K131491

## 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

SUBMITTED BY:

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AUG 0 9 2013

NAME OF DEVICE:

| | |
|---|---|
| Trade Name: | LIAISON® Toxo IgM II<br>LIAISON® Control Toxo IgM II |
| Common Names/Descriptions: | Toxoplasma IgM Assay and Toxo IgM Controls |
| Classification Names: | Toxoplasma *gondii* Serological Reagent: Class II , 21 CFR 866.3780; Microbiology (83) |
| Product Code: | LGD |

PREDICATE DEVICE: Diamedix Is-Toxoplasma IgM Capture Test System (K001707)

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® Toxo IgM II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the qualitative determination of IgM antibodies to *Toxoplasma gondii* in human serum samples. It is intended for use as an aid in the presumptive diagnosis of acute or recent *Toxoplasma gondii* infection, including pregnant women. It is recommended that the LIAISON® Toxo IgM II assay be performed in conjunction with a *Toxoplasma gondii* IgG assay.
This assay has not been cleared/approved by the FDA for blood/plasma donor screening.

The LIAISON® Control Toxo IgM II (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Toxo IgM II assay on the LIAISON® XL Analyzer.

KIT DESCRIPTION:

The method for qualitative determination of specific IgM to Toxoplasma gondii is an antibody capture chemiluminescence immunoassay (CLIA). The principal components of the test are magnetic particles (solid phase) coated with IgG (mouse, monoclonal) is used for coating magnetic particles (solid phase) and a mouse monoclonal antibody to human IgM, *Toxoplasma gondii* antigen, and a conjugate of mouse monoclonal antibodies to *Toxoplasma gondii* 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 mouse monoclonal antibody conjugate reacts with *Toxoplasma gondii* antigen and the immune complex thus formed reacts with IgM already bound to the solid phase. After the incubations, 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 *Toxoplasma gondii* IgM concentration present in calibrators, samples or controls.

All assay steps and incubations are performed by the LIAISON® XL Analyzer.

COMPARISON TO PREDICATE DEVICE:

| Table 1: Table of Similarities | | |
|---|---|---|
| **Characteristic** | **New Device DiaSorin LIAISON® Toxo IgM II** | **Predicate Device Diamedix Is-Toxoplasma IgM Capture Test Kit (K001707)** |
| Intended Use | The LIAISON® Toxo IgM II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer for the qualitative determination of IgM antibodies to *Toxoplasma gondii* in human serum specimens. It is intended for use as an aid in the presumptive diagnosis of acute or recent *Toxoplasma gondii* infection, including pregnant women. It is recommended that the LIAISON® Toxo IgM II assay be performed in conjunction with a *Toxoplasma gondii* IgG assay. This product has not been cleared/approved by the FDA for blood/plasma donor screening. | The Diamedix Is-Toxoplasma IgM Capture Test Kit is a capture enzyme immunoassay (EIA) for the presumptive qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum by capture enzyme immunoassay. When performed in conjunction with an anti-*Toxoplasma gondii* IgG assay, the Is-Toxoplasma IgM Capture assay can be used as an aid in the presumptive diagnosis of acute, recent or reactivated *Toxoplasma gondii* infection. Performance has not been established in newborns. This product has not been cleared/approved by the FDA for blood/plasma donor screening. |
| Measured Analyte | IgM antibodies to *Toxoplasma gondii* | IgM antibodies to *Toxoplasma gondii* |
| Reagent Storage | On-board or in refrigerator @ 2-8°C | In refrigerator @ 2-8°C |
| Calibrators | Included with kit | Included with kit |
| Controls | 2 levels (negative and positive) | 2 levels (negative and positive) |
| Sample matrix | Human Serum | Human Serum |
| Antigen | *Toxoplasma gondii*, RH strain | *Toxoplasma gondii*, RH strain |
| Capture Antibody | Mouse monoclonal anti-human IgM | Mouse monoclonal anti-human $IgM_{Fc}$ |

| Table 2 : Table of Differences | | |
|---|---|---|
| **Characteristic** | **New Device DiaSorin LIAISON® Toxo IgM II** | **Predicate Device Diamedix Is-Toxoplasma IgM Capture Test Kit (K001707)** |
| Assay Type | Chemiluminescent Immunoassay | Enzyme Immunoassay |
| Calibration | Two point verification of stored master curve | Single point Cut-Off Calibrator |
| Unit of Measure | AU/mL | Index Value |
| Cut-Off | 10.0 AU/mL | 1.10 Index Value |
| Equivocal Zone | 8.0 – 9.9 AU/mL | 0.90 – 1.09 Index Value |
| Sample size | 20 µL | 2 µL |
| Sample Handling/ Processing | Automated | Manual or Automated |
| Assay Time | 40 minutes | 140 minutes |
| Controls | Provided Separately | Included with kit |
| Capture Reagent | Magnetic particles coated with IgG to human IgM (mouse monoclonal) | Microwells coated with mouse monoclonal anti-human IgM (heavy chain) |
| Conjugate | Mouse monoclonal antibodies to *Toxoplasma gondii* conjugated to an isoluminol derivative | Mouse monoclonal anti-*Toxoplasma gondii* conjugated to horseradish peroxidase |
| Measurement System | Photomultiplier (flash chemiluminescence reader) | Spectrophotometer (EIA microtiter plate reader) |

PERFORMANCE DATA:

COMPARATIVE CLINICAL STUDIES:

Prospective and Retrospective studies were performed to evaluate the performance of the LIAISON® Toxo IgM II assay among individuals who were sent to the lab for *Toxoplasma gondii* IgM testing, pregnant women (Prospective) and on frozen or repository samples from individuals with a positive *Toxoplasma gondii* IgM result by the comparator assay (Retrospective).

**A. Prospective:**

The prospective populations consist of non-selected subjects sent to the laboratory for *Toxoplasma gondii* IgM testing (US and European subjects) and pregnant women.

The prospective US population consisting of 204 individuals were 96.1% Female (n=196) and 3.9% Male (n=8) ranging in age from 18 years to 42 years. There were 147 samples from patients where the age was unknown.

The prospective European population consisted of 600 individuals. Age and gender for these samples are unknown.

The prospective population of pregnant women consists of 201 females with ages ranging from 14 years to 44 years. There were 70 samples from subjects in the 1st trimester, 50 samples form subjects in the second trimester and 81 samples from subjects in the 3rd trimester of pregnancy.

Prospective US Population Comparison

| | | Percent Agreement | Exact 95% Confidence Interval |
|---|---|---|---|
| Negative | 203/203 | 100.0% | 98.2 – 100.0% |
| Positive | 0/1 | NA | 1.3 – 84.2% |

Prospective European Population Comparison

| | | Percent Agreement | Exact 95% Confidence Interval |
|---|---|---|---|
| Negative | 499/506 | 98.9 % | 97.1 – 99.4% |
| Positive | 93/94 | 98.9 % | 94.3 – 99.7% |

Pregnant Women Population Comparison

| | | Percent Agreement | Exact 95% Confidence Interval |
|---|---|---|---|
| Negative | 194/197 | 98.5 % | 94.1 – 99.1% |
| Positive | 1/4 | 25.0 % | 4.6 – 70.0% |

**B. Retrospective/PreSelected Population;**

The retrospective population was defined as pre-selected samples from individuals who had a positive *Toxoplasma gondii* IgM result by the comparator assay. Thirty three (33) samples were included in this study. The 33 individuals from the retrospective population were 93.9% Females (n=31) and 6.1% Males (n=2) ranging in age from 15 to 47 years.

Retrospective Population Comparison

| | | Percent Agreement | Exact 95% Confidence Interval |
|---|---|---|---|
| Positive | 33/33 | 100.0 % | 89.7 – 99.9% |

The results demonstrate that the LIAISON® Toxo IgM II assay can be used with the LIAISON® XL Analyzer for the qualitative detection of IgM antibodies to *Toxoplasma gondii.*

**C. CDC Panel Study:**

The CDC Toxoplasma 1998 Human Serum Panel is comprised of 100 frozen blind specimens (32 Toxoplasma IgM true positive samples and 65 Toxoplasma IgM true negative samples and 3 dilutions of 3 true Toxoplasma IgM positive samples). The panel was tested by LIAISON® Toxo IgM II assay at site #3.

The results were submitted to the CDC (Reference Immunodiagnostic Lab, Biology and Diagnostic Branch Division of Parasitic Diseases) for data analysis. As communicated

by the CDC, the LIAISON® Toxo IgM II assay correctly detected the 32 Toxoplasma IgM true positive samples (100% agreement) and the 65 Toxoplasma IgM true negative samples (100% agreement).

**D. Prevalence:**

The observed prevalence of the LIAISON® Toxo IgM II assay was calculated for the prospective populations consisting of the 804 samples from patients sent to the lab for *Toxoplasma gondii testing* and 201 pregnant women.
The prevalence may vary depending upon geographical location, age, gender, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

The observed prevalence of LIAISON® Toxo IgM II assay for the US population is 0%, the European population had a prevalence of 16.7% and pregnant women a prevalence of 1.5%.

PRECISION:

Precision was assessed by measuring repeatability at one site using two kit controls and seven serum samples prepared to span the measuring range of the assay. Mean, standard deviation, and coefficient of variation (%CV) were calculated using multiple sources of variability that include within-run, within-day, between-day, and total variability. The following results were obtained from one site with one kit lot assayed in duplicate in two assays per day over 20 operating days.

| Sample ID | Sample N | Mean AU/mL | Within-Run | | Within-Day | | Between-Day | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Negative Control* | 80 | <3.0* | 23.92* | 3.7%* | 9.78* | 1.5%* | 17.06* | 2.6%* | 30.96* | 4.8%* |
| Positive Control | 80 | 18.4 | 0.46 | 2.50% | 0.46 | 2.50% | 1.4 | 7.60% | 1.54 | 8.40% |
| Toxo IgM-A* | 80 | <3.0* | 28.18* | 3.2%* | 15.26* | 1.7%* | 36.26* | 4.1%* | 48.39* | 5.5%* |
| Toxo IgM-B | 80 | 4.9 | 0.1 | 2.10% | 0.1 | 2.00% | 0.21 | 4.30% | 0.25 | 5.20% |
| Toxo IgM-C | 80 | 15.9 | 0.53 | 3.30% | 0.4 | 2.50% | 1.07 | 6.80% | 1.26 | 8.00% |
| Toxo IgM-D | 80 | 36.1 | 1.13 | 3.10% | 1.03 | 2.80% | 3.66 | 10.10% | 3.97 | 11.00% |
| Toxo IgM-E | 80 | 54.6 | 1.48 | 2.70% | 1.27 | 2.30% | 5.53 | 10.10% | 5.86 | 10.70% |
| Toxo IgM-F | 80 | 86.8 | 2.16 | 2.50% | 2.16 | 2.50% | 8.21 | 9.40% | 8.75 | 10.10% |
| Toxo IgM-G | 80 | 121 | 4.27 | 3.50% | 2.38 | 2.00% | 11.55 | 9.50% | 12.54 | 10.40% |

*Dose and corresponding AUs were below the reading range of the assay.

REPRODUCIBILITY

Reproducibility was assessed across all three testing sites using two kit controls and 7 serum samples prepared to span the measuring range of the assay. Mean, standard deviation, and coefficient of variation (%CV) were calculated using multiple sources of variability that include within-run, within-day, between-day, site to site and total variability. The following results were obtained from three sites with two kit lots assayed in duplicate in two assays per day over 20 operating days.

| Sample ID | Sample N | Mean AU/mL | Within-Run | | Within-Day | | Between-Day | | Site to Site | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Negative Control* | 480 | <3.0* | 55.66* | 8.1%* | 34.30* | 5.0%* | 48.37* | 7.1%* | 33.92* | 5.0%* | 93.67* | 13.7%* |
| Positive Control | 480 | 18.1 | 0.76 | 4.20% | 0.34 | 1.90% | 1.62 | 9.00% | 0.61 | 3.40% | 1.89 | 10.50% |
| Toxo IgM-A* | 480 | <3.0* | 38.12* | 4.0%* | 27.82* | 2.9%* | 58.87* | 6.2%* | 50.16* | 5.3%* | 105.01* | 11.0%* |
| Toxo IgM-B | 480 | 4.7 | 0.14 | 3.00% | 0.1 | 2.10% | 0.36 | 7.50% | 0.14 | 2.90% | 0.42 | 9.00% |
| Toxo IgM-C | 480 | 15.6 | 0.52 | 3.40% | 0.35 | 2.30% | 1.31 | 8.40% | 0.55 | 3.60% | 1.53 | 9.90% |
| Toxo IgM-D | 480 | 34.2 | 1.39 | 4.10% | 0.89 | 2.60% | 3.43 | 10.00% | 2.33 | 6.80% | 4.41 | 12.90% |
| Toxo IgM-E | 480 | 52.5 | 2.22 | 4.20% | 1.73 | 3.30% | 5.65 | 10.80% | 3.46 | 6.60% | 7.08 | 13.50% |
| Toxo IgM-F | 480 | 84.6 | 3.51 | 4.10% | 2.28 | 2.70% | 8.05 | 9.50% | 4.52 | 5.30% | 10.04 | 11.90% |
| Toxo IgM-G | 480 | 114.9 | 4.74 | 4.10% | 3.64 | 3.20% | 12.41 | 10.80% | 6.47 | 5.60% | 15.13 | 13.20% |

*Dose and corresponding AUs were below the reading range of the assay.

## CONCLUSION

The results from the nonclinical and clinical studies submitted in this premarket notification demonstrate that the LIAISON® Toxo IgM II is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DiaSorin Inc.
C/O Sandra Zimniewicz
1951 Northwestern Avenue
Stillwater, MN 55082

August 9, 2013

Re: K131441
Trade/Device Name: LIAISON® Toxo IgM II, LIAISON® Control Toxo IgM II
Regulation Number: 21 CFR 866.3780
Regulation Name: *Toxoplasma gondii*, Serological Reagent
Regulatory Class: Class II
Product Code: LGD
Dated: May 17, 2013
Received: May 20, 2013

Dear Ms. Zimniewicz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131441

Device Name: LIAISON® Toxo IgM II
LIAISON® Control Toxo IgM II

Indications for Use: The DiaSorin LIAISON® Toxo IgM II assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the qualitative determination of IgM antibodies to *Toxoplasma gondii* in human serum. The LIAISON® Toxo IgM II is intended for use as an aid in the presumptive diagnosis of acute or recent *Toxoplasma gondii* infection, including pregnant women. It is recommended that the LIAISON® Toxo IgM II assay be performed in conjunction with a *Toxoplasma gondii* IgG assay. This assay has not been cleared/approved by the FDA for blood/plasma donor screening.

The DiaSorin LIAISON® Control Toxo IgM II is intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON® Toxo IgM II assay on the LIAISON® XL Analyzer.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ribhi Shawar -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K131441