K110745

GOLD STANDARD DIAGNOSTICS

MAR - 2 2012

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

1) **Submitter's Name:** Gold Standard Diagnostics
   Address: 2851 Spafford St. Davis, CA. 95618
   Phone Number: 530-759-8000
   Contact Person: Napoleon Monce
   Date: September 20, 2011

2) **Product and Trade Name:**
   Helicobacter pylori IgG ELISA

   Common Name or Classification Name:
   Campylobacter pylori

   Product Code:
   LYR

3) **Legally marketed device to which the submitter claims equivalence:**
   Micro Detect, Inc. Pylori Detect IgG ELISA for the qualitative detection of IgG antibodies against *H. pylori* in human serum. The test is intended as an aid in the diagnosis of infection by *H. pylori* in patients with gastrointestinal symptoms. K973508.

4) **Description of the device:**
   The assay requires a total of 90 minutes incubation time. The test uses purified antigen coated on microtiter wells. Serum is added to each well and incubated for 30 minutes at 37°C. If *H. pylori* IgG antibodies are present they will bind to the antigen in the well. Unbound serum is removed by washing the wells three times. An HRP-conjugated anti-human IgG is then added to each well and incubated for 30 minutes at 37°C. If *H. pylori* antibody is present, it will bind to the antibody attached to the antigen on the well. The wells are again washed three times to remove any unbound conjugate. A TMB substrate is added to each well and incubated for 30 minutes at 37°C. If enzyme is present, it will react with the substrate to generate a colored product. After the incubation period, the reaction is stopped with a Stop Solution and the color intensity is measured spectrophotometrically.

5) **Intended use of the device:**
   The *Helicobacter pylori (H. pylori)* ELISA IgG test kit is intended for the qualitative detection of IgG antibodies to *H. pylori* in human serum in the adult population. This test is intended to aid in the diagnosis of *H. pylori* in patients suspected of having *H. pylori* infection, and in patients with gastrointestinal symptoms, and is to be used in conjunction with clinical findings.

6) **Comparison with the predicate device:**

The Gold Standard Diagnostics *H. pylori* ELISA IgG Test Kit was compared to a commercially marketed kit by Micro Detect, Inc. the Pylori Detect IgG (K973508) catalog number HpKi-G. Both kits have the same intended use and use the same methodology. Below are tables comparing the reagents provided, the procedures, and their performances.

Table 1: Reagent Comparison

Gold Standard Diagnostics *H. pylori* ELISA IgG Test Kit	**Micro Detect Inc. Pylori Detect IgG**
Antigen coated Microtiter Plate – 96 wells	Antigen coated Microtiter Plate – 96 wells
Wash Solution – 20x	Diluent/Wash Concentrate – 25x
Diluent – Ready to Use	Diluent/Wash Concentrate – 25x
IgG Conjugate – Anti Human HRP	IgG Conjugate – Anti Human Peroxidase
Substrate – Tetramethylbenzidine (TMB)	Substrate – Tetramethylbenzidine (TMB)
Stop Solution – Acid mixture	Stop Solution – Sulfuric Acid
H. pylori IgG Positive Control	*H. pylori* IgG Positive Control
H. pylori IgG Cutoff Control	*H. pylori* IgG Calibrator
H. pylori IgG Negative Control	*H. pylori* IgG Negative Control

Table 2: Procedure Comparison

Gold Standard Diagnostics *H. pylori* ELISA IgG Test Kit	**Micro Detect Inc. Pylori Detect IgG**
Dilute Samples 1:101 in Diluent	Dilute Samples 1:101 in reconstituted Diluent/Wash
Add 100ul of Samples and Controls	Add 100ul of Samples and Controls
Incubate for 30 minutes at 37°C	Incubate for 20 minutes at Room Temperature
Wash four times with reconstituted Wash	Wash three times with reconstituted Wash

Solution	Solution
Add 100ul of Conjugate	Add 100ul of Conjugate
Incubate for 30 minutes at 37°C	Incubate for 20 minutes at Room Temperature
Wash four times with reconstituted Wash Solution	Wash three times with reconstituted Wash Solution
Add 100ul of Substrate	Add 100ul of Substrate
Incubate for 30 minutes at 37°C	Incubate for 15 minutes at Room Temperature
Add 50ul of Stop Solution	Add 100ul of Stop Solution
Read with Spectrophotometer at 450nm	Read with Spectrophotometer at 450nm

6(b1) Nonclinical tests:

The intra and inter assay precision was calculated by running six patient sera (four positives and two negatives) at three different sites. The results are summarized in the table below:

		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Site 1	**Ave:**	0.884	1.022	0.965	1.302	0.185	0.168
	SD:	0.063	0.043	0.050	0.006	0.011	0.016
Intra-Assay	**CV:**	7.2%	4.3%	5.2%	0.4%	6.0%	9.5%
Site 2	**Ave:**	0.935	0.958	0.817	1.329	0.147	0.153
	SD:	0.028	0.034	0.042	0.015	0.005	0.007
Intra-Assay	**CV:**	3.0%	3.6%	5.1%	1.1%	3.4%	4.3%
Site 3	**Ave:**	1.013	1.093	0.933	1.476	0.181	0.177
	SD:	0.016	0.103	0.068	0.106	0.013	0.011
Intra-Assay	**CV:**	4.5%	9.4%	7.3%	7.2%	7.0%	6.4%

Inter-Assay	**Ave:**	0.974	1.057	0.925	1.414	0.177	0.172
	SD:	0.070	0.098	0.078	0.114	0.018	0.014
	CV:	7.2%	9.3%	8.4%	8.0%	10.1%	8.4%

Reproducibility:

The reproducibility of the assay was done by testing three samples in triplicate (a high negative, low positive and a moderate positive) for five days, twice a day, at three sites with two technicians per site. The results are summarized in the table below:

		5 Day Average:	**Sample 1**	**Sample 2**	**Sample 3**
Site 1	Tech 1	OD:	0.338	0.708	1.030
		SD:	0.047	0.074	0.095
		CV:	13.9%	10.4%	9.2%
	Tech 2	OD:	0.354	0.692	1.055
		SD:	0.043	0.060	0.107
		CV:	12.2%	8.7%	10.1%
Site 2	Tech 1	OD:	0.329	0.693	1.034
		SD:	0.044	0.037	0.050
		CV:	13.4%	5.4%	4.9%
	Tech 2	OD:	0.360	0.693	1.022
		SD:	0.052	0.032	0.049
		CV:	14.4%	4.7%	4.8%
Site 3	Tech 1	OD:	0.300	0.516	0.888
		SD:	0.048	0.054	0.032
		CV:	16.1%	10.5%	3.6%
	Tech 2	OD:	0.374	0.642	0.928
		SD:	0.041	0.094	0.128
		CV:	11.0%	14.6%	13.7%

Cross Reactivity:

An adsorption study was performed to evaluate any cross reactivity. Briefly, sera with different levels of antibodies to *H. pylori* were adsorbed with either *H. pylori*, *Candida albicans*, *E. coli*, *Borrelia burgdorferi*, *Clostridium* spp., *Campylobacter*, *Bacillus*, *Enterobacter*, *Pseudomonas*, *Haemophilus Influenza*, and *Proteus*. The identity of the bacteria used were identified by the ATCC and confirmed with the MALDI-TOF method. The bacteria were evaluated at a concentration of 10^7 cfu/ml or higher.

Sera with different levels of antibodies to *H. pylori,* were adsorbed with the recommended organisms. The adsorbed samples were compared to the untreated samples and the mean percent inhibition was calculated. The results are summarized in the following table:

Organism	Concentration (cfu/ml)	Mean percent inhibition
Helicobacter pylori		96%
Candida albicans	$2.40x10^7$	1.8%
Escherichia coli	$6.90x10^7$	9.5%
Borrelia burgdorferi	$1.00x10^8$	5.5%
Clostridium spp.	$1.20x10^7$	6.0%
Campylobacter	$1.50x10^9$	4.7%
Bacillus Cereus	$4.40x10^7$	18.2%
Enterobacter	$1.80x10^8$	2.1%
Pseudomonas	$1.45x10^8$	5.1%
Haemophilus Influenza	$7.90x10^7$	3.8%
Proteus	$1.40x10^8$	4.6%

The mean percent inhibition for *H. pylori* was 96%, and 1.8% to 9.5% with the other organisms. There seems to be a weak cross reactivity with *Bacillus Cereus.* Taking into account the normal test variation, the remaining cross reactivity with *Bacillus Cereus* may affect high negative samples close to the equivocal range. Overall no effects on the analytical specificity were seen on the Gold Standard Diagnostics *H. pylori* ELISA IgG assay.

Interfering Substance

The effect of potential interfering substances on samples using the Gold Standard Diagnostics *H. pylori* ELISA IgG assay was evaluated. High levels of hemoglobin, bilirubin, cholesterol and triglycerides in serum samples were tested at the assay cutoff (9-11 units) in triplicate. The recommended concentrations from the guideline "Interference Testing InClinical Chemistry" from the Clinical and Laboratory Standards Institute were used (see table below). The tested substances did not affect the performance of the Gold Standard Diagnostics *H. pylori* ELISA IgG assay.

Substance	Concentration	*H. pylori* concentration	Mean Percent Inhibition
Hemoglobin	2 g/L	9-11 units	3%
Bilirubin	342 µmol/L	9-11 units	11%
Cholesterol	13 mmol/L	9-11 units	1%
Triglyceride	37 mmol/L	9-11 units	-19%

Leukocytes, intestinal secretions or mucus, fat, and medications used to relieve diarrhea or other gastric symptoms were not tested, therefore, it is not known if these substances will interfere with the assay as they were not evaluated.

6(b2): Clinical Comparison:

The performance of the Gold Standard Diagnostics *H. pylori* ELISA IgG assay was determined by conducting a correlation study using 625 samples being routinely tested for H. pylori. The samples were tested on both the Gold Standard Diagnostics *H. pylori* ELISA IgG assay and a commercially available ELISA assay (Micro Detect Inc. K973508) as the predicate device. The results are summarized in the following table:

		Micro Detect IgG ELISA		
		Positive	Equivocal	Negative
Gold Standard Diagnostics IgG ELISA	Positive	203	3	13
	Equivocal	5	2	8
	Negative	11	5	375
	Total	**219**	**10**	**396**

The discrepant samples were further tested on a third assay, the DiaMedix *H. pylori* IgG assay (which is also commercially available). Of the 11 Gold Standard Diagnostics negative samples, Micro Detect Inc. positive samples, the third assay called nine samples positive and two samples negative. Of the 13 Gold Standard Diagnostics positive samples, Micro Detect Inc. negative samples, the third assay called one sample borderline, two negative, and ten samples positive. The comparison data produced the following:

% Positive Agreement = 92.7% (203/219) with 95% CI: 88.5% to 95.5%;
% Negative Agreement = 94.7% (375/396) with 95% CI: 92.0% to 96.5%
% Equivocal Agreement = 20% (2/10) with 95% CI: 5.7% to 51.0%
Overall Agreement = 92.8% (580/625)

6(b3) Conclusion:

From the data and comparison above, it is our contention that the Gold Standard Diagnostic *H. pylori* IgG ELISA test is substantially equivalent to the commercially marketed Micro Detect, Inc. Pylori Detect IgG kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Gold Standard Diagnostics
c/o Napoleon Monce
Director, Product Development
2851 Spafford Street
Davis, California 95618

MAR - 2 2012

Re: K110745
Trade Name: *Helicobacter pylori* ELISA IgG Test Kit
Regulation Number: 21 CFR §866.3110
Regulation Name: Campylocbacter fetus serological reagents.
Regulatory Class: Class I
Product Code: LYR
Dated: February 21, 2012
Received: February 23, 2012

Dear Mr. Monce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

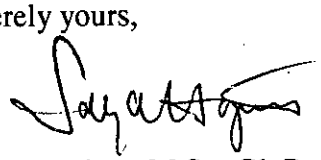
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K110745**

Device Name: **Gold Standard Diagnostics Helicobacter pylori ELISA IgG Test Kit**

Indications For Use:

The *Helicobacter pylori (H. pylori)* ELISA IgG test kit is intended for the qualitative detection of IgG antibodies to *H. pylori* in human serum in the adult population. This test is intended to aid in the diagnosis of *H. pylori* in patients suspected of having *H. pylori* infection, and in patients with gastrointestinal symptoms, and is to be used in conjunction with clinical findings.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110745