

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:** K082050

**B. Purpose for Submission:** Initial Premarket Notification

**C. Measurand:** IgM Antibody to *Hepatitis A Virus* in serum and *heparinized* plasma

**D. Type of Test:** Qualitative, Chemiluminescent Immunoassay (CLIA)

**E. Applicant:** *Diasorin, Inc.*

**F. Proprietary and Established Names:** LIAISON<sup>®</sup> HAV IgM

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
LOL : Hepatitis A Test (IgM Antibody)	Class II	866.3310	Microbiology (83)

**H. Intended Use:**

The LIAISON<sup>®</sup> HAV IgM assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to hepatitis A virus (IgM anti-HAV) in human serum and heparinized plasma using the LIAISON<sup>®</sup> Analyzer. Assay results, in conjunction with other serological and clinical information, may be used for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis as an aid in the laboratory diagnosis of acute or recent HAV infection.

**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.**

3) Special conditions for use statement(s):

For Prescription use only

4) Special instrument requirements: LIAISON<sup>®</sup> Analyzer with Chemiluminescence reader

**I. Device Description:** The LIAISON<sup>®</sup> HAV IgM assay is an *in vitro* diagnostic device that consists of magnetic particles, calibrators, specimen diluent, conjugate and HAV antigen. The kit contains 100 tests. Additionally, controls are required to run the assay. The LIAISON<sup>®</sup> HAV IgM immunoassay is performed on the LIAISON<sup>®</sup> Analyzer (Model 15970) that was previously cleared (K062473, K071480). Magnetic particles are beads coated with mouse monoclonal antibodies (IgG) to human IgM. During first incubation, the magnetic particles are incubated with serum or heparinized plasma to capture IgM antibodies to *Hepatitis A Virus*. During the second incubation, the antibody conjugate reacts with HAV antigen just added and the immune complex thus formed reacts with IgM already bound to the solid phase. The unbound material is removed with a wash cycle after each incubation. Subsequently, a flash chemiluminescence reaction is induced by adding the starter reagents. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) that is indicative of IgM anti-HAV present in the samples.

**J. Substantial Equivalence Information:**

a) Predicate device name (s):

PMA: Diasorin Inc. Enzyme Immunoassay for detection of IgM Antibody to Hepatitis A Virus (IgM anti-HAV) in human serum or plasma (ETI-HA-IGMK Plus)

b) Predicate Numbers (s):

P890014/S02

Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>LIAISON<sup>®</sup> HAV IgM</b>	<b>ETI-HA-IGMK PLUS PMA No. P890014/S02</b>
Intended Use	The LIAISON <sup>®</sup> HAV IgM assay is an <i>in vitro</i> chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to hepatitis A virus (IgM anti-HAV) in human serum and heparinized plasma using the LIAISON <sup>®</sup> Analyzer. Assay results, in conjunction with other serological and clinical information, may be used for	ETI-HA-IGMK PLUS is an <i>in vitro</i> enzyme immunoassay intended for use in the qualitative determination of IgM antibody to hepatitis A virus (IgM antiHAV) in human serum or plasma.

	testing specimens from individuals who have signs and symptoms consistent with acute hepatitis as an aid in the laboratory diagnosis of acute or recent HAV infection.	
Controls	2 (Negative and Positive)	2 (Negative and Positive)
Sample Matrix	Serum or heparinized plasma	Serum or plasma
Reagent Storage	2-8°C, On-board or in Refrigerator	2-8°C Refrigerator only
<b>Differences</b>		
<b>Item</b>	<b>LIAISON® HAV IgM</b>	<b>ETI-HA-IGMK PLUS PMA No. P890014/S02</b>
Type of Assay	Chemiluminescence Immunoassay	Enzyme Immunoassay
Sample Handling/processing	Automated	Manual
Cutoff	Index Value 1.0	Cutoff = Calibrator x absorbance + 0.250
Calibrators	Two	One
Detector	Mouse monoclonal antibody to HAV conjugated to an isoluminol derivative	Horseradish peroxidase-labeled mouse monoclonal antibody to HAV
Capture Reagent	Magnetic particles coated with IgG to human IgM (mouse monoclonal)	Microwells coated with mouse monoclonal antibody to human IgM
Equivocal zone	Index Value of >0.90 and <1.1	Absorbance within 80 – 100% of assay cutoff
Sample Volume	20 µL	10 µL
Measurement System	Photomultiplier (flash chemiluminescence reader)	Spectrophotometer (EIA Microtiter plate reader)
Total incubation	40 minutes	3.5 hours (210 minutes)

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

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>

**L. Test Principle:** The method for qualitative determination of IgM anti-HAV is an antibody capture chemiluminescence immunoassay (CLIA). IgG to human IgM (mouse monoclonal) is used for coating magnetic particles (solid phase). A mouse monoclonal antibody to HAV is linked to an isoluminol derivative (isoluminol-

antibody conjugate). During the first incubation, IgM antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the antibody conjugate reacts with HAV antigen and the immune complex thus formed reacts with the IgM already bound to the solid phase. After each 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 indicative of IgM anti-HAV present in the calibrators, samples or controls.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:* A five-day reproducibility study was conducted at three external laboratories. A coded panel comprised of 12 frozen contrived serum samples was prepared by DiaSorin S.p.A. and provided to the sites. The coded panel samples were prepared by spiking reactive samples into negative samples to achieve high negative, low reactive and high reactive results. The two negative panel samples were not spiked. The coded panel was tested at all three sites, one run per day using four replicates per run for five operating days. The mean Index value and coefficient of variation (%CV) of the results were computed for each of the tested specimens for each of the sites.

Sample		N	Mean	Within run	Between runs	Total (by site)	Between sites	Overall	
ID#	Matrix		Index	%CV	%CV	%CV	%CV	SD	%CV
NC	Buffer	60	0.15	14.2	15.6	19.6	63.6	0.08	54.2
PC	Buffer	60	2.17	5.2	4.7	6.5	10.3	0.23	10.7
HAMu-el	Serum	60	0.73	4.4	9.1	9.7	24.9	0.17	23.5
HAMu-e2	Serum	60	0.81	6.9	9.9	11.6	23.2	0.18	22.6
HAMu-n1	Serum	60	0.49	4.9	7.8	9.1	23.8	0.11	22.7
HAMu-n2	Serum	60	0.42	4.4	7.0	8.0	23.3	0.09	21.2
HAMu-P1	Serum	60	6.87	5.2	7.5	9.2	10.3	0.87	12.7
HAMu-P2	Serum	60	4.48	6.7	9.7	11.3	15.8	0.78	17.4
HAMu-P3	Serum	60	2.45	5.3	6.7	9.5	19.4	0.46	18.8
HAMu-P4	Serum	60	2.17	4.1	7.9	8.4	14.6	0.34	15.5
HAMu-P5	Serum	60	1.95	4.0	8.7	8.9	10.4	0.25	12.6
HAMu-P6	Serum	60	1.53	4.0	7.1	7.6	18.9	0.27	17.4
HAMu-P7	Serum	60	1.31	4.8	9.5	10.0	16.2	0.22	16.8
HAMu-P8	Serum	60	1.24	5.6	12.6	12.8	22.4	0.28	22.5

A twenty day precision study was performed at DiaSorin Inc. The same coded panel tested in the 5 day study, was also used in the 20 day study. The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens.

Panel ID	N	Mean Index	Within run		Between day		Between runs		Total Index	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
NC	80	<<0.10	NA	NA	NA	NA	NA	NA	NA	NA
PC	80	2.20	0.148	6.9	0.173	7.9	0.034	1.6	0.214	9.8
HAMu-e1	80	0.77	0.028	3.6	0.093	12.0	0.005	0.7	0.096	12.4
HAMu-e2	80	0.87	0.039	4.6	0.078	8.9	0.006	0.7	0.086	9.9
HAMu-n1	80	0.46	0.014	3.1	0.041	9.1	0.002	0.4	0.043	9.5
HAMu-n2	80	0.41	0.015	3.6	0.091	21.5	0.079	19.3	0.108	26.4
HAMu-P1	80	7.08	0.242	3.5	0.764	10.8	0.019	0.3	0.795	11.2
HAMu-P2	80	4.65	0.194	4.5	0.385	8.3	0.058	1.2	0.435	9.4
HAMu-P3	80	2.73	0.074	2.7	0.221	8.1	0.015	0.5	0.228	8.4
HAMu-P4	80	2.39	0.080	3.3	0.172	7.2	0.008	0.4	0.185	7.7
HAMu-P5	80	2.01	0.062	3.1	0.13	6.5	0.019	0.9	0.144	7.1
HAMu-P6	80	1.68	0.063	3.8	0.111	6.6	0.017	1.0	0.123	7.3
HAMu-P7	80	1.40	0.053	3.8	0.117	8.4	0.013	1.0	0.126	9.0
HAMu-P8	80	1.30	0.065	5.3	0.122	9.4	0.014	1.1	0.14	10.8

- b. Linearity/assay reportable range: NA
- c. Traceability, Stability, Expected values (controls, calibrators, or methods): NA
- d. Detection limit: This device is for the qualitative detection of HAV- IgM antibody and the limit of detection was not determined.
- e. Analytical sensitivity:

### 1. Analytical Sensitivity as Seroconversion Panel Performance

Five commercially available HAV seroconversion panels were tested using LIAISON<sup>®</sup> HAV IgM and the FDA approved comparator assay to determine when is to detect IgM antibodies after infection and how long IgM can be detected after infection. The results are summarized in the following table:

Panel ID	DiaSorin LIAISON HAV IgM*		Comparator Assay*		Difference in Days from Last Reactive Result
	Post Bleed Day of Earliest Reactive Result	Post Bleed Day of Last Reactive Result	Post Bleed Day of Earliest Reactive Result	Post Bleed Day of Last Reactive Result	
<b>PHT901 seroconversion</b>	<b>12</b>	<b>17</b>	<b>12</b>	<b>17</b>	<b>0</b>
<b>PHT902 seroconversion</b>	<b>16</b>	<b>21</b>	<b>16</b>	<b>21</b>	<b>0</b>
<b>RP004 seroconversion</b>	<b>6</b>	<b>62</b>	<b>6</b>	<b>62</b>	<b>0</b>
<b>RP013 seroconversion</b>	<b>8</b>	<b>189</b>	<b>8</b>	<b>189</b>	<b>0</b>
<b>HAV01 seroconversion</b>	<b>0</b>	<b>77</b>	<b>0</b>	<b>91</b>	<b>14</b>

\* Only reactive results were used; equivocal results were not used to determine a reactive result.

The time point of the serial bleed when HAV IgM was first detected and the bleed when it was no longer detected by the LIAISON<sup>®</sup> HAV IgM was equivalent to the comparator assay in four out of five seroconversion panels. In one panel out of five the last day of detection between the two assays differed by 14 days.

**2. Cross Reactivity:** The cross-reactivity study for the LIAISON<sup>®</sup> HAV IgM assay was designed to evaluate potential interference from other 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, human anti-mouse antibodies). A total of 195 samples were tested and no cross reactivity was observed. Results are presented in the following table.

<b>Organism/Condition</b>	<b>N</b>	<b>Comparator HAV IgM Assay</b>	<b>LIAISON® HAV IgM Reactive</b>	<b>LIAISON® HAV IgM Negative</b>	<b>LIAISON® HAV IgM Equivocal</b>
<b>IgG anti-Measles</b>	3	Negative	0	3	0
<b>IgG anti-Mumps</b>	8	Negative	0	8	0
<b>IgG anti-VCA</b>	3	Negative	0	3	0
<b>IgG anti-EA</b>	3	Negative	0	3	0
<b>IgG anti-CMV</b>	3	Negative	0	3	0
<b>IgG anti-Rubella</b>	2	Negative	0	2	0
<b>IgG anti-Toxoplasma</b>	3	Negative	0	3	0
<b>IgG anti-HSV-1/2</b>	1	Negative	0	1	0
<b>IgG anti-HSV-2</b>	6	Negative	0	6	0
<b>IgG anti-syphilis</b>	4	Negative	0	4	0
<b>Anti-VZV</b>	3	Negative	0	3	0
<b>Anti-HTLV I/II</b>	3	Negative	0	3	0
<b>Anti-HCV</b>	4	Negative	0	4	0
<b>Anti-Borrelia</b>	4	Negative	0	4	0
<b>Anti-HBs</b>	3	Negative	0	3	0
<b>Anti-HIV</b>	10	Negative	0	10	0
<b>Anti-Parvovirus B19</b>	4	Negative	0	4	0
<b>IgM anti-HBc</b>	4	Negative	0	4	0
<b>IgM anti-Borrelia</b>	5	Negative	0	5	0
<b>IgM anti-CMV</b>	5	Negative	0	5	0
<b>IgM anti-EBV</b>	5	Negative	0	5	0
<b>IgM anti-HSV</b>	7	Negative	0	7	0
<b>IgM anti-Rubella</b>	6	Negative	0	6	0
<b>IgM anti-Toxoplasma</b>	5	Negative	0	5	0
<b>IgM anti-VZV</b>	6	Negative	0	6	0
<b>Anti-Influenza virus</b>	3	Negative	0	3	0
<b>HBsAg</b>	3	Negative	0	3	0
<b>HBeAg</b>	6	Negative	0	6	0
<b>Nucleotides</b>	4	Negative	0	4	0
<b>ENA</b>	4	Negative	0	4	0
<b>Rheumatoid Factor</b>	17	Negative	0	17	0
<b>γ-globulin</b>	36	Negative	0	36	0
<b>HAMA</b>	12	Negative	0	12	0
<b>Total</b>	195		0	195	0

3. **Interference:** Controlled studies were performed to determine whether the presence of hemoglobin, lipemia, bilirubin, serum albumin and gamma globulin affect assay performance. The highest concentrations which were considered not to impact results are as follows: hemolysis (at 1000 mg/dL hemoglobin), lipemia (at 3000 mg/dL triglycerides), icterus (at 20 mg/dL bilirubin), serum albumin (at 5 g/dL),  $\gamma$ -Globulin (at 4 g/dL).

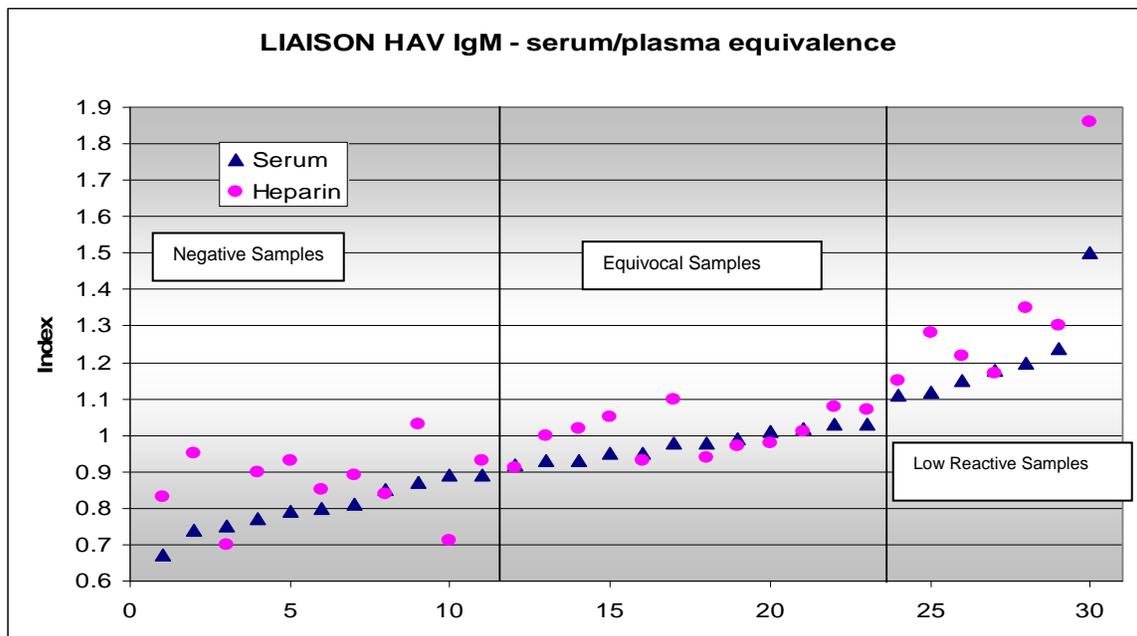
f. Assay cut-off: NA

2. Comparison studies:

a. Method comparison with reference method:

*Diasorin Inc.* Enzyme Immunoassay for detection of IgM Antibody to Hepatitis A Virus (IgM anti-HAV) in human serum or plasma (ETI-HA-IGMK Plus)

b. *Matrix comparison:* Fifty sample sets of matched serum/plasma were used in the study to evaluate the risk of a potential nonspecific reaction related to the use of heparinized plasma. A graph of the serum and corresponding heparinized plasma result for each borderline sample is presented below. The samples are grouped by “Negative”, “Equivocal”, and “Low Reactive” category, as established by the serum result. The graph confirms that the heparinized plasma results are similar to the serum results.



### 3. Clinical studies:

a. *Clinical Sensitivity:* NA

b. *Clinical specificity:* NA

## **Performance Characteristics**

### **Summary of Clinical Studies**

Prospective and Retrospective studies were performed to evaluate the performance of the LIAISON<sup>®</sup> HAV IgM assay using samples sent to the testing laboratory for Hepatitis A or other testing, from patients which were at high risk for viral hepatitis, showed signs and symptoms of hepatitis infection, or were receiving an HAV vaccination.

The prospective studies consisted of 500 samples sent to the laboratory of Hepatitis A testing, 239 samples from individuals at risk for viral hepatitis, and 150 samples from pediatric patients.

The retrospective study consisted of 123 samples from individuals with documented acute Hepatitis A infection.

### **Prospective**

#### **Individuals sent to the Lab for Hepatitis A testing (HAV testing population)**

A total of 500 samples collected from the Northeastern U.S. were included in this study. Of the samples from individuals sent to the lab for HAV testing, 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.

#### **Individuals At Risk for Viral Hepatitis**

A total of 239 individuals at risk for viral hepatitis due to lifestyle, behavior or occupation were included in this study. The 239 individuals were from the following at risk groups: 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 the at risk individuals, 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).

The data for the combined prospective populations are shown in the following table.

**Comparison of the HAV Testing Population and the At Risk Population with the LIAISON<sup>®</sup> HAV IgM and the Comparator ELISA**

LIAISON <sup>®</sup> HAV IgM	Comparator ELISA			Total
	Reactive	Borderline	Negative	
Reactive	0	0	1	1
Equivocal	0	0	0	0
Negative	0	0	738	738
<b>Total</b>	<b>0</b>	<b>0</b>	<b>739</b>	<b>739</b>

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	# of samples	Negative Percent Agreement	Exact 95% Confidence Intervals
Negative	738/739	99.9%	99.4 – 100%

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**Pediatric Population**

One hundred and eight (108) prospectively collected pediatric samples were tested. The 108 pediatric samples were collected from children in the United States. Of these 108 samples 57.4% were females (n=62) and 42.6% were males (n=46), ranging in age from 2 to 17.

The table below shows the comparison of the LIAISON<sup>®</sup> HAV IgM and the Comparator ELISA for the 108 samples from the “pediatric” prospective population.

**Comparison of the Pediatric Population with the LIAISON<sup>®</sup> HAV IgM and the Comparator ELISA**

LIAISON <sup>®</sup> HAV IgM	Comparator ELISA			Total
	Reactive	Borderline	Negative	
Reactive	0	0	0	0
Equivocal	0	0	0	0
Negative	0	0	108	108
<b>Total</b>	<b>0</b>	<b>0</b>	<b>108</b>	<b>108</b>

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	# of samples	Negative Percent Agreement	Exact 95% Confidence Intervals
Negative	108/108	100%	97.3 – 100%

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**Acute HAV Infection (Retrospective)**

The retrospective population consisted of 123 samples from individuals who had an (Acute) HAV infection. Of these 123 samples, 32.5% females (n=40) and 51.2% males (n=63) ranging in age from 4 to 51. For 15.5% of the samples (n= 19) gender and age were unknown. One sample (0.8%) was age 18, but gender was unknown. Of the 123 samples 42 were acutely infected pediatric patients

The 42 pediatric samples that had an acute infection were collected from children in Egypt. Of the pediatric samples, 30.9% were females (n=13) and 69.1% were males (n=29) all ranging in age from 4 to 17.

**Comparison of the Acute HAV Infection Population with the LIAISON<sup>®</sup> HAV IgM and the Comparator ELISA**

LIAISON <sup>®</sup> HAV IgM	Comparator ELISA			Total
	Reactive	Borderline	Negative	
Reactive	119	4	0	123
Equivocal	0	0	0	0
Negative	0	0	0	0
<b>Total</b>	<b>119</b>	<b>4</b>	<b>0</b>	<b>123</b>

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	# of samples	Percent Agreement	Exact 95% Confidence Interval
Reactive	119/123	96.7%	92.7 – 98.9%

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4. Clinical cut-off: NA

5. Expected values:

The expected prevalence results of the LIAISON<sup>®</sup> HAV IgM assay were determined in 802 apparently healthy adults from the Western (historically high prevalence) and the Eastern (historically lower prevalence) regions of the U.S. Three hundred and one (301) samples were from the Western U.S. and 501 were samples from the Eastern U.S.

Of the Western U.S. individuals 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 were 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, none of the individuals were found to be reactive for HAV IgM 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 none of the individuals were found to be reactive for HAV IgM antibodies. The expected results for the Western

and Eastern regions of the U.S. are presented in the tables below.

**Expected Results for the LIAISON® HAV IgM Assay from the Western U.S. Population (n=301)**

	<b>N</b>	<b>Negative</b>	<b>Equivocal</b>	<b>Reactive</b>	<b>Reactive Prevalence</b>
<b>Total</b>	<b>301</b>	<b>301</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>Gender</b>					
<b>Female</b>	<b>162</b>	<b>162</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>Male</b>	<b>139</b>	<b>139</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>Age range (years)</b>	<b>N</b>	<b>(-)</b>	<b>(E)</b>	<b>(+)</b>	
<b>≤18</b>	<b>12</b>	<b>12</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>&lt;10</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>10 - 19</b>	<b>15</b>	<b>15</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>20 - 29</b>	<b>81</b>	<b>81</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>30 - 39</b>	<b>68</b>	<b>68</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>40 - 49</b>	<b>52</b>	<b>52</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>50 - 59</b>	<b>48</b>	<b>48</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>60 - 69</b>	<b>31</b>	<b>31</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>≥ 70</b>	<b>5</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>NA</b>

**Expected Results for the LIAISON® HAV IgM Assay from the East U.S. Population (n=501)**

	<b>N</b>	<b>Negative</b>	<b>Equivocal</b>	<b>Reactive</b>	<b>Reactive Prevalence</b>
<b>Total</b>	<b>501</b>	<b>501</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>Gender</b>					
<b>Female</b>	<b>233</b>	<b>233</b>	<b>1</b>	<b>44</b>	<b>NA</b>
<b>Male</b>	<b>268</b>	<b>268</b>	<b>0</b>	<b>56</b>	<b>NA</b>
<b>Age range (years)</b>	<b>N</b>	<b>(-)</b>	<b>(E)</b>	<b>(+)</b>	
<b>≤18</b>	<b>46</b>				
<b>&lt;10</b>	<b>0</b>				
<b>10 - 19</b>	<b>49</b>	<b>49</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>20 - 29</b>	<b>39</b>	<b>39</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>30 - 39</b>	<b>78</b>	<b>78</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>40 - 49</b>	<b>107</b>	<b>107</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>50 - 59</b>	<b>142</b>	<b>142</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>60 - 69</b>	<b>52</b>	<b>52</b>	<b>0</b>	<b>0</b>	<b>NA</b>
<b>≥ 70</b>	<b>34</b>	<b>34</b>	<b>0</b>	<b>0</b>	<b>NA</b>

**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. The LIAISON<sup>®</sup> HAV IgM Assay including Calibrators and LIAISON<sup>®</sup> Control HAV IgM (Part numbers: 310210, 310211) on the LIAISON<sup>®</sup> Analyzer are substantially equivalent to the ETI-HA-IGMK Plus) for the qualitative determination of IgM antibodies to *Hepatitis A Virus* in serum and *heparinized* plasma.