Brown Clinic Northridge
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BROWN CLINIC
LABORATORY PROCEDURE MANUAL

PROCEDURE: Urea Nitrogen

PURPOSE: The BUN method used on the Dimension EXL200 integrated chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of urea nitrogen in **serum**, **plasma** and **urine**.

PRINCIPLE:
Urea is the major nitrogen-containing metabolic product of protein catabolism in humans. The principal utility of urea nitrogen determination lies in conjunction with measurement of creatinine in serum or plasma to discriminate between prerenal and postrenal azotemia. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases. Increases in serum urea nitrogen may be due to prerenal, renal or postrenal causes.[1]

The urea nitrogen method employs a urease/glutamate dehydrogenase coupled enzymatic technique.[2]

Urease specifically hydrolyzes urea to form ammonia and carbon dioxide. The ammonia is used by the enzyme glutamate dehydrogenase (GLDH) to reductively aminate α-ketoglutarate(α-KG), with simultaneous oxidation of reduced nicotinamide-adenine dinucleotide (NADH). The change in absorbance at 340 nm due to the disappearance of NADH is directly proportional to the BUN concentration in the sample and is measured using a bichromatic (340, 383 nm) rate technique.

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \alpha\text{-KG} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-glutamate} + \text{NAD}$$

INSTRUMENT, REAGENTS & SUPPLIES:
Reagents

Wells[a]	Form	Ingredient	Concentration[b]
1-3	Tablet[c]	α-KG	4.69 mmol/L
		NADH	0.34 mmol/L

		Urease	6.8 U/mL
		Activator	
		and Stabilizers	
4–6	Liquid[d]	GLDH	2.0 U/mL
		Stabilizers	

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value per test at manufacture.
c. Tablet contains excipients.
d. Used to rehydrate tablets in wells 1–3.

Risk and Safety:
Safety data sheets(MSDS/SDS)available on www.siemens.com/healthcare

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact and ingestion.[2]

For *in vitro* diagnostic use

Reagent Preparation: Mixing and diluting are automatically performed by the Dimension® system.

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 5 days.

SPECIMEN REQUIREMENTS:
Normal procedures for collecting and storing serum, plasma and urine may be used for samples to be analyzed by this method.[2]

Specimen:

- patient preparation: none required
- specimen types: serum or heparinized plasma, urine
- handling: analyze immediately or refrigerate at 2-8 degrees C
- Stability: Separated plasma or serum is good for 3-5 days at room temperature, 7 days at 4 degrees C and indefinitely at -20 degrees C

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 BUN Flex® reagent cartridge, Cat. No. DF21, is required to perform the BUN test. This test is performed on the Dimension® clinical chemistry system after the method is calibrated.

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

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: 3 µL
- Reagent 1 Volume: 90 µL
- Diluent Volume: 277 µL
- Test Temperature: 37°C
- Wavelength: 340 and 383 nm
- Type of Measurement: bichromatic rate

Backup:
Refer to Brown Clinic Backup Policy

Calibration The general calibration procedure is described in your Dimension® system manual (also see Appendix B). The following information should be considered when calibrating the urea nitrogen method:

Assay Range:	0–150 mg/dL [0–53.5 mmol/L]
Reference Material:	CHEM I Calibrator (Cat. No. DC18B or DC18C)
Suggested Calibration Levels**:	0, 85, 165 mg/dL [0, 30.3, 59.0 mmol/L]
Calibration Scheme:	Three levels in triplicate
Calibration Frequency:	Every new reagent cartridge lot
	Every month for any one lot
	For each new lot of Flex reagent cartridges
	After major maintenance or service, if indicated by quality control results
	As indicated in laboratory quality control procedures
	When required by government regulations
Assigned Coefficients:	C_0 0.6409
	C_1 –0.9785

**The conversion factor of 2.14 must be applied to the BUN calibrator bottle values (mg/dL) prior to calibrating if the laboratory wishes to express the results of urea nitrogen as urea.

INTERPRETATION:
The instrument automatically calculates and prints the concentration of urea nitrogen in mg/dL [mmol/L] using the calculation scheme illustrated in your Dimension® system manual.

For purposes of diagnosis and treatment, results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

REFERENCE RANGE:

Serum: 7–18 mg/dL [2.5–6.4 mmol/L][2]

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

REPORTING:
report format: mg/dl

LIMITATIONS:

Results	> 150 mg/dL [53.5 mmol/L]
Manual dilution	Serum/Plasma: make appropriate dilution with Purified Water to obtain result within the assay range. Enter dilution factor.
	Serum/Plasma: reassay. Resulting readout is corrected for dilution.
Autodilution (AD)	Refer to your Dimension® system (for serum, plasma) literature.

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.

Reference: BUN Flex® reagent cartridge insert sheet PN 717021.001 Issue Date 2015-01-30 Rev. J

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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
8-8-12	Lori Murray	Changed instrumentation to EXL200
4/7/15	Heather Hall	Update information from package insert dated 7/30/2014
8/26/15	Amy Harms	Updated Risk and Safety dated 1/30/15
10/17/17	Heather Hall	Modified Backup process