BECKMAN COULTER™ CE

SYNCHRON® System(s) Chemistry Information Sheet

ALB Albumin

REF 442765

For *In Vitro* Diagnostic Use

ANNUAL REVIEW

Reviewed by:	Date	Reviewed by:	Date

PRINCIPLE

INTENDED USE

ALB reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and Synchron® Systems Multi Calibrator, is intended for the quantitative determination of albumin concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

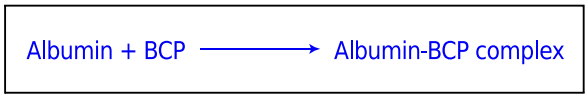
Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver and/or kidneys.

METHODOLOGY

ALB reagent is used to measure albumin concentration by a timed endpoint method.[1,2] 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.

CHEMICAL REACTION SCHEME



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SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[3] 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.

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.[4]
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.[4]

Additional specimen storage and stability conditions as designated by this laboratory:

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.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:

Two ALB Reagent Cartridges (2 x 300 tests)

VOLUMES PER TEST

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

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Bromcresol purple	0.28 mmol/L

Also non-reactive chemicals necessary for optimal system performance.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

Synchron® Systems Multi Calibrator
At least two levels of control material
Saline

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 unless the expiration date is exceeded. DO NOT FREEZE.

Reagent storage location:

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.

> ⚠ CAUTION
>
> Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.[5]

Calibrator storage location:

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 600/800 Systems *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

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be 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 Systems *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.

REPORTING RESULTS

Equivalency between the SYNCHRON CX and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The reference intervals listed below were taken from literature.[6]

Table 2.0 Reference intervals

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S. I. UNITS
Literature	Serum or Plasma	3.5 – 5.0 g/dL	35 – 50 g/L

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S. I. UNITS
Laboratory			

Refer to References (6,7,8) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

1. 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:

Table 3.0 Acceptable Anticoagulants

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

LIMITATIONS

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

INTERFERENCES

Table 4.0 The following substances were tested for interference with this methodology:

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT
Bilirubin	Porcine	30 mg/dL	NSI[a]
Lipemia	Human	+ 4 (visual)	NSI
Hemoglobin	Human	500 mg/dL	NSI

a NSI = No Significant Interference (within ±0.4 g/dL or 6%).

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

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

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

Table 5.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	1.0 – 7.0 g/dL	10 – 70 g/L

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

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 6.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or Plasma (in the range of 1.0 to 7.0 g/dL):

Y (UniCel DxC Systems)	= 0.978X - 0.07
N	= 150
MEAN (UniCel DxC Systems)	= 4.4
MEAN (SYNCHRON CX Systems)	= 4.5
Correlation Coefficient (r)	= 0.995

Refer to References (12) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON® System(s) should exhibit precision values less than or equal to the following:

Table 7.0 Precision Values

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[a]		% CV
		g/dL	g/L	g/dL	g/L	
Within-run	Serum/Plasma	0.2	2.0	6.7	66.7	3.0
Total	Serum/Plasma	0.3	3.0	6.7	66.7	4.5

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for the UniCel DxC System(s) evaluated using the NCCLS Proposed Guideline EP5-A appears in the table below.[13] Each laboratory should characterize their own instrument performance for comparison purposes.

Table 8.0 NCCLS EP5-A Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE	No. Systems	No. Data Points[a]	Test Mean Value (g/dL)	EP5-A Calculated Point Estimates	
					SD	%CV
Within-run	Serum/Plasma Level 1	1	80	2.2	0.04	1.9
	Serum/Plasma Level 2	1	80	3.7	0.07	1.8
	Serum/Plasma Level 3	1	80	5.1	0.08	1.6
Total	Serum/Plasma Level 1	1	80	2.2	0.05	2.1
	Serum/Plasma Level 2	1	80	3.7	0.07	1.9
	Serum/Plasma Level 3	1	80	5.1	0.08	1.6

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

Refer to References (13) for guidelines on performing precision testing.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on UniCel DxC System(s) and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

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

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

REFERENCES

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4. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).

5. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).

6. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1990).

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10. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D.C. (1989).

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12. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Tentative Guideline, NCCLS publication EP9-T, Villanova, PA (1993).

13. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, 2nd Edition, Approved Guideline, Vol. 19, No. 2, NCCLS publication EP5-A, Villanova, PA (1999).

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