SYNCHRON® System(s) Chemistry Information Sheet

ALBm
Albumin
REF 467858

For In Vitro Diagnostic Use

ANNUAL REVIEW

Reviewed by:  Reviewed by:  Date
Refer to coversheet in front of method

PRINCIPLE

INTENDED USE

ALBm reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 800 System and SYNCHRON® Systems Protein Calibrator, is intended for 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

The SYNCHRON® System(s) determines albumin concentration by means of a bichromatic digital endpoint methodology using bromcresol purple (BCP) reagent.¹²

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.

CHEMICAL REACTION SCHEME

![Chemical Reaction Scheme](image)

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 specimens of choice. Acceptable anticoagulants are listed in 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.

Additional specimen storage and stability conditions as designated by this laboratory:
Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

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:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

PATIENT PREPARATION

SPECIAL INSTRUCTIONS FOR PATIENT PREPARATION AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

SPECIMEN HANDLING

SPECIAL INSTRUCTIONS FOR SPECIMEN HANDLING AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” manual

REAGENTS

CONTENTS

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

VOLUMES PER TEST

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>5 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Reagent Volume</td>
<td>570 µL</td>
</tr>
</tbody>
</table>
REACTIVE INGREDIENTS

REAGENT CONSTITUENTS
Bromcresol purple 0.35 mmol/L
Also non-reactive chemicals necessary for optimal system performance.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
SYNCHRON® Systems Protein 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
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.

REAGENT STORAGE LOCATION:
In Chemistry dept. room L568 at room temperature.

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.
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.

CALIBRATOR STORAGE LOCATION:

Thawed Multical vial in-use kept refrigerated in Calibrator tray. Unopened Multical kept frozen, Chemistry freezer 8.
Refer to “DxC 800 Calibrator Quick reference” write up in DxC 800 Procedure manual.

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 SYNCHRON LX Maintenance Manual and Instrument Log, or the UniCel DxC 600/800 Systems Instructions for Use (IFU) manual.

3. For detailed calibration instructions, refer to the SYNCHRON LX Operations Manual, or 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 SYNCHRON LX Diagnostics and Troubleshooting Manual, or the UniCel DxC 600/800 System 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 bottle of reagent, 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.
NOTICE

Do not use controls containing diethylamine HCl.

TABLE 1 QUALITY CONTROL MATERIAL

Monitrol levels 1 and 2 vials in use kept refrigerated after thawing. Unopened Monitrol kept frozen until just before use. Refer to “DXC 800 Control Analysis” in DXC 800 procedure manual for other control material used and storage. Control preparations and acceptance of QC results are in "Policies and Procedures" manual.

TESTING PROCEDURE(S)

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 SYNCHRON LX Operations Manual, or 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.

REPORTING RESULTS

Equivalency between the SYNCHRON LX 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 interval listed below was taken from literature and a study performed on SYNCHRON Systems.

TABLE 2 REFERENCE INTERVALS

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S. I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Serum or Plasma</td>
<td>3.4 – 4.8 g/dL</td>
<td>34 – 48 g/L</td>
</tr>
<tr>
<td>SYNCHRON</td>
<td>Serum or Plasma</td>
<td>3.5 – 4.8 g/dL</td>
<td>35 – 48 g/L</td>
</tr>
</tbody>
</table>
INTERVALS | SAMPLE TYPE | AGE | CONVENTIONAL UNITS
--- | --- | --- | ---
Laboratory | Serum or Plasma | 0-7 days | 1.9-4.0 g/dL
| | | 8 days – <1 year | 2.7-4.8 g/dL
| | | 1 year – <18 years | 3.1-4.8 g/dL
| | | > 18 years | 3.5-4.8 g/dL

Note:
2. Normal range for children 8 days to less than 18 years old adopted from Beckman Coulter’s “Pediatric Reference Range Guidelines for Synchron Systems” Bulletin 9345
3. Normal range for adults was determined by testing 270 male and female healthy blood donors at UCSF.

ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:

Refer to “DXC 800 Linearity and Reportable Range” chart in Technical Notes section of DXC 800 Procedure manual.

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 COMPATIBLE ANTICOAGULANTS

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>AVERAGE PLASMA-SERUM BIAS (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
<tr>
<td>Lithium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

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

TABLE 4 INCOMPATIBLE ANTICOAGULANTS

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>PLASMA-SERUM BIAS (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium Oxalate/Sodium Fluoride</td>
<td>2.0 / 2.5 mg/mL</td>
<td>-2.3</td>
</tr>
</tbody>
</table>

LIMITATIONS

Brom cresol 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:
TABLE 5 INTERFERENCE

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL TESTED</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>Bovine</td>
<td>30 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>RBC hemolysate</td>
<td>500 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipid d</td>
<td>500 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Glutathione</td>
<td>NA e</td>
<td>5.0 mmol/L</td>
<td>NSI</td>
</tr>
<tr>
<td>Methylbenzethonium Chloride</td>
<td>NA</td>
<td>2.0 mg/dL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

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

3. Refer to References (10,11,12) 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 6 ANALYTICAL RANGE

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>1.0 – 7.0 g/dL</td>
<td>10 – 70 g/L</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>1.0 – 7.0 g/dL</td>
</tr>
</tbody>
</table>

Refer to “DXC800 Linearity and Reportable Range” chart in Technical notes section of DXC800 Procedure manual if needed.

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).

EQUIVALENCY

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

Serum or Plasma (in the range of 0.8 to 7.4 g/dL):

\[
Y \text{(SYNCHRON LX Systems)} = 0.962X + 0.07
\]

\[
N = 99
\]

\[
\text{MEAN (SYNCHRON LX Systems)} = 3.84
\]
Serum or Plasma (in the range of 0.8 to 7.4 g/dL):

- MEAN (SYNCHRON CX® 7 DELTA) = 3.92
- Correlation Coefficient (r) = 0.9947

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

- Y (UniCel DxC Systems) = 0.990X + 0.05
- N = 158
- MEAN (UniCel DxC Systems) = 4.1
- MEAN (SYNCHRON LX Systems) = 4.1
- Correlation Coefficient (r) = 0.999

Refer to References (13) 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 8 MAXIMUM PERFORMANCE LIMITS**

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD g/dL</th>
<th>CHANGEOVER VALUE g/dL</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Serum/Plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within-run</td>
<td>Serum/Plasma</td>
<td>0.20</td>
<td>10</td>
<td>2.0</td>
</tr>
<tr>
<td>Total</td>
<td>Serum/Plasma</td>
<td>0.30</td>
<td>10</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Comparative performance data for a SYNCHRON LX System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below. Each laboratory should characterize their own instrument performance for comparison purposes.

**TABLE 9 NCCLS EP5-T2 PRECISION ESTIMATE METHOD**

<table>
<thead>
<tr>
<th>TYPE OF IMPRECISION</th>
<th>SAMPLE TYPE</th>
<th>No. Systems</th>
<th>No. Data Points</th>
<th>Test Mean Value (g/dL)</th>
<th>EP5-T2 Calculated Point Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-run</td>
<td>Serum</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>2.28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>4.83</td>
</tr>
<tr>
<td>Total</td>
<td>Serum</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>2.28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>4.83</td>
</tr>
</tbody>
</table>

**NOTICE**

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX® System and are not intended to represent the performance specifications for this reagent.

**ADDITIONAL INFORMATION**

For more detailed information on SYNCHRON LX Systems or UniCel DxC Systems, refer to the appropriate system manual.
SHIPPING DAMAGE

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


Beckman Coulter, Inc., 250 South Kraemer Blvd., Brea, CA 92821
ENDNOTES

a  NSI = No Significant Interference (within ±0.4 g/dL or 4%).

b  Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

c  NSI = No Significant Interference (within ±0.4 g/dL or 4%).

d  Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

e  NA = Not applicable.

f  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.

g  The point estimate is based on the 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.