510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K161139

B. Purpose for Submission:

To obtain substantial equivalence for the LIAISON® *H. pylori* IgG assay and LIAISON® *H. pylori* IgG Control Set.

C. Measurand:

Helicobacter pylori IgG antibodies in human serum

D. Type of Test:

Chemiluminescence Immunoassay

E. Applicant:

DiaSorin Inc.

F. Proprietary and Established Names:

LIAISON® *H. pylori* IgG, LIAISON® *H. pylori* IgG Control Set

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3110 - *Campylobacter fetus* serological reagents

2. Classification:

   Class I

3. Product codes:

   LYR; *Helicobacter pylori*
   JJX; single (specified) analyte controls (assayed and unassayed)
   JJQ; colorimeter, photometer, spectrophotometer for clinical use

4. Panel:

   83 Microbiology

H. Intended Use:

1. Intended use(s):

   The LIAISON® *H. pylori* IgG assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative determination of IgG antibodies to *Helicobacter pylori* in human serum from symptomatic adults as an aid in the diagnosis of *Helicobacter pylori* infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. The test has to be performed on the LIAISON® XL Analyzer.

   The LIAISON® *H. pylori* IgG Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® *H. pylori* IgG assay.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   LIAISON® XL Analyzer

I. Device Description:

The LIAISON *H. pylori* lgG assay is a two-step, indirect assay for the determination of IgG antibodies to *Helicobacter pylori* by chemiluminescence immunoassay. The principle components of the test are magnetic particles (solid phase) coated with *H. pylori* antigen and anti-human IgG monoclonal antibodies labelled with an isoluminol derivative.

During the first incubation, *H. pylori* antibodies present in calibrators, samples or controls (sold separately) bind to the solid phase functionalized with *H. pylori* antigen. During the second incubation, the antibody conjugate reacts with *H. pylori* IgG already bound to the solid phase. After each incubation, the unbound material is removed with a wash cycle (wash buffer sold separately). Subsequently, the starter reagents (sold separately) are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of *H. pylori* IgG concentration present in calibrators, samples or controls.

The calibrator concentrations (Index Values) are referenced to an in-house standard preparation. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of antibodies to *H. pylori* present in the calibrator, controls or sample. Table 1 summarizes the interpretation of results.

Table 1. Interpretation of results:

Index	Results	Interpretation
<0.80	Negative (No further testing)	A negative result generally indicates that the patient has not been infected, but does not always rule out acute *H. pylori* infection.
≥0.80 and <0.90	Equivocal (Retest)	Equivocal samples must be retested by the LIAISON® *H. pylori* IgG assay in order to confirm the initial result. Samples which are positive (≥0.90) at the second test should be considered positive. Samples which are negative (<0.80) at the second test should be considered negative. For samples that are equivocal on retesting; a new specimen should be collected and tested.
≥ 0.90	Positive (No further testing)	Indicates the presence of detectable IgG antibody to *H. pylori*.

The results are only intended to be read on the LIASON® XL Analyzer (sold separately). The LIAISON XL Analyzer was FDA cleared (K103529). The LIAISON® XL Analyzer with software version 4.0.0.4 was FDA cleared in April 2013 with the DiaSorin LIAISON® TSH assay K130469. There have been changes to the LIAISON® XL Analyzer software since it was cleared under K130469, and the subject iteration of the software is 4.1.0.3 SP1 dated 10/2015.

The LIAISON® *H. pylori* IgG assay is an i*n vitro* diagnostic device consisting of reagents provided in individual compartments within a plastic container called the Reagent Integral. The assay configuration for the LIAISON® *H. pylori* IgG assay allows for the performance of 100 tests. A list of the components that make up the Reagent Integrals is listed below in Table 2.

Table 2. Reagent Integral

Magnetic Particles (2.4 mL)	[SORB]	Magnetic particles coated with *H. pylori* antigen in phosphate buffer containing BSA, surfactant, and <0.1% sodium azide.
Calibrator 1 (1.0 mL)	[CAL|1]	Human serum containing *H. pylori* IgG, <0.1% sodium azide and 0.1% ProClin® 300.
Calibrator 2 (1.0 mL)	[CAL|2]	Human serum containing *H. pylori* IgG, <0.1% sodium azide and 0.1% ProClin® 300.
Conjugate (28.0 mL)	[CONJ]	Mouse monoclonal antibodies to human IgG conjugated to an isoluminol derivative, in phosphate buffer, BSA, 0.2% ProClin® 300 and 0.01% gentamicin sulfate.
Specimen Diluent (2 x 28.0 mL)	[DIL|SPE]	BSA, phosphate buffer, 0.2% ProClin® 300, an inert yellow dye.
Number of Tests		100

ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

All reagents are supplied ready to use.

Materials required but not provided (system related)

LIAISON® XL Analyzer
LIAISON® Wash/System Liquid ([REF] 319100) LIAISON® XL Waste Bags ([REF] X0025) LIAISON® XL Cuvettes ([REF] X0016) LIAISON® XL Starter Kit ([REF] 319200) LIAISON® XL Disposable Tips ([REF] X0015)

Additional required materials not provided:
LIAISON® *H. pylori* IgG Control Set ([REF] 318981)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   IMMULITE® 2000 *H. pylori* IgG (assay)

2. Predicate 510(k) number(s):

   K000463 (assay)

3. Comparison with predicate:

Similarities		
Item	Device K161139	Predicate K000463
Intended Use	The LIAISON® *H. pylori* IgG assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative determination of IgG antibodies to *Helicobacter pylori* in human serum from symptomatic adults as an aid in the diagnosis of *Helicobacter pylori* infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. The test has to be performed on the LIAISON® XL Analyzer. The LIAISON® *H. pylori* IgG Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® *H. pylori* IgG assay.	For *in vitro* diagnostic use with the IMMULITE® 2000 Systems Analyzers – for the qualitative detection of IgG antibodies to *Helicobacter pylori* in human serum from symptomatic adults, as an aid in the diagnosis of *Helicobacter pylori* infection
Measured Analyte	IgG antibodies to *H. pylori*	Same
Assay Type	Solid Phase Two Step Chemiluminescent	Same
Sample Handling	Automated	Same
Reagent Storage	On-board or in refrigerator @ 2-8°C	In refrigerator @ 2-8°C
Calibration	Two point verification of stored master curve	Same
Calibration Calculation of Result	Qualitative assay	Same
Sample Matrix	Human Serum	Same
Sample SizeVolume	10 µL	Same
Controls	Provided separately	Same

Differences		
Item	Device K161139	Predicate K000463
Unit of Measure	Index	U/mL
Assay Time	30 minutes	60 minutes
Conjugate	Mouse monoclonal antibodies to human IgG linked to an isoluminol derivative	Monoclonal murine anti-human IgG antibodies labeled with alkaline phosphatase in buffer
Measurement System	Photomultiplier (flash chemiluminescence reader)	Luminometer
Cutoff	0.85 Index	1.00 U/mL
Equivocal Zone	0.80 – < 0.90 Index	0.90 – < 1.10 U/mL
Controls	2 levels: negative and positive	3 levels: negative, low positive, positive
Control Stability Open Use	12 weeks	2 weeks
Calibration Stability	4 weeks	1 week

K. Standard/Guidance Document Referenced (if applicable):

- EP05-A2, Evaluation of Precision Performance of Quality Measurement Methods; Approved Guideline - Second Edition 2004
- Clinical and Laboratory Standards Institute (CLSI) EP15-A3, Vol .28, No.3, User Verification of Precision and Estimation of Bias; Approved Guideline - Third Edition
- EP07-A2, Interference Testing in Clinical Chemistry – Approved Guideline – Second Edition 2005

L. Test Principle:

This test is a Chemiluminescence Immunoassay (CLIA) – Immunoassay technology based on the emission of light as a result of a chemical reaction. During the first incubation, *Helicobacter pylori* antibodies present in diluted calibrators, samples or controls bind to the solid phase. During the second incubation, the monoclonal antibody conjugate reacts with anti-*H. pylori* IgG that is already bound to the solid phase. After each of the incubations, unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and therefore, the amount of isoluminol-antibody conjugate, are measured by a photomultiplier as RLUs and are indicative of the presence of anti-*H. pylori* IgG in calibrators, samples or controls.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was assessed by measuring repeatability at one site using two kit controls and six serum samples containing high negative (samples #1 and #2), low positive (samples #3 and #4) and moderate positive (samples #5 and #6) concentrations of *H. pylori* IgG. Samples and kit controls (negative and positive) were assayed in duplicate in two runs per day over 12 operating days with multiple technicians. Mean, standard deviation, and coefficient of variation (%CV) were calculated using multiple sources of variability that included within-run, within-day, between-day, and total variability. The results are summarized in Table 3

Table 3. Precision Study Results

	Mean	Within Run		Within Day		Between Day		Total	
Sample ID	Index	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Ctrl	1341*	115	8.6%	46.8	3.5%	145	10.8%	190	14.2%
Neg Ctrl	1320*	120	9.1%	52.6	4.0%	119	9.0%	177	13.4%
Pos Ctrl	2.77	0.145	5.2%	0.119	4.3%	0.112	4.1%	0.218	7.9%
Pos Ctrl	2.73	0.144	5.3%	0.176	6.5%	0.053	1.9%	0.234	8.6%
Sample #1	0.74	0.049	6.6%	0.043	5.7%	0.051	6.8%	0.082	11.1%
Sample #2	0.71	0.048	6.7%	0.000	0.0%	0.030	4.2%	0.055	7.7%
Sample #3	1.32	0.071	5.4%	0.040	3.1%	0.075	5.7%	0.111	8.4%
Sample #4	1.25	0.081	6.5%	0.015	1.2%	0.053	4.3%	0.098	7.9%
Sample #5	1.52	0.076	5.0%	0.074	4.9%	0.000	0.0%	0.106	7.0%
Sample #6	1.50	0.084	5.6%	0.042	2.8%	0.095	6.3%	0.133	8.9%

Sample N=48

*Precision calculations for the two negative controls were based on the RLU signal instead of the Index value

Reproducibility was assessed across three testing sites using two kit controls and six serum samples containing high negative, low positive and moderate positive concentrations of *H. pylori* IgG and kit controls (negative and positive) as duplicate samples were assayed in replicates of three. Mean, standard deviation, and coefficient of variation (%CV) were calculated using multiple sources of variability that include within-run, within-day, between-day, site to site and total variability. Table 4 illustrates the following results that were obtained from three sites with two kit lots assayed in duplicate in two assays per day over 12 operating days.

Table 4. Reproducibility Study Results

Sample ID	Mean Index	Within Run		Run to Run Within Day		Day to Day Within Site		Site to Site		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Ctrl	1013*	54.0	5.3%	25.4	2.5%	19.1	1.9%	50.4	5.0%	80.4	7.9%
Neg Ctrl	996*	43.7	4.4%	25.4	2.6%	0.900	0.1%	79.8	8.0%	94.5	9.5%
Pos Ctrl	3.34	0.111	3.3%	0.060	1.8%	0.013	0.4%	0.062	1.9%	0.141	4.2%
Pos Ctrl	3.36	0.103	3.1%	0.012	0.4%	0.068	2.0%	0.019	0.6%	0.126	3.7%
Sample #1	0.626	0.035	5.6%	0.010	1.6%	0.016	2.5%	0.061	9.8%	0.073	11.7%
Sample #2	0.628	0.025	4.0%	0.018	2.9%	0.005	0.7%	0.047	7.4%	0.056	9.0%
Sample #3	1.28	0.043	3.4%	0.004	0.3%	0.030	2.4%	0.064	5.0%	0.083	6.5%
Sample #4	1.27	0.050	3.9%	0.011	0.9%	0.035	2.7%	0.044	3.5%	0.076	6.0%
Sample #5	1.82	0.061	3.3%	0.049	2.7%	0.045	2.5%	0.067	3.7%	0.113	6.2%
Sample #6	1.74	0.060	3.4%	0.034	1.9%	0.041	2.4%	0.067	3.8%	0.104	6.0%

Sample N=90

* Precision calculations for the two negative controls were based on the RLU signal instead of the Index value

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

The calibrator concentrations (Index Values) are referenced to an in-house standard preparation.

Stability

Reagents Integral:

Open use stability at 2-8°C was performed using one Reagent Integral Lot at specified intervals. All testing results were acceptable for up to eight weeks. An open use stability of eight weeks at 2-8°C was supported. Open use stability on board the LIAISON® Analyzer was performed using one Reagent Integral Lot at specified intervals. All testing results were acceptable for up to eight weeks (see Table 5a). Controls were tested at 2-8°C and found to be stable up to the stated expiration date if unopened or up to 12 weeks after opening (see Table 5b). Serum sample stability was acceptable for up to three days at 2-8°C or for up to five freeze thaw cycles (see Table 5c).

Table 5a. Reagent stability

Unopened stored @ 2-8°C	Up to the stated expiration date
Opened stored @ 2-8°C	8 weeks
Opened stored on analyzer	8 weeks

Table 5b. Control stability

Unopened stored @ 2-8°C	Up to the stated expiration date
Opened stored @ 2-8°C	12 weeks

Table 5c. Sample stability

Storage @ 2-8°C	3 days
Freeze/Thaw	Up to 5 freeze/thaw cycles

Expected values:

- Calibrator 1 is manufactured to have a target Index value range of 0.80 – 2.2.
- Calibrator 2 is manufactured to have a target Index value range of 4.0 – 8.0.
- The negative control is manufactured to a target Index value less than 0.6*.
- The positive control is manufactured to have a target Index value of 1.75*.

*The target Index value range for each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

d. Detection limit:

Not applicable

e. Analytical specificity:

Cross reactivity:
Controlled studies of potentially cross-reacting microorganisms that may cause symptoms similar to an *H. pylori* infection were performed on the LIAISON® *H. pylori* IgG assay. None of the organisms affected positive or negative test results. Table 6 is a list of all the organisms tested.

Table 6. Cross reactivity organisms

Organism	Organism	Organism
Aeromonas hydrophila	*Enterococcus faecalis*	*Salmonella Group B*
Bacillus cereus	*Escherichia coli*	*Salmonella Group C*
Bacillus subtilis	*Escherichia fergusonii*	*Salmonella Group D*
Campylobacter coli	*Escherichia hermannii*	*Salmonella Group E*
Campylobacter fetus	*Haemophilus influenzae*	*Serratia liquefaciens*
Campylobacter hyointestinalis	*Helicobacter pylori*	*Shigella boydii*
Campylobacter jejuni	*Klebsiella pneumoniae*	*Shigella flexneri*
Campylobacter upsaliensis	*Lactobacillus lactis*	*Shigella sonnei*
Candida albicans	*Listeria monocytogenes*	*Staphylococcus aureus*
Citrobacter freundii	*Peptostreptococcus anaerobius*	*Staphylococcus epidermidis*
Clostridium difficile	*Plesiomonas shigelloides*	*Vibrio parahaemolyticus*
Clostridium perfringens	*Proteus vulgaris*	*Yersinia enterocolitica*
Clostridium sordellii	*Pseudomonas aeruginosa*	
Enterobacter cloacae	*Pseudomonas fluorescens*	

High Dose Hook Effect (false negative):

Analysis of high-dose hook effect was evaluated by testing three samples with *H. pylori* IgG levels out-of-range > 9.4 index values. The testing produced index values that were above the measuring range with no sample misclassification, indicating that no hook effect was observed.

Interference:

Testing was performed to determine interference in the presence of exogenous substances from commonly used medications (Table 7a) relevant to gastrointestinal tract complications or endogenous substances that may be found in serum (Table 7b). Two matched sample pools containing antibodies to *H. pylori* IgG near the clinical decision point (low positive and high negative) were tested neat and spiked with the respective interferent.

Acceptance criteria required that the percent change in signal not be more than +/- 10% and that the qualitative result must not change. No interference was observed in the LIAISON® *H. pylori* IgG at the highest concentration for each substance listed below.

Table 7a Exogenous substances

Substance (Drug)	Tested Concentration
Barium Sulfate	5.0 mg/mL
Stearic Acid	2.65 mg/mL
Palmitic Acid	1.3 mg/mL
Imodium® AD	0.007 mg/mL
Kaopectate	0.87 mg/mL
Metronidazole	12.5 mg/mL
Mucin	3.33 mg/mL

Substance (Drug)	Tested Concentration
Mylanta	4.2 mg/mL
Pepto Bismol®	0.87 mg/mL
MiraLAX®/PEG 3350	25 mg/mL
Prilosec	0.5 mg/mL
Gas X®/ Simethicone	0.625 mg/mL
Tagamet	0.5 mg/mL
Tums®	0.5 mg/mL
Vancomycin	2.5 mg/mL

Table 7b. Endogenous substances

Substance (Endogenous)	Tested Concentration
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Unconjugated bilirubin	40 mg/dL
Conjugated bilirubin	40 mg/dL
Ascorbic Acid	6000 mg/dL
Cholesterol	500 mg/dL
Protein	13500 mg/dL
Whole Blood	25%
White Blood Cells	5%

f. Assay cut-off:

The LIAISON® *H. pylori* IgG assay defines a sample as positive if the Index value is greater than or equal to 0.90 Index, and defined as negative if the Index value is less than 0.80 Index. Samples with results greater than or equal to 0.80 Index and less than 0.90 Index are classified as equivocal.

The preliminary cutoff was determined by testing 417 selected *H. pylori* positive and negative serum samples in parallel with the LIAISON® *H. pylori* IgG assay and a comparison method. This cut-off was validated during clinical studies by testing a prospective population of 504 specimens; that were 110 positive for IgG antibodies to *Helicobacter pylori*, 381 negative for IgG antibodies to *Helicobacter pylori*, and 13 equivocal results as determined by the IMMULITE® 2000 *H. pylori* IgG assay. The 13 equivocal results by the comparison method were not included in the cutoff validation data analysis. The results of the cutoff assay were determined to be appropriate for the LIAISON® *H. pylori* IgG assay.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Comparative testing:

A prospective study was performed to compare the performance of the LIAISON® *H. pylori* IgG assay to an FDA-cleared predicate device. The study consisted of 504 samples from individuals who were sent to the laboratory for *Helicobacter pylori IgG* testing. The age of the patients ranged from 18-91 years old.

The positive percent agreement and negative percent agreement and the 95% confidence interval for each prospective population are shown in Table 8 below: Equivocals from the comparator assay were removed from the analysis. Equivocals from the subject assay were calculated against the performance calculations for Positive Percent Agreement and Negative Percent Agreement.

Table 8. Performance of the LIAISON *H. pylori* IgG Assay

LIAISON® *H. pylori* IgG	Comparator Assay			Total
	Positive	Equivocal	Negative	
Positive	105	7	1	113
Equivocal	1	2	2	5
Negative	4	4	378	386
Total	110	13	381	504

	Percent Agreement	Exact 95% Confidence Intervals
Positive	95.5% (105/110)	90.4 – 98.4%
Negative	99.2% (378/381)	97.9 – 99.8%

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The observed seroprevalence from the LIAISON® *H. pylori* IgG assay was calculated from the 504 samples sent to the lab for *H. pylori* IgG testing. The samples were collected from multiple U.S. geographical locations from 151 male (30%) and 353 female (70%) adult subjects. Known ages ranged from 18 to 91 years.

The *H. pylori* seroprevalence may vary depending upon geographical location, age, gender, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

The *H. pylori* IgG seropervelence as observed with the LIAISON® *H. pylori* IgG assay is 22.4% (113/504) for the current submission. Equivocal results from the LIAISON® *H. pylori* IgG assay are considered negative for the seroprevalence calculations.

N. Instrument Name:

LIAISON® XL Analyzer

O. System Descriptions:

1. Modes of Operation:

The LIAISON® *H. pylori* IgG assay is a two-step, indirect chemiluminescence immunoassay (CLIA) for qualitative determination of IgG antibodies to *H. pylori***.** The principal components of the test are magnetic particles (solid phase) coated with *H. pylori* antigen and a conjugate of anti-human IgG monoclonal antibodies labelled with an isoluminol derivative. During the first incubation, *H. pylori* antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the monoclonal antibody conjugate reacts with *H. pylori* IgG that is already bound to the solid phase. After each incubation, unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and therefore, the amount of isoluminol-antibody conjugate, are measured by a photomultiplier as relative light units (RLU) and are indicative of the presence of *H. pylori* IgG in calibrators, samples or controls.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes _____ or No ____X____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___X_____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ____X____ or No _____

3. Specimen Identification:

   Specimens are identified by unique barcodes

4. Specimen Sampling and Handling:

   Specimens can be processed directly from primary collection vials or as aliquots of the specimen in secondary vials.

5. Calibration:

   DiaSorin's LIAISON® *H. pylori* IgG assay generates a continuous response (relative light units, RLU) which is used in sample grading to provide a qualitative (positive, negative, or equivocal) reportable result. The sample grading is based on the use of a calibration curve referenced to an 'In-house' anti-*H. pylori* IgG reference standard curve (Master Curve) and is controlled by the use of two calibrators (Calibrator 1 and Calibrator 2) provided in the Reagent Integral.

   The Master Curve is stored on the LIAISON® XL Analyzer and specifically matched to the kit in use via the instructions encoded in the RFID tag attached to the Reagent Integral. Each 10 point Master Curve has been generated by a mathematical elaboration of the data resulting from multiple testing (a minimum of 10 runs) of Master Standards.

   The Master Standards are prepared from pooled human serum positive for anti-*H. pylori* IgG also referred to as the 'in house' Primary Standard Reference Preparation.

   The kit calibrators are manufactured by diluting stock solutions consisting of individual or pooled human serum positive for anti-*H. pylori* IgG at an established Index value with Universal Negative Serum according to MP25832 and MP25833. The kit calibrators are tested with a specific Integral lot against the Master Calibrators to assess the concentration. They are subsequently corrected by dilution or concentration if the result (Index value) is out of the target range.

   Calibrator 1 is manufactured to have a target anti-*H. pylori* IgG of 1.2 Index value.
   Calibrator 2 is manufactured to have a target anti-*H. pylori* IgG of 6.0 Index value.

   The Calibrators are assayed by the user with a specific Reagent Integral lot to transform the Master Curve into a Working Curve and further used to calculate sample results. The LIAISON® XL Analyzer Working Curve is obtained by the user during assay calibration by assigning a curve to the two point kit calibrators based upon the Master Curve. This Working Curve is used to calculate the patient sample results. The Analyzer is calibrated in triplicate whenever one of the following conditions occurs:

   - Quality Control results are out of the acceptable range.
   - With each new lot of reagents (Reagent Integral or Starter Reagents)
   - After each servicing of the LIAISON® XL Analyzer
   - The previous calibration was performed more than four weeks before

6. Quality Control:

   LIAISON® *H. pylori* IgG Control Set ([REF] 318981) is intended to monitor for substantial reagent failure. LIAISON® controls should be run in singlicate to monitor the assay performance. Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A35 and 42 CFR 493.1256(c) for guidance on appropriate quality control practices.

   The expected range of control concentrations is provided on the certificate of analysis, the test is valid. If control values lie outside the expected ranges, the test is invalid and patient results cannot be reported. Assay calibration should be performed if a control failure is observed and controls and patient specimens must be repeated.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.