510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233480

B Applicant

Beckman Coulter Inc.

C Proprietary and Established Names

Access SHBG

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CDZ	Class I, reserved	21 CFR 862.1680 - Testosterone Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:
Modified device

B Measurand:
Sex Hormone Binding Globulin (SHBG)

C Type of Test:
Quantitative immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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 SHBG assay is indicated for use in the assessment of androgen disorders.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use

D Special Instrument Requirements:

DxI 9000 Access Immunoassay Analyzer

IV Device/System Characteristics:

A Device Description:

The Access SHBG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Sex Hormone Binding Globulin (SHBG) levels in human serum and plasma (lithium heparin). The Access SHBG reagent pack is provided in the two assay packs containing 50 tests per pack for 100 tests. This reagent pack consists of the following reagents:

- R1a (3.25 mL): Paramagnetic particles coated with mouse monoclonal anti-SHBG, protein (bovine, mouse) buffered matrix, <0.1% sodium azide, 0.1% ProClin 300
- R1b (13.25 mL): Mouse monoclonal anti-SHBG alkaline phosphatase (bovine) conjugate, buffered matrix with protein (bovine), <0.1% sodium azide, 0.1% ProClin 300
- R1c (9.86 mL): TRIS buffer with <0.1% sodium azide and 0.1% ProClin 300

Other materials needed to run the assay, but not included in the kit, include: Access SHBG Calibrators, Quality Control (QC) materials, Lumi-Phos PRO, UniCel DxI Wash Buffer II, and Access Wash Buffer II (optional material for dilution).

B Principle of Operation:

The Access SHBG assay is a sequential two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel along with paramagnetic particles coated with monoclonal anti-SHBG antibody and saline buffer with proteins. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. A second monoclonal anti-SHBG antibody conjugated to alkaline phosphatase is added to the reaction vessel. After the second incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate 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 analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Access Sex Hormone Binding Globulin Reagent

B Predicate 510(k) Number(s):
K083867

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233480	K083867
Device Trade Name	Access SHBG	Access Sex Hormone Binding Globulin Reagent
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative determination of Sex Hormone Binding Globulin (SHBG) levels in human serum and plasma	Same
Technology	Two-step immunoenzymatic assay	Same
Format	Chemiluminescent	Same
Measuring Range	0.33 – approximately 200 nmol/L (up to the highest calibrator)	Same
General Device Characteristic Differences		
Instrument	DxI 9000 Access Immunoassay Analyzer	Access UniCel DxI 800 Immunoassay System
Substrate	Lumi-Phos Pro Substrate	Access Substrate

VI Standards/Guidance Documents Referenced:

Clinical & Laboratory Standards Institute (CLSI) EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
CLSI EP06-2nd Edition-: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability (within-run) and within-laboratory (total) precision were evaluated in accordance with the CLSI Guideline EP05-A3. The study was run on three DxI 9000 Access Immunoassay Analyzers using three reagent lots and three calibrator lots. Five (5) serum samples with SHBG concentrations spanning the analytical measuring interval were assayed in duplicate in two runs per day over 20 days. Results from multiple lots were similar. The results from one representative lot are provided in the table below:

Concentration (nmol/L)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	80	0.82	0.02	2.3	0.01	1.5	0.03	3.7	0.04	4.6
Sample 2	80	18	0.3	1.4	0.2	1.4	0.4	1.9	0.5	2.7
Sample 3	80	47	0.7	1.6	0.6	1.6	0.8	1.8	1.3	2.7
Sample 4	80	90	1.4	1.5	1.4	1.5	1.7	1.9	2.6	2.9
Sample 5	80	198	3.0	1.5	3.4	1.5	2.3	1.2	5.1	2.6

2. Linearity:

Studies were performed using serum samples across the assay measuring range to evaluate the linearity of the Access SHBG assay on the DxI 9000 Access Immunoassay Analyzer in accordance with the CLSI Guideline EP06-Ed2. The data was analyzed using a weighted linear regression model.

The results of these linearity studies support that the Access SHBG assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the proposed analytical measuring interval of 0.33 nmol/L – approximately 200 nmol/L (up to the highest calibrator).

3. Analytical Specificity/Interference:

   Previously established in K083867.

4. Assay Reportable Range:

   See section VII.A.2 Linearity above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The Access SHBG calibrators and controls are traceable to WHO 95/560 reference material.

6. Detection Limit:
   Determination of the Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were conducted in accordance with the CLSI guideline EP17-A2. The LoQ was defined as the lowest concentration of analyte which has within-laboratory imprecision less than or equal to 20% CV. Results are summarized below.

LoB (nmol/L)	LoD (nmol/L)	LoQ (nmol/L)
0.005	0.01	0.06

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was performed comparing the Access SHBG assay on the DxI 9000 Access Immunoassay Analyzer to the Access SHBG assay on the Access 2 Immunoassay System using a protocol based on CLSI EP09c-A3. Patient samples falling within the analytical measuring interval of the comparator device were evaluated. A total of one hundred and fifty-one (151) samples were evaluated: 138 samples were individual native serum samples, 3 samples were individual native serum samples supplemented with SHBG antigen, 9 samples were pools of serum samples, and 1 was a serum sample depleted of antigen. The study was run on three DxI 9000 Access Immunoassay Analyzers and three Access 2 instruments with three reagent pack lots and three calibrator lots. The Passing-Bablok regression analysis results between the candidate device (dependent variable, y) and the comparator device (x, comparator), are shown below:

N	Concentration Range (nmol/L)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
151	0.63 - 235	1.01	1.00-1.03	-0.019	-0.46 - 0.29	1.00

2. Matrix Comparison:

Previously established in K083867.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Previously established in K083867.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.