K060204

6.0 510(k) SUMMARY

OCT 18 2006

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: LIAISON® EA IgG / LIAISON® Control EA IgG

Common Names/Descriptions: Immunoassay for the detection of IgG antibodies to EBV early antigen-diffuse [EA(D)]

Classification Names: EPSTEIN-BARR VIRUS, OTHER

Product Code: LSE

PREDICATE DEVICE: DiaSorin ETI-EA-G Kit (K992191)

DEVICE DESCRIPTION:

INTENDED USE: The DiaSorin LIAISON® EA IgG kit uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® Analyzer for the qualitative detection of specific IgG antibodies to Epstein-Barr virus early antigen-diffuse [EA(D)] in human serum. **This assay uses a 47-kDa recombinant antigen expressed in *E. coli* DH-1 cells. When used in conjunction with other EBV markers,** this assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis (IM). LIAISON® Control EA IgG kit is used in conjunction with LIAISON® EA IgG immunoassay for monitoring substantial reagent failure.

KIT DESCRIPTION: The method for qualititative determination of specific IgG to Epstein-Barr virus early antigen-diffuse [EA(D) recombinant polypeptide] is an indirect chemiluminescence immunoassay (CLIA). All assay steps (with the exception of magnetic particle resuspension) and incubations are performed by the LIAISON® Analyzer. The principal components of the test are magnetic particles (solid phase) coated with EA(D) recombinant polypeptide and a conjugate of mouse monoclonal antibody to human IgG linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, EA(D) antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the antibody conjugate reacts with EA(D) antibodies that are 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 hence the amount of isoluminol-antibody conjugate, is measured by a

photomultiplier as relative light units (RLU) and is indicative of the presence of EA(D) IgG antibodies present in calibrators, samples or controls.

PERFORMANCE DATA:

COMPARATIVE CLINICAL TRIALS: The clinical trials were conducted at two external US laboratories and at DiaSorin. Testing was performed on repository and prospective samples as defined below. The samples were tested by LIAISON® EA IgG and comparison assay (DiaSorin ETI-EA-G ELISA Kit), at the trial sites per the manufacturers' instructions for use.

Prospective Samples: *Subjects Sent to the Laboratory for EBV Testing:*

LIAISON® EA IgG	DiaSorin ETI-EA-G		Total
	Positive	Negative	
Positive (≥11.0 U/mL)	297	20	**317**
Equivocal (9.0-10.9 U/mL)	17	12	29
Negative (<9.0 U/mL)	15	462	477
Total	329	494	823

	Percent Agreement	Exact 95% confidence interval
Positive	90.3% (297/329)	86.6 – 93.3%
Negative	93.5% (462/494)	91.0 – 95.5%
Overall	92.2% (759/823)	90.2 – 94.0%

Retrospective Samples: *VCA IgM-positive Samples*

LIAISON® EA IgG	DiaSorin ETI-EA-G		Total
	Positive	Negative	
Positive (≥11.0 U/mL)	70	0	70
Equivocal (9.0-10.9 U/mL)	0	0	0
Negative (<9.0 U/mL)	0	0	0
Total	70	0	70

	Percent Agreement	Exact 95% confidence interval
Positive	100.0% (70/70)	94.9 – 100.0%
Negative	N.C.* (0/0)	N.C.*
Overall	100.0% (70/70)	94.9 – 100.0%

* N.C. - Not Calculated – Inadequate sample number

REPRODUCIBILITY: Reproducibility studies were performed at 3 sites using a coded panel comprised of 9 frozen repository serum samples. The serum panel was prepared to represent from low- to mid-positive analyte level. The same coded panel was tested at all sites, in three replicates per run for ten runs. Results expressed in U/mL are summarized in the following table.

ID#	N	mean (U/mL)	within run S.D.	within run %CV	between run S.D.	between run %CV	between site S.D.	between site %CV	overall S.D.	overall %CV
EAS1	90	47.6	1.78	3.71	4.56	8.65	2.46	5.16	4.78	10.04
EAS2	90	99.1	6.10	6.06	9.24	8.60	4.64	4.68	10.82	10.92
EAS3	90	112.3	7.50	7.07	15.81	13.19	2.84	2.53	17.26	15.36
EA1	90	18.2	0.93	5.17	1.56	5.50	1.37	7.52	1.85	10.15
EA2	90	20.4	0.63	3.17	2.27	5.87	2.31	11.33	2.34	11.45
EA3	90	47.4	2.07	4.60	4.87	5.18	5.09	10.75	5.28	11.15
EA4	90	35.9	1.58	4.60	4.02	6.02	4.08	11.35	4.30	11.99
EA5	90	52.4	2.03	3.88	4.54	3.55	5.01	9.56	4.94	9.43
EA6	90	18.1	0.60	3.38	1.72	4.12	1.86	10.27	1.80	9.91

INTERFERENCE: Controlled studies of potentially interfering substances showed that the assay performance was not affected by hemolysis (at 1000 mg/dL hemoglobin), lipemia (at 3000 mg/dL triglycerides), icterus (at 20 mg/dL bilirubin).

CROSS-REACTIVITY: The cross-reactivity studies for the LIAISON® EA IgG assay were designed to evaluate potential interference from IgG immunoglobulins directed against other Epstein-Barr virus antibodies (VCA, EBNA), closely-related members of the herpes virus family (HSV-1/2, HSV-2, VZV, CMV), from other organisms that may cause symptoms similar to EBV (*Toxoplasma gondii*, rubella virus) and from other conditions that may result from atypical immune system activity (rheumatoid factor (RF), antinuclear antibodies (ANA)). In addition, potential interference from human anti-mouse antibodies (HAMA) was evaluated.

Organism / condition	Number of Samples	Positive or equivocal LIAISON® EA IgG Result
EBV VCA IgG	3	(0/3)
EBV VCA IgG/EBNA IgG	4	(0/4)
CMV IgG	27	(2/27)
VZV IgG	6	(0/6)
HSV-1/2 IgG	21	(1/21)
HSV-2 IgG	1	(0/1)
Toxoplasma gondii IgG	17	(4/17)
Rubella virus IgG	87	(8/87)
RF	2	(0/2)
ANA	10	(0/10)
HAMA	5	(0/5)
Total	183	(15/183)

Fifteen specimens out of 183 total specimens tested from the cross-reaction panel returned positive or equivocal results in the LIAISON® EA IgG assay. ~~were positive. There was no conclusive evidence of interference observed, however due to the limited availability of certain samples, the possibility of cross-reactivity cannot be excluded.~~ Five of the fifteen discordant samples were equivocal by LIAISON® EA IgG. Equivocal results by LIAISON® EA IgG are included in the calculations of non-agreement since it was not possible to acquire follow-up samples collected one to two weeks later as recommended. Since the highest rate of disagreement was associated with conditions caused by organisms taxonomically unrelated to the Epstein-Barr virus (*Toxoplasma gondii* and rubella virus), the apparent cross-reactivity may be due to performance differences between the two EA IgG test methods. In fact, the observed percent agreement between the two EA IgG methods (91.8%) with these samples is similar to that obtained with the prospective clinical samples (93.5% negative sample agreement).

The recombinant EA(D) antigen used in the assay is expressed in *E. coli* DH-1 cells. The performance characteristics of this device with samples containing antibodies against *E. coli* have not been established.

WARNING: Assay interference due to circulating antibodies against HIV and Hepatitis A, Hepatitis B and Hepatitis C viruses has not been evaluated. The user is reponsible for establishing cross-reactivity performance with these infectious agents.

CONCLUSION

The LIAISON® EA IgG assay showed equivalent performance to the corresponding FDA-cleared assay. The DiaSorin LIAISON® EA IgG assay demonstrated agreement with the comparison method higher then 92% among prospectively collected samples and 100% agreement among retrospective selected samples. The results demonstrated that LIAISON® EA IgG assay can be used with the LIAISON® Analyzer for the qualitative detection of IgG antibodies to EA(D) recombinant polypeptide and can be intended for use as an aid in the clinical laboratory diagnosis of Epstein-Barr viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis (IM)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. Don Kafader
Director of Regulatory Affairs
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P.O. Box 285
Stillwater, MN 55082

OCT 1 8 2006

Re: k060204
Trade/Device Name: DiaSorin LIAISON® EA IgG Assay
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein-Barr virus Serological Reagents
Regulatory Class: Class I
Product Code: LSE
Dated: October 6, 2006
Received: October 13, 2006

Dear Mr. Kafader:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

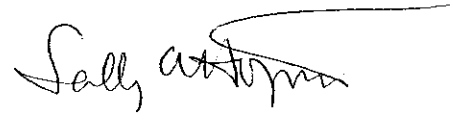
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use

510(k) Number (if known): K060204

Device Name: LIAISON® EA IgG Assay and LIAISON® EA IgG Controls

Indications For Use: The LIAISON® EA IgG assay and LIAISON® EA IgG Controls use chemiluniescent immunoassay (CLIA) technology on the LIAISON Analyzer for the qualitative determination of IgG antibodies to Epstein-Barr virus early antigen-diffuse [EA(D)] in human serum. This assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis (IM).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060204