JUN - 9 2008

K073501

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3723

Contact Person: Theresa A. Bush

Date PreparedJune 6, 2008

Device Name

Proprietary name: (1) Elecsys Toxo IgG Immunoassay
(2) Elecsys PreciControl Toxo IgG

Common name: (1) Toxoplasma IgG assay
(2) PreciControl Toxo IgG

Classification name: (1) *Toxoplasma gondi* serological reagents
(2) Single (specified) analyte controls (assayed and unassayed)

Elecsys Toxo IgG Test System

Device Description	(1) The Elecsys Toxo IgG Immunoassay is a two-step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. In the first incubation, 10 µL of sample, a biotinylated recombinant T. gondii-specific antigen, and a T. gondii-specific recombinant antigen labeled with a ruthenium complex a form a sandwich complex. Then, after addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode. A human serum-based calibrator is provided with the test kit, and the recommended control material is PreciControl Toxo IgG. (2) The Elecsys Precicontrol Toxo IgG contains two levels of human serum with Toxo IgG antibodies.
Intended use	(1) The Elecsys Toxo IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to *Toxoplasma gondi* in human serum and Li-heparin, K3-EDTA, and sodium citrate plasma. This assay may be used as an aid in the assessment of immune status and as an aid in the diagnosis of primary infection. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers. (2) Elecsys PreciControl Toxo IgG is used for quality control of the Elecsys Toxo IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Indications for Use	(1) The Elecsys Toxo IgG assay may be used as an aid in the assessment of immune status and as an aid in the diagnosis of primary infection.
Substantial equivalence	The Elecsys Toxo IgG Test System is substantially equivalent to the VIDAS TOXO IgG II Test System cleared in K993319

510(k) Summary, Continued

Substantial equivalence – similarities

Toxo IgG Immunoassay Comparison

Elecsys Toxo IgG Test System

Feature	Elecsys Toxo IgG Immunoassay	Predicate Device: VIDAS TOXO IgG II Test System (K993319)
Intended Use	The Elecsys Toxo IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to *Toxoplasma gondi* in human serum and Li-heparin, K3-EDTA, and sodium citrate plasma. This assay is intended for use as an aid in the assessment of immune status and as an aid in the diagnosis of primary infection. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers. NOTE: This assay has not been cleared by the FDA for blood/plasma donor screening.	The VIDAS Toxo IgG II (TXG) assay is an automated quantitative test for use on the VIDAS analyzer for the measurement of anti-toxoplasma IgG in human serum using the ELFA technique (Enzyme Linked Fluorescence Assay). It is intended for use as an aid in determination of immune status. This test is not intended for use in screening blood donors.
Indication for Use	aid in the assessment of immune status and as an aid in the diagnosis of primary infection.	an aid in determination of immune status
Assay Protocol	Electrochemiluminescent Immunoassay	enzyme-linked fluorescent immunoassay (ELFA)
Sample Type	Human serum, lithium heparin plasma, potassium EDTA plasma and sodium citrate plasma. When citrated plasma is used, the values found are approximately 15% lower	Serum
Instrument Platform	Roche Elecsys 2010/ **cobas e** 411 and MODULAR ANALYTICS E170 (Elecsys module)/ **cobas e** 601 analyzers.	VIDAS ® Instrument
Calibrator	Included in kit	Included in kit
Calibrator levels	Two	One
Format	Human serum	Human serum
Calibrator Stability	After opening at 2-8C: 8 weeks On Elecsys 2010/ **cobas e** 411: up to 5 hours On E170/ **cobas e** 601: use only once	Store between 2-8 °C.
Calibration frequency	Once per reagent lot and • After 1 month when using same reagent lot • After 7 days when using same reagent kit • As required per QC findings or pertinent regulations	• Every new reagent lot • Every 14 days

Elecsys Toxo IgG Test System

Controls	PreciControl Toxo IgG (sold separately)	Positive and negative control included in kit.
Traceability	3rd International Standard for Anti-Toxoplasma serum (TOXM) from NIBSC, UK	WHO standard
Reagent Stability	Unopened 2-8°C – up to expiration Opened 2-8°C – 12 weeks Onboard– 2 weeks or 12 weeks (if stored alternately in refrigerator and on the analyzer- ambient temperature 20-25°C; up to 84 hours opened in total.)	Unopened kit: Store at 2-8°C. Do not freeze After opening: Store at 2-8°C . Pouch should be immediately resealed with dessicant ; stable until expiration date
Measuring Range	0.125-650 IU/mL	Linear up to 250 or 300 IU/mL
Precision	Intrassay: (range of values) Low Control: SD = 0.02-0.05 IU/mL High Control: 2.02-4.78 CV % Plasma Samples < 1 IU/mL: 0.014-0.079 SD IU/mL Plasma Samples > 1 IU/mL: CV 1.76-3.09% Inter-assay: Low Control: SD 0.047 -0.077 IU/mL High Control: CV 2.9-5.1 % Plasma Samples < 5 IU/mL: SD 0.039-0.089 IU/mL Plasma Samples > 5 IU/mL: CV 2.7 – 5.3%	Within-run: Negative: SD = 0.25 IU/mL Low positive: 5.13% CV High positive: 7.21 % CV Total: Negative: SD = 0.43 IU/mL Low positive: 6.70% CV High positive: 10.88 % CV
Limit of Blank	0.130 IU/mL	Not stated.
Limit of Detection	0.175 IU/mL	Not stated.

Elecsys Toxo IgG Test System

<table>
<tr>
<td>Analytical Specificity</td>
<td>193 specimens were tested representing a variety of disease. Results shown in table:
<table>
<tr><th>Cross-reactant</th><th>No. tested</th><th>Elecsys Toxo IgG/ Reference Neg/Neg</th><th>Elecsys Toxo IgG/ Reference Pos/Neg</th><th>Elecsys Toxo IgG/ Reference Neg/Pos</th><th>Elecsys Toxo IgG/ Reference Pos/Pos</th></tr>
<tr><td>AMA [f]</td><td>15</td><td>3</td><td>0</td><td>0</td><td>11</td></tr>
<tr><td>ANA [g]</td><td>26</td><td>8</td><td>1</td><td>0</td><td>15</td></tr>
<tr><td>Chlamydia</td><td>4</td><td>2</td><td>0</td><td>0</td><td>2</td></tr>
<tr><td>CMV</td><td>8</td><td>0</td><td>0</td><td>0</td><td>8</td></tr>
<tr><td>EBV [h]</td><td>9</td><td>4</td><td>0</td><td>0</td><td>4</td></tr>
<tr><td>Gonorrhea</td><td>5</td><td>2</td><td>0</td><td>0</td><td>3</td></tr>
<tr><td>HAV</td><td>10</td><td>7</td><td>0</td><td>0</td><td>3</td></tr>
<tr><td>HBV</td><td>23</td><td>14</td><td>1</td><td>0</td><td>8</td></tr>
<tr><td>HCV [i]</td><td>11</td><td>5</td><td>0</td><td>0</td><td>5</td></tr>
<tr><td>HIV</td><td>13</td><td>10</td><td>1</td><td>0</td><td>2</td></tr>
<tr><td>HSV [j]</td><td>8</td><td>1</td><td>0</td><td>0</td><td>6</td></tr>
<tr><td>Influenza</td><td>16</td><td>12</td><td>0</td><td>0</td><td>4</td></tr>
<tr><td>Malaria</td><td>10</td><td>4</td><td>0</td><td>0</td><td>6</td></tr>
<tr><td>Parvo B19</td><td>10</td><td>9</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>Rubella</td><td>10</td><td>4</td><td>0</td><td>0</td><td>6</td></tr>
<tr><td>Syphilis</td><td>5</td><td>3</td><td>0</td><td>0</td><td>2</td></tr>
<tr><td>TPAHj</td><td>3</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>VZV</td><td>7</td><td>4</td><td>1</td><td>0</td><td>2</td></tr>
<tr><td>Sub-total</td><td>186</td><td>93</td><td>4</td><td>0</td><td>89</td></tr>
<tr><td>Total</td><td>193</td><td colspan="4">186</td></tr>
</table>
f. One sample was repeatedly equivocal by the Elecsys Toxo IgG immunoassay
g. Two samples were repeatedly equivocal by the reference method
h One sample was repeatedly equivocal by the reference method
i One sample was repeatedly equivocal by the Elecsys Toxo IgG immunoassay
j One equivocal sample was not repeated on the reference method</td>
<td>No crossreactivity or interference due to RF, ANA and EBV.</td>
</tr>
<tr>
<td>Interferences</td>
<td>The assay is unaffected by icterus (bilirubin < 684 µmol/L or < 40 mg/dL), hemolysis (Hb < 1.24 mmol/L or < 2 g/dL), lipemia (Intralipid < 2000 mg/dL), and biotin < 246 nmol/L or < 60 ng/mL.
Criterion: Recovery of positive samples within ± 20% of initial value.
Rheumatoid factor was not observed to cause any consistent bias. However, elevated levels of RF may lead to erroneous results in some instances No interference due to 18 commonly used pharmaceuticals or to spiramycine, sulfadiazine, folic acid, and pyrimethamine.</td>
<td>Avoid using obviously hemolyzed, lipemic, or icteric samples.</td>
</tr>
<tr>
<td>Expected Values</td>
<td>In a prospective study of 515 subjects from a United States reference laboratory, the prevalence of IgG antibodies to T. gondii was shown to be 37.1%. The prevalence was 42.7% in pregnant women, 43.6% in males, 36.6% in females.
The prevalence from a European study of 470 prospectively collected samples was 37.4%. The prevalence was 9.6% in pregnant women, 41.2% in males and 11.2% in females. Prevalence in the group of unknown gender was 65.1%.</td>
<td>The prevalence of toxoplasmosis varies depending upon geographical location, age and gender of the population studied, specimen collection and handling, and other factors. In Europe, the prevalence rate ranges from 20% to 85%. In the United States, the prevalence is lower: 12% to 41%. Prevalence in other countries can vary from 18% to 65%</td>
</tr>
</table>

Elecsys Toxo IgG Test System

Method Comparison	US Routine Clinical Specimens Negative Agreement: 93.4 % (310/332) 90.1%-95.8% Positive Agreement 100 % (183/183) 98.0% - 100.0% European Site Prospective study results: Negative Agreement: 91.1% (288/316) 87.5 – 94.0 % Positive Agreement: 99.3% (151/152) 96.4-100.0% European Site Frozen sample results: Negative Agreement: 68.1 (32/47) 52.9 -80.9% Positive Agreement: 9999.7% (378/379) 98.5-100.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Theresa Bush
Regulatory Affairs Principal
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

JUN - 9 2008

Re: K073501
Trade/Device Name: Elecsys® Toxo IgG Immunoassay and Elecsys® PreciControl Toxo IgG
Regulation Number: 21 CFR 866.3780
21 CFR 862.1660
Regulation Name: *Toxoplasma gondii* Serological Reagents
Quality Control Material (assayed and unassayed)
Regulatory Class: Class II
Product Code: LGD, JJX
Dated: April 30, 2008
Received: May 1, 2008

Dear Ms. Bush:

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 advice for your device on our labeling regulation (21 CFR Part 801), 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K073501

Device Name: Elecsys® Toxo IgG Immunoassay

Indications For Use:

The Elecsys Toxo IgG immunoassay is for the in vitro quantitative determination of IgG antibodies to *Toxoplasma gondi* in human serum and Li-heparin, K3-EDTA, and sodium citrate plasma. This assay is intended for use as an aid in the assessment of immune status and as an aid in the diagnosis of primary infection.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and **cobas e** immunoassay analyzers.

NOTE: This assay has not been cleared by the FDA for blood/plasma donor screening.

Prescription Use **XXX**	And/Or	Over the Counter Use ____.
(21 CFR Part 801 Subpart D)		(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 Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073501

Indications for Use

510(k) Number (if known): K073501

Device Name: Elecsys PreciControl Toxo IgG

Indications For Use:

Elecsys PreciControl Toxo IgG is used for quality control of the Elecsys Toxo IgG immunoassay on the Elecsys and **cobas** e immunoassay analyzers.

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073501