DXC 800 (ALBG) ALBUMIN GREEN

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☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of albumin by the BCG method on the DXC800.

BACKGROUND

Clinical Significance

The various functions of albumin in the blood stream include the transport of insoluble organic anions, the binding of toxic heavy metals, the transport of poorly soluble hormones, the maintenance of plasma colloidal osmotic pressure, and the provision of a reserve store of protein. Low serum values can result from malnutrition or liver disease, an increase in catabolism, increased excretion in urine or feces, or a change in distribution between the intravascular and extravascular compartments. High serum values can result from dehydration.

Methodology

Albumin + BCG ⇨BCG - Albumin complex. In an acid pH, the albumin binds to the BCG causing an increase in absorbance. The increase in absorbance at 630nm due to the formation of the BCG –Albumin complex is directly proportional to the concentration of albumin in the sample.

RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the procedural notes section of this work instruction. Whole blood or urine are not recommended for use as samples.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Reagent Preparation

Reagent comes in four 125mL bottles per package and is provided in a ready to use format. Pour approximately half of one bottle of reagent into compartment "A" of a user defined cartridge. Avoid bubble formation. Label the cartridge as ALBG.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria.

Reagent Storage and Stability

DCL Albumin Reagent is stable until the expiration date stated on the label at 18-26ºC.
The reagent solution should be clear. Turbidity would indicate deterioration.

CALIBRATION

Calibrator Required

DC-CAL Calibrator (human)

Calibrator Preparation

Reconstitute with exactly 3.0 mL of the supplied diluent using a pipette and allow to sit for 30 minutes. Swirl gently before using. Accurate reconstitution of the calibrator is critical. Calibrate using water and the reconstituted DC-CAL.

Calibrator Storage and Stability

DC-CAL Calibrator (human); store at 2-8C. Stable 3 days after reconstitution.

NOTE: New lots of calibrator may require a change in set points. See DXC Manual for User-defined set up

Calibration Information

1. The system must have a lot-specific user-defined set points and a valid calibration adjustment in memory before controls or patient samples can be run.

2. Under typical operating conditions the ALBG reagent cartridge must be calibrated every 24 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program samples and controls for analysis.

4. After loading samples and controls onto the system, follow the protocols for system operations. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

The SYNCHRON® System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

PERFORMANCE CHARACTERISTICS

Reference Range

Age	Range (g/dL)
0 – 4 days	2.9- 4.6
4 days – 14 yrs	3.9 –5.6
14- 18 yrs	3.5- 4.7
18-60 yrs	3.5-5.0
60-90 yrs	3.3-4.8
90 yrs +	3.0- 4.7

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	1 g/dL- 6 g/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of detection	1 g/dL	Results below 1 report <1 g/dL
Upper limit of detection	6 g/dL	Results > 6 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >12 are reported as >12 g/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for ALBG determination is 6 g/dL.

LIMITATIONS

None identified.

Interferences

The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	No significant interference
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No significant interference
Lipemia	Intralipid[d]	400 mg/dL INDEX of 10	No significant interference

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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8/13/15- New version .02. Added max dilution Changed 14-18 yr ref range to match Cerner.			
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