

## 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION

### DECISION SUMMARY

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

K141116

**B. Purpose of Submission:**

Clearance of the Workcell Upgrade Kit which allows the LIAISON XL Analyzer to be used with a compatible Laboratory Automated System (LAS).

**C. Measurand:**

Total antibodies to Hepatitis A (anti-HAV)

**D. Type of Test:**

Qualitative Chemiluminescence Immunoassay

**E. Applicant:**

DiaSorin Inc.

**F. Proprietary and Established Names:**

LIAISON<sup>®</sup> Anti-HAV

LIAISON<sup>®</sup> XL with LIAISON<sup>®</sup> XL Workcell Upgrade Kit

**G. Regulatory Information:**

1. Regulation section:

21 CFR 866.3310 Hepatitis A virus (HAV) serological assays

2. Classification:

Class II

3. Product code:

LOL, JJF

4. Panel:

Microbiology (83)

## H. Intended Use:

### 1. Intended use(s):

The LIAISON<sup>®</sup> 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<sup>®</sup> Analyzer family. 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 XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for *in vitro* diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer. It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

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

The performance characteristics of LIAISON<sup>®</sup> controls have not been established for any other assays or instrument platforms different from LIAISON<sup>®</sup>, LIAISON<sup>®</sup> XL and LIAISON<sup>®</sup> XL with LIAISON<sup>®</sup> XL Workcell Upgrade Kit.

### 2. Indication(s) for use:

Same as Intended Use

### 3. Special conditions for use statement(s):

For prescription use only.

### 4. Special instrument requirements:

For use with the LIASON XL Analyzer.

## I. Device Description:

The LIAISON XL Analyzer is an *in vitro* diagnostic device consisting of loading areas (for samples, reagent integrals, ancillary reagents, starter reagents, cuvettes, disposable tips,

water, wash buffer, maintenance liquid), incubator, wash station, reader, and a barcode reader for reagents and samples. Installation of the LIAISON XL Workcell Upgrade Kit allows the LIAISON XL Analyzer to be used with a compatible LAS and extends the sample pipetting capabilities to a point-in-space located external to the analyzer.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

LIASON XL Analyzer

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

K103529

3. Comparison with predicate:

<b>Similarities</b>		
<b>Element</b>	<b>New Device: LIASON XL with LIASON XL Workcell Upgrade Kit K141116</b>	<b>Predicate: LIASON XL Analyzer K103529</b>
<b>Intended Use</b>	<p>The LIAISON<sup>®</sup> Anti-HAV assay is an <i>in vitro</i> 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<sup>®</sup> Analyzer family. 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.</p> <p>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.</p> <p>The LIAISON XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for <i>in vitro</i> diagnostic analysis</p>	<p>The LIAISON<sup>®</sup> Anti-HAV assay is an <i>in vitro</i> 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<sup>®</sup> Analyzer family. 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.</p> <p>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.</p> <p>The LIAISON<sup>®</sup> XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for <i>in vitro</i> diagnostic analysis</p>

<b>Similarities</b>		
<b>Element</b>	<b>New Device: LIASON XL with LIASON XL Workcell Upgrade Kit K141116</b>	<b>Predicate: LIASON XL Analyzer K103529</b>
	<p>of CLIAs on human specimens cleared for use on the analyzer. It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.</p> <p>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.</p> <p>The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON®, LIAISON® XL and LIAISON® XL with LIAISON® XL Workcell Upgrade Kit.</p>	<p>of CLIAs on human serum or plasma. The system menu includes infectious disease, bone and mineral, and endocrinology CLIAs. It is to be used only with FDA cleared chemiluminescence immunoassays that are marketed by DiaSorin for the LIAISON® XL Analyzer.</p> <p>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 different from LIAISON® and LIAISON® XL.</p>
<b>Principles of Operation</b>	Chemiluminescence using magnetic particle solid phase and chemiluminescent tracer	Same
<b>Optical System</b>	High-sensitive, low-noise photomultiplier tube (PMT) operating as an ultra-fast photon counter. Linear measuring range: 300 – 650 nm. Light peak of chemiluminescence emitted at 450 nm.	Same

<b>Differences</b>		
<b>Element</b>	<b>New Device: LIASON XL Workcell Upgrade Kit K141116</b>	<b>Predicate: LIASON XL Analyzer K103529</b>
<b>Sample Aspiration</b>	<p>Directly from sample tube in the sample bay of the analyzer</p> <p>Directly from sample tube presented by the Workcell to the aspiration point- in-space position at the analyzer interface (in LAS mode).</p>	Directly from sample tube in the sample bay of the analyzer

<b>Differences</b>		
<b>Element</b>	<b>New Device: LIAISON XL Workcell Upgrade Kit K141116</b>	<b>Predicate: LIAISON XL Analyzer K103529</b>
<b>Sample Identification from bar-coded tubes</b>	Bar-coded sample tubes (mono dimension barcode) read directly by analyzer bar code reader (stand-alone mode) and Bar-coded sample tubes (mono dimension barcode) read by Workcell barcode scanner.	Bar-coded sample tubes (mono dimension barcode) read directly by analyzer bar code reader
<b>LAS Communication</b>	LIAISON XL software communicates with Workcell via LAS interface communication protocol	N/A

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

CLSI EP15-A2, User Verification of Performance for Precision and Trueness – Approved Guideline; Second Edition April 2006.

**L. Test Principle:**

The DiaSorin LIAISON XL Analyzer equipped with the LIAISON XL Workcell Upgrade Kit is a fully automated, closed, continuous loading *in vitro* diagnostic immunoassay system utilizing chemiluminescent technology. The analyzer uses DiaSorin proprietary reagents to measure chemiluminescence resulting from the reaction of an analyte in a sample with a magnetic particle solid phase coated with antigen or antibody and a chemiluminescent tracer. The analyzer is intended for use in professional clinical laboratories only. The LIAISON XL with LIAISON XL Workcell Upgrade Kit has the same principle of the procedure as the LIAISON XL Analyzer.

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

1. Analytical performance:

a. Precision:

A 5 day precision study was conducted at one external site to verify the precision of the LIAISON XL Analyzer with the LIAISON XL Workcell Upgrade Kit using the previously cleared LIAISON Anti-HAV Assay (K103529). Testing was performed using the LIAISON XL with LIAISON XL Workcell Upgrade Kit in both the stand-alone and connected modes using three kit lots.

The study used a panel comprised of five frozen contrived serum samples prepared by DiaSorin S.p.A. The samples were diluted or spiked to represent negative, near the cut-off, and low positive anti-HAV levels. All panel members were stored frozen prior to testing. The panel was tested in four replicates per run, one run per day, for five operating days. The mean, standard deviation, and coefficient of variation (%CV)

of the results were computed for each of the tested specimens. The within-run results were used to calculate the assay's repeatability and the between-day results were used to calculate the assay's precision.

Sample ID	N	Mean	Within run		Between run (day)		Overall	
		(index)	SD	CV%	SD	CV%	SD	CV%
1	60	1.66	0.031	1.9%	0.050	3.0%	0.073	4.4%
2	60	1.07	0.020	1.8%	0.026	2.4%	0.074	7.0%
3	60	0.771	0.014	1.8%	0.017	2.1%	0.055	7.2%
4	60	0.585	0.010	1.8%	0.019	3.2%	0.062	10.5%
5	60	0.902	0.017	1.9%	0.026	2.9%	0.070	7.7%

Sample ID	N	Mean	Within run		Between run (day)		Overall	
		(index)	SD	CV%	SD	CV%	SD	CV%
1	60	1.61	0.030	1.9%	0.034	2.1%	0.057	3.6%
2	60	1.04	0.017	1.6%	0.025	2.4%	0.054	5.2%
3	60	0.743	0.014	1.9%	0.021	2.9%	0.042	5.6%
4	60	0.568	0.011	2.0%	0.018	3.2%	0.047	8.2%
5	60	0.880	0.015	1.7%	0.026	2.9%	0.048	5.4%

The observed total precision using three lots of LIAISON Anti-HAV reagents ranged from 4.4% to 10.5% with the LIAISON XL with LIAISON XL Workcell Upgrade Kit in stand-alone mode and 3.6% to 8.2% with the LIAISON XL with LIAISON XL Workcell Upgrade Kit in connected mode. The level of precision of the LIAISON XL with LIAISON XL Workcell Upgrade Kit in both stand-alone and connected modes is equivalent to the stated precision of the predicate device.

b. Linearity/assay reportable range:

See K082049

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

See K082049

d. Detection limit:

See K082049

e. Analytical reactivity/specificity:

See K082049

f. Assay cut-off:

See K082049

g. Interfering species

See K082049

2. Comparison studies:

a. Method comparison with predicate device:

The agreement study consisted of testing 140 frozen serum samples on the LIAISON XL and the LIAISON XL with LIAISON XL Workcell Upgrade Kit in both stand-alone and connected modes using the LIAISON Anti-HAV Assay. The samples were either retrospectively collected or contrived by DiaSorin and all samples were kept frozen prior to testing. A total of 140 samples were tested of which 28 samples were contrived (20%).

The samples procured for the agreement study consisted of the following index populations:

- 39 negative samples scoring an index greater than or equal to 1.90 Index (27.9%);
- 64 samples scoring an intermediate index (near the cut-off), ranging from 1.90 through 0.4 (45.7%);
- 37 positive samples scoring an index smaller than 0.400 (26.4%).

Testing of the LIAISON XL was performed at DiaSorin S.p.A. and the LIAISON XL with LIAISON XL Workcell Upgrade Kit testing was performed at an external site. Method comparison testing was performed using one kit lot of the LIAISON Anti-HAV assay. Results were obtained using the following instrument configurations:

- a. One LIAISON XL Analyzer (reference)
- b. One LIAISON XL Analyzer with LIAISON XL Workcell Upgrade Kit connected to an FDA cleared automation solution, pipetting from sample bay (stand-alone mode)
- c. One LIAISON XL Analyzer with LIAISON XL Workcell Upgrade Kit connected to an FDA cleared automation solution, pipetting from point in space (connected mode)

The agreement results comparing the LIAISON XL Analyzer and the LIAISON XL Analyzer with LIAISON XL Workcell Upgrade Kit in stand-alone mode are reported in Table 3 and Table 4:

<b>Table 3: LIAISON XL with LIAISON XL Workcell Upgrade Kit in Stand-Alone Mode</b>				
<b>LIAISON XL with Workcell in Stand-Alone Mode</b>	<b>LIAISON XL Analyzer</b>			
	<b>Neg</b>	<b>Eqv</b>	<b>Pos</b>	<b>Total</b>
<b>Neg</b>	71	0	0	71
<b>Eqv</b>	0	0	0	0
<b>Pos</b>	0	1	68	69
<b>Total</b>	71	1	68	140

<b>Table 4: Analysis of Agreement Results for LIAISON XL Analyzer Workcell Upgrade Kit in Stand-Alone Mode</b>			
<b>Agreement</b>	<b>Found</b>	<b>Percentage</b>	<b>95% CI Range</b>
<b>Negative Percent Agreement</b>	71/71	100%	94.9 – 100%
<b>Positive Percent Agreement</b>	68/68	100%	94.7 – 100%

The agreement results comparing the LIAISON XL Analyzer and the LIAISON XL Analyzer with LIAISON XL Workcell Upgrade Kit in connected mode are reported in Table 5 and Table 6:

<b>Table 5: LIAISON XL with LIAISON XL Workcell Upgrade Kit in Connected Mode</b>				
<b>LIAISON XL with Workcell in Connected Mode</b>	<b>LIAISON XL Analyzer</b>			
	<b>Neg</b>	<b>Eqv</b>	<b>Pos</b>	<b>Total</b>
<b>Neg</b>	71	0	0	71
<b>Eqv</b>	0	0	0	0
<b>Pos</b>	0	1	68	69
<b>Total</b>	71	1	68	140

<b>Table 6: Analysis of Agreement Results for LIAISON XL with LIAISON XL Workcell Upgrade Kit in Connected Mode</b>			
<b>Agreement</b>	<b>Found</b>	<b>Percentage</b>	<b>95% CI Range</b>
<b>Negative Percent Agreement</b>	71/71	100%	94.9 – 100%
<b>Positive Percent Agreement</b>	68/68	100%	94.7 – 100%

Two discordant results were observed as shown in Table 3 and Table 5. The LIAISON XL Analyzer Workcell Upgrade Kit in stand-alone mode and connected mode yielded one equivocal result and the LIASONS XL Analyzer yielded a positive result for the same sample. This sample was the only discordant result observed during the study. The stated Positive and Negative percent agreements are acceptable to establish equivalence between all analyzer configurations tested.

b. Matrix comparison:

Not applicable

3. Clinical studies:

See K082049

4. Clinical cut-off:

See K082049

5. Expected values/Reference range:

See K082049

**N. Instrument Names:**

LIAISON XL Analyzer

**O. System Descriptions:**

1. Modes of Operation:

Compared to the predicate device, an additional mode of operation is made available by the LIAISON XL Workcell Upgrade Kit. The LIAISON XL Workcell Upgrade Kit allows the LIAISON XL Analyzer to be used with a compatible LAS by extending the sample pipetting capabilities to a point-in-space.

2. Software:

No software changes were reported. For software information refer to K130469.

3. Specimen Identification:

The addition of the WorkCell Upgrade Kit supports bar-coded sample tubes (mono dimension barcode) to be read by the barcode scanner and transfer the specimen information to the LIAISON XL Analyzer.

4. Specimen Sampling and Handling:

No changes in specimen sampling or handling were reported. For this information refer to previously FDA-cleared 510(k) Premarket Notifications K103529.

5. Calibration:

No changes in calibration were reported. For this information refer to K103529.

6. Quality Control:

No changes in quality control were reported. For this information refer to K103529.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered in the “Performance Characteristics” Section above:**

None

**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.