**CHEM.DXI.ASSAY.8.0 DXI Sex Hormone Binding Globulin (SHBG)**

**PRINCIPLE** 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. 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 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 in the 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, mulit-point calibration curve.

**DOCUMENT OWNER** Manager, Regional Chemistry

**RELATED DOCUMENTS** CHEM.DXI.1.0 DXI Operation Procedure

**SPECIMEN**

A. Specimen Type

 1. Serum

 2. Plasmas (heparin)

B. Specimen Stability

 1. Room Temperature (15-30°C) – 8 hours

 2. Refrigerated (2-8°C) – 5 days

 3. Frozen (<-20°C) – 2 months or for shipment

C. Special Instructions

 1. Thaw specimens no more than two times

 2. Avoid using hemolyzed or lipemic samples

**REAGENTS**

A. The reagent is ready to use.

B. Store upright and refrigerate at 2-10°C.

C. Refrigerate at 2-10°C for a minimum of two hours before use on the instrument.

D. Stable until the expiration date on the label when stored at 2-10°C.

E. Stable at 2-10°C for 28 days after initial use.

F. Mix contents of new (un-punctured) reagent packs by gently inverting pack several times before loading onto the instrument.

G. Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.

H. For in vitro diagnostic use I. Handle all reagents with caution and avoid contact with skin, eyes, or mouth. Refer to the Method Manual for any known toxicity.

**EQUIPMENT** Beckman Coulter Access UniCel DxI 600

**CALIBRATION** A. An active calibration curve is required for all tests. B. Calibration is required every 28 days for Access SHBG. C. Calibrators are provided lyophilized. Reconstitute each vial volumetrically with 1mL CLWR. Allow 30 minutes for dissolution. Mix gently before use. D. Lyophilized calibrators are stable until the expiration date stated on the label when stored at 2-8°C. E. Reconstituted stability is 28 days at 2-8°C. F. Refer to calibration card for exact concentrations. G. Refer to the appropriate system manual and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

**QUALITY CONTROL**

1. Refer to CHEM.QC.REGIONAL.2.0 Quality Control Testing Intervals for QC Testing Intervals for appropriate control materials and testing intervals.
2. Refer to CHEM.QC.REGIONAL.1.0 Regional Chemistry laboratory Quality Control for criteria on accepting/rejecting patients based on control results.
3. Refer to CHEM.QC.REGCHEM.2.2 QC PREP and STABILITY

**PROCEDURE** A. See, DXI Operating Procedure, CHEM.DXI.1.0 for specific details.

B. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

**DILUTIONS** A. for auto or manual dilution refer to CHEM.DXI.1.2 for specific details.

The DxI system onboard dilution feature automates the dilution process, using predefined assay sample and the Wash Buffer/ Sample Diluent volumes, allowing samples to be quantitated. Results Reported by the system are adjusted for dilution.

**REPORTING RESULTS**

Refer to, CHEM. DXI 1.1 for Test Codes, AMR, CRR, Critical and Normal Ranges for specific details

**RESULT ENTRY**

A. Sunquest

 1. OEM or MEM

 2. Worksheet: DXI

 3. Method: DXI

 4. Test Code: SHBG

B. Toplab

 1. Enter results in Toplab using Toplab Common Pathway: 3,3,1

 2. Toplab Worklist: DXI1

 3. Test Code: 30740

C. If HIS or LIS systems are not functional, see the Computer Downtime CHEM.LIS.5.0 procedure.

**PROCEDURE NOTES** Use 250 µL of sample for each determination run with the DXI system. The Access SHBG assay has been evaluated at an ambient temperature range of 18-32°C. For optimal results, assay calibration and patient sample testing should be conducted under similar conditions. If ambient laboratory temperature varies by more than ±5°C from the temperature of calibration, review quality control results and recalibrate as necessary

**LIMITATIONS**

A. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interferes with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.

C. For patients presenting with cirrhosis or sub-clinical thyroid conditions, carefully evaluate results as these conditions can potentially cause erroneous results.

**REFERENCES**

A. Beckman Coulter Access Immunoassay Systems SHBG reagent insert (A48617C)

B. Beckman Coulter Access Immunoassay Systems SHBG Calibrator insert (A87716C)