

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k040750

**B. Purpose for Submission:**

Clearance of a new potassium meter

**C. Measurand:**

Potassium ( $K^+$ )

**D. Type of Test:**

Quantitative potentiometric assay

**E. Applicant:**

Clinical Analysis Corporation

**F. Proprietary and Established Names:**

CAC Bio-Chem Analyzer

**G. Regulatory Information:**

1. Regulation section:  
21 CFR §862.1600, Potassium test system
2. Classification:  
Class II
3. Product code:  
CEM, Electrode, ion specific, potassium
4. Panel:  
Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):  
The CAC Bio-Chem Analyzer is a microprocessor controlled electromechanical, portable instrument for the quantitative determination of specific analytes in whole blood and plasma. The instrument deploys single-use, single analyte disposable test cartridges for the following test analyte: potassium.

Potassium 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.

2. Indication(s) for use:

Potassium 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.

3. Special conditions for use statement(s):

The CAC Bio-Che Analyzer is for professional point-of-care use.

4. Special instrument requirements:

CAC Bio-Chem Analyzer

**I. Device Description:**

The CAC Bio-Chem Analyzer is a handheld meter that uses ion specific electrode technology to measure potassium levels in whole blood or plasma. A single-use disposable cartridge contains ISE cartridges, a calibration solution capsule, and channels for sample addition. Each cartridge comes with disposable pipettes for sample application. See Traceability below for information about calibration of the assay.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

AVL 9180 Electrolyte Analyzer

2. Predicate 510(k) number(s):

k961458

3. Comparison with predicate:

The device and the predicate share the same intended use.

Similarities		
Item	Device	Predicate
platform	Handheld	Desktop
results	quantitative	quantitative

Differences		
Item	Device	Predicate
Analytes measures	K <sup>+</sup> only	Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>2+</sup> , Cl <sup>-</sup> , Li <sup>2+</sup>
Matrix	Whole blood and plasma	Whole blood, serum, and urine
Test principle	Potentiometric	Ion specific electrode

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

None referenced

**L. Test Principle:**

The concentration of potassium in the sample is determined by ion specific electrode that is contained within the reagent cartridge and read by the handheld analyzer. Sample is applied

to the cartridge which is then placed in the analyzer. Analysis is automatically activated. The system pumps the calibration solution over both a reference electrode and the measuring electrode to calibrate the system. The sample is then pumped over the measuring electrode and the test results are displayed on the analyzer.

#### M. Performance Characteristics (if/when applicable):

##### 1. Analytical performance:

###### a. *Precision/Reproducibility:*

Precision was evaluated at three point-of-care sites. The sites included a hospital, a dialysis clinic, and a physician's office. Three levels of whole blood control material were assayed 30 times each by two operators per site (3 nurses, 2 phlebotomists, and a receptionist). Results are summarized below (units = mM K<sup>+</sup>):

		Operator 1			Operator 2			Total		
		Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
<b>Level 1</b>	<b>Site 1</b>	6.6	0.15	2.21	6.7	0.16	2.38	6.6	0.16	2.45
	<b>Site 2</b>	6.8	0.17	2.45	6.6	0.19	2.91	6.7	0.19	2.84
	<b>Site 3</b>	6.6	0.19	2.88	6.6	0.17	2.49	6.6	0.18	2.70
<b>Level 2</b>	<b>Site 1</b>	4.6	0.15	3.30	4.7	0.18	3.77	4.7	0.17	3.59
	<b>Site 2</b>	4.6	0.21	4.44	4.7	0.19	4.09	4.6	0.20	4.24
	<b>Site 3</b>	4.6	0.17	3.59	4.6	0.20	4.28	4.6	0.18	3.92
<b>Level 3</b>	<b>Site 1</b>	2.8	0.18	6.58	2.8	0.21	7.58	2.8	0.20	7.04
	<b>Site 2</b>	2.8	0.20	7.22	2.8	0.20	7.17	2.8	0.20	7.14
	<b>Site 3</b>	2.8	0.17	5.94	2.9	0.16	5.70	2.8	0.17	5.92

Results from all three sites and all six operators are summarized below (units = mM K<sup>+</sup>):

	Mean	SD	% CV
<b>Level 1</b>	6.6	0.18	2.7
<b>Level 2</b>	4.6	0.18	4.0
<b>Level 3</b>	2.8	0.19	6.7

###### b. *Linearity/assay reportable range:*

The linearity of the assay was evaluated by testing samples in duplicate that were prepared as follows (same preparation technique for whole blood samples and plasma samples):

- Two samples were spiked to 9.0 mM (sample 1) and 2.0 (sample 2) mM K<sup>+</sup> respectively (the whole blood samples were verified by testing on a commercially available assay)
- The 9.0 mM sample was diluted serially using the 2.0 mM sample to produce 9 additional evenly spaced samples with ratios of 9:1, 8:2, 7:3, 6:4, 5:5, 4:6, 3:7, 2:8, and 1:9 (Sample 1:Sample 2).
- The two starting samples and the 9 intermediate mixtures were tested in duplicate using the device and the results were plotted on the y axis vs. the expected values.

The resulting regression statistics are as follows:

Whole blood: (Observed) =  $1.0006(\text{Expected}) - 0.0307$ ;  $R^2 = 0.9975$

Plasma: (Observed) =  $0.9909(\text{Expected}) + 0.0091$ ;  $R^2 = 0.9947$

These results indicate that the assay is linear across the measuring range of 2.0 – 9.0 mM K<sup>+</sup>.

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

Each cartridge includes a calibration capsule containing 10.0 mM KCl and 175 mM NaCl. This solution is prepared gravimetrically (to at least 3 significant figures) from KCl and NaCl in water. The concentration is checked using a commercially available assay. Batches are also compared to previous batches using the CAC Bio-Chem analyzer to verify consistency.

d. *Detection limit:*

The reportable range of the assay is 2 – 9 mM K<sup>+</sup>. The instrument will report results less than 2 mM as “Below reportable range.” The limit of detection for the CAC Bio-Chem Analyzer was calculated to be 1.34 mM K<sup>+</sup> from adding two standard deviations of the  $\Delta\text{ADC}$  values from the level of noise. Therefore, the reportable range of the instrument starts above the lower limit of detection for the device.

e. *Analytical specificity:*

Increasing levels of Na<sup>+</sup>, Li<sup>2+</sup>, NH<sub>4</sub><sup>+</sup>, and Ca<sup>2+</sup> were added to potassium-containing samples and the change in potassium concentration was evaluated. The above-mentioned ions do not interfere with potassium measurements using this device. Samples containing 4.0 mM potassium were evaluated for interference by increasing hemoglobin, lipids, and bilirubin concentrations. Samples with up to 5% w/v hemoglobin, up to 20 mg/dL bilirubin, and up to 40 mg/dL of lipids (a commercially available mixture of capric, caprylic, lauric, myritic, and palmitic acids was used) do not significantly interfere with potassium measurements using this device.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

To test the performance of the device at three point-of-care locations (a hospital, a dialysis clinic, and a physician’s office), a total of 78 whole blood samples and 76 plasma samples were tested using the device and the predicate by users typical of the types of professionals that would be using the device. Results are summarized below:

Whole blood: (Device) =  $0.962(\text{Predicate}) + 0.151$ ;  $R^2 = 0.9861$

Plasma: (Device) =  $0.9796(\text{Predicate}) - 0.0449$ ;  $R^2 = 0.9859$

b. *Matrix comparison:*

Not applicable. Both matrices were evaluated for accuracy and precision.

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:  
The sponsor cites a clinical laboratory reference and provides the following reference ranges for normal individuals:  
  
Adults: 3.5 – 5.1 mM  
Children: 3.4 – 4.7 mM

**N. Instrument Name:**  
CAC Bio-Chem Analyzer

**O. System Descriptions:**

1. Modes of Operation:  
Open Tube
2. Software:  
Operating System: Wind River's VxWorks Real Time Operating System  
Processor: Intel StrongArm 1100  
Compiler: gnu C/C++ (Wind River)  
User interface: menu-driven, color-coded  
Communications: serial port (RS232 levels; 9600 baud, 8 data, 1 stop, no parity)  
Ethernet port: access inhibited outside user's local network  
  
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:  
Yes   3   or No
3. Specimen Identification:  
Manual data entry or barcode
4. Specimen Sampling and Handling:  
Manual, open tube direct sampling

5. Calibration:

Capsule containing calibration material is included in the test cartridge. The calibration is done automatically by the instrument upon initiation of analysis.

6. Quality Control:

The sponsor recommends that quality control be performed according to state and local regulations. As described above, calibration is automatic with sample analysis.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Not applicable

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

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