DXC 600 (BUN) UREA NITROGEN OR UREA

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PURPOSE

To provide instructions for the quantitative determination of BUN on the DXC 600.

PRINCIPLE

BUN reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Urea Nitrogen concentration in human serum, plasma or urine.

BACKGROUND

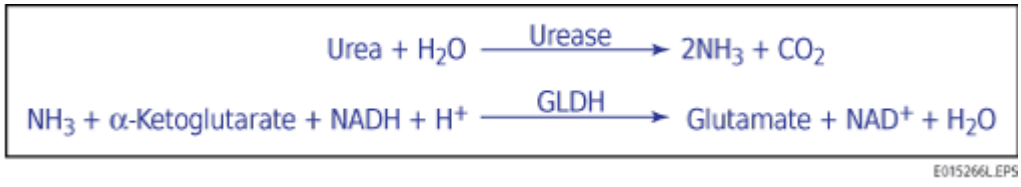
Clinical Significance

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

Methodology

BUN reagent is used to measure urea nitrogen concentration by an enzymatic rate method.[1,2] In the reaction, urea is hydrolyzed by urease to ammonia and carbon dioxide. Glutamate dehydrogenase (GLDH) catalyzes the condensation of ammonia and α-ketoglutarate to glutamate with the concomitant oxidation of reduced β-nicotinamide adenine dinucleotide (NADH) to β-nicotinamide adenine dinucleotide (NAD).
The SYNCHRON® System(s) automatically dilutes urine samples and proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent for serum or plasma and one part diluted sample to 100 parts reagent for urine. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of urea nitrogen in the sample and is used by the System to calculate and express the urea nitrogen concentration.

Chemical Reaction



RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
M-F-CH0820	DXC 600 Controls
M-F-CH0826	DXC 600 Calibrators

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Freshly collected urine may also be used for testing. 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

1. 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.
2. 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.
3. 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	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • FROZEN 3 MONTHS. • URINE RECOMMENDED TO BE TESTED WITH 2 HOURS OR KEPT REFRIGERATED OR ON ICE. No preservative required for urine.

Sample Preparation

Sample preparation is not required. Urine samples are diluted (1:10) automatically by the system using the DIL1 cartridge.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

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 BUN Reagent Cartridges (2 x 300 tests)

Volumes per Test

Serum or Plasma

Sample Volume	3uL
Total Reagent Volume	300uL
Cartridge, Volumes	A 28uL B 15uL

Urine

Sample Volume	20uL
Diluent Volume	180uL
Sample Volume	3uL
Total Reagent Volume	300uL
Cartridge, Volumes	A 28uL B 15uL

Reactive Ingredients

α-Ketoglutarate	2.9mmol|L
NADH	0.35mmol/L
Urease	>24KIU/L
Glutamate dehydrogenase	1.3KIU/l

Also non-reactive chemicals necessary for optimal system performance

Reagent Preparation

No preparation is required.

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.

Reagent Storage and Stability

BUN reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.
DIL 1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL 1 is stable for 60 days on instrument or until the expiration date, if sooner.

CALIBRATION

Calibrator Required
SYNCHRON® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.
2. Under typical operating conditions the BUN reagent cartridge must be calibrated every 24 hours and also with certain parts replacement or maintenance procedures, as defined in the SYNCHRON LX *Maintenance Manual and Instrument Log*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual for information on this feature.
3. For detailed calibration instructions, refer to the SYNCHRON LX *Operations Manual*, or 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 SYNCHRON LX *Diagnostics and Troubleshooting Manual*, or 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 DXC 600 Controls

STEPS

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be 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 SYNCHRON LX *Operations Manual*, or 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.

ANTICOAGULANT TEST RESULTS

1. 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:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	29 Units/mL	No Significant Interference (within ±4.0 mg/dL or 6%).
Lithium Heparin	29 Units/mL	No Significant Interference (within ±4.0 mg/dL or 6%).
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	No Significant Interference (within ±4.0 mg/dL or 6%).
Sodium Heparin	29 Units/mL	No Significant Interference (within ±4.0 mg/dL or 6%).

2. The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Sodium Citrate	6.6 mg/mL	-5.0

PERFORMANCE CHARACTERISTICS

Reference Range

Serum / Plasma	7 – 23 mg/dL
Urine 24 hour	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	5 – 100 mg/dL
Urine	50 – 1000 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower Limit of range: serum/plasma	5 mg/dL	Results below 5, report as <5 mg/dL
Upper limit of range: serum/plasma	100 mg/dL	Results >100 mg/dL should be diluted, starting at X2, with 0.9% saline
Lower limit range: urine**	50 mg/dL	Results below 50, report as <50 mg/dL
Upper limit of range: urine**	1000 mg/dL	Results >1000 mg/dL should be diluted, starting at X10 with 0.9% saline

Sensitivity
Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for BUN determination is 5 mg/dL (1.8 mmol/L).

LIMITATIONS
None identified.

Interferences
1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL	No Significant Interference (within ±4.0 mg/dL or 6%).
Hemoglobin	RBC hemolysate	500 mg/dL	No Significant Interference (within ±4.0 mg/dL or 6%).
Lipemia	Intralipid[h]	500 mg/dL	No Significant Interference (within ±4.0 mg/dL or 6%).

2. Fluoride is a known inhibitor of urease activity and will decrease the reaction rate of this chemistry.

3. The presence of ammonium ions in anticoagulants may produce falsely elevated results.

4. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

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

REFERENCES

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
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