

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

A. 510(k) Number: k040976

B. Purpose For Submission:

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

C. Analyte: Creatinine

D. Type of Test:

Quantitative, Photometric End-Point

E. Applicant: GenChem, Inc.

F. Proprietary and Established Names:

GenChem, Inc., Creatinine Reagent Kit

G. Regulatory Information:

Regulation section:

1. Regulation section:

21 CFR §862.1225 - Creatinine test system.

2. Classification:

Class II

3. Product Code:

CGX (creatinine)

4. Panel:

75 (Chemistry)

H. Intended use(s):

1. Intended use(s)

The GenChem Creatinine Test Reagent System is intended for the quantitative determination of creatinine in serum, plasma and urine on the Beckman SYNCHRON CX3 System and as an aid in the diagnosis of renal impairment and diseases such as chronic glomerulonephritis, diabetic nephropathy, and chronic intestinal nephritis as an indicator of glomerular filtration rate.

2. Indication(s) for use:

The GenChem Creatinine Test Reagent System is intended for the quantitative determination of creatinine in serum, plasma and urine on the Beckman SYNCHRON CX3 System and as an aid in the diagnosis of renal impairment and diseases such as chronic glomerulonephritis, diabetic nephropathy, and chronic intestinal nephritis as an indicator of glomerular filtration rate.

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

4. Special instrument Requirements: Beckman CX3 System.

I. Device Description:

The device is a reagent containing alkaline picrate for the determination of creatinine for optimum system operation on the Beckman SYNCHRON CX3 system.

J. Substantial Equivalence Information:

1. Predicate device name(s): Beckman Creatinine Reagent for the CX3

2. Predicate K number(s): (k915077)

3. Comparison with Predicate:

Device Name	GenChem Creatinine Reagent Kit	Predicate Device Beckman Creatinine
510(k) Number	(k040976)	(k915077)
Chemical Principle	Jaffe rate method	Jaffe rate method
Intended Use	For the quantitative determination of creatinine in serum, plasma or urine	For the quantitative determination of creatinine in serum, plasma or urine
Format	2 part liquid	2 part liquid
Composition	Alkaline picrate	Alkaline picrate
Linearity	Serum or plasma 0-25 mg/dL Urine 10-400 mg/dL	Serum or plasma 0-25 mg/dL Urine 10-400 mg/dL
Storage	Room temperature	Room temperature

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:

Creatinine + Picric Acid → Creatinine-Picrate Complex (red)

Creatinine from the sample combines with picric acid in the alkaline reagent to form a red complex. The rate of increase in absorbance at 520 nm, measured seconds after the sample addition, is proportional to the concentration of creatinine in the sample

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

Control sera and 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 Creatinine Recoveries (mg/dL)

Sample	n	Within Run			Total	
		mean	SD	%CV	SD	%CV
Serum 1	60	0.5	0.05	9.8	0.05	9.8
Serum 2	60	4.0	0.02	0.5	0.02	0.5
Serum 3	60	7.4	0.03	0.5	0.05	0.7
Urine 1	59	40.3	0.41	1.0	0.56	1.4
Urine 2	60	222.9	2.29	1.0	2.79	1.3

b. Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards ranging from 0 to 25.7 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 0.994 with an intercept of -0.05, a standard error of estimate of 0.11 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	Usable Ranges	
	Conventional Units	SI Units
Serum/Plasma	0.2 to 25 mg/dL	0.2 - 2210 mmol/L
Urine	10 - 400 mg/dL	0.88 - 35.36 mmol/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 is 0.2 mg/dL and is documented through the repetitive assay of diluted serum control. The observed sensitivity limit, calculated as three standard deviations of a 21 replicate within run precision study, is 0.01 mg/dL and is below the claimed limit of 0.2 mg/dL.

Analyte	Limit of Detection
Creatinine	0.2 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 creatinine level of 1.1 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, ranging from 0.4 to 30.4 mg/dL and urine specimens ranging from 12.1 to 400 mg/dL were collected from adult patients and assayed for creatinine on a SYNCHRON CX3 System using GenChem and Beckman creatinine reagents. Results were compared by least squares linear regression and the following statistics were obtained:

VALUE	SERUM	PLASMA	URINE
Intercept	0.0	0.05	-0.3
Slope	0.991	0.998	1.000
R ² Value	0.997	0.998	1.000
N	80	80	79
Range	0.4 - 30.4	0.4 - 30.4	12.1 - 400 mg/dL

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 creatinine are listed below. Use these ranges only as guides. Each laboratory should establish its own normal ranges.

Specimens	Normal Ranges ¹	
	Conventional Units	SI Units
Serum/Plasma	0.6 - 1.3 mg/dL	53 - 115 mmol/L
Urine	11 - 26 mg/day/kg	97 - 230 mmol/day/kg

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.