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Changes: § 5
Deletions: §

LIAISON® *H. pylori* IgG (REF 318980)

1. INTENDED USE

The DiaSorin 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® Analyzer Family.*

2. SUMMARY AND EXPLANATION OF THE TEST

Helicobacter pylori is a gram-negative, helix-shaped, bacterium found in the human stomach. It is the causative agent of chronic gastritis or inflammation of the stomach lining, duodenal and stomach ulcers, and is associated with an increased risk of stomach cancer.[1] Although the exact route of transmission is not known; oral-oral and/or fecal-oral routes are generally accepted.[2, 3] Once colonization of the stomach is established, *H. pylori* will likely persist indefinitely unless antimicrobial intervention is prescribed.
Unlike a majority of bacterial species, *H. pylori* are capable of colonizing the harsh acidic environment of the stomach. To accomplish this, *H. pylori* uses flagella to actively burrow through the mucus reaching the stomach's epithelial cell layer.[4] Additionally, *H. pylori* produces urease, which degrades urea into carbon dioxide and ammonia, helping to neutralize the gastric acid present in the stomach.
Several methods are used to diagnose *H. pylori* infection including gastric biopsy, UBT (urea breath test), stool antigen, and serological testing. The LIAISON® *H. pylori* IgG assay detects the presence of IgG antibodies to *H. pylori* antigen in human serum. Serological testing is the first choice for the detection of *H. pylori* infection because it is easy to perform compared to the more invasive diagnostic tests. However, a positive serologic test does not confirm the active disease. It indicates the presence of *H. pylori* antibodies which confirms both a possibility for past infections or potential current infections.

3. PRINCIPLE OF THE PROCEDURE

The LIAISON® *H. pylori* IgG assay is a 2-step, indirect assay 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, is measured by a photomultiplier as relative light units (RLU) and is indicative of the presence of *H. pylori* IgG in calibrators, samples or controls.

4. MATERIALS PROVIDED

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.

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

All reagents are supplied ready to use. The order of reagents reflects the layout of containers in the Reagent Integral.

*(LIAISON® and LIAISON® XL)

Materials required but not provided (system related)

LIAISON® XL Analyzer	LIAISON® 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)	LIAISON® Wash/System Liquid (REF 319100) LIAISON® Waste Bags (REF 450003) LIAISON® Module (REF 319130) LIAISON® Starter Kit (REF 319102) LIAISON® XL Starter Kit (REF 319200) LIAISON® Cleaning Kit (REF 310990) LIAISON® Light Check 12 (REF 319150)

Additional required materials:
LIAISON® *H. pylori* IgG Control Set (REF 318981)

5. WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC- Not for internal or external use in humans or animals.

General Safety:

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipette solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country.
- Do not use kits or components beyond the expiration date given on the label.

Chemical Hazard and Safety Information: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

Reagents Containing Human Source Material:
Warning – Treat as potentially infectious. Each serum/plasma donor unit used in the preparation of this product has been tested by an U.S. FDA approved method and found non-reactive for the presence of the antibody to Human Immunodeficiency Virus 1 and 2 (HIV 1/2), the Hepatitis B surface antigen (HBsAg), and the antibody to Hepatitis C (HCV). While these methods are highly accurate, they do not guarantee that all infected units will be detected. This product may also contain other human source diseases for which there is no approved test. Because no known test method can offer complete assurance that HIV, Hepatitis B Virus (HBV) and HCV or other infectious agents are absent, all products containing human source material should be handled following universal precautions; and as applicable in accordance with good laboratory practices as described in the Centers for Disease Control and the National Institutes of Health current manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL); or the World Health Organization current edition, Laboratory Biosafety Manual.

GHS/CLP:

	ProClin®	Sodium Azide
CAS No.:	55965-84-9	26628-22-8
Reagents:	CAL 1 CAL 2 CONJ DIL SPE	SORB CAL 1 CAL 2
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3	None required
Signal Word:	Warning	None required
Pictogram:	 GHS07 – Exclamation mark	None required
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects.	None required
Precautionary Statements:	P261 – Avoid breathing mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing, and eye protection.	None required

REAGENTS CONTAINING SODIUM AZIDE: 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.

6. PREPARATION OF THE REAGENT INTEGRAL

Please note the following important reagent handling precautions:

6.1 Resuspension of magnetic particles

Magnetic particles must be completely resuspended before the integral is placed on the instrument. Follow the steps below to ensure complete suspension:

- Before the seal is removed, rotate the small wheel at the magnetic particle compartment until the color of the suspension has changed to brown. Gentle and careful side-to-side mixing may assist in the suspension of the magnetic particles (avoid foam formation). Visually check the bottom of the magnetic particle vial to confirm that all settled magnetic particles have resuspended.
- Repeat as necessary until the magnetic particles are completely resuspended.
- After removal of the seal carefully wipe the surface of each septum to remove residual liquid if necessary.

6.2 Foaming of reagents

In order to ensure optimal performance of the integral, foaming of reagents should be avoided. Adhere to the recommendation below to prevent this occurrence:

- Visually inspect the reagents to ensure there is no foaming present before using the integral. If foam is present after re-suspension of the magnetic particles, place the integral on the instrument and allow the foam to dissipate. The integral is ready to use once the foam has dissipated and the integral has remained onboard and mixing.

6.3 Loading of integral into the reagent area

LIAISON® Analyzer

- Place the integral into the reagent area of the analyzer with the bar code label facing left and let it stand for 30 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

LIAISON® XL Analyzer

- LIAISON® XL Analyzer is equipped with a built-in solid-state magnetic device which aids in the dispersal of microparticles prior to placement of a Reagent Integral into the reagent area of the analyzer. Refer to the analyzer operator's manual for details.
    a. Insert the reagent integral into the dedicated slot.
    b. Allow the reagent integral to remain in the solid-state magnetic device for at least 30 seconds (up to several minutes). Repeat as necessary.

- Place the integral into the reagent area of the analyzer with the label facing left and let it stand for 15 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

7. STORAGE AND STABILITY OF THE REAGENT INTEGRAL

Upon receipt, the Reagent Integral must be stored in an upright position to facilitate re-suspension of magnetic particles. When the Reagent Integral is stored unopened the reagents are stable at 2-8°C up to the expiration date. Do not freeze. The Reagent Integral should not be used past the expiration date indicated on the kit and Reagent Integral labels. After removing seals Reagent Integral may be returned to the kit box and stored upright at 2-8°C or stored on board the Analyzer for 8 weeks. Refer to Section 9 for calibration intervals.

8. SPECIMEN COLLECTION AND PREPARATION

This assay can only test human serum samples. Blood should be collected aseptically by venipuncture. Serum samples should be allowed to clot. Centrifuge samples and separate serum from the clot as soon as possible. No additives or preservatives are required to maintain integrity of the sample. Samples having particulate matter, turbidity, lipemia, or erythrocyte debris may require clarification by filtration or centrifugation before testing. Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. Check for and remove air bubbles before assaying.
Samples are stable at room temperature for up to 24 hours. If the assay is performed within 8 days of sample collection, the samples should be kept at 2-8°C; otherwise they should be stored frozen (-20°C or below). If samples are stored frozen, mix thawed samples well before testing. Samples may be frozen-thawed 5 times. Self-defrosting freezers are not recommended for sample storage.

The minimum specimen volume required for a single determination is 160 µL [10 µL specimen for testing + 150 µL dead volume (volume left at the bottom of the aliquot tube which the instrument cannot aspirate)].

9. CALIBRATION

Individual LIAISON® *H. pylori* IgG Reagent Integrals contain specific information for calibration of the particular Reagent Integral lot. Test of assay specific calibrators allows the detected relative light units (RLU) values to adjust the assigned master curve. Each calibration solution allows for 8 calibrations to be performed.
Recalibration in triplicate is mandatory whenever at least 1 of the following conditions occurs:

- With each new lot of reagents (Reagent Integral or Starter Reagents).
- The previous calibration was performed more than 4 weeks prior.
- Quality Control results are out of the acceptable range.
- The Analyzer has been serviced.

Refer to the analyzer operator's manual for calibration instructions.

Measuring range: The LIAISON® *H. pylori* IgG assay measures between 0.01 and 9.4 Index value.
The lowest reportable value is 0.01 Index. Values below 0.01 Index should be reported as < 0.01 Index.
Values above 9.4 Index should be reported as > 9.4 Index.

10. ASSAY PROCEDURE

To ensure proper test performance, strictly adhere to the operating instructions of the Analyzer.

LIAISON® Analyzer: Each test parameter is identified via the bar codes on the reagent integral label. In the event that the barcode label cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instruction.

LIAISON® XL Analyzer: Each test parameter is identified via information encoded in the Reagent Integral Radio Frequency Identification transponder (RFID Tag). In the event that the RFID Tag cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral: contact your local DiaSorin technical support for instruction.
For details, refer to the analyzer operator's manual

The analyzer operations are as follows:

LIAISON®:

1. Dispense sample, calibrator or control into reaction module.
2. Dispense specimen diluent and magnetic particle into reaction module.
3. Incubate
4. Wash with Wash/System liquid
5. Dispense conjugate into reaction cuvette
6. Incubate
7. Wash with Wash/System liquid
8. Add the Starter Reagents and measure the light emitted

LIAISON® XL:

1. Dispense specimen diluent and magnetic particle into reaction cuvette
2. Dispense sample, calibrator or control into reaction cuvette
3. Incubate
4. Wash with Wash/System liquid
5. Dispense conjugate into reaction cuvette
6. Incubate
7. Wash with Wash/System liquid
8. Add the Starter Reagents and measure the light emitted

11. QUALITY CONTROL

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-A3[5] and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

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. If control values lie within the expected ranges 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.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should be established for all quality control materials used.

The range of concentrations of 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.

12. INTERPRETATION OF RESULTS

Test results are reported as positive or negative for the presence of IgG antibodies to *H. pylori*. However, diagnosis of infectious diseases should not be established on the basis of a single test result, but should be determined in conjuction with clinical findings and other diagnostic procedures as well as in association with medical judgement.

The Analyzer automatically calculates *H. pylori* IgG levels expressed as Index values and grades the results. For details, refer to the analyzer operator's manual.

Warning – If the sample result displays "invalid RLU" and an exclamation mark (!) flag, the result obtained lies below the assay signal range. The sample must be retested. If the sample upon retest still displays "invalid RLU", call DiaSorin Technical Support.

The cut-off value for the LIAISON® *H. pylori* IgG assay was determined to be an index value of 0.85.
Patient results should be interpreted as follows:

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*.

Note: The magnitude of the reported Index value is not indicative of the amount of *H. pylori* IgG present in the patient sample.

13. LIMITATIONS OF THE PROCEDURE

1. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.
2. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
3. Bacterial contamination of samples may affect the test results.
4. Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination are not recommended and should not be tested.
5. Do not heat inactivate serum.
6. Heterophilic antibodies in human serum can react with reagent immunoglobulins or other reagent material, interfering with *in vitro* immunoassays.
7. Patients routinely exposed to animals, animal serum products, or other immunogenic products that may elicit heterophilic antibody production against the assay's reagents can be prone to this interference and anomalous values may be observed.
8. The LIAISON® *H. pylori* IgG assay has not been evaluated in a pediatric population.
9. *Borrelia burgdorferi* was not tested in the cross-reactivity study.

Integrals may not be exchanged between analyzer types (LIAISON® and LIAISON® XL). Once an integral has been introduced to a particular analyzer type, it must always be used on that analyzer until it has been exhausted. Due to traceability issues resulting from the above statement, patient follow-ups may not be concluded between analyzer types. These must be accomplished on one particular analyzer type (either LIAISON® or LIAISON® XL).

14. EXPECTED VALUES

Stomach colonization by the bacterium *H. pylori* is extremely common in humans; approximately two-thirds of the world's population is infected with *H. pylori*.[8] Although generally asymptomatic, it can lead to duodenal and gastric ulcers. *H. pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.[8] The infection rates can vary from 20 to 30% in economically developed regions to 80 to 90% in developing regions.[9]

15. SPECIFIC PERFORMANCE CHARACTERISTICS

15.1 Method Correlation:

A total of 504 serum samples, prospectively collected from subjects sent to laboratory for *H. pylori* IgG testing, were tested by the LIAISON® *H. pylori* IgG assay and a comparator *H. pylori* IgG assay. Results are summarized in the table below.

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

Positive Agreement = (105/110) 95.5% 95% CI (90.4% - 98.4%)
Negative Agreement = (378/381) 99.2% 95% CI (97.9% - 99.8%)
Overall Agreement = (485/504) 96.2% 95% CI (94.3% - 97.7%)

15.2 Precision

LIAISON® Analyzer: 2 kit controls run as duplicate samples, and 6 serum samples were prepared and tested at DiaSorin Inc. twice per day in duplicate, over 12 operating days on 1 LIAISON® Analyzer, with multiple technicians using 1 reagent lot to determine precision of the LIAISON® *H. pylori* IgG assay. Samples were prepared to the following levels: 2 high negative, 2 low positive, 2 moderate positive. The testing was performed according to CLSI EP5-A3[6].

	Sample	Mean Index	Within-Run		Within-Day		Between-Day		Total	
Sample ID	N	Value	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Control	48	641*	25.4*	4.0%*	9.7*	1.5%*	10.1*	1.6%*	29.0*	4.5%*
Neg Control	48	619*	40.2*	6.5%*	7.3*	1.2%*	10.5*	1.7%*	42.2*	6.8%*
Pos Control	48	2.85	0.08	2.8%	0.04	1.3%	0.09	3.0%	0.12	4.3%
Pos Control	48	2.88	0.07	2.4%	0.08	2.9%	0.08	2.8%	0.14	4.7%
High Neg #1	48	0.66	0.02	2.6%	0.01	1.8%	0.03	4.3%	0.04	5.4%
High Neg #2	48	0.67	0.04	6.4%	0.00	0.0%	0.04	5.6%	0.06	8.3%
Low Pos #3	48	1.22	0.05	4.0%	0.05	4.5%	0.05	4.3%	0.09	7.4%
Low Pos #4	48	1.28	0.02	1.5%	0.01	0.8%	0.05	3.8%	0.05	4.1%
Mod Pos #5	48	1.31	0.10	7.5%	0.00	0.0%	0.03	2.0%	0.09	7.0%
Mod Pos #6	48	1.31	0.06	4.4%	0.06	4.3%	0.05	4.1%	0.10	7.4%

*Negative Kit Control precision calculations are based on signal (RLU).

LIAISON® XL Analyzer: 2 kit controls run as duplicate samples, and 6 serum samples were prepared and tested at DiaSorin Inc. twice per day in duplicate, over 12 operating days on 1 LIAISON® XL Analyzer, with multiple technicians using 1 reagent lot to determine precision of the LIAISON® *H. pylori* IgG assay. Samples were prepared to the following levels: 2 high negative, 2 low positive, 2 moderate positive. The testing was performed according to CLSI EP5-A3[6].

	Sample	Mean Index	Within-Run		Within-Day		Between-Day		Total	
Sample ID	N	Value	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Control	48	1341*	115*	8.6%*	46.8*	3.5%*	145*	10.8%*	190*	14.2%*
Neg Control	48	1320*	120*	9.1%*	52.6*	4.0%*	119*	9.0%*	177*	13.4%*
Pos Control	48	2.77	0.14	5.2%	0.12	4.3%	0.11	4.1%	0.22	7.9%
Pos Control	48	2.73	0.14	5.3%	0.18	6.5%	0.05	1.9%	0.23	8.6%
High Neg #1	48	0.74	0.05	6.6%	0.04	5.7%	0.05	6.8%	0.08	11.1%
High Neg #2	48	0.71	0.05	6.7%	0.00	0.0%	0.03	4.2%	0.05	7.7%
Low Pos #3	48	1.32	0.07	5.4%	0.04	3.1%	0.07	5.7%	0.11	8.4%
Low Pos #4	48	1.25	0.08	6.5%	0.01	1.2%	0.05	4.3%	0.10	7.9%
Mod Pos #5	48	1.52	0.08	5.0%	0.07	4.9%	0.00	0.0%	0.11	7.0%
Mod Pos #6	48	1.50	0.08	5.6%	0.04	2.8%	0.09	6.3%	0.13	8.9%

*Negative Kit Control precision calculations are based on signal (RLU).

15.3 Interfering Substances

Controlled studies of potentially interfering substances from commonly used medications relevant to digestive complications and endogenous interferents was performed in low positive and high negative *H. pylori* IgG serum showed no interference in the LIAISON® *H. pylori* IgG at the highest concentration for each substance listed below. The testing was based on CLSI-EP7-A2[7].

Interfering Substance: Drug

Substance (Drug)	Concentration Tested
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
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

Endogenous Substance

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%

15.4 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 at a final concentration of 1.2 x 10^7 CFU/mL. Low positive and high negative *H. pylori* IgG serum were spiked with each microorganism and tested by the LIAISON® *H. pylori* IgG assay. None of the organisms affected positive or negative test results.

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*	

15.5 High Dose Hook Effect

No High dose hook effect was observed for *H. pylori* IgG concentrations in serum up to > 9.4 Index values.

16. References

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