K061247
JUL 31 2006

510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	DiaSorin LIAISON® Treponema Assay
Common Names/Descriptions:	Immunoassay for the detection of antibodies to *Treponema pallidum* to aid in the diagnosis of Syphilis in human serum
Classification Names:	Treponema pallidum treponemal test reagents
Product Code:	LIP
PREDICATE DEVICES	Trinity CAPTIA™ Syphilis (T. Pallidum) G (K014233)

DEVICE DESCRIPTION:

INTENDED USE: The LIAISON® Treponema assay uses chemiluminescence immunoassay (CLIA) technology for the qualitative detection of total antibodies of any class (IgG/IgM) directed against *Treponema pallidum* in human serum.
The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with non treponemal laboratory tests and clinical findings, may aid in the diagnosis of syphilis infection.
The LIAISON® Treponema Assay is not intended for use in screening blood or plasma donors.

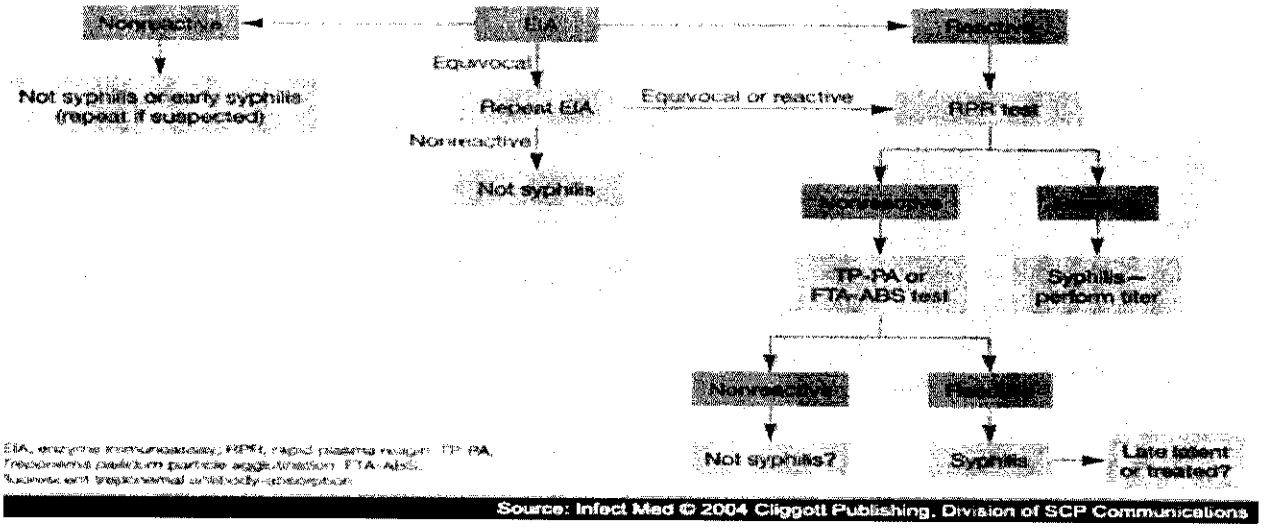
KIT DESCRIPTION: The method for determination of specific total antibodies to *Treponema pallidum* is a one-step chemiluminescence immunoassay (CLIA).
All assay steps and incubations are performed by the LIAISON® Analyzer, with the exception of initial magnetic particle resuspension.
Recombinant antigens specific for *Treponema pallidum* are used for coating the magnetic particles (solid phase) and are used in the tracer when linked to an isoluminol derivative (isoluminol-antigen conjugate). During the incubation step antibodies present in the calibrators, samples or controls bind to the solid phase. The conjugate reacts

with the antibodies already bound to the solid phase. After the incubation, the unbound material is removed with a wash cycle.
Subsequently, the starter reagents are added and a flash Chemiluminescence reaction is induced. The light signal and hence the amount of isoluminol-antigen conjugate is measured by a photomultiplier as relative light units (RLU) and is indicative of total antibodies to *Treponema pallidum* present in calibrators, controls or samples.

PERFORMANCE DATA:

Performance testing of the LIAISON® Treponema Assay for comparative clinical trials consisted of running selected samples for two (2) studies to support the intended use.
Study 1: Clinical Laboratory Screen Test (Treponemal Test followed by a Non-Treponemal test). This study consisted of samples from:
Medically Diagnosed Syphilis infection (Retrospective samples n=51 patients from the US and n =127 patients from Europe) Total n = 178.
Laboratory samples sent for Syphilis HIV Positive Samples (Prospective n=999)
Pregnancy Samples (Prospective n=200)
Apparently Healthy Adults (Prospective n = 992)
Study 2: Diagnostic Confirmatory test (Traditional testing algorithm a non-treponemal test followed by a Treponemal test.) This study consists of: RPR/VDRL positive samples (Retrospective n=204).

COMPARATIVE CLINICAL TRIALS: The clinical trials were conducted at two external US laboratories and at DiaSorin,Inc. Testing was performed on prospective and retrospective samples as described in the two clinical studies above. The samples were tested by LIAISON® Treponema Assay and the comparator assay Trinity CAPTIA™ Syphilis (T.pallidum) G at the trial sites per the manufacturer's instructions for use. Discordant samples were further tested by RPR and TP-PA per the recommendations for non-treponemal testing and use of another treponemal method when following the algorithm to Screen for Syphilis: (Treponema Test as Screen) from (*Use of Treponemal Tests to Screen for Syphilis*, by Victoria Pope, PhD, Infect. Med 21 (8):399-404, 2004 Cliggottt Publishing Division of CMP Healthcare Media).



Source: Infect Med © 2004 Cliggott Publishing, Division of SCP Communications

Study 1: Clinical Laboratory Screen Test

Medically Diagnosed Syphilis Infection – One Hundred Seventy-eight samples with different stages of syphilis. Fifty one of the samples were from the US and 127 were from Europe.

	Percent Agreement		95% Exact Confidence Interval
Positive	98.8%	(165/167)	96.3 – 99.8%
Negative	16.7%	(1/6)	8.5-58.1%
Overall	93.3%	(166/178)	89.3 – 96.1%

Samples sent to Laboratory for Syphilis testing – Nine Hundred Ninety-nine samples.

	Percent Agreement		95% Exact Confidence Interval
Positive	55%	(22/40)	38.6 – 70.7%
Negative	98.9%	(909/919)	98.0 – 99.5%
Overall	93.2%	(931/999)	91.4 - 94.7%

HIV positive samples – Two Hundred samples.

	Percent Agreement		95% Exact Confidence Interval
Positive	75.8%	(61/91)	65.8 – 83.5%
Negative	96.2%	(100/104)	90.4 – 98.9%
Overall	84.5%	(169/200)	78.7 – 89.2%

Pregnancy Samples - Two Hundred samples from pregnant women.

	Percent Agreement		95% Exact Confidence Interval
Positive	100%	(4/4)	38.9 - 100%
Negative	100%	(192/192)	98.1 - 100%
Overall	98.0%	(200/200)	95.0 – 99.5%

Apparently Healthy Adults – Nine Hundred Ninety-two samples

	Percent Agreement		95% Exact Confidence Interval
Positive	62.7%	(54/86)	51.7 – 73.0%
Negative	99.3%	(881/887)	98.5 – 99.8%
Overall	94.2%	(935/992)	92.6 – 95.6%

Study 2: Diagnostic Confirmatory Test

RPR/VDRL Positive samples – Two Hundred four samples.

	Percent Agreement		95% Exact Confidence Interval
Positive	99.5%	(200/201)	98.2 - 100%
Negative	100.0%	(2/2)	15.8 - 100%
Overall	99.0%	(202/204)	97.3 - 100%

Conclusion:
Study 1:
The LIAISON® Treponema Assay demonstrated overall agreement with the comparator kit following the Algorithm to Screen for Syphilis: Treponema test as Screen:
Medically Diagnosed Syphilis Samples, 93.3% (95% CI = 89.3 – 96.1%)
Samples sent to the Laboratory for Syphilis testing, 93.2% (95% CI = 91.4 – 94.7%)
HIV positive samples, 84.5% (95% CI = 78.7 – 89.2%)
Pregnancy samples, 98.0% (95% CI = 95.0 – 99.5%)
Apparently Healthy Adults, 94.2% (95% CI = 92.6 – 95.6%)

The results demonstrate that the LIAISON® Treponema Assay can be used with the LIAISON® Analyzer for the qualitative detection of total antibodies in human serum when used as a clinical diagnostic screening test (**not intended for use with blood donors or for screening the general population).**

Study 2:
The LIAISON® Treponema Assay demonstrated overall agreement with the comparator kit for RPR/VDRL positive samples of 99.0% (95% CI = 97.3 - 100%) when following the Traditional Algorithm: A non-treponemal test followed by a treponemal test.

The results demonstrate that the LIAISON® Treponema Assay can be used with the LIAISON® Analyzer for the qualitative detection of total antibodies in human serum when used as a diagnostic confirmatory test **(not intended for use with blood donors**

Equivocal, repeat and resolution testing.

All equivocal results were repeated in duplicate on the Trinity CAPTIA™ Syphilis (T. Pallidum)-G kit and the LIAISON® Treponema assay per the respective package inserts. All samples that were positive on the Trinity CAPTIA™ kit were also repeated in duplicate per the package insert. Samples that were discordant between the Trinity CAPTIA™ kit and the LIAISON® Treponema kit were tested further with a non-treponemal test (RPR) and with a treponemal kit capable of picking up total antibodies (TP-PA). The resolution of the discordants was carried out by following the Algorithm suggested by Victoria Pope Ph.D, as shown above, and the percent agreements for positive, negative and overall were recalculated.

Study 1 – Resolved:
Medically Diagnosed Syphilis Samples, 97.7% (95% CI = 94.9 – 99.2%)
Samples sent to the Laboratory for Syphilis testing, 98.7% (95% CI = 97.8 – 99.3%)
HIV positive samples, 94.5% (95% CI = 90.4 – 97.2%)
Pregnancy samples, 100% (95% CI = 98.2 – 100%)
Apparently Healthy Adults, 98.3% (95% CI = 97.3 – 99.0%)

Study 2 – Resolved:
RPR/VDRL positive samples, 100% (95% CI = 98.2 – 100%)

REPRODUCIBILITY: Reproducibility studies were performed at 3 sites using a coded panel comprised of 9 "engineered" serum samples. The same coded panel samples were tested at all 3 sites. Samples were run in 4 replicates per run for 5 days. The results expressed for Index and RLU's are summarized in the tables below. Samples 1007 and 1008 were negative samples that read below the limit of the curve so Index values were nondetectable.

Reproducibility Index

sample ID	N	mean Index	within run %CV	between run %CV	total (by site) %CV	between site %CV	overall %CV Index	overall sd Index
1001	60	0.94	4.90	4.19	6.27	5.76	7.91	0.07
1002	60	1.07	2.86	3.99	4.82	4.54	6.07	0.06
1003	60	1.42	3.03	3.57	5.34	7.02	8.08	0.11
1004	60	0.95	3.86	3.60	4.97	6.76	7.43	0.07
1005	60	0.99	2.62	6.22	6.35	6.81	8.60	0.09
1006	58	1.26	1.89	3.93	4.19	6.70	6.93	0.09
1007	58	ND	ND	ND	ND	ND	ND	ND
1008	60	ND	ND	ND	ND	ND	ND	ND
1009	60	13.13	3.11	3.75	5.45	4.87	6.93	0.91
NC	60	0.25	7.02	12.16	13.57	17.76	20.06	0.05
PC	60	5.06	2.70	4.94	4.78	5.76	7.28	0.37

Reproducibility RLU

sample ID	N	mean RLU	within run %CV	between run %CV	total (by site) %CV	between site %CV	overall %CV RLU	overall sd RLU
1001	60	7845	4.72	4.31	6.41	5.52	7.87	617
1002	60	8901	2.70	3.95	4.82	4.55	6.07	540
1003	60	11873	1.94	4.52	5.75	7.58	8.76	1040
1004	60	7934	3.65	4.27	5.32	6.72	6.98	605
1005	60	8320	2.49	7.08	7.08	6.60	9.34	777
1006	58	10550	1.97	5.02	5.21	7.51	8.23	868
1007	58	1051	7.78	5.91	9.40	13.65	14.87	157
1008	60	1047	11.17	8.95	20.02	4.32	23.66	248
1009	60	105839	2.98	4.77	5.57	8.81	9.24	9778
NC	60	2027	6.19	6.19	9.26	16.04	15.94	323
PC	60	40799	3.44	4.95	5.89	10.84	10.70	4365

Conclusion:
The material submitted in this premarket notification supports a substantial equivalence claim. The labelling is sufficient and satisfies the requirements of 21CFR 809.10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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JUL 3 1 2006

Re: k061247
Trade/Device Name: DiaSorin LIAISON® Treponema Assay
Regulation Number: 21 CFR § 866.3830
Regulation Name: Enzyme–linked immunoabsorption assay, Treponema pallidum
Regulatory Class: II
Product Code: LIP
Dated: July 21, 2006
Received: July 24, 2006

Dear Ms. DePouw:

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.

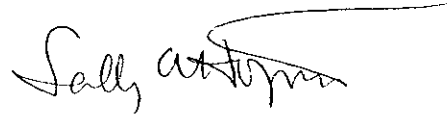
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

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
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Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510(k) Number (if known): K061247

Device Name: LIAISON® Treponema Assay

Indications for Use: The LIAISON® Treponema Assay and the LIAISON® Treponema Serum Controls uses chemiluminescence immunoassay (CLIA) technology for the qualitative detection of total antibodies of any class (IgG/IgM) directed against *Treponema pallidum* in human serum. The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with nontreponemal laboratory tests and clinical findings, may aid in the diagnosis of syphilis infection. The LIAISON® Treponema Assay is not intended for use in the screening of blood or plasma donors.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(K) K061247