TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	7/2/2015
Department:	Core	**Due Date:**	8/2/2015
		Implementation:	**8/3/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Albumin by Dimension® Xpand Chemistry Analyzer	**GEC.C14 v1**
Total Protein by Dimension® Xpand Chemistry Analyzer	**GEC.C15 v1**

Description of change(s):

Most changes are minor and the following apply to both of them

Section	Reason
1, 7.1	Add analyzer name
3.2	Specify anticoagulant
5.3	Edit calibration levels statement
6.4, 6.6	Replace LIS with Unity Real Time
6.7	Add use of TEA for lot to lot runs
8.2	Remove Lynx
10.5	Remove use of code REP from dilutions, remove code QNSR
15	Update to standard wording
16	Update titles

Albumin only

Section	Reason
4.2	Update hazard statement

A copy of the Albumin SOP is attached, changes are highlighted and deletions are crossed out in red

These revised SOPs will be implemented on August 3, 2015

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training

Technical SOP

Title	**Albumin by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 3/3/2011
Owner	Robert SanLuis Date: 3/3/2011

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Albumin	Dimension® Xpand Chemistry Analyzer	ALB

Synonyms/Abbreviations
Alb

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The albumin method is an adaptation of the bromocresol purple (BCP) dye-binding method reported by Carter and Louderback, et al. Because of an enhanced specificity of BCP for albumin this method is not subject to globulin interference. 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 (nonabsorbing at 600 nm)	---------->	Albumin-BCP complex (absorbs at 600 nm)

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	Posture affects serum protein concentration; it is lower when a subject is in the supine position.

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum	
Collection Container	Plasma: Mint green top tube Serum: Red top tube, Serum separator tube (SST)	
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL	
Transport Container and Temperature	Collection container or Plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	8 hours
	Refrigerated:	(2-8°C) 2 days
	Frozen:	(-20°C or colder) 1 month

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Criteria	
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Blood collection tubes containing both potassium oxalate and sodium fluoride will decrease albumin results by 10%. Request a new specimen if either is submitted. Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request redraw. Credit the test with the appropriate LIS English text code.
Other Considerations	Allow to clot completely prior to centrifugation.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Albumin	Siemens, Flex® reagent cartridge, Cat. No. DF13

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Irritant. Contains 2-chloracetamide.
May cause an allergic skin reaction.
Wear protective gloves/protective clothing/eye protection/face protection.
Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention

Reagent	**Albumin**
Container	Reagent cartridge
Storage	Store at 2-8°C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. • Once wells 1 – 6 have been entered by the instrument, they are stable for 3 days.
Preparation	Reagents are supplied ready for use. No additional preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Total Protein/Albumin Calibrator	Siemens Dimension®, Cat. No. DC31

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	Total Protein/Albumin Calibrator
Preparation	• Remove vials from refrigerator and allow to stand at room temperature for 10 to 15 minutes. • Volumetrically add 2.00 ± 0.01 mL of room temperature (22 - 28°C) Millipore® water to each vial. • Replace stopper, and let stand for 5 minutes. Do not invert. • Swirl vials gently for 60 seconds, and then gently invert 20 times. • Let vials stand for 10 minutes, and then gently invert 20 times. • Let vial stand for additional 30 minutes. Then invert 20 times and swirl gently. • Use immediately or refrigerate at 2-8°C for future use. Prior to use, inspect vials for undissolved material. If present, position vial to fully immerse undissolved material in liquid. Let stand 10 minutes, invert 20 times and swirl gently.

Storage/Stability	• Store at 2-8°C. • The unopened reagents are stable until the expiration date printed on the label. • Assigned values are stable for 8 hours after reconstitution when stoppered and stored at 2-8°C.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Total Protein/Albumin Calibrator
Assay Range	0.6 – 8.0 g/dL
Calibration levels	See reagent package insert for lot specific assigned values in g/dL
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot. • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate.
Assigned Coefficients	C_0 –1.060 C_1 0.023

5.4 Calibration Procedure

1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated - if lot number is incorrect Press F1: Other Lot
3. Enter all information on screen
4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.
6. Press F7: Load/run
7. Load cups into assigned position
8. Press F4: RUN

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Control Levels 1 & 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	Liquichek Unassayed Chemistry Controls Levels 1 and 2
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Open controls are stable for 15 days at 2-8°C. Unopened and unthawed controls are stable until the expiration date at -20 to -70°C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension X-pand® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.

- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Calibrated pipettes and disposable tips
- Plastic serum tubes and serum cups
- Purified water (Millipore® or equivalent)

8. PROCEDURE

ALB Flex® reagent cartridge Cat. No. DF13 is required to perform this test.

Albumin is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	**Instrument Set-Up Protocol**
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

8.2	**Specimen/Reagent Preparation**
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	**Specimen Testing**
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® Xpand system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

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

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of albumin in g/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results to one decimal point.

10.3 Units of Measure

g/dL

10.4 Clinically Reportable Range (CRR)

0.6 - 24.0 g/dL

10.5 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa policy for specific information.

Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated

IF the result is …	THEN…
<0.6 g/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: <0.6 g/dL
≥8.0 g/dL	**On Board Automated Dilution:** Results ≥8.0 g/dL will automatically have repeat testing performed into the instrument using dilution factor of 2.5. No multiplication is necessary. ~~Append the result with code – REP.~~
> 20.0 g/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 3 **Diluent:** Purified water. Enter dilution factor as a whole number on the "Enter Sample

	Data" screen. ~~Report the assay with code of –REP.~~
>24.0 g/dL	If the recommended dilution does not give results within the clinically reportable range, report as: ">24.0 g/dL-REP" Bring to the attention of your supervisor prior to releasing result.

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Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>19 years):	3.4 – 5.0 g/dL	3.4 – 5.0 g/dL
Pediatric:		
0 – 7 days	1.9-4.0	2.4-3.9
8 – 30 days	1.9-4.4	2.1-4.5
31 – 90 days	2.0-4.2	2.1-4.8
91 – 180 days	2.3-4.4	2.2-4.9
6 – 12 months	2.3-4.7	2.2-4.7
13 months – 3 years	3.5-4.7	3.5-4.2
4 – 6 years	3.6-5.2	3.6-5.2
7 – 9 years	3.8-5.6	3.8-5.6
10 – 19 years	3.8-5.6	3.8-5.6

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

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 can also be explained by malnutrition or a low protein diet.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

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 Xpand Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

Concentration	S.D.
0.69 g/dL	> 0.10 g/dL
3.84 g/dL	> 0.12 g/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.6 – 8.0 g/dL

14.2 Precision

Material	Mean g/dL	Standard Deviation (%CV)	
		Within-run	Total
Multiqual® Control			
Normal	4.23	0.056 (1.3)	0.072 (1.7)
Abnormal	3.21	0.050 (1.6)	0.073 (2.3)

14.3 Interfering Substances

CMPF (3-carboxy-4-methyl-5-propyl-2-furanpropanoic acid) present in sera of patients with renal failure has been reported to give falsely low albumin values.

Lipemia at 1000 mg/dL and above tripped a test report message; therefore the magnitude of the interference could not be determined.

HIL Interference:
The ALB method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI/NCCLS EP7-P. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Test Concentration SI Units	ALB Conc g/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL [0.62 mmol/L]	2.3	<10
Bilirubin	80 mg/dL [1368 µmol/L]	2.3	<10
Lipemia (Intralipid®)	600 mg/dL [6.78 mmol/L]	2.3	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart

14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
18. Current package insert ALB Flex® Reagent Cartridge DF13

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144
2. Package Insert, ALB Flex® Reagent Cartridge DF13, Siemens Healthcare Diagnostics Inc., 01/30/2015.
3. Package Insert, Total Protein/Albumin Calibrator DC31, Siemens Healthcare Diagnostics Inc., 12/2012.
4. Package insert, Liquichek Unassayed Serum Chemistry Controls, Bio-Rad Laboratories, 05/2014.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C042.003		
000	6/8/15	1, 7.1	Add analyzer name	L Barrett	R SanLuis
000	6/8/15	3.2	Specify anticoagulant	L Barrett	R SanLuis
000	6/8/15	4.2	Update hazard statement	L Barrett	R SanLuis
000	6/8/15	5.3	Edit calibration levels statement	L Barrett	R SanLuis
000	6/8/15	6.4,6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
000	6/8/15	6.7	Add use of TEA for lot to lot runs	L. Barrett	R SanLuis
000	6/8/15	8.2	Remove Lynx	L Barrett	R SanLuis
000	6/8/15	10.5	Remove use of code REP from dilutions, remove code QNSR	L Barrett	R SanLuis
000	6/8/15	15	Update to standard wording	L. Barrett	R SanLuis
000	6/8/15	16	Update document titles	L Barrett	R SanLuis
000	6/8/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None