at room temperature (18-30° C) for 30 ± 5 min.
4. Discard contents of the wells. Wash the wells 3 times with Wash Solution.
5. Add 100 µl of Conjugate to each well.
6. Incubate at room temperature (18-30° C) for 30 ± 5 min.
7. Wash the wells as in #4 above.
8. Add 100 µl Substrate Solution to each well.
9. Incubate at room temperature for 30 ± 5 min.
10. Add 100 µl Stop Solution to each well.
11. Read the absorbances at 450/600-630 nm against the reagent blank.

INTENDED USE

For the qualitative determination of IgG antibodies to *Helicobacter pylori* antigen in human sera by indirect enzyme immunoassay. The *H. pylori* IgG assay may be used as an aid in the diagnosis of *H. pylori* infection in adult patients with gastrointestinal symptoms.

SUMMARY AND EXPLANATION

H. pylori infection has been strongly associated with gastrointestinal diseases including gastritis, duodenal ulcer, and gastric ulcer.[1,2] *H. pylori* is detectable in 80-100% of these patients.[1,3] There are two categories of testing for the presence of *H. pylori*, invasive and non-invasive. Invasive techniques include culture of biopsy samples, direct detection of urease activity in biopsy sample, and histologic examination of biopsy sample.[4] Non-invasive techniques include urea breath tests and serological methods. Due to the risk to the patient and expense, non-invasive techniques are preferred over invasive techniques. In the urea breath test patients are administered labeled urea and the production of labeled carbon dioxide is measured. One method of labeling the urea used exposes the patient to small amounts of radiation while the other method requires the use of a mass spectrometer.[5,6] The advantage of the serologic test over the breath test is that it is more convenient to the patient, requires only common lab equipment and poses less risk to the patient. There has been correlation between the clinical presentation, presence of *H. pylori*, and elevated serum levels of *H. pylori* antibodies.[1,7,8]

The Immunosimplicity® *Is-H. pylori* IgG Test Kit is an EIA procedure intended for the qualitative detection of *H. pylori* IgG antibodies.

PRINCIPLE OF THE PROCEDURE

Purified *H. pylori* antigen is bound to microwells. Diluted patient sera, Cut-Off Calibrator and controls are placed in the microwells and incubated. Anti-*H. pylori* IgG antibodies, if present, will bind to the antigen forming antigen-antibody complexes. Residual sample is eliminated by aspirating and washing. Conjugate (horseradish peroxidase-labeled anti-human IgG) is added and will bind to these complexes. Unbound conjugate is removed by aspiration and washing. Substrate is then added and incubated. In the presence of bound enzyme the substrate is converted to an end product. The absorbance of this end product can be read spectrophotometrically at 450 nm (reference 600-630 nm). Color development above a certain level denotes the presence of antibody.

REAGENTS

Each Is-H. pylori IgG Test Kit contains reagents for 96 tests.

Antigen Wells	Twelve, 8-well microwell breakapart strips, color-coded dark green, coated with purified *H. pylori* antigen (ATCC#49503).
Cut-Off Calibrator	One vial with blue cap containing 0.5 ml of human serum or defibrinated plasma, weakly reactive for *H. pylori* IgG antibodies, 0.1% sodium azide. The Cut-Off Calibrator is used to determine the cut-off of the assay.
Low Positive Control	One vial with white cap containing 0.5 ml of human serum or defibrinated plasma, reactive for *H. pylori*, 0.1% sodium azide. Assigned range printed on label. The positive control is used to control the low range of the assay.
Negative Control	One vial with black cap containing 0.5 ml of human serum or defibrinated plasma non-reactive for *H. pylori* antibodies, 0.1% sodium azide. Assigned range printed on label. The negative control is used to control the negative range of the assay.
	Note: The Cut-Off Calibrator and controls are prepared from different serum lots.
Sample **A** Diluent	One bottle with blue cap containing 60 ml Phosphate buffer with protein stabilizers. Contains 0.2% sodium azide, Proclin® 300, 90 ppm active ingredient. Color-coded blue.
Wash **T** Concentrate (20X)	Two bottles with clear caps containing 50 ml of Tris buffer with detergent and Proclin® 300, 15 ppm active ingredient. Each bottle is sufficient to make 1050 ml of wash solution.
Conjugate	One bottle with red cap containing 25 ml goat anti-human immunoglobulin G labeled with horseradish peroxidase. Also includes protein stabilizers and preservatives. Color-coded pink.
Substrate **HRP**	One amber bottle with brown cap containing 25 ml buffered TMB solution (3,3',5,5' tetramethylbenzidine).
Stop **N** Solution	One bottle with white cap containing 30 ml of 1 N Sulfuric Acid. **CAUTION:** Acids are corrosive. Avoid contact with skin or eyes. If contact is made, flush area with copious amounts of water. See Precautions section.

Store these reagents at 2 to 8° C.

OTHER MATERIALS REQUIRED

Manual Users:

Wash bottle or automated microplate washer.

Pipettors capable of dispensing appropriate volumes.

Timer.

One liter graduated cylinder.

One liter wash solution reservoir.

Deionized or distilled water.

Absorbent toweling.

Tubes or microwell plate for sample dilution.

Reader capable of reading absorbance at 450 nm, reference at 600-630 nm. (Performance characteristics have not been established for single wavelength readers).

Automated EIA Processor Users:

One liter graduated cylinder.

Deionized or distilled water.

Pre-dilution cups, strips or plates.

ProbeClean™ Concentrate, or tip washing detergent solution, if applicable.

PRECAUTIONS

REAGENTS: For *in vitro* Diagnostic Use.

1. Handle samples, Calibrator, controls and the materials that contact them as potential biohazards. Each donor unit in the Calibrator and controls has been found negative for Hepatitis B surface antigen and HIV-I antibodies by FDA-approved third generation tests. However, because no method can offer complete assurance that HIV-1, Hepatitis B virus, or other infectious agents are absent, these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health Manual, “Biosafety in Microbiological and Biomedical Laboratories”, 1993.
2. Never pipette by mouth.
3. Avoid contact with open skin and mucous membranes.

4. Certain of the test reagents contain Proclin® 300 as a preservative. When disposing of reagents containing Proclin® 300, flush drains with copious amounts of water to dilute the active components below active levels.

5. Reagents containing Sodium Azide:

   (a) **CAUTION:** Some reagents in this kit contain Sodium Azide as preservative. Sodium Azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts", in the Manual Guide – Safety Management No. CDC-22, issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

   European Communities Hazardous Substance Risk Phrases (Regulation (EC) No 1272/2008)

   H300 –Fatal if swallowed.
   H310 – Fatal if contact with skin.
   EUH032 – Contact with acids liberates very toxic gas.
   H410 – Very toxic to aquatic life with long lasting effect.
   P264 – Wash all exposed external body areas thoroughly after handling.
   P302+P352 – IF ON SKIN: Wash with plenty of water and soap.
   P301+P310/P330 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
   P270 – Do not eat, drink or smoke when using this product.
   P501 – Dispose of contents/container as hazardous waste.
   P391 – Collect spillage.
   P273 – Avoid release to the environment. Refer to special instructions/ Safety Data Sheet.

   (b) Sodium Azide inhibits horseradish peroxidase activity. Care must be taken to ensure that azide is not carried over from other reagents into conjugate and substrate steps.

6. Avoid contamination of the TMB substrate solution with conjugate or other oxidants which will cause the solution to change color prematurely.

ADDITIONAL PRECAUTIONS:

1. Do not interchange reagents from different reagent lots except for Sample **A** Diluent, Wash **T** Concentrate, Substrate **HRP** and Stop **N** Solution.
2. Do not use reagents beyond their expiration date. Expiration dates are printed on the reagent labels.
3. Store unused reagents at 2 to 8°C.
4. Incubations above or below the recommended temperatures or times may give erroneous results.
5. The EIA method is a very sensitive technique. Maintain consistent pipetting technique, incubation times, and temperature conditions throughout the test procedure. Cross contamination between reagents can invalidate the test.
6. Antigen coated microwells should be stored with the desiccant in the resealable bag provided and returned to the refrigerator immediately after use.
7. *(Manual Procedure Only)* The washing procedure is very important and requires special attention. (Please refer to the Procedure section.)

   NOTE: *Improperly washed wells may give erroneous results.*

8. The concentration of anti-*H. pylori* IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.

SPECIMEN COLLECTION

Whole blood should be collected by accepted medical techniques. Separated serum should remain at 22°C for no longer than 8 hours. If assays are not completed within 8 hours, serum should be refrigerated (2-8°C). If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at –20°C. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen sera to room temperature slowly and mix gently, avoiding foam formation. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Grossly contaminated, hemolyzed, lipemic, or icteric specimens should not be used. The CLSI, formerly NCCLS, provides recommendations for collecting and storing blood specimens, (Approved Standard - Procedures for the Handling and Processing of Blood Specimens, H18A3).

CAUTION: *Serum samples must not be heat-inactivated prior to use.*

PROCEDURE

Allow all test components and patient samples to warm to room temperature before use. Invert reagent bottles gently several times before use. Return promptly to the refrigerator after use.

Prepare Wash Solution by adding 50 ml of Wash Concentrate (20X) to one liter of deionized or distilled H_2O.

MANUAL USERS:

1. Prepare 1:21 dilutions of the Cut-Off Calibrator (in triplicate), controls and patient samples in Sample Diluent. (e.g., by addition of 10 µl sample to 200 µl Sample Diluent).
2. Mix sample dilutions gently by withdrawing and expelling in a pipette tip 2 or 3 times or by vortex mixing for 2 or 3 seconds. Transfer 100 µl of Calibrator, controls and diluted patient samples, to the antigen wells. Avoid formation of bubbles when transferring diluted samples.

   NOTE: Include one well which contains 100 µl of Sample Diluent as a reagent blank. This will ultimately be used to "zero" the photometer before reading test results.

3. Allow the wells to incubate uncovered at room temperature (18-30°C) for 30 ± 5 minutes.
4. Aspirate or discard the contents of the wells. Remove any excess moisture in the wells by tapping on paper toweling. Wash the wells by rinsing 3 times with at least 300 µl of Wash Solution. Remove excess moisture from the wells after washing. When using an automated washer, follow the manufacturer's instructions.
5. Place 100 µl of Conjugate into each well, avoiding bubble formation.
6. Allow the wells to incubate uncovered at room temperature (18-30°C) for 30 ± 5 minutes.
7. Wash the wells as described in Step 4 above.
8. Place 100 µl of Substrate into each well, avoiding bubble formation.
9. Allow the wells to incubate uncovered at room temperature (18-30°C) for 30 ± 5 minutes.
10. Place 100 µl of Stop Solution into each well, avoiding bubble formation.
11. Read the absorbance of the wells at 450 nm using a reference wavelength of 600-630 nm. The plate should be read within 60 minutes of adding Stop Solution.

AUTOMATED EIA PROCESSOR USERS:

When using an Automated EIA Processor, refer to the Operator's Manual for the test setup and procedures.

NOTE: *Automated EIA Processor users must validate their equipment to demonstrate that the results obtained are equivalent to those obtained using manual assay.*

QUALITY CONTROL

1. The Positive and Negative Controls must be included in each test run.
2. The absorbance of the Blank must be < 0.25.
3. The absorbance of the Cut-Off Calibrator must be >0.10.
4. The Positive and Negative Controls must be within their assigned ranges.

NOTE: Additional controls may be tested according to guidelines or requirements of local, state, or federal regulations or accrediting organizations. For guidance on appropriate quality control practices please refer to CLSI, formerly NCCLS, C24-A2, Statistical Quality Control for Quantitative Measurements: Principles and Definitions.

RESULTS

1. Calculation

Calculate the mean absorbance of the Cut-Off Calibrator. Note: When calculating the mean absorbance value for the Cut-Off Calibrator exclude any absorbance value that deviates by more than 15% from the mean of the three absorbance values. Use the mean of the remaining two replicates in calculations. Exclusion of more than one of the three absorbance values invalidates the run.

Determine the Index Value for each patient specimen or control using the following formula:

$$\frac{\text{Absorbance of Sample}}{\text{Mean Absorbance of Cut-Off Calibrator}} = \text{Index Value}$$

An Automated EIA Processor (e.g. MAGO® Plus Automated EIA Processor) will calculate results using the above formula and will print them automatically.

Example : Absorbance values obtained for Cut-Off Calibrator : 0.276, 0.288, 0.258 (after subtraction of blank)

Mean Absorbance of Cut-Off Calibrator = 0.274

Sample Absorbance = 1.150

Index Value = 1.150 / 0.274 = 4.2

2. Interpretation

Index Value	*Interpretation*
< 0.90	No detectable antibodies to *H. pylori.*
0.90 – 1.09	Equivocal for IgG antibodies to *H. pylori.* Sample should be retested. If retest results are equivocal, the sample should be reported as equivocal, tested by another method, or a new sample should be tested.**
≥ 1.10	*H. pylori* IgG antibody detected.

** Equivocal samples that give positive results on retest should be reported as positive. Equivocal results that give negative results on retest should be reported as negative.

3. Reporting Results

When the Index Value is reported for a single specimen the following statement should be included "The following results were obtained with the *Is-H. pylori* IgG Test Kit. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody present. The magnitude of the reported IgG level cannot be correlated to an endpoint titer".

CUT-OFF ESTABLISHMENT

The *Is-H. pylori* IgG Test Kit cut-off value was established to optimally differentiate those individuals with, from those without, immunological experience to *H. pylori.* The optimal cut-off was determined by statistical analysis of the results of one hundred and sixteen sera shown to be negative for *H. pylori* IgG antibodies in the *Is-H. pylori* IgG Test Kit as well as other methods. The mean and standard deviation of the absorbance values for these sera were 0.097 and 0.045 respectively. The cut-off was determined as being equal to the mean plus 3 standard deviations, 0.097 + (3 x 0.045) = 0.232. The Cut-Off Calibrator has been titrated to equal this result. Therefore, the mean value of the Cut-Off Calibrator will be equal to the cut-off for the assay. To account for the inherent variations in EIA methods, an equivocal range of ± 10% has been included.

LIMITATIONS

1. The results obtained with the *Is-H. pylori* IgG Test Kit serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves.
2. Assay performance characteristics have not been established for visual result determination.
3. The test should be performed on serum. The use of whole blood or plasma has not been established.
4. The performance characteristics of the *Is-H. pylori* IgG Test Kit have not been determined for a pediatric population.
5. Screening of the general population should not be performed due to the large percentage of people colonized with *H. pylori.* Testing should only be performed when clinical symptoms are present.
6. Results from immunosuppressed patients should be interpreted with caution.
7. The performance characteristics of the *Is-H. pylori* IgG Test Kit with automated equipment other than the MAGO® Plus Automated EIA Processor have not been established.
8. Icteric, lipemic, hemolyzed, or heat inactivated sera may cause erroneous results and should be avoided.
9. A positive result does not differentiate between a current or past infection. It also does not mean the clinical symptoms are due to infection with *H. pylori.* The clinical diagnosis has to be made with the clinical signs and symptoms of the patient.
10. Patients infected with *C. jejuni, C. coli*, and *C. fetus* may cause false positives in the *Is-H. pylori* Test Kit.
11. The performance characteristics have not been established on fresh serum samples.

EXPECTED VALUES

The expected value of *H. pylori* IgG antibodies in the normal population is negative. However, apparently healthy, asymptomatic individuals may test positive for *H. pylori* antibodies. The incidence of these antibodies increases with increasing age.

In the present studies sera from 176 normal individuals of various ages and genders from different geographic locations were evaluated in the *Is-H. pylori* IgG Test Kit. One hundred forty-four samples (81.82%) were negative for antibodies to *H. pylori* IgG, thirty-two samples (18.18%) were positive and no samples (0%) were equivocal for *H. pylori* IgG antibodies. The age distribution and prevalence for this population is shown in Table 1. Histograms showing the distribution of Index Values for the positive and negative populations are shown in Figures 1 and 2.

TABLE 1

	Number of donors	Prevalence
Total Number	176	18.18%
Geographic locations: Various	176	18.18%
Age		
4 – 10	9	0.0%
11 – 20	15	6.7%
21 – 40	49	8.16%
41 – 60	57	15.79%
61 – 80	33	33.33%
81 - 91	13	53.85%

FIGURE 1
***Is-H. pylori* Positive Population**

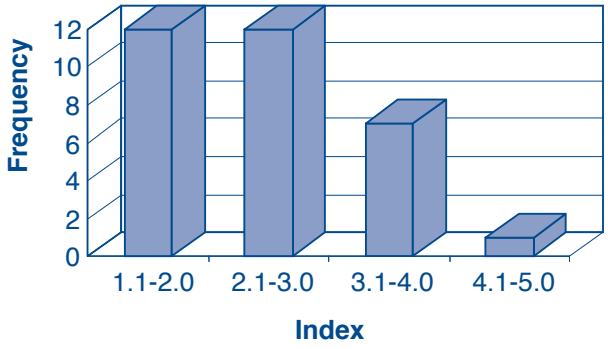
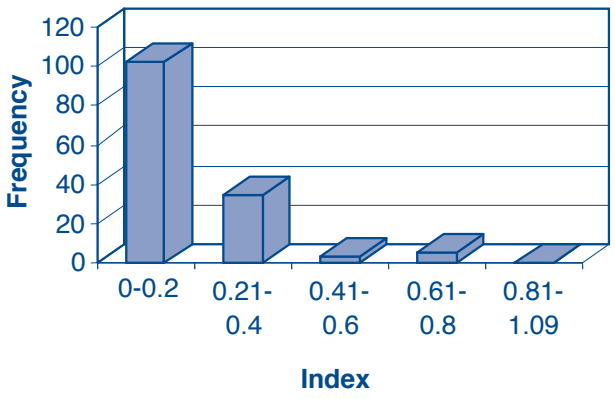


FIGURE 2
***Is-H. pylori* Negative Population**



PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity Using Characterized Sera

Frozen retrospective sera from two hundred forty-nine patients were characterized using biopsy with culture, stain and CLO results for *H. pylori*. Based on the results of this testing, the patient sera were characterized as follows :

* 121 sera were characterized as positive. These were positive for *H. pylori* by biopsy.
* 128 sera were characterized as negative. These were negative for *H. pylori* by biopsy.

The sera were tested on the *Is-H. pylori* IgG Test Kit at a clinical commercial laboratory. The data is summarized in Table 2.

TABLE 2
***Is-H. pylori* IgG**

		POSITIVE	*EQUIVOCAL	NEGATIVE
H. pylori Clinical Status (Biopsy)	POSITIVE	112	3	6
	NEGATIVE	12	3	113

			95% CI
Sensitivity	= 112/118	= 94.9%	89.3% - 98.1%
Specificity	= 113/125	= 90.4%	83.8% - 94.9%
Overall Agreement	= 225/243	= 92.6%	88.5% - 95.6%

* Equivocal results were excluded from the above calculations.

B. Relative Agreement Versus Another ELISA

Frozen retrospective sera from two hundred forty-nine patients (same samples from Table 2) were tested at a clinical commercial laboratory using the *Is-H. pylori* IgG Test Kit and another commercially available kit for *H. pylori* IgG antibodies. The data in Table 3 illustrate the relative agreement of the *Is-H. pylori* IgG Test Kit versus another commercial ELISA.

TABLE 3
***Is-H. pylori* IgG**

		POSITIVE	*EQUIVOCAL	NEGATIVE
Another ELISA	POSITIVE	122	3	0
	*EQUIVOCAL	1	1	3
	NEGATIVE	1	2	116

- Of the 125 sera positive on the alternate ELISA tested, 122 were positive for *Is-H. pylori* IgG, none were negative, and 3 were equivocal.
- Of the 119 sera negative on the alternate ELISA tested, 1 was positive for *Is-H. pylori* IgG, 116 were negative, and 2 were equivocal.
- Of the 5 sera equivocal on the alternate ELISA tested, 1 was positive for *Is-H. pylori* IgG, 1 was negative, and 3 were equivocal.
- Overall Relative Agreement = 238/239 = 99.6%

* Equivocal results were excluded from calculations

NOTE: Please be advised that 'relative' refers to the comparison of the assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison's accuracy to predict disease.

C. Precision

To determine the precision of the *Is-H. pylori* IgG Test Kit, four positive and two negative sera were assayed ten times each in three different runs at three different sites. The three sites included: the manufacturer, a research & development laboratory, and a clinical commercial laboratory. The intra- and interassay precision obtained at each site is shown in Tables 4, 5, and 6.

TABLE 4
Site #1 - Intra-Assay and Interassay Precision

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.51	3.85	1.47	5.05	1.45	4.97	1.47	4.80
B (POS)	2.60	2.16	2.58	4.20	2.59	3.69	2.59	3.35
C (POS)	2.23	3.66	2.23	3.65	2.20	2.98	2.22	3.39
D (POS)	1.73	3.82	1.72	2.19	1.70	3.57	1.71	3.24
E (NEG)	0.19	10.81	0.16	13.54	0.14	36.64	0.17	23.60
F (NEG)	0.36	37.22	0.32	16.08	0.34	11.54	0.34	24.91

TABLE 5
Site #2- Intra-Assay and Interassay Precision

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.34	4.92	1.32	5.00	1.38	4.39	1.35	4.93
B (POS)	2.25	5.85	2.27	5.17	2.45	6.18	2.33	6.78
C (POS)	1.97	3.40	1.96	4.24	2.11	4.83	2.01	5.41
D (POS)	1.46	6.27	1.45	4.52	1.62	4.02	1.51	6.93
E (NEG)	0.18	12.48	0.17	11.70	0.22	10.28	0.19	15.39
F (NEG)	0.40	11.01	0.35	20.01	0.47	12.50	0.41	18.56

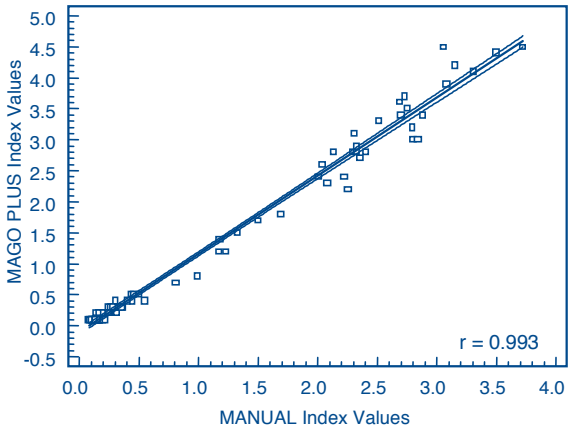
TABLE 6
Site #3- Intra-Assay and Interassay Precision

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.41	7.59	1.30	5.70	1.27	4.60	1.33	7.64
B (POS)	2.54	4.41	2.30	3.74	2.19	2.52	2.34	7.31
C (POS)	2.13	5.91	1.96	4.89	1.90	3.43	2.00	6.94
D (POS)	1.56	6.16	1.50	4.59	1.45	2.08	1.50	5.42
E (NEG)	0.16	19.99	0.18	6.38	0.16	6.25	0.17	13.77
F (NEG)	0.34	10.92	0.34	13.65	0.27	15.74	0.32	16.60

D. Correlation of Manual and MAGO Plus Results

The *Is-H. pylori* IgG Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the manual and MAGO Plus procedures, the results of 100 serum samples tested by both methods were plotted. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in Figure 3. The data indicate good correlation with a Pearson Correlation Coefficient of 0.993.

FIGURE 3
Manual and MAGO Plus Result Correlation



E. MAGO Plus Precision

The precision of the assay when performed on the MAGO® Plus Automated EIA Processor was determined by assaying six sera ten times each in three different runs. Table 7 shows the intra-and interassay precision obtained using the MAGO Plus.

TABLE 7
Site #2- Intra-Assay and Interassay Precision - MAGO Plus

SERUM	INTRA-ASSAY RUN 1		INTRA-ASSAY RUN 2		INTRA-ASSAY RUN 3		INTERASSAY	
	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%	MEAN INDEX	CV%
A (POS)	1.19	8.36	1.02	15.19	1.25	5.66	1.15	12.83
B (POS)	2.12	4.87	2.20	9.34	2.27	2.97	2.20	6.71
C (POS)	1.97	4.18	1.89	5.82	1.90	4.96	1.92	5.19
D (POS)	1.37	6.01	1.45	4.88	1.54	7.62	1.45	7.82
E (NEG)	0.13	37.16	0.12	35.14	0.20	62.36	0.15	57.40
F (NEG)	0.32	24.65	0.34	24.80	0.34	15.19	0.33	21.33

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Procilin® 300 is a registered trademark of Rohm and Haas Corp. Philadelphia, PA.

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