

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

A. 510(k) Number: k042270

B. Purpose for Submission: New Device

C. Analyte: Potassium

D. Type of Test: Quantitative ion selective electrode

E. Applicant: StatChem, Inc.

F. Proprietary and Established Names: Stat K In Vitro Diagnostic Test System

G. Regulatory Information:

H. Regulation section: 21 CFR §862.1600 Potassium test system

1. Classification: Class II
2. Product Code: CEM
3. Panel: 75 (Clinical Chemistry)

I. Intended Use:

1. Intended use / Indication(s) for use: The StatChem Stat K is a device intended to measure potassium in anticoagulated venous whole blood and assayed within twenty minutes of collection. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. It may be used by a central laboratory or at point of care sites.
2. Special condition for use statement(s): Not Applicable
3. Special instrument Requirements: Not Applicable

J. Device Description:

The Stat K In Vitro Diagnostic Test System consists of a battery operated hand-held Analyzer and a precalibrated and disposable Sensor cartridge. The Sensor cartridge is liquid-free allowing storage at room temperature for several months without degradation of performance. The Sensor cartridge is precalibrated at the factory thus requiring no operator interaction to perform calibration. The Sensor cartridge is designed for single use only. This device is exceptionally simple to use as the operator is required to perform four elementary steps to complete the test: (1) Insert Sensor Cartridge, (2) Peel Sensor

cap when prompted, (3) Apply blood sample when prompted, and, (4) Read results on LCD display.

K. Substantial Equivalence Information:

1. Predicate device name(s): Stat K System; BECKMAN SYNCHRON CX5® PRO SYSTEM; Corning 614 Na/K Analyzer
2. Predicate K number(s): K915345 (Stat K System); K011465 (BECKMAN SYNCHRON CX5® PRO SYSTEM); K843530 (Corning 614 Na/K Analyzer)
3. Comparison with predicates:

Similarities (Portable Diagnostics Stat K)		
Item	Device	Predicate
Methodology	Same	Ion-Selective Electrode
Power Source	Same	Battery Operated
Hand held	Same	Yes
Temperature Compensated	Same	Yes
System Control	Same	Microprocessor
Calibration Membrane	Same	Gel based
Measuring Range	Same	2.0 – 8.0 mEq/L
Differences (Portable Diagnostics Stat K)		
Item	Device	Predicate
Specimen Type	Venous Whole Blood	Whole Blood, Serum or Plasma
Analyzer/Cartridge Interface	Semiconductor Element	Bar Code
Sensing Membrane	Plastic Polymer	Gel based

Similarities (CORNING 614 NA/K ANALYZER)		
Item	Device	Predicate
Methodology	Same	Ion-Selective Electrode
Temperature Compensated	Yes	Yes
System Control	Microprocessor	Microprocessor
Precision Claims	Within-run CV \leq 3.0% (Whole Blood)	Within-run CV \leq 1.5% (Whole Blood) Between-run CV \leq 2.0 % (Whole Blood)
	Total Precision CV \leq 2.0 % (aqueous potassium solution)	No Claims Made
Differences (CORNING 614 NA/K ANALYZER)		
Item	Device	Predicate
Analyte(s)	Potassium	Multiple Analytes
Measuring Range	2.00 – 8.00 mEq/L	0.50 – 9.99 mEq/L
Specimen Type	Venous Whole Blood	Whole Blood, Serum, or Urine
Power Source	Battery Operated	Alternating Current
Display	Liquid Crystal	Vacuum Fluorescent Display
Analyzer/Cartridge Interface	Semiconductor Element	Does not apply
Sensing Membrane	Plastic Polymer	Solvent based
Calibration Membrane	Gel based	None
Single Use	Yes	Batch

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

FDA Guidance for the content of Pre-market Submissions for Software Contained in Medical Devices, issued May 29, 1998; IEC 61010 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; NCCLS EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices; NCCLS EP9-A2 Method Comparison and Bias Estimation Using Patient Samples

M. Test Principle:

The Stat K Potassium Sensor uses an ion selective membrane to determine the concentration of potassium ions in solution. The physical structure of the potassium selective Valinomycin membrane is such that the complexing sites on the membrane selectively bind to Potassium ions. When complexing occurs, an electrical potential is generated proportional to the logarithm of the potassium ion concentration in the sample. The concentration of Potassium ions is calculated from the electrode potential by use of the Nernst Equation.

N. Performance Characteristics (if/when applicable):1. Analytical performance:

a. Precision/Reproducibility: The precision performance of this device was evaluated in two separate experiments, one using aqueous solutions with known concentrations of potassium and the other using venous whole blood.

For the aqueous samples, with-in run and total imprecision were calculated using an experimental design based on NCCLS EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices. Testing consisted of 1 run per day with 8 replicates per run for 5 days. Acceptance criteria for both within-run and total precision were established as a % coefficient of variation of 3.3% or less at potassium concentrations of 3.0 and 6.0 mEq/L. Results were as follows:

Target concentration 3.0 mEq/L	Day 1	Day 2	Day 3	Day 4	Day 5
Replicate	K Result (mEq/L)				
1	3.05	3.06	3.00	2.88	3.01
2	2.92	3.05	3.03	2.99	2.98
3	3.00	3.00	3.01	2.90	3.02
4	3.06	3.00	2.98	2.99	2.99
5	2.95	2.99	2.91	3.13	3.00
6	2.98	3.03	2.98	2.87	3.02
7	3.03	2.95	2.99	3.00	2.98
8	2.95	2.99	2.90	2.99	2.99

Within-run imprecision (mEq/L)	0.05
Within-run CV (%)	1.7
Total imprecision (mEq/L)	0.05
Total CV (%)	1.6

Target concentration 6.0 mEq/L	Day 1	Day 2	Day 3	Day 4	Day 5
Replicate	K Result (mEq/L)				
1	6.09	6.22	6.01	6.00	5.89
2	5.82	6.03	5.99	6.01	5.98
3	5.82	6.14	6.02	5.99	6.04
4	6.13	5.99	5.81	5.99	5.96
5	6.14	5.87	5.94	5.95	6.15
6	6.01	5.98	6.02	5.98	6.07
7	5.99	5.92	6.00	5.99	5.99
8	6.10	5.77	5.99	6.07	6.15

Within-run imprecision (mEq/L)	0.10
Within-run CV (%)	1.7
Total imprecision (mEq/L)	0.09
Total CV (%)	1.6

Using the venous whole blood samples, within-run imprecision was evaluated by measuring the potassium concentration in a total of 6 venous whole blood samples collected at 3 sites over 2 days. Seven replicate measurements of each sample were completed in 32 minutes or less. Acceptance criteria were established as: the average percent coefficient of variation of the six samples must be less than or equal to 3.5% with no individual CV exceeding 4.0%. Results were as follows:

	Site 1 Day 1	Site 1 Day 2	Site 2 Day 1	Site 2 Day 2	Site 3 Day 1	Site 3 Day 2
Rep	K Result (mEq/L)					
1	4.02	4.10	5.71	2.95	7.06	6.85
2	3.88	4.34	5.83	3.04	6.79	6.98
3	3.98	4.29	5.90	2.89	6.87	6.75
4	3.69	4.21	5.97	2.99	6.66	6.61
5	3.90	4.30	5.90	2.89	6.61	7.10
6	3.92	4.10	5.80	2.92	6.85	6.86
7	3.91	4.18	5.99	2.88	6.81	6.89
Mean	3.90	4.22	5.87	2.94	6.81	6.86
Std Dev	0.10	0.10	0.10	0.06	0.15	0.16
CV (%)	2.7	2.3	1.7	2.0	2.2	2.3

b. Linearity/Assay Reportable Range: The linearity of this device was established by assaying commercially available whole blood chemistry controls of known concentration. The five known concentrations were 2.10, 3.50, 5.00, 6.50, and 7.90 mEq/L. Each sample was assayed in duplicate for a total of ten measurements. The mean of the duplicate measurements was plotted against the known concentrations and the line of best fit was calculated. Acceptable performance was established as a coefficient of determination (r^2) value of ≥ 0.975 . Results were as follows:

Known Concentration (mEq/L)	Replicate 1	Replicate 2	Mean
2.0	1.94	1.94	1.94
3.5	3.64	3.79	3.72
5.0	5.03	5.35	5.19
6.5	6.72	6.74	6.73
7.9	7.95	7.90	7.93

The calculated coefficient of correlation (r) was 0.998

c. *Traceability, Stability, Expected values (controls, calibrators, or method):*

The sponsor has submitted the following protocol to establish the expiration dating of the Stat K sensors. Sensors will be taken from a routine production run, stored at 18 to 25 °C, and used to assay an aqueous potassium solution at 6.00 mEq/L. An analytical run is defined as eight (8) replicates of the known potassium solution. A run will be conducted at 30 day intervals beginning at day 30 and ending at day 570. Acceptable performance is defined as a coefficient of variation of $\leq 4.0\%$ and a bias of not more than ± 0.15 mEq/L.

d. *Detection limit:* The lower limit of detection is 2.00 mEq/L. See section M.1.b.

e. *Analytical specificity:* The sponsor refers the user to the specificity testing done on the predicate device, Portable Diagnostic Services Stat K System. Users are also referred to a discussion of ion-selective electrodes in Tietz Textbook of Clinical Chemistry – Second Edition, 1994.

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

This study compared Lithium heparinized split samples on the Stat K and the Corning 614. Measurements were taken in duplicate and the mean of the measurements was used to calculate the line of best fit:

Slope = 0.97 (95% CI 0.91, 1.04)

y-intercept = 0.12 mEq/L (95% CI -0.20, 0.43)

Predicted bias at 3.36 mEq/L: 0.03 mEq/L (95% CI -0.06, 0.13)

Predicted bias at 6.00 mEq/L: -0.03 mEq/L (95% CI -0.13, 0.07)

r = 0.979

n = 40

Range of data: 3.36 – 7.27 mEq/L

b. *Matrix comparison:*

Not applicable. The Stat K is intended for use with venous whole blood only.

3. Clinical studies:

a. *Clinical sensitivity:* Not Applicable

b. *Clinical specificity:* Not Applicable

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:

Newborn – one month:	3.7 – 5.9 mEq/L
One month – one year:	4.1 – 5.3 mEq/L
Ages 1 – 10:	3.5 – 5.1 mEq/L
Adults:	3.8 – 5.2 mEq/L

These ranges and supportive documentation are derived from previously established literature:

B.E. Statland, Clinical Decision Levels for Lab Tests; Oradell, NJ: Medical Economic Books, 1987 and P.C. Painter, T.Y. Cope, J.L. Smith, Reference Ranges, Table 41-20, in Tietz Textbook of Clinical Chemistry – Second Edition, C.A. Burtis and E.R. Ashwood, Eds. Philadelphia: W.B. Saunders Company, 1994).

A. Conclusion:

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