DXC 600 (ALB) ALBUMIN

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PURPOSE

To provide instructions for the quantitative determination of albumin on the DXC 600.

PRINCIPLE

ALB reagent, when used in conjunction with UniCel® DxC 600 System and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Albumin concentration in human serum or plasma.

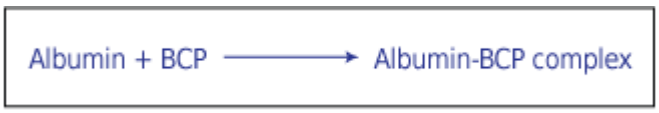
BACKGROUND

Clinical Significance

Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver and/or kidneys.

Methodology

ALB reagent is used to measure albumin concentration by a timed endpoint method. In the reaction, albumin combines with bromcresol purple (BCP) to form a colored product.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The System monitors the change in absorbance at 600 nanometers. This change in absorbance is directly proportional to the concentration of ALB in the sample and is used by the System to calculate and express ALB concentration.



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
M-F-CH-0820	Chemistry Controls
M-F-CH-0826	Chemistry Calibrators
M-F-CH-1940	DXC 600 (AMR) 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 chemistry information sheet. Whole blood or urine are not recommended for use as a sample. Serum or lithium heparin plasma are the preferred specimens.

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 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 • After 48 hours, freeze at -15 to -20ºC

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

Contents

Each kit contains the following items:
Two ALB Reagent Cartridges (2 x 300 tests)

Volume per Test	
Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	A 300 µL B – – C – –

Reactive Ingredients	
Bromcresol purple	0.28 mmol/L
Also non-reactive chemicals necessary for optimal system performance.	

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

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

Reagent Storage and Stability

ALB reagent, when stored unopened at room temperature, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 30 days. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the ALB reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual.

3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the UniCel DxC 600 System *Instructions for Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will print out with error codes and the system will alert the operator of the failure. An explanation of these error codes can be found in the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Document M-F-CH0820 Chemistry Controls

STEPS

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

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

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System ***Instructions For Use*** (IFU) manual.

CALCULATIONS

The system 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.

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference	Deming Regression Analysis
Lithium Heparin	14 Units/mL	Y = 1.006X - 0.01; r = 0.996
Sodium Heparin	14 Units/mL	Y = 0.988X + 0.08; r = 0.994

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Conventional Units
Serum or Plasma	3.5 –5.0 g/dL

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	1.0 - 7.0 g/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed. The appropriate dilution factor should be applied to the reported result.

Reporting results outside of analytical range

Lower limit of detection	1.0 g/dL	Results below 1.0, report <1.0 g/dL
Upper limit of detection	7.0 g/dL	Results >7.0 g/dL should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >14.0 are reported as >14.0 g/dL.

LIMITATIONS

Bromcresol purple dye is specific for human albumin. Bovine-based albumin controls may recover differently.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin	Porcine	30 mg/dL INDEX of 20	No Significant interference (within ±0.4 g/dL or 6%)
Lipemia	Human	320 mg/dL INDEX of 8 Airfuge recommended	No Significant interference (within ±0.4 g/dL or 6%)
Hemoglobin	Human	500 mg/dL INDEX of 10	No Significant interference (within ±0.4 g/dL or 6%)

2. Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC System(s), refer to the appropriate system manual.

REFERENCES

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Updated reportable range and current process			
Committee Approval Date	☒ Date: 8/26/14 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 8/26/14