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

Brown Clinic
506 First Ave. SE
Watertown, SD

BROWN CLINIC
LABORATORY PROCEDURE MANUAL

PROCEDURE: Uric Acid

PURPOSE:
The URCA method used on the Dimension EXL200 Integrated chemistry system is an in vitro diagnostic test intended for the quantitative determination of uric acid in **serum** and **plasma**.

SUMMARY:
The uric acid method is a modification of the uricase method first reported by Bulger and Johns[1], later modified by Kalckar.[2] Measurement of uric acid by monitoring the loss of absorbance at 293 nm following uricase treatment is generally recognized as being more specific and less subject to interference than other, indirect methods.

PRINCIPLES OF PROCEURE:

Uric acid, which absorbs light at 293 nm is converted by uricase to allantoin, which is nonabsorbing at 293 nm. The change in absorbance at 293 nm due to the disappearance of uric acid is directly proportional to the concentration of uric acid in the sample and is measured using a bichromatic (293,700 nm) endpoint technique.

$$\text{Uric acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + H_2O_2 + CO_2$$

(absorbs at 293 nm) (nonabsorbing at 293 nm)

INSTRUMENT, REAGENTS & SUPPLIES:

Wells[a]	Form	Ingredient	Concentration[b]	Source
1-3, 7	Liquid	Buffer Stabilizers		
8	Liquid	Uricase Stabilizers	8 IU/mL	Bacterial

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value per test at manufacture.

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact and ingestion.[3]

For *in vitro* diagnostic use

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

REAGENT 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 1-3 and 7 have been entered by the instrument, they are stable for 72 hours. Once well 8 has been entered by the instrument, it is stable for 30 days.

SPECIMEN REQUIREMENTS:
Recommended procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.

Specimen:

- Patient preparation: no preparation required
- Specimen type: serum or heparinized plasma
- Stability: Separated specimens are stable for 1 day at room temperature, 3-5 days at 2-8ºC. For longer storage, specimens may be frozen at -20ºC or colder for up to 6 months.
- Corvac® and SST® collection tubes do not affect the URCA method.

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 URCA Flex® reagent cartridge, Cat. No. DF77 is required to perform the URCA test. This test is performed on the Dimension® clinical chemistry system after the method is calibrated (see Reference Material Test Steps in Calibration section).

CHEM 1 Calibrator, Cat. No. DC18B or DC18C is needed for calibration along with quality control material.

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.

An alternate sample size of 10 µL can be programmed; refer to the Operator's Guide for the use of alternate sample size.

Test Conditions

- Sample Size: 17 µL, $(10\ \mu L)_d$
- Reagent 1 Volume: 132 µL
- Reagent 2 Volume: 26 µL
- Diluent Volume: 231 µL
- Test Temperature: 37°C
- Wavelength: 293 and 700 nm
- Type of Measurement: bichromatic endpoint

Backup Process:

Refer to Brown Clinic Backup Process Policy

CALIBRATION:

Assay Range:	0-20.0 mg/dL [0 - 1190 µmol/L]
Calibration Scheme:	3 levels, n=3
Units:	mg/dL [µmol/L]
Typical Calibration Levels:	0, 12, 23 mg/dL
Calibration Frequency:	Every new reagent cartridge lot
	Every 3 months 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:	Standard sample size = 17µL C_o 0.146 C_1 -0.070 Alternate Sample Size = 10 µL C_o 0.001 C_1 -0.123

INTERPRETATION:

The instrument automatically calculates and prints the concentration of uric acid in mg/dL [µmol/L] using the calculation scheme illustrated in your Dimension® system manual.

EXPECTED VALUES:

Serum: 2.6-7.2 mg/dL

REPORTING: mg/dl

LIMITATIONS:
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® Operator's Guide.

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: Flex® reagent cartridge insert sheet PN 717077.001 Issue date 10/20/2016

Origination Date: 9-10-07
Date of Implementation: 11-10-10
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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
6/16/15	Amy Harms	Removed urine references and Updated limitations.
7/11/17	Lori Murray	formatting
10/18/17	Heather Hall	Updated information to insert dated 10/20/16, modified backup process