Brown Clinic Northridge
511 14th Ave. NE
Watertown, SD

Brown Clinic
506 First Ave. SE
Watertown, SD

# BROWN CLINIC
# LABORATORY PROCEDURE MANUAL

**PROCEDURE:** Albumin

## PURPOSE:

The ALB method used on the Dimension EXL200 Integrated Chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of albumin in **serum** and **plasma**. Measurements of albumin are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Albumin is the protein of the highest concentration in plasma. Albumin is formed exclusively in the liver and serves as a transport and binding protein for calcium, fatty acids, bilirubin, hormones, vitamins, trace elements and drugs. It is also of prime importance in maintaining the colloidal osmotic pressure in both the vascular and extravascular spaces. Decreased serum albumin concentration can result from liver disease. It can also result from kidney disease, which allows albumin to escape into the urine. Decreased serum albumin may also be explained by malnutrition or a low protein diet.

## PRINCIPLE:

The albumin method is an adaptation of the bromocresol purple (BCP) dye-binding method reported by Carter[1] and Louderback, et al.[2] Because of an enhanced specificity of BCP for albumin [1, 3, 4] this method is not subject to globulin interference.[5] Multiple wavelength blanking increases sensitivity and minimizes spectral interference from lipemia.

In the presence of a solubilizing agent, BCP binds to albumin at pH 4.9. The amount of albumin-BCP complex is directly proportional to the albumin concentration. The complex absorbs at 600 nm and is measured using a polychromatic (600, 540, 700 nm) endpoint technique.

pH 4.9

Albumin + BCP dye----------->Albumin-BCP complex

(nonabsorbing at 600 nm) (absorbs at 600 nm)

## INSTRUMENT, REAGENTS & SUPPLIES:

| Wells[a] | Form | Ingredient | Concentration[b] |
|---|---|---|---|
| 1–6[c] | Liquid | BCP dye | $2.7 \times 10^{-4}$ M |
| | | Acetate Buffer | |
| | | Surfactant | |
| | | Microbial inhibitor | |

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value per test.
c. See Precautions.

**Precautions:** Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact and ingestion.[6]

Irritant. Contains 2-chloraceetamide

R43: May cause sensitization by skin contact

S24: Avoid contact with skin

S37: Wear suitable gloves

Safety Data Sheets (SDS/MSDS) available on www.siemens.com/healthcare

For *in vitro* diagnostic use

**Reagent Preparation:** All reagents are liquid and ready-to-use.

**STORAGE & STABILITY:**
Store at 2 – 8° C.

**Expiration:** Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. Once wells have been entered by the instrument, they are stable for 72 hours.

**SPECIMEN REQUIREMENTS:**
Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.[6]

**Specimen:**

- patient preparation: no required preparation
- specimen type: serum or heparinized plasma
- handling: analyze immediately or refrigerate at 2-8 degrees C
- Stability: Specimens are stable for 8 hours at room temperature, 2 days at 2-8 degrees C. For longer storage, specimens may be frozen at -10 degrees C or colder.
- Heparin, in the concentrations routinely found in commercially available blood collection tubes (14.3 U/mL), does not interfere with the ALB method. Lithium heparin (280 U/mL [280000 U/L]) lowers the ALB result by 2.4 g/dL [24 g/L] at an albumin concentration of 4.1 g/dL [41 g/L].
- Blood collection tubes containing both potassium oxalate and sodium fluoride will decrease albumin results by 10%.
- Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot to lot.

**CONTROLS:**
At least once daily run solutions at two levels of a quality control material with known concentrations.

For further details, refer to your Dimension® system manual. The result obtained should fall within limits defined by the day-to-day variability of the system as measured in the user's laboratory. If the results fall outside the laboratory's acceptable limits, follow the procedure in the quality control policy.

**PROCEDURE:**
The ALB Flex® reagent cartridge, Cat. No. DF13, is required to perform the ALB test. This test is performed on the Dimension® clinical chemistry system after the method is calibrated.

**Test Steps** Sampling [e], reagent delivery, mixing, and processing and printing of results are automatically performed by the Dimension® system. For details of this processing, refer to your Dimension® system manual.

e. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus the dead volume; "precise" container filling is not required.

**Test Conditions**

- Sample Size: 5 µL
- Reagent 1 Volume: 125 µL
- Diluent Volume: 370 µL
- Test Temperature: 37° C
- Wavelength: 540, 600 and 700 nm
- Type of Measurement: polychromatic endpoint

**Backup:**
Refer to Brown Clinic Backup Policy

**Calibration** The general calibration procedure is described in the Dimension® system manual (also see Appendix B).

The following information should be considered when calibrating the albumin method:

| | |
|---|---|
| Assay Range: | 0.6–8.0 g/dL [6–80 g/L] |
| Reference Material: | Purified human albumin or secondary calibrators such as Total Protein/Albumin Calibrator (Cat. No. DC31) |
| Suggested Calibration Levels: | 0.5, 4.5, 8.3 g/dL [5, 45, 83 g/L] |
| Calibration Scheme: | Three levels in triplicate |
| Calibration Frequency: | Every new reagent cartridge lot. Every 3 months for any one lot |
| Assigned Coefficients: | $C_0$ –1.060 |

$C_1$ 0.023

**INTERPRETATION:**
The instrument automatically calculates and prints the concentration of albumin in g/dL [g/L] using the calculation scheme illustrated in the Principles of Operation Section of the Reference Manual.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

**REFERENCE RANGE:**
3.4–5.0 g/dL [34–50 g/L]

This reference population consisted of the following: 240 males, 240 females

The reference interval was calculated non-parametrically and represents the central 95% of the population.

Posture affects serum protein concentration; it is lower when a subject is in the supine position.[10]

Each laboratory should establish its own reference interval for albumin as performed on the Dimension® system.

**REPORTING**:

report format: g/dl

**LIMITATIONS:**
Results: >8.0 g/dL [80 g/L]

Manual dilution: Make appropriate dilution with Purified Water to obtain result within the assay range. Enter dilution factor.

Reassay. Resulting readout is corrected for dilution.

Autodilution (AD): Refer to your Dimension® system literature.

Results less than 0.6 g/dL [6 g/L] should be reported as "less than 0.6 g/dL [6 g/L]" instead of the numerical number.

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension® system manual.

**Analytical Specificity**

For Known Interfering Substances section refer to package insert.

For Known Non-Interfering Substance refer to package insert.

For Additional Technical Information refer to package insert.

**REFERENCES:**

**Reference: ALB Flex® reagent cartridge insert sheet PN 717013.001 Issue Date 2015-01-30**

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Written By: ____Lori Murray MT(ASCP)_____ Date: _8-8-12

Approved By: _____Aaron Shives, MD_____ Date: ___10/21/2017_____
Laboratory Director

**REVIEW - REVISION SUMMARY DOCUMENTATION**

| Date | By | Revision Summary |
|---|---|---|
| 07/10 | Lori Murray | New format |
| 08/08/12 | Lori Murray | Chg analyzer type to EXL 200 |
| 4/7/15 | Heather Hall | Update information to package insert dated 2-12-2008 |
| 8/3/15 | Heather Hall | Updated Precautions |
| 2-17 | Lori Murray | backup method |
| 10/17/17 | Heather Hall | Modified backup method |