UnityPoint Health Pekin
Department of Pathology
Pekin, IL 61554

Effective Date: 02/18/19
Date Reviewed/ Date Revised: 02/18/19

URINE PROTEIN

Siemens Dimension® Rxl®Max
UTP and UTPCRR

I. PRINCIPLE

The urine protein (UCFP) method uses Pyrogallol red which combines with sodium molybdate to form a red complex with maximum absorbance at 470nm. The protein in the sample reacts with this complex in acid solution to form a bluish-purple colored complex, which absorbs at 600nm. The 600nm absorbance 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.

II. CLINICAL SIGNIFICANCE

Measurement of the protein content in urine is used in diagnosis and treatment of kidney diseases.

III. SPECIMEN

A. Normal procedures for collecting urine samples.
B. Urine specimens must be free of any particulate matter. Centrifuge if cloudy or turbid before testing.
C. Specimens stored at 4°C are stable for at least three days

IV. REAGENT

A. UCFP Flex® reagent cartridge, Cat. No DF26
B. Wells 1 – 5 contain liquid Pyrogallol red in methanol at 0.20mM, sodium molybdate, stabilizers and surfactants
C. Wells 7 – 8 contain liquid NaOH, 0.5N
D. Open wells are stable for 5 days.
E. Individual unopened reagent cartridges are stable according to the expiration date on the carton.
F. Sealed cartridge wells on the analyzer are stable for 30 days.
G. Reagents are liquid and ready to use. Store at 2-8^{0}C.

V. INSTRUMENTATION/EQUIPMENT

A. Siemens Dimension® RXL Max® Chemistry analyzer

VI. CALIBRATION

A. UCFP Calibrator, Cat. No. DC45
B. Five calibration levels at 6.0, 30.0, 60.0, 135.0, 270.0 mg/dL.
C. Calibration frequency is every 2 months for one lot number and a new calibration is required for each new lot number of reagent flex, after major maintenance or service, if

indicated by quality control results, as indicated by quality control procedure, and when required by CAP regulations.

VII. QUALITY CONTROL

A. Quality Control is performed daily using the Bio-Rad Liquichek Urine Chemistry control consisting of two levels of control.
B. All QC procedures must be followed if results are outside the acceptable limits.

VIII. PROCEDURE:

A. Random urine protein: UTP
   1. Urine specimen is tested straight and untreated.
   2. Identify specimen with two forms of information. Specimen should have a Sunquest generated barcode label with the patient information.
   3. Specimen should be centrifuged before testing if cloudy or turbid.
   4. Place patient barcoded tube onto analyzer and start by pressing "RUN"
   5. If the protein result exceeds the linear range (AMR) of 250mg/dL, a manual dilution must be performed with CLR water to obtain a result within the assay range. Enter the dilution factor on the analyzer for the result that is corrected for dilution. See the AMR chart for information.

B. Urine Protein Creatinine Ratio~~n~~: UTPCRR
   1. Process the urine specimen as in steps A.1 -5.
   2. If the creatinine exceeds linear range a manual dilution must be performed with CLR water. The recommended manual dilution is 1:2

~~Urine specimen is tested straight and untreated.~~
~~1. Identify specimen with two forms of information. Specimen should have a Sunquest generated barcode label with the patient information.~~
~~1. Specimen should be centrifuged before testing if cloudy or turbid.~~
~~1. Place patient barcoded tube onto analyzer and start by pressing "RUN"~~
~~1. If the protein result exceeds the linear range (AMR) of 250mg/dL, a manual dilution must be performed with CLR water to obtain a result within the assay range. Enter the dilution factor on the analyzer for the result that is corrected for dilution. See the AMR chart for information.~~
~~2. If the creatinine exceeds linear range manual dilution.~~

Formatted: Justified

IX. REPORTING RESULTS

A. The AMR of the UCFP is 6- 250mg/dL.
B. The CRR of UCFP is 6 – 5000mg/d~~D~~L~~l~~
~~B.~~C. AMR of urine creatinine is 13- 400mg/dL. The CRR for urine creatinine is13 - 800mg/dL.
~~C.~~D. Calculation of the protein creatinine ratio is provided by Sunquest.

$$\frac{\text{Urine Protein}}{\text{Urine Creatinine}} = \text{Urine Protein/Creatinine Ratio}$$

X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. The analyzer reporting system contains flags and messages for user information. See the Dimension® RxL Max® Operator's Guide for information on these messages. Address the messages before reporting patient results.

XI. REFERENCES

A. Siemens Healthcare Diagnostics, Inc. UCFP Method Insert Sheet, 12/2017
B. Dade Behring Inc. Dimension® RxL Max® Operator's Guide 06/2008

POLICY CREATION :		***Date***
Author:	***Suzanne Behle, MT (ASCP)***	***02/18/19***
Medical Director:	***Lori Racsa, DO***	***02/18/19***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)			
Rev	Description of Change	Author	Effective Date

Reviewed by

Lead	Date	Coordinator/ Manager	Date	Medical Director	Date