510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K082049

B. Purpose for Submission:

New device

C. Measurand:

Total antibodies to Hepatitis A virus (HAV)

D. Type of Test:

Qualitative Chemiluminescence Immunoassay

E. Applicant:

DiaSorin Inc.

F. Proprietary and Established Names:

LIAISON® Anti- HAV and the LIAISON® Control Anti-HAV

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3310 – Hepatitis A Virus Serological Reagents

2. Classification:

   Class II (Special Controls)

3. Product code:

   LOL: Hepatitis A Test (antibody and IgM antibody), JJX

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use(s):
   The LIAISON® Anti-HAV assay is an in vitro chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

   This assay is not intended for screening blood or solid or soft tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing assay performance characteristics in these populations.

   Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

   The LIAISON® Control Anti-HAV (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Anti-HAV assay.

   The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms.

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® Analyzer

I. Device Description:
The method for qualitative determination of anti-HAV is a competitive sandwich chemiluminescence immunoassay (CLIA) based on neutralization. The assay uses magnetic particles (solid phase) coated with IgG antibodies to HAV (mouse monoclonal), and a mouse monoclonal anti- HAV antibody conjugate linked to an isoluminol derivative (isoluminol-antibody conjugate).

The first incubation step consists of adding the HAV antigen to calibrators, samples or controls, during which anti-HAV present in calibrators, samples or controls binds to a fixed and limited amount of HAV, thus forming an HAV-anti-HAV immune complex. After this step the second incubation follows and it involves addition of magnetic microparticles and conjugate into the reaction module, during which the antibody conjugate and the solid-phase antibody compete with anti-HAV present in the specimen for HAV, that allows the conjugate to bind to the solid phase and thus formation of a sandwich. If all HAV added is sequestered in an HAV-anti-HAV immune complex during the first incubation, no sandwich is formed during the second incubation. After the second incubation, the 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 hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is inversely indicative of anti-HAV present in calibrators, samples or controls.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   DiaSorin ETI-AB-HAVK PLUS.

2. Predicate PMA number(s):

   P890019/S005

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients	Qualitative determination of total antibodies to hepatitis A virus (anti-HAV) in human serum or plasma. This assay is indicated as an aid in the diagnosis of current or previous hepatitis A virus infection and as an aid in the identification of HAV-susceptible individuals for vaccination.
Specimen Matrix	Serum or heparinized plasma	Serum or plasma
Antigen	HAV	HAV
Standardization	Anti-HAV Reference preparation,	WHO Anti-HAV

Similarities		
Item	Device	Predicate
	the level of reactivity corresponds to 20 mIU/ml	Immunoglobulin 2nd International Standard 20mIU/ml
Controls (level)	2 (Negative and Positive)	2 (Negative and Positive)

Differences		
Item	Device	Predicate
Assay Technology	Competitive Sandwich chemiluminescence immunoassay (CLIA) based on neutralization	Competitive Sandwich enzyme linked immunoassay (EIA) based on neutralization
Capture Reagent	Magnetic particles coated with mouse monoclonal antibody to HAV	Micro-titer wells coated with mouse monoclonal antibody to HAV
Detector/Tracer	Mouse monoclonal antibody to HAV conjugated to isoluminol derivative.	Horseradish Peroxidase-labeled mouse monoclonal antibody to HAV.
Sample handling and processing	Automated	Manual
Measurement System	Photomultiplier (flash chemiluminescence reader)	Spectrophotometer (EIA Micro-titer plate reader)
Sample Volume	80μl	50μl
Calibrators	two	one
Total Incubation	50 minutes	3.5 hours

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

1. Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays, Feb. 9, 2006. http://www.fda.gov/cdrh/ode/guidance/1536.pdf

2. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. http://www.fda.gov/cdrh/ode/guidance/337.pdf

3. CLSI EP15-A2, User verification of Performance for Precision and Trueness; 2006

4. CLSI EP07-A2, Interference Testing in Clinical Chemistry; 2005

5. CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; 2004

6. GP10-A, Assessment of Clinical Accuracy of Laboratory Tests using Receiver Operating Characteristic (ROC) Plots; 2004

L. Test Principle:

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Chemiluminescence Immunoassay (CLIA)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*

    A five-day reproducibility/precision study was conducted at three external
    laboratories. A panel comprised of 12 frozen coded samples prepared by
    spiking positive serum samples into negative serum samples to achieve high
    negative, low positive and high positive results, was prepared by DiaSorin
    S.p.A. and provided to the sites. The two negative panel samples were not
    spiked. The LIAISON® Control Anti-HAV set was also included in the five-
    day study. The coded panel was tested at all three sites, using four replicates
    per run in one run per day for five operating days. The mean Index value,
    standard deviation, and coefficient of variation (%CV) of the results were
    computed for each of the tested specimens for each of the sites:

Sample ID	Site 1 Mean Index	Site 1 Total SD	Site 1 Total %CV	Site 2 Mean Index	Site 2 Total SD	Site 2 Total %CV	Site 3 Mean Index	Site 3 Total SD	Site 3 Total %CV	Overall (3 sites) Mean Index	Overall Total SD	Overall Total %CV
NC	>>2.7	NA	NA	>>2.7	NA	NA	>>2.7	NA	NA	>>2.7	NA	NA
PC	0.42	0.03	7.2	0.36	0.03	7.3	0.20	0.07	10.8	0.33	0.10	30.0
HAVu-e1	1.13	0.10	8.9	0.92	0.08	8.9	0.99	0.04	3.9	1.01	0.12	11.5
HAVu-e2	1.14	0.13	11.2	0.93	0.08	8.4	0.98	0.03	3.3	1.01	0.12	12.3
HAVu-e3	1.17	0.11	9.4	0.95	0.08	8.5	0.97	0.05	5.2	1.03	0.13	12.5
HAVu-e4	1.21	0.15	12.4	1.00	0.10	9.8	1.03	0.04	4.1	1.08	0.14	13.2
HAVu-n1	1.47	0.16	11.2	1.29	0.14	11.2	1.20	0.06	4.9	1.33	0.17	12.4
HAVu-n2	1.33	0.21	16.1	1.07	0.08	7.6	1.16	0.06	4.9	1.19	0.17	14.5
HAVu-p1	0.27	0.03	12.4	0.23	0.02	8.6	0.29	0.02	7.4	0.26	0.04	14.5
HAVu-p2	0.16	0.02	11.6	0.10	0.05	45.5	0.16	0.02	9.5	0.14	0.04	28.1
HAVu-p3	0.84	0.10	12.0	0.67	0.08	12.2	0.67	0.03	4.3	0.73	0.11	15.0
HAVu-p4	0.89	0.09	9.9	0.72	0.07	9.4	0.76	0.03	3.6	0.79	0.10	12.5
HAVu-p5	1.00	0.08	8.3	0.80	0.10	12.0	0.84	0.03	3.7	0.88	0.11	12.8
HAVu-p6	0.84	0.09	10.8	0.67	0.08	11.7	0.72	0.03	4.4	0.74	0.11	13.4

    b. *Linearity/assay reportable range:*

    Not Applicable

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

    Controls:

The DiaSorin LIAISON® Anti-HAV immunoassay uses two controls contained in the LIAISON® Control Anti-HAV kit at different reactivities of anti-HAV. The Negative Control is intended to provide an assay response characteristic of negative patient specimens (targeted range >1.75 Index). The Positive Control is intended to provide an assay response characteristic of positive patient specimens (targeted range 0.07-0.70 Index). The Positive Control is prepared by diluting human serum/defibrinated plasma at high level of anti-HAV with fetal calf serum, while the Negative Control consists of human serum/defibrinated plasma not reactive for anti-HAV. The Controls are tested for release with approved Reagent Integral lots to determine their Index. If necessary, the potency of the Positive Control may be adjusted until the test results fall within the target range. When the expected Index is obtained, the Positive Control is filled into vials and tested again on an approved Reagent Integral lot to assess the final Index.

Calibration:

DiaSorin's LIAISON® Anti-HAV 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 HAV antibody preparation and controlled by the use of two calibrators (Calibrator 1 and Calibrator 2) provided in the Reagent Integral. The calibrators are assayed by the user to transform the kit lot specific Master Curve into a Working Curve. The Master Curves are stored on the LIAISON® Analyzer and specifically matched to the kit in use via the instructions encoded in the bar codes printed on the Reagent Integral label. Each Master Curve is generated by a mathematical elaboration of the data resulting from multiple testing (at least 10 runs) of an internal Reference Calibration Curve. During user calibration, the Calibrator results are used to create a Working Curve by mathematical adjustment of the Master Curve. The Working Curve is then used to calculate sample results. The analyzer is calibrated in triplicate whenever one of the following conditions occurs (see LIAISON® Analyzer Operator's manual):

- A new lot of Reagent Integral or a new lot of Starter Kit is used.
- The previous calibration was performed more than two weeks before.
- The analyzer has been serviced.
- Control values lie outside the expected ranges.

Calibrator 1 is calibrated at 0.16-0.39 Index units and Calibrator 2 at 2.0-4.0 Index units. Calibrator 1 is manufactured by diluting human positive anti-HAV serum/defibrinated plasma with fetal calf serum to obtain the target Index. Calibrator 2 consists of human serum/defibrinated plasma negative for anti-HAV. The lot-specific Index values of the Calibrators are encoded on bar codes printed on the Reagent Integral label. The process by which assay

calibration is established and maintained is comprised of the following steps:

• Creation of an 'In-house' Reference Preparation during the development phase. This step involves the selection of appropriate serum/defibrinated plasma and assignment of an arbitrary Index value. The final material is dispensed in aliquots and stored frozen. It is used as anti-HAV Standard Curve for calibration of Reagent Integral lots.

• Prior to depletion of the current Reference Preparation, a new Reference Preparation is prepared by the selection of appropriate serum/defibrinated plasma material, serial dilution with human negative serum/defibrinated plasma, and assignment of Index values to the obtained points by calibration against the current Reference Preparation.

d.   *Detection limit:*

Not Applicable

e.   *Analytical specificity:*

The analytical specificity of the LIAISON® Anti-HAV assay was evaluated using 346 samples. The samples were confirmed positive for the following potential cross reacting agents: viruses that may cause symptoms similar to HAV infection (EBV, CMV, Rubella, Measles, Mumps, HBV, HCV), other organisms that may cause infectious disease (VZV, HSV, HIV, *Toxoplasma gondii*) and from other conditions that may result from atypical immune system activity (i.e. rheumatoid factor, RF, antinuclear autoantibodies, ANA). All samples tested were confirmed negative to Anti-HAV antibodies using an FDA cleared device. From the 346 samples tested 8 samples were positive and 6 were equivocal on the Liaison® Anti-HAV test. The incident of the discordant samples is not significantly different from the claimed assay specificity. The potential cross reactivity was identified to be due to antibodies against HIV 1/2, anti-nuclear autoantibodies and rheumatoid factor.

Organism/Condition	N	Comparator Anti-HAV Assay	LIAISON® Anti-HAV Positive	LIAISON® Anti-HAV Negative	LIAISON® Anti-HAV Equivocal
Anti-VZV (IgG)	22	Negative	0	22	0
Anti-VZV (IgM)	3	Negative	0	3	0
Anti-EBV VCA IgG	21	Negative	0	21	0
Anti-EBV EA IgG	14	Negative	0	14	0
Anti-Toxoplasma IgG	7	Negative	0	7	0
Anti-Toxoplasma IgM	10	Negative	0	10	0
Anti-HBs	11	Negative	0	11	0
Anti-HBc IgM	13	Negative	0	13	0

Organism/Condition	N	Comparator Anti-HAV Assay	LIAISON® Anti-HAV Positive	LIAISON® Anti-HAV Negative	LIAISON® Anti-HAV Equivocal
Anti-HBc	25	Negative	0	25	0
Anti-HBe	3	Negative	0	3	0
HBeAg	23	Negative	0	23	0
HBsAg	27	Negative	0	27	0
Anti-CMV IgG	14	Negative	0	14	0
Anti-Rubella IgG/IgM	29	Negative	0	29	0
Anti-HSV 1 / 2 IgG	25	Negative	0	24	1
Anti-HSV 2 IgG	19	Negative	0	19	0
Anti-HIV 1 / 2	4	Negative	4	0	0
Anti-HCV	5	Negative	0	5	0
Anti-Mumps IgG	8	Negative	0	8	0
Anti-Measles IgG	3	Negative	0	3	0
Anti-Measles IgM	11	Negative	0	11	0
RF+	5	Negative	2	2	1
ANA	24	Negative	2	19	3
ENA	3	Negative	0	2	1
Nucleotides	1	Negative	0	1	0
γ-globulin	6	Negative	0	6	0
HAMA	10	Negative	0	10	0
Total	346		8	332	6

DiaSorin evaluated the effect of potential interfering substances on sample results generated using the LIAISON® Anti-HAV based on the guidelines established in CLSI EP7-A2. Twelve samples at different anti-HAV levels (2 positive, 4 borderlines, 4 equivocal, 2 high negative) were prepared with and without the potentially interfering substances hemoglobin, triglycerides, bilirubin and albumin. All samples were tested with the LIAISON® anti-HAV assay and results were compared using a paired t-test. The results showed that the assay performance was not affected by hemolysis at ≤1000 mg/dL hemoglobin (2% change, 100% concordance of results with and without interferent), lipemia at ≤3000 mg/dL triglycerides (7% change, 92% (11/12) concordance of results with and without interferent), icterus at ≤5 mg/dL bilirubin (0% change, 100% concordance of results with and without interferent) and serum albumin at ≤5 g/dL (3% change, 92% (11/12) concordance of results with and without interferent).

f. *Assay cut-off:*

The analytical sensitivity represents the cut-off dose that is the dose discriminating between presence and absence of the analyte. It was evaluated by testing the anti-HAV WHO International Standard (Anti-Hepatitis A Immunoglobulin 2nd International Standard (1998). The WHO preparation

was serially diluted to obtain dilutions at the nominal values of 80, 40, 20, 10 and 5 mIU/mL. The dilutions were tested in the LIAISON® Anti HAV assay for three days, two runs per day using two different kit lots. A summary of the results is presented in the table below. The obtained analytical sensitivity calculated by interpolation of the cut-off value on the obtained curve, was 18 mIU/mL.

WHO expected values mIU/ml	Mean Index	sd	+2sd	-2sd
80	0.20	0.023	0.25	0.16
40	0.43	0.040	0.51	0.35
20	0.90	0.061	1.02	0.78
10	1.53	0.126	1.78	1.27
5	2.09	0.114	2.32	1.86

The cut-off was set at an index value of 1.0 which is corresponds to approximately 20mIU/ml. The accuracy of the assays cut-off was analysedby ROC analysis using 997 clinical samples. The analysis demonstrated that the selected cut-off provides the best level of specificity without compromising sensitivity and a grey zone of +/- 10% of the cut-off was included to address the observed assay imprecision. The cut-off was validated in U.S. clinical trials in which 998 samples were tested. The samples consisted of single samples from different selected populations (500 samples from individuals who were sent to the laboratory for Hepatitis A testing, 239 samples from individuals who were considered to be 'at risk' for viral hepatitis, 108 samples from a pediatric population and 151 samples from individuals who have a current or had a previous HAV infection). Based on available clinical and laboratory data, the samples were classified as expected negative or positive for antibodies to Hepatitis A and were evaluated with the LIAISON® Anti-HAV assay.

Analytical sensitivity demonstrated by Seroconversion Panel Performance
Four commercially available HAV seroconversion panels and one mixed titer panel were tested using LIAISON® Anti-HAV and the FDA approved comparator assay to determine the sensitivity of the assay. The results are summarized in the following table:

Sero-conversion Panel ID	DiaSorin LIAISON HAV		Comparator Assay		Difference in Days from Last Positive Result
	Post Bleed Day of Earliest Positive Result	Post Bleed Day of Last Positive Result	Post Bleed Day of Earliest Positive Result	Post Bleed Day of Last Positive Result	
PHT902	3	163	0	163	0
RP004	0	62	6	62	0
RP013	8	189	8	189	0
HAV01	0	91	0	91	0

2. Comparison studies:

    a. *Method comparison with reference method:*

    Prospective and retrospective studies were performed to compare the performance of the LIAISON® Anti-HAV assay to an FDA cleared predicate device. The prospective study consisted of 739 samples from individuals who were sent to the laboratory for HAV testing or samples from individuals "At Risk" for viral hepatitis, 108 samples from a pediatric population and 73 adults who participated in a vaccine study.

    The retrospective study consisted of 109 samples from adults with a current or previous hepatitis A infection and 42 pediatric patients with current hepatitis A infection:

    The data was analyzed including counting the equivocal results from the comparator and the investigational device against the performance of the investigational device.

    Prospective

    HAV Testing and At Risk Populations

    Of the 739 samples in this study 500 were excess serum samples from individuals in the Northeastern U.S. sent to the laboratory for HAV testing. In this group 59.8% were female (n=299) ranging in age from 20 - 101 yrs. and 40.2% were male (n=201) ranging in age from 17 to 89. The remaining 239 samples were from individuals at risk for viral hepatitis due to lifestyle, behavior or occupation. This group consisted of the following: homosexual males (n=38), healthcare workers (n=10), commercial sex workers (n=34), drug users (n=77), prison inmates (n=49), dialysis patients (n=25) and hemophiliacs (n=6). Of these subjects 29.7% were females (n=71) ranging in age from 17 to 79, and 43.1% were males (n=103) ranging in age from 16 to 79. The age and gender were unknown for the remaining 27.2% (n=65).

    Two samples were Equivocal by the Comparator ELISA assay after repeat testing per the Instructions for use.

    The data for the populations are shown in the tables below.

HAV Testing Population and the At Risk Population

		Predicate ELISA					
		Positive	Borderline	Negative	Total	PPA& NPA	95% Confidence Interval
LIAISON® Anti-HAV	Positive	230	0	3	233	230/239= 96.6%	93.5-98.0
	Equivocal	1	1	2	4		
	Negative	7	1	494	502	494/499= 99.0%	97.9-99.6
	Total	238	2	499	739		

Pediatric Population

		Predicate ELISA					
		Positive	Indeterminate	Negative	Total	PPA& NPA	95% Confidence Interval
LIAISON® Anti-HAV	Positive	11	0	2	13	11/14= 78.6%	49.2-95.3
	Equivocal	1	0	1	2		
	Negative	1	1	91	93	91/94= 96.8%	92.0-99.1
	Total	13	1	94	108		

Retrospective

Of the 151 retrospective samples 109 were from adults with a current or previous hepatitis A infection collected in Eastern U.S. and Egypt. They consisted of 31.2% females (n=34) and 35.8% males (n=39) ranging in age from 18 to 51. For 32.1% (n=35) of the samples, gender and age were unknown. One sample (0.9%) was 18 years of age, with an unknown gender. The other 42 samples were from pediatric patients with current hepatitis A infection collected in Egypt. They consisted of 31% female (n=13) and 69% male (n=29), ranging in age from 4-17 years.

Current/Previous HAV Infection Adult Population

		Predicate ELISA					
		Positive	Indeterminate	Negative	Total	PPA& NPA	95% Confidence Interval
LIAISON® Anti-HAV	Positive	109	0	0	109	109/109= 100%	98-100%
	Equivocal	0	0	0	0		
	Negative	0	0	0	0	NA	NA
	Total	109	0	0	109		

Current HAV Infection Pediatric Population

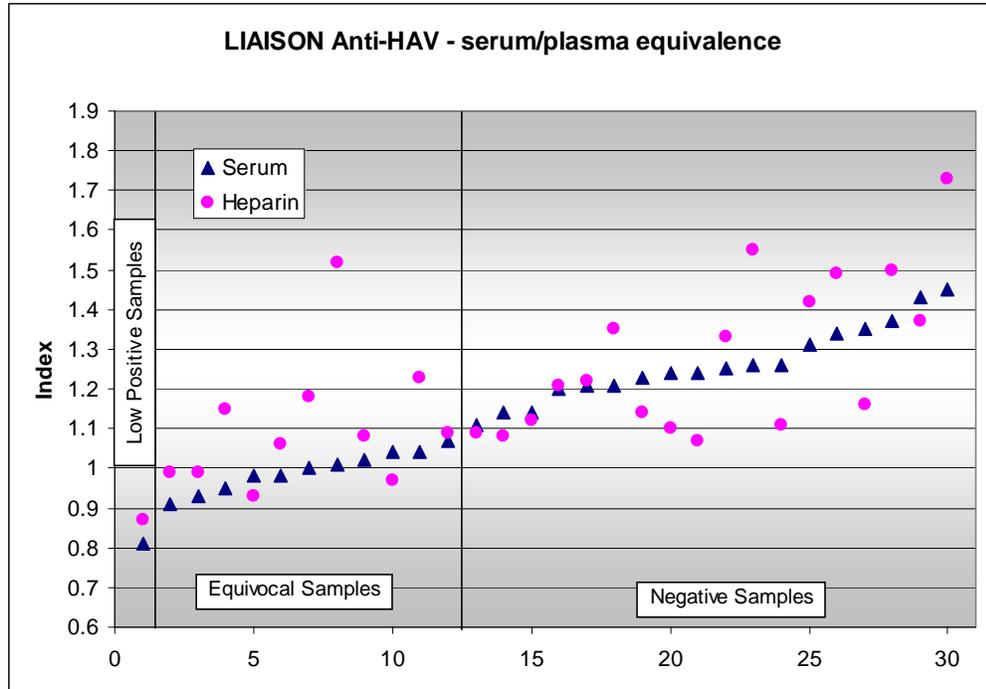|		Predicate ELISA					
		Positive	Indeterminate	Negative	Total	PPA& NPA	95% Confidence Interval
LIAISON® Anti-HAV	Positive	42	0	0	42	42/42= 100%	98-100%
	Equivocal	0	0	0	0		
	Negative	0	0	0	0	NA	NA
	Total	42	0	0	42		

Vaccine study

The HAV antibody response to vaccination was evaluated with the three different vaccines currently licensed in the United States: TWINRIX® (Hepatitis A, Inactivated and Hepatitis B (recombinant), HAVRIX® (Hepatitis A, Inactivated) both manufactured by GlaxoSmithKline Biologicals and VAQTA® (Hepatitis A, Inactivated) manufactured by MERCK & CO., INC. For TWINRIX® vaccine, 9 matched sets of pre- and post-vaccine samples were available. For HAVRIX® vaccine, 32 matched sets of pre- and post-vaccine samples were available. For VAQTA® vaccine, 32 matched sets of pre- and post-vaccine samples were available.

		Comparator			LIAISON® Anti-HAV		
		Pos.	Eqv.	Neg.	Pos.	Eqv.	Neg.
TWINRIX	Pre-vaccine	0	0	9	0	0	9
	2 wk Post 2nd dose	9	0	0	9	0	0
	2 wk Post 3rd dose	9	0	0	9	0	0
HAVRIX	Pre-vaccine	0	0	32	0	0	32
	4wk Post-vaccine	31	0	1	29	1	2
VAQTA	Pre-vaccine	0	0	32	0	0	32
	4 wk Post-vaccine	31	0	1	31	0	1

b. *Matrix comparison :*

Fifty sample sets of matched serum/plasma were used in the study to evaluate the risk of potential unspecific reaction related to the use of sodium heparin plasma. The graph demonstrates the comparison grouped by negatives, equivocal and low reactive samples and demonstrates similarity between the matrices.

LIAISON Anti-HAV - serum/plasma equivalence

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):

   Not Applicable

4. Clinical cut-off**:**

   See 1 f

5. Expected values/Reference range:

   The prevalence and expected values for the LIAISON® Anti-HAV assay were determined in 802 apparently healthy adults from the Western (n=301) and the Eastern (n=501), regions of the U.S.

   Of the Western U.S. study population 53.8% were Females (n=162) ranging in age from 9 to 87 and 46.2% were Males (n=139) ranging in age from 16 to 76.

The majority of the individuals were Caucasian (60.8%), with other ethnic groups represented as follows: Hispanic (17.6%), African Americans (15.3%), Asian (6.0%) and Middle Eastern (0.3%). In the study group from the Western region, 26.3% of the individuals were found to be positive for anti-HAV antibodies.

Of the Eastern U.S. individuals 46.5% were Females (n=233) ranging in age from 17 to 83, and 53.5% were Males (n=268) ranging in age from 17 to 82. The majority of the individuals were Caucasian (69.9%), with other ethnic groups represented as follows: Hispanic (14.0%), African American (12.1%) and Asian (4.0%). In the study group from the Eastern region 20% of the individuals were found to be positive for Anti-HAV antibodies.

The Expected results for the Western and Eastern regions of the U.S. are presented in the tables below.

One sample from each of the regions gave an Equivocal result after repeat testing per Instructions for use:

Expected results for the LIAISON® Anti-HAV assay from the Western U.S. (High Prevalence – n=301)

	N	Negative	Equivocal	Positive	Positive Prevalence
Total	301	221	1	79	26.3%
Gender					
Female	162	115	0	47	29.0%
Male	139	106	1	32	23.0%
Age range (years)	N	(-)	(Eqv)	(+)	
≤18	12	9	0	3	25.0%
<10	1	0	0	1	
10 - 19	15	10	0	5	33.3%
20 - 29	81	56	0	25	30.9%
30 - 39	68	47	0	21	30.9%
40 - 49	52	42	1	9	17.3%
50 - 59	48	41	0	7	14.6%
60 - 69	31	22	0	9	29.0%
≥ 70	5	3	0	2	40.0%

Expected results for the LIAISON® Anti-HAV assay from the Eastern U.S. (Low Prevalence – n=501)

	N	Negative	Equivocal	Positive	Positive Prevalence
Total	501	400	1	100	20.0%
Gender					
Female	233	188	1	44	18.9%
Male	268	212	0	56	20.9%
Age range (years)	N	(-)	(Eqv)	(+)	
≤18	46	0	0	0	0.0%
<10	0	NA	NA	NA	NA
10 - 19	49	49	0	0	0.0%
20 - 29	39	33	0	6	15.4%
30 - 39	78	63	1	14	18.0%
40 - 49	107	95	0	12	11.2%
50 - 59	142	101	0	41	28.9%
60 - 69	52	37	0	15	28.9%
≥ 70	34	22	0	12	35.3%

N. Proposed Labeling:

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

O. Conclusion:

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