DXC 800 (BUNM) UREA NITROGEN OR UREA

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☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of BUN on the DXC 800.

PRINCIPLE

BUNm or UREAm reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems AQUA CAL 1, 2 and 3, is intended for the quantitative determination of Urea Nitrogen or Urea concentration in human serum, plasma or urine. The system can be configured to report results as either Urea Nitrogen in default units of mg/dL or Urea in default units of mmol/L.

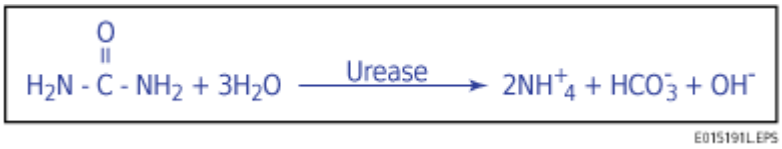
BACKGROUND

Clinical Significance

Urea nitrogen or urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Methodology

The SYNCHRON® System(s) determines urea nitrogen or urea concentration by means of an enzymatic conductivity rate method. A precise volume of sample (10 microliters) is injected into a reaction cup containing a urease solution. The ratio used is one part sample to 76 parts reagent. The reaction converts the non ionic species (urea) to one which is ionic (ammonium ion and bicarbonate). During the reaction, the timed rate of increase of solution conductivity is directly proportional to the concentration of urea present in the reaction cup.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC 800 Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma or properly collected urine (random/timed) are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.

Sample Type	Volume	Sample Stability
Plasma/Serum/Urine	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months. • URINE RECOMMENDED TO BE TESTED WITHIN 2 HOURS OR KEPT REFRIGERATED OR ON ICE. No preservative required for urine.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

SAMPLE PREPARATION

Urine Sample Preparation

All urine samples, including urine controls, must be diluted one part sample with nine parts normal saline prior to analysis on UniCel DxC 800 Systems. These dilutions should be made according to the following table:

URINE SAMPLE DILUENT

Sample	Dilution	Volume of Sample	Volume of Diluent
Controls	1:10	100 µL	900 µL
Samples	1:10	100 µL	900 µL

All urine results reported by the UniCel DxC 800 System must be multiplied by a correction factor of 10 (see CALCULATIONS Section of this chemistry information sheet).

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two Urease Concentrate Bottles (2 x 200 mL)
Two Diluent Bottles (2 x 1800 mL)
Two Wetting Agent (2 x 10 mL)

Volume *per Test*	
Sample Volume	10 µL
Ordac Sample Volume	5 µL
Total Reagent Volume	765uL

Reactive Ingredients	
Jack Bean Urease	25 U/mL

Also non-reactive chemicals necessary for optimal system performance

Reagent Preparation

Proceed to STEP 3. Currently, BUNm Wetting Agent is not being added to the BUN Reagent Diluent bottle. If instructed to add BUNm Wetting Agent, do as follows:

1. Pour contents of the BUNm Wetting Agent bottle (10mL) into the 2000 mL bottle containing the BUN Reagent Diluent (1800 mL).

2. Replace the cap and MIX GENTLY BY INVERTING TEN (10) TIMES. The resulting mixture may be slightly cloudy. This does not impact performance. Pour contents of the BUN Reagent Concentrate bottle (200mL) into the 2000 mL bottle containing the BUN Reagent Diluent and BUNm Wetting Agent. Proceed to STEP 4.

3. Pour the contents of the BUN Reagent Concentrate bottle (200 mL) into the 2000 mL bottle containing the BUN Reagent Diluent.

4. Replace the cap and MIX GENTLY BY INVERTING TEN (10) TIMES.

5. Record the preparation date on the end label.

6. Allow the reagent to warm to room temperature. This will require 2-3 hours if the Diluent was stored at room temperature. This will require 8-12 hours if the Diluent was stored refrigerated. A 32° or 37°C water bath or incubator may be used to speed up the equilibration to room temperature. Loosen the cap slightly to allow for out gassing.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria. **Do not reuse old reagent or mix fresh reagent with old reagent.**

Reagent Storage and Stability

1. Urea Nitrogen Reagent (BUN) Concentrate stored unopened at +2°C to +8°C is stable until the expiration date indicated on each bottle.

2. Urea Nitrogen (BUN) Diluent stored unopened at the **RECOMMENDED ROOM TEMPERATURE** (+18°C to +30°C), is stable until the expiration date indicated on each bottle.

3. Once mixed and loaded onto the instrument, Urea Nitrogen Reagent is stable for 15 days or until the expiration date, whichever is sooner.

4. Reagent frozen in transit will lose urease activity and may fail to calibrate. If frozen reagent calibrates, it will not have claimed on-instrument or unopened bottle stability. Frozen reagent should be discarded.

CALIBRATION

Calibrator Required

SYNCHRON® Systems AQUA CAL 1, 2 and 3

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. Unopened calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.

2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

1. The system must have a valid calibration in memory before controls or patient samples can be run.

2. Under typical operating conditions the BUNm or UREAm assay must be calibrated every 72 hours or with each new bottle of Urea Nitrogen reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions for Use* (IFU) manual.

3. For detailed calibration instructions refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH-0820 DXC 800 Controls

STEPS

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program samples and controls for analysis.

4. After loading samples and controls onto the system, follow the protocols for system operation. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

The conversion factors between BUNm and UREAm are:
1 mg/dL BUNm = 2.14 mg/dL UREAm
1 mg/dL BUNm = 0.357 mmol/L UREAm

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
Lithium Heparin	14 Units/mL	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
Sodium Heparin	14 Units/mL	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
Potassium Oxalate / Sodium Fluoride	2.0 / 2.5 mg/dL	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).

PERFORMANCE CHARACTERISTICS

Reference Range

Plasma/Serum 8 – 25 mg/dL
Urine 12 – 20 g/24 hr

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units (Urea Nitrogen)
Serum or Plasma	1 – 150 mg/dL
Serum or Plasma (ORDAC)	130 – 300 mg/dL
Urine	10 – 1500 mg/dL
Urine (ORDAC)	1300 – 3000 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed. See Section Urine Sample Preparation

Reporting results outside of analytical range

Lower Limit of range: serum/plasma	1 mg/dL	Results below 1, report as <1 mg/dL
Upper limit of range: serum/plasma	300 mg/dL	**DO NOT DILUTE.** Results >300 report as >300 mg/dL
Lower limit range: urine	10 mg/dL	Results below 10, report as <10 mg/dL
Upper limit of range: urine	3000 mg/dL	Results >3000 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X10. Results >30,000 are reported as >30,000 mg/dL

See the following: Section Urine Sample Preparation.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for the urea nitrogen or urea determination is 1 mg/dL (0.4 mmol/L) for serum or plasma and 10 mg/dL (3.57 mmol/L) for urine.

LIMITATIONS

None identified

Interferences

The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
Lipemia	Intralipid[d]	500 mg/dL INDEX of 10 Airfuge recommended	No Significant Interference (within ±3.0 mg/dL of urea nitrogen or 6%).
L-Dopa	NA[e]	40 µg/mL	-3 mg/dL
Methylbenzethonium Chloride	NA	0.5 mg/dL	-5 mg/dL

1. If urine samples are cloudy or turbid, it is recommended that they be centrifuged before dilution and analysis.
2. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >8, should be ultracentrifuged and analysis performed on the infranate.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Deleted EDTA as acceptable specimen, added max dilutions Added points 1 and 2 to Interferences. Changed serum ref ranges to match LIS.			
☒ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: ☒ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 9/25/15