AUG 2 7 2009

510(k) Summary

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

The assigned 510(k) number is: k083867

Applicant: Beckman Coulter, Inc.
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Date Prepared: August 18, 2009

Reagent

Classification Name: Radioimmunoassay, testosterones and dihydrotestosterone

Trade Name: Access SHBG Reagent*

Device Classification: 21 CFR 862.1680

Device Class: Class I

Classification Panel: Clinical Chemistry

Product Code: CDZ

Calibrator

Classification Name: Calibrator Secondary

Trade Name: Access SHBG Calibrators*

Device Classification: 21 CFR 862.1150

Device Class: Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

Controls

Classification Name: Single (Specified) Analyte Controls (assayed and unassayed)

Trade Name: Access SHBG QC*

Device Classification: 21 CFR 862.1660

Device Class: Class I

Classification Panel: Clinical Chemistry

Product Code: JJX

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* The Access SHBG assay and the Access UniCel Dxl 800 Immunoassay Analyzer are registered trademarks of Beckman Coulter, Inc.

Intended Use:

The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems. The Access Sex Hormone Binding Globulin assay is indicated for use in the assessment of androgen disorders.

The Access SHBG Calibrators are intended to calibrate the Access SHBG assay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.

The Access SHBG QC is intended for monitoring system performance of the Access SHBG assay.

Device Description:

The Access SHBG assay is a sequential two-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel along with paramagnetic particles coated with anti-SHBG antibody. During incubation, the SHBG antigen in the sample binds to the immobilized anti-SHBG antibody on the solid phase. Alkaline phosphatase conjugated anti-SHBG antibody is then added and reacts with a different antigenic site on the SHBG molecule. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of SHBG in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

Predicate Device:

DPC Immulite SHBG** (K941797)

** The IMMULITE SHBG assay and IMMULITE 2000 analyzer are registered trademarks of Siemens Healthcare Diagnostics.

Reagents:

Similarities

Characteristics	Access SHBG Immumoassay	DPC Immulite SHBG (predicate)
Product Type	Immunoassay	Immunoassay
Intended Use	The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems. The Access SHBG assay is indicated for use in the assessment androgen disorders.	For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer-for the quantitative measurement of SHBG in serum, as an aid in the differential diagnosis of hirsutism.
Assay Format	Chemiluminescent, two-site sandwich immunoassay	Chemiluminescent, two-site sandwich immunoassay
Sample types	Human serum or plasma (heparin).	Human serum or plasma (heparin).
Method Comparison	Access SHBG was compared to the predicate device. 158 samples ranging 5.7 nmol/L to 184.5 nmol/L were evaluated and the correlation coefficient obtained was 0.94.	

Reagents:

Differences

Characteristics	Access SHBG Immumoassay	DPC Immulite SHBG (predicate)
Composition	Access Reagent Pack Well R1a: Paramagnetic particles coated with mouse monoclonal anti-SHBG, protein (bovine, mouse) buffered matrix, <0.1% sodium azide, 0.1% ProClin. Well R1b: Mouse monoclonal anti-SHBG alkaline phosphate (bovine) conjugate, buffered matrix with protein (bovine), <0.1% sodium azide, 0.1% ProClin. Well R1c: TRIS buffer with <0.1% sodium azide and 0.1% ProClin 300.	SHBG Bead Pack 200 beads, coated with monoclonal murine anti-SHBG. SHBG Reagent Wedge 11.5 mL alkaline phosphatase (bovine calf intestine) conjugated to polyclonal rabbit anti-SHBG antibody in buffer.
Analytical Sensitivity	Limit of Blank 0.017 nmol/L. Limit of Detection 0.33 nmol/L	0.2 nmol/L
Interferences	The Access SHBG assay utilized the CLSI EP7-A2 guidance evaluating a high and low patient sample spiked with interferents at a high and low levels. The Access did not show significant interference with triglycerides (Intralipid), protein (human serum albumin), bilirubin, cortisol, hemoglobin, estradiol, testosterone, 5α-DHT, 11-Deoxycortisol acetaminophen, acetylsalicylic acid, alpha-fetoprotein (AFP), heparin, ibuprofen, GAS6, laminin, multivitamin supplement thyroglobulin (Tg), thyroxine-binding globulin (TBG), transferrin at relevant levels.	The DPC device exhibits no interference with 30 µL/mL of packed red blood cells, 200 mg/L bilirubin, 100,000 ng/mL cortisol, 5 g/dL protein (human serum albumin), 20,000 ng/mL testosterone, 3,600 pg/mL estradiol, 20,000 ng/mL 5α-DHT, and 4000 ng/mL 11-Deoxycortisol.
Analytical Range	0.33 nmol/L to ~200 nmol/L	0.2 nmol/L to 180 nmol/L.
Analytical Specificity	The Access SHBG assay utilized the CLSI EP7-A2 guidance evaluating a high and low patient sample spiked with interferents at a high and low levels. The Access did not show significant cross-reactivity with 5α-dihydroxytestosterone, 11-deoxycotrisol, estradiol, GAS6, laminin, protein S, testosterone, alpha-fetoprotein, thyroglobulin, thyroxine-binding globulin, and transferrin.	The DPC assay exhibits no cross-reactivity with 400 IU/mL alpha-fetoprotein, 300 ng/mL thyroglobulin, 193 µL thyroxine-binding globulin, and 4 mg/mL transferrin.

Expected Values	Males (20-50 years of age), 151 subjects, mean 38.2 nmol/L; 95 Percentile, 13.3-89.5 nmol/L. Females (non-pregnant, 20-46 years of age), 141 subjects, mean 47.2 nmol/L; 95 Percentile 18.2-135.5 nmol/L. Females (post-menopausal 47-91 years of age) 131 subjects, mean 49.6 nmol/L; 95 Percentile, 16.8-125.2 nmol/L.	Males, 122 subjects, mean 32 nmol/L; 95 Percentile, 13-71 nmol/L. Females (non-pregnant), 111 subjects, mean 51 nmol/L; 95 Percentile, 18-114 nmol/L.

Calibrators

Similarities

Characteristics	Access SHBG Immumoassay	DPC IMMULITE SHBG (predicate)
Intended Use	The Access SHBG Calibrators are intended to calibrate the Access SHBG assay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.	IMMULITE Adjustors (Low, High) are used for calibrating the quantitative IMMULITE SHBG assay on the IMMULITE 2000 systems.

Differences

Characteristics	Access SHBG Immumoassay	DPC Immulite SHBG (predicate)
Calibrator Components	S0: Lyophilized buffered protein (bovine) matrix, <0.1% sodium azide, 0.5% Proclin 300 S1-S5: Lyophilized purified human SHBG, protein (bovine) buffered matrix, at levels of approximately 3, 9, 27, 80 and 200 nmol/L, with <0.1% sodium azide, 0.5% ProClin 300.	Two vials (Low and High) of lyophilized SHBG in a nonhuman protein/buffer matrix.
Traceability	WHO 95/560	DPC's IRMA-Count SHBG assay

Controls

Similarities

Characteristics	Access SHBG Immumoassay	DPC IMMULITE SHBG (predicate)
Intended Use	The Access SHBG QC is intended for monitoring system performance of the Access SHBG assay.	IMMULITE SHBG Controls are used for monitoring system performance of the IMMULITE SHBG assay.

Differences

Characteristics	Access SHBG Immumoassay	DPC Immulite SHBG (predicate)
Calibrator Components	QC1: Lyophilized purified human SHBG at a level of approximately 10 nmol/L, protein (bovine) buffered matrix, <0.1% sodium azide, 0.5% ProClin 300. QC2: Lyophilized purified human SHBG at a level of approximately 100 nmol/L, protein (bovine) buffered matrix, <0.1% sodium azide, 0.5% ProClin 300.	Two vials (LSHC1, LSHC2) of lyophilized SHBG in a nonhuman protein/buffer matrix.

Summary of Analytical Studies

Imprecision:
This assay exhibits a total imprecision of <7% at concentrations greater than 2nmol/L. The study consisted of four patient samples at varying SHBG levels, on three separate pack lots, in duplicate, running for 20 different days, completing 2 runs per day, over a period of 28 days on two Dxl 800 instruments provided the following data, analyzed via analysis of variance (ANOVA).

SampleID	Mean (n=480) (nmol/L)	Within-run		Total	
		SD	CV (%)	SD	CV (%)
1	6.3	0.3	4.7	0.3	5.4
2	38	1.8	4.6	2.0	5.3
3	80	3.6	4.5	4.4	5.5
4	171	8.1	4.8	9.0	5.2

A polynomial regression of all imprecision data (4 samples spanning the range of the assay), provides an overall estimation of the imprecision. Data was further analyzed utilizing linear modeling plotting the log of the sample concentration by the log of the standard deviation, as shown in the following table, and determining the upper limit of 95% confidence interval of this regression fit.

Dose (nmol/L)	Estimated CV%	Estimated SD
2	5.3%	0.11
5	5.3%	0.27
10	5.3%	0.53
15	5.3%	0.79
25	5.3%	1.32
40	5.3%	2.11
60	5.3%	3.17
80	5.3%	4.22
100	5.3%	5.27
150	5.3%	7.89
180	5.3%	9.47

Analytical Sensitivity:
Limit of Blank (Analytical Sensitivity)
Limit of Blank (LoB) for Access SHBG was determined to be 0.017 nmol/L. LoB was tested using a protocol based on CLSI EP17-A. The 97.5% upper confidence limit of this estimate was determined as LoB.

Limit of Detection
Limit of Detection (LoD) of Access SHBG assay was determined to be 0.33 nmol/L, based on the lowest level sample where the beta-percentile (defined as the percentage of observations below LoB) was 5% or less. The LoD study was run under a protocol based on CLSI EP17-A.

Dilution Recovery (Linearity): Dilution recovery studies were performed by diluting three serum samples at 206.58 nmol/L (sample 1), 35.81 nmol/L (sample 2), and 2.90 nmol/L (sample 3) respectively, with Access Wash Buffer II. Sample mean recovery values were 103% Mean Recovery for sample 1, 101% Mean Recovery for sample 2. and 100% Mean Recovery for sample 3.

Methods Comparison (External Site):
A comparison of 158 values, with a range of observations of 5.7-184.5 nmol/L, using the Access SHBG assay on the UniCel Dxl 800 immunoassay system and a commercially available enzyme immunoassay system gave the following statistical data using Passing Bablok calculations:

- Intercept (95% Confidence Interval)= 1.84 (0.54-3.00) nmol/L
- Slope (95% Confidence Interval)= 1.09 (1.06-1.12)
- Correlation Coefficient (r^2)= 0.94

Analytical Specificity: There was no significant interference from compounds tested based on EP7-A2. Compounds include Acetaminophen, Acetylsalicylic acid, Alpha-Fetoprotein (AFP), conjugated and unconjugated Bilirubin, Cortisol, 11-deoxycortisol, 5α-dihydroxytestosterone, Hemoglobin, Heparin, Human serum albumin (HSA), Ibuprofen, Estradiol, GAS6, Laminin, Multivitamin supplement, Protein S, Testosterone, Thyroglobulin (Tg), Thyroxine-binding Globulin (TBG), Transferrin, Triglycerides (Intralipid).

Additionally, there was no cross-reactivity for molecules tested based on EP7-A2. Molecules include Alpha-Fetoprotein, Cortisol, 5α-dihydroxytestosterone, 11-deoxycortisol, Estradiol, GAS6, Laminin, Protein S, Testosterone, Thyroglobulin (Tg), Thyroxine-binding Globulin (TBG), Transferrin.

Stability: SHBG reagents are stable for 28 days after opening, calibrators are stable for 28 days after opening, and controls are stable for 28 days after opening. The calibration curve is stable for 28 days.

Conclusion

As summarized above the Access SHBG, SHBG Calibrators, and SHBG QC on the Access Immunoassay Systems are substantially equivalent to the DPC Immulite SHBG assay for the measurement Sex Hormone Binding Globulin in serum or plasma. Substantial equivalence for the reagent and calibrators has been demonstrated as recommended by the FDA guidance for Industry "Format for Traditional and Abbreviated 510(k)s" (Issued on August 12, 2005) and for controls as recommended by the FDA Guidance for Industry "Points to Consider Document on Assayed and Unassayed Quality Control Material" (Draft Guidance released for comment on February 3, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Beckman Coulter, Inc.
c/o Mr. Tyler Foutch
1000 Lake Hazeltine Dr.
Chaska, MN 55318-1084

AUG 2 7 2009

Re: k083867
Trade/Device Name: Access Sex Hormone Binding Globulin Reagent
Regulation Number: 21 CFR § 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Code: CDZ, JIT, JJX
Dated: July 20, 2009
Received: July 22, 2009

Dear Mr. Foutch:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k083867

Device Name: Access Sex Hormone Binding Globulin Reagent

For *in vitro* diagnostic use.

Indication For Use:

The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems. The Access Sex Hormone Binding Globulin assay is indicated for use in the assessment of androgen disorders.

The Access SHBG Calibrators are intended to calibrate the Access SHBG assay for the quantitative determination of Sex Hormone Binding Globulin levels in human serum and plasma using the Access Immunoassay Systems.

The Access SHBG QC is intended for monitoring system performance of the Access SHBG assay.

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 Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

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

510(k) K083867