

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: k040973

B. Purpose For Submission:

Premarket Notification 510(k) for GenChem, Inc. intentions to manufacture and market the GenChem Bun Reagent Kit.

C. Analyte: Bun (Blood Urea Nitrogen)

D. Type of Test:

Quantitative, Photometric End-Point

E. Applicant: GenChem, Inc.

F. Proprietary and Established Names:

GenChem, Inc, BUN Reagent

G. Regulatory Information:

Regulation section:

1. Regulation section:

21 CFR §862.1770 - Urea nitrogen test system.

2. Classification:

Class II

3. Product Code:

CDS

4. Panel:

75 (Chemistry)

H. Intended use(s):

1. Intended use(s)

GenChem BUN Reagent is to be used for the quantitative determination of urea nitrogen in serum, plasma and urine on the Beckman SYNCHRON CX3 System to aid in the diagnosis of renal function and pre renal disease states, such as cardiac decompensation and others.

2. Indication(s) for use:

GenChem BUN Reagent is to be used for the quantitative determination of urea nitrogen in serum, plasma and urine on the Beckman SYNCHRON CX3 System to aid in the diagnosis of renal function and pre renal disease states, such as cardiac decompensation and others.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements: Beckman CX3 Systems.

I. Device Description:

The device is a reagent containing sufficient Urease, surfactants and other ingredients necessary for optimum system operation on the Beckman SYNCHRON CX3 System.

J. Substantial Equivalence Information:

GenChem claims substantial equivalence to the Beckman BUN reagent for the CX3.

1. Predicate device name(s): Beckman Bun reagent for the CX3

2. Predicate K number(s): (k761061)

3. Comparison with Predicate:

Device Name	GenChem Bun Reagent Kit	Predicate Device Beckman Electrode, Ion Specific, Urea Nitrogen
510(k) Number	(k040973)	(k761061)
Chemical Principle	Urease, Conductivity	Urease, Conductivity
Intended Use	For the quantitative determination of urea nitrogen in serum, plasma, and urine	For the quantitative determination of urea nitrogen in serum, plasma, and urine
Format	Liquid, ready to use	Liquid, ready to use
Composition	Urease, buffer	Urease, buffer
Linearity	0-150 mg/dL	0-150 mg/dL
Storage	2-8 °C	2-8 °C

K. Standard/Guidance Document Referenced (if applicable):

Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A.
 Linearity was performed according to NCCLS EP6-A Guideline.
 Analytical specificity Determined according to NCCLS EP7-A.

L. Test Principle:

This test utilizes a conductivity reaction method. In 1961, Chin and Kroontje reported a procedure for urea determination that measured the conductivity of the ammonium bicarbonate end product. This method was later modified to measure the rate of increase in the reagent conductivity.

Principle of Procedure



Urea from the sample is converted to ionic ammonium bicarbonate by the urease reagent. The rate of increase in conductivity, measured 11.5 seconds after sample addition, is proportional to the concentration of urea in the sample.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

Control sera and diluted urine pools were each assayed twice per day in triplicate on a SYNCHRON CX3 System. Data were collected on ten different days over a thirty day period.

Precision of BUN Recoveries in (mgN/dL)

Sample	n	Within Run			Total Imprecision	
		mean	1SD	%CV	1SD	%CV
Serum 1	60	7.1	0.65	9.1	0.66	9.4
Serum 2	60	35.4	0.62	1.8	0.66	1.9
Serum 3	60	63.8	0.50	0.8	0.80	1.3
Urine 1	60	21.7	0.89	4.1	0.82	3.8
Urine 2	60	112.2	0.75	0.7	1.25	1.1

b. Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards ranging from 0 to 158 mg/dl were analyzed in triplicate on the

Beckman CX3 and the results analyzed by the Least Squares method. The results gave a slope of 0.995 with an intercept of -0.12, a standard error of estimate of 0.49 and $r^2 = 1.00$ and is shown below. Specimens exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

Specimens	Range	Usable Ranges	
		Conventional Units	SI Units
All	Normal	2 - 150 mgN/dL	2-53.6mmol/L
All	ORDAC*	150 - 300 mgN/dL	53-107.2mmol/L

c. Traceability (controls, calibrators, or method):

Beckman Calibration Standards 1 and 2 for the CX3 System

d. Detection limit:

The sensitivity of this method was investigated by assaying serum first with a known concentration and then diluting the sample until the minimum result obtained and then run in replicates of 10 on the SYNCHRON CX3 System. Under the conditions described the limit of detection for this method was found to be 2.0 mg/dL.

Analyte	Limit of Detection
BUN	2.0 mg/dL

e. Analytical specificity:

Determined according to NCCLS EP7-A. Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with a BUN level of 15 mg/dL. Stock solutions of the substance to be tested were prepared at 20x concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Heparin, Lithium Heparin Ammonium Heparin, and EDTA are acceptable anticoagulants.

f. Assay cut-off:

Not applicable for this type of device.

2. Comparison studies:

a. Method comparison with predicate device:

Serum and plasma specimens, and urine specimens diluted with 9 parts normal saline, ranging from 4 to 300 mg/dL were collected from adult patients and assayed for urea nitrogen on a SYNCHRON CX3 System using GenChem and Beckman BUN reagents.

Results were compared by least squares linear regression and the following statistics were obtained:

VALUE	SERUM	PLASMA	URINE
Intercept	-0.3	-0.2	0.9
Slope	0.995	0.989	0.979
R ² Value	0.999	0.998	1.000
N	80	80	79
Range	4-300	4-300	6-142

b. Matrix Comparison

See above method comparison studies.

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values for urea are listed below. Use these ranges only as guides. Each laboratory should establish its own normal ranges.

Specimens	Reference Ranges ¹	
	Conventional Units	SI Units
Serum/Plasma	7 - 18 mgN/dL	2.5 – 6.4 mmol/L
Urine	12 - 20 gN/day	428 - 714 mmol/day

¹ Burtis, C.A., Ashwood, E.R. (eds.). Tietz Textbook of Clinical Chemistry. W.B. Saunders Company. Philadelphia, PA. (1994).

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.