TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	10/15/2014
Department:	Core	**Due Date:**	11/11/2014
		Implementation:	**11/12/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Protein, Urine and Cerebrospinal Fluid by Dimension Vista® System SGAH.C116, WAH.C112 v1

Description of change(s):

Section	Reason
5.2	Remove calibrator off board stability
6, 17	Add Urine Chemistry Control *
16	Update titles

* No change to this, were just missing from original SOP

This revised SOP will be implemented on November 12, 2014

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

Approved draft for training at all sites

Technical SOP

Title	**Protein, Urine and Cerebrospinal Fluid by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis, ~~Jean Buss~~ Date: 10/7/2014

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
Urine Total Protein, Random	Dimension Vista® System	UTPR
Urine Total Protein, 24 hour		UTP24
CSF Total Protein		CTP

Synonyms/Abbreviations
UTP, Urinary protein, CSFP; CTP is included in Batteries/Packages: CPRO UTPR is included in Batteries/Packages: UTP24

Department
Chemistry

2. ANALYTICAL PRINCIPLE

In the reaction sequence, pyrogallol red combines with sodium molybdate to form a red complex with maximum absorbance at 470 nm. The protein in the sample reacts with this complex in acid solution to form a bluish-purple colored complex, which absorbs at 600 nm. The absorbance at 600 nm is directly proportional to the concentration of protein in the sample. The analyte concentration is determined by calculation using a logit curve fit on a previously stored calibration curve.

Pyrogallol red-molybdate + protein ----------> PR-MO-protein 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 cerebrospinal fluid may be used for samples to be analyzed by this method. Urine: A timed 24 hour collection is preferred. See Laboratory Test Directory (electronic) for collection instructions. Random Urine: Clean catch specimen. Deliver to laboratory promptly.
Special Collection Procedures	CSF: Cerebrospinal fluid should be collected with care to avoid contamination with plasma protein.
	24 hour Urine: **Inpatient:** See Laboratory Test Directory (electronic) for details. Refrigerate during collection. **Outpatient:** Provide patient with prepared instructions sheet and container.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type	**-Preferred**	Urine: 24 hour specimen CSF: Sterile tube number 1 from lumbar puncture tray.
	-Other Acceptable	Urine: Random urine or other timed collections CSF: Tube 3 may be used, if not needed for other testing.

Form revised 2/02/2007

Criteria			
Collection Container	Timed Urine Collection: 24 hour container, no additives or preservatives. Random Urine: Urine collections cup CSF: Sterile tubes from lumbar puncture tray.		
Volume - Optimum **- Minimum**	24 hr Urine: Total voided in 24 hrs. N/A	Random Urine: 10 mL 5 mL	CSF: 1 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature		
Stability & Storage Requirements	Room Temperature:	Urines: 2 hours CSF: test immediately upon receipt	
	Refrigerated:	3 days	
	Frozen:	Urine: 1 year CSF: 6 months	
	Instrument on board aliquot stability	2 hours	
Timing Considerations	CSF specimens take priority in specimen handling		
Unacceptable Specimens & Actions to Take	**CSF** samples are unlikely to be recollected; therefore, utilize discretion in rejecting a sample of this type. **Consult your supervisor.** Specimens that are unlabeled, improperly labeled, markedly hemolyzed, or those that do not meet the stated criteria are unacceptable. **Urines:** Request a recollection and credit the test with the appropriate code. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Consult the English text code list for "test not performed" messages from the LIS. Document the request call in the LIS.		
Compromising Physical Characteristics	**CSF:** Blood present in the cerebrospinal fluid invalidates the protein values since it reflects contamination with plasma proteins. **Urine:** Centrifuge urine before analyzing to remove particulates.		
Other Considerations	Measure total 24 hour volume and enter volume into LIS. Prepare, label, and refrigerate an aliquot in a small urine collection cup. Record 24 hour volume on aliquot.		

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
UCFP	Siemens, Flex® reagent cartridge, Cat. No. K3026

4.2 Reagent Preparation and Storage

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. 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.

Reagent	**UCFP**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 6 have been entered by the instrument, they are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
UCFP CAL	Siemens Dimension Vista®, Cat. No. KC260

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) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

Calibrator	UCFP CAL
Preparation	Calibrator is ready for use. No preparation is required.

Storage/Stability	• Store at 2 - 8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	UCFP CAL
Assay Range	5 – 250 mg/dL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 60 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	5 levels, n = 5

5.4 Calibration Procedure

Auto Calibration:

1. Place the required calibrator vials in a carrier. Make sure the barcode labels are entirely visible through the slots.
2. Place the carrier in the loading area.
3. Position the carrier with the labels facing away from the user.
4. Press the **Load** button.
5. Automatic calibration requires that calibrators be on the instrument. As the time for processing approaches, the instrument reviews onboard inventory for the appropriate calibrators.

Manual Calibration:

1. Verify that calibrators and reagents are in inventory on the instrument.
2. Press **System > Method Summary > Calibration**.
3. Select a method from the sidebar menu. Press the **Order Calibration** button on the screen.
4. Verify that the information on the screen is correct. Verify that the calibrator lot is correct using the drop-down menu.
   a. When calibrating using Vials press **OK**.
   b. When calibrating using Cups, check the Use Cups box. This displays the rack and cup position fields. For additional cups use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU. Scan the rack barcode and place calibrator cups in an adapter in position 1 on a rack. Press **OK** and load the rack on the instrument.

5. The status field in the calibration screen changes sequentially to Awaiting Scheduling, Preparing Calibrators and Processing.

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™ Spinal Fluid Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 751 and 752
Liquichek™ Urine Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 397 and 398

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. A barcode label is produced and placed on the vial.

Control	Liquichek Spinal Fluid Control, Levels 1 and 2,
Preparation	Before sampling, allow the control to reach room temperature (18-25°C) and swirl the contents gently to ensure homogeneity.
Storage/Stability	Once the vial is opened, all analytes will be stable for 30 days at 2-8°C. This product is stable until the expiration date when stored at 2-8° C.

Control	Liquichek Urine Chemistry Control, Levels 1 and 2
Preparation	Before sampling, allow the control to reach room temperature (18-25°C) and swirl the contents gently to ensure homogeneity.
Storage/Stability	Once the vial is opened, all analytes will be stable for 30 days at 2-8°C. This product is stable until the expiration date when stored at 2-8° C.

Form revised 2/02/2007

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Dimension Vista® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension Vista® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

Form revised 2/02/2007

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Vista® 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 the LIS. The LIS 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 Vista® 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

- Aliquot Plates
- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

UCFP Flex® reagent cartridge Cat. No. K3026 is required to perform this test.

Urinary/Cerebrospinal Fluid Protein is performed on the Dimension Vista® 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	Sample Processing
1.	A sample rack holding tubes or cups is placed on the rack input lane.
2.	The sample shuttle moves the rack to the barcode reader which identifies the rack and samples to the system.
3.	The rack moves into the sample server and to the rack positioner.
4.	At the same time, aliquot plates move from the aliquot loader into position.
5.	The aliquot probe aspirates the sample from the tubes or cups and dispenses it into the wells of the aliquot plates.
6.	After each aspirate-dispense action, the probe is thoroughly rinsed inside and out to prevent sample carryover.
7.	When sample aspiration is completed, the sample server moves the rack back to the sample shuttle, where it is placed on the output lane and can be removed by the operator.

8.2	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension Vista® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension Vista® Operator's 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 Vista® 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.

8.2	Specimen Testing
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 Volume:	3.68 µL
Reagent Volume:	128.68 µL
Reaction Time:	2 minutes
Test Temperature:	37° C
Wavelength:	600 & 700 nm
Type of measurement:	Bichromatic endpoint

9. CALCULATIONS

The instrument automatically calculates the concentration of urinary/cerebrospinal fluid protein in mg/dL.
For 24 hour urines, the LIS will calculate the total mg of protein/24hrs if the protein result from the aliquot is within the CRR. If below 5mg/dL, the total mg/24 hrs is manually calculated as follows:

$$\frac{(5\text{mg/dL}) \times (\text{Total Urine Volume})}{100} = \#\ \text{mg/24hrs}$$

A “less than” character should be placed in front of the numerical value when reporting.
For values above the CRR (2500mg/dL), the same calculation is used as above except substitute 2500 for 5 and use the “greater than” character (>) in front of the numerical answer from the calculation.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

5 – 2500 mg/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 listing 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…
< 5 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 5 mg/dL See section 9 for calculation of total mg of protein/24 hours.
≥ 250 mg/dL	**On Board Automated Dilution:** Results ≥ 250 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 1.84. No multiplication is necessary.
> 460 mg/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 10 **DILUENT**: Water Enter dilution factor as a whole number. Re-assay. Readout is corrected for dilution.
> 2,500 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 2,500 mg/dL-REP". See section 9 for calculation of total mg of protein/24 hours. Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

CSF Total Protein:

Age	Female	Male
Adult (>18 years):	15 – 45 mg/dL	15 – 45 mg/dL
Pediatric:		
0 – 14 days	15-153	15-100
15 – 30 days	15-100	15-96
31 days – 2 months	15-93	15-48
3 – 6 months	15-44	15-48
7 – 23 months	15-48	15-50
2 – 7 years	15-45	15-45
8 – 18 years	15-45	15-40

Urine Total Protein Random:
<12 mg/dL

Urine Protein, 24 hour:
<149 mg/24 hr

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Measurement of the protein content in urine is used in diagnosis and treatment of kidney diseases. Measurement of the protein content in cerebrospinal fluid is used in the diagnosis and treatment of central nervous system diseases.

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 Vista Operator's Guide.

The expected maximum observed standard deviations for repeatability using n = 5 replicates at the following urinary/cerebrospinal fluid protein concentrations are:

UCFP Concentration	Acceptable S.D. Maximum
30 mg/dL	2.4 mg/dL
100 mg/dL	10.9 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

5 – 250 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Liquichek Urine Chem. Control			
Level 1	27.8	0.6 (2)	1.1 (4)
Level 2	74.6	1.0 (1)	1.4 (2)
Level 3	106.1	2.6 (2)	2.7 (3)
Liquichek Spinal Fluid Control			
Level 1	38.4	0.8 (2)	1.1 (3)
Level 2	88.3	1.2 (1)	1.8 (2)

14.3 Interfering Substances

Hemolyzed samples should be avoided since hemolysis increases UCFP results. Hemoglobin at 10 mg/dL increases UCFP result by 22% at UCFP level of 48 mg/dL .

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 Vista® Clinical Chemistry System Operator's Manual
2. Dimension Vista® Calibration/Verification Procedure
3. Dimension Vista® Cal Accept Guidelines
4. Dimension Vista® Calibration summary
5. Dimension Vista® Sample Processing, Startup and Maintenance procedure
6. Laboratory Quality Control Program
7. QC Schedule for Siemens Dimension Vista®
8. Laboratory Safety Manual
9. Material Safety Data Sheets (MSDS)
10. Dimension Vista® Limits Chart (AG.F200)
11. Quest Diagnostics Records Management Procedure
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
14. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
17. Current package insert UCFP Flex® Reagent Cartridge K3026

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, UCFP Flex® Reagent Cartridge K3026, Siemens Healthcare Diagnostics Inc., 08/20/2013.
3. Package Insert, UCFP CAL, Siemens Healthcare Diagnostics Inc., 10/2012.
4. Package Insert, Liquichek Spinal Fluid Control, Bio-Rad Laboratories, 09/2013.
5. Package Insert, Liquichek Urine Chemistry Control, Bio-Rad Laboratories, 04/2014.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	10/7/14		Update owner	L Barrett	R SanLuis
000	10/7/14	5.2	Remove calibrator off board stability	A Chini	R SanLuis
000	10/7/14	6, 17	Add Urine Chemistry Control	A Chini	R SanLuis
000	10/7/14	16	Update titles	L Barrett	R SanLuis
000	10/7/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis

19. ADDENDA

None