DXC 800 (ALBM) ALBUMIN-02

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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 on the DXC 800.

PRINCIPLE

ALBm reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems Protein Calibrator, is intended for quantitative determination of Albumin concentration in human serum or plasma.

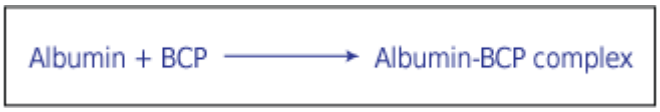
BACKGROUND

Clinical Significance

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

Methodology

The SYNCHRON® System(s) determines albumin concentration by means of a bichromatic digital endpoint methodology using bromcresol purple (BCP) reagent. A precise volume of sample (5 microliters) is injected in a reaction cup containing bromcresol purple (BCP) reagent. The ratio used is one part sample to 114 parts reagent. Albumin from the sample combines with the reagent to form a bromcresol purple albumin complex. The system monitors the change in absorbance at 600 nanometers. This change in absorbance 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 800 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 specimens of choice. 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.

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
Serum/Plasma	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

Contents

Each kit contains the following items:
Two ALBm Reagent Bottles (2 x 2 L)

Volume per Test	
Sample Volume	5 µL
Total Reagent Volume	570 µL

Reactive Ingredients	
Bromcresol purple	0.35 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

ALBm reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. ALBm reagent is stable on instrument for 60 days, unless the expiration date is exceeded. If the reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting the bottle at least 10 times.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Protein Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems Protein Calibrator, when stored unopened at -15°C to -20°C, will remain stable until the expiration date printed on the label. Once opened, calibrators are stable for 60 days at +2°C to +8°C unless the expiration date is exceeded.

Calibration Information

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

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

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 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 be printed with error codes and the system will alert the operator of the failure. For information on error codes, 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-CH-0820 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 operation.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual

CALCULATIONS

SYNCHRON® System(s) perform 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	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	NSI (within ±0.4 g/dL or 4%).
Lithium Heparin	14 Units/mL	NSI (within ±0.4 g/dL or 4%).
Sodium Heparin	14 Units/mL	NSI (within ±0.4 g/dL or 4%).

The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (mg/dL)
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	-2.3[b]

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Male and Female	
	Age	Range
Serum/ Plasma	0-4 days	2.9-4.6 g/dL
Serum/ Plasma	4 days-14 yrs	3.9-5.6 g/dL
Serum/Plasma	14-18 yrs	3.3-4.7 g/dL
Serum/Plasma	18-60 yrs	3.5-5.0 g/dL
Serum/Plasma	>60 yrs	3.0-4.7 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.

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 the dilution factor applied. The maximum allowable dilution is X2. Results >14 are reported as >14 g/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for ALBm determination is 1 g/dL (10 g/L).

LIMITATIONS

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

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	NSI
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	NSI
Lipemia	Intralipid[d]	500 mg/dL INDEX of 10 Airfuge recommended	NSI

Substance	Source	Level Tested	Observed Effect
Glutathione	NA[e]	5.0 mmol/L	NSI
Methylbenzethonium Chloride	NA	2.0 mg/dL	NSI

Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.

Refer to References for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

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

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