

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k112834

B. Purpose for Submission:

New calibrator materials

C. Measurand:

Carbon Dioxide, Uric Acid, Cholesterol, Triglyceride, Sodium, Potassium, Chloride, Urea Nitrogen, Creatinine, Total Calcium, Phosphorus, Magnesium, Lithium, Ionized Calcium, Lactate, Glucose.

D. Type of Test:

Not Applicable

E. Applicant:

Verichem Laboratories, Inc.

F. Proprietary and Established Names:

ISE Standard Kit
Multi-Chemistry Standard Kit
Uric Acid Standard Kit
Urine Chemistry Standard Kit
Urine Uric Acid Standard Kit
Cholesterol Standard Kit
Carbon Dioxide Standard Kit
Electrolyte Standard Kit
ISE Standard (S4)

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1150 - Calibrator

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See indications for use, below.

2. Indication(s) for use:

Device Name: ISE Standard Kit

Indications for Use:

The Verichem ISE Standard Kit is intended for the calibration of sodium, potassium, chloride, lithium, ionized calcium and carbon dioxide assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Multi-Chemistry Standard Kit

Indications for Use:

The Verichem Multi-Chemistry Standard Kit is intended for the calibration of sodium, potassium, lactate, chloride, glucose, urea nitrogen, creatinine, calcium, phosphorus, magnesium and triglyceride assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Uric Acid Standard Kit

Indications for Use:

The Verichem Uric Acid Standard Kit is intended for the calibration of uric acid assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Urine Chemistry Standard Kit

Indications for Use:

The Verichem Urine Chemistry Standard Kit is intended for the calibration of sodium, potassium, chloride, urea nitrogen, creatinine, calcium, phosphorus and magnesium assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Urine Uric Acid Standard Kit

Indications for Use:

The Verichem Urine Uric Acid Standard Kit is intended for the calibration of uric acid assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Cholesterol Standard Kit

Indications for Use:

The Verichem Cholesterol Standard Kit is intended for the calibration of total cholesterol assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Carbon Dioxide Standard Kit

Indications for Use:

The Verichem Carbon Dioxide Standard Kit is intended for the calibration of carbon dioxide assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: Electrolyte Standard Kit

Indications for Use:

The Verichem Electrolyte Standard Kit is intended for the calibration of sodium, potassium, lithium, chloride and ionized calcium assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

Device Name: ISE Standard (S4)

Indications for Use:

The Verichem ISE Standard (S4) is intended for the calibration of sodium, potassium, chloride and carbon dioxide assays performed on a number of clinical chemistry instrument systems. A complete list of instrument models are found in the package insert. For *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

A complete list of instrument models are found in the package inserts.

I. Device Description:

All calibrator materials included in this submission are aqueous, primary standards containing known amounts of each component for in vitro diagnostic use.

J. Substantial Equivalence Information:

1. Predicate device name(s):

pHoenix Diagnostics ISE Standards
Multi-Chemistry Linearity Standard
Beckman – Synchron Multi - Calibrator

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

k023268
k875285
k110251

3. Comparison with predicate:

Feature	Candidate Device:	Predicate Device:
	Multi-Analyte Chemistry Standards (k112834) – CO2 Standard Kit Electrolyte Standard Kit ISE Standard Kit ISE Standard (S4)	pHoenix Diagnostics ISE Standards (k023268)
Intended Use	Used for calibration of	Same

	automated methods for the quantitative determination of analytes	
Format	Liquid	Same
Measurement of Analytes	Na, K, Cl, Ca, CO ₂ , Ionized Ca, Li	Na, K, Cl, Ca, Li, CO ₂ , pH

Feature	Candidate Device: Multi- Chemistry Standards (k112834) – Urine Chemistry Standard Kit	Predicate Device: Multi-Chemistry Linearity Standard (k875285)
Intended Use	Used for the calibration of automated methods for the quantitative determination of analytes	Same
Format	Liquid	Same
Measurement of Analytes	sodium, potassium, lactate, chloride, glucose, urea nitrogen, creatinine, calcium, phosphorus, magnesium and triglyceride in serum sodium, potassium, chloride, urea nitrogen, creatinine, calcium, phosphorus and magnesium in urine	Sodium, Potassium, Chloride, Urea nitrogen, Urea, Glucose, Creatinine, Calcium in serum

Feature	Candidate Device: Multi-Analyte Chemistry Standards (k112834) – Urine Uric Acid Standard Kit Cholesterol and uric acid standard kits	Predicate Device: Beckman – Synchron Multi – Calibrator (k110251)
Intended Use	Used for the calibration of automated methods for the quantitative determination	Same

	of analytes	
Format	Liquid	Same
Measurement of Analytes	sodium, potassium, lactate, chloride, glucose, BUN, creatinine, calcium, phosphorus, magnesium, triglyceride, uric acid, and cholesterol in serum Uric acid in urine	Lactate, magnesium, albumin, BUN, calcium, cholesterol, creatinine, glucose, inorganic phosphorus, total protein, triglycerides and uric acid in serum

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

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final Guidance for Industry – Version 2011. Date: 02/22/1999

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Not Applicable

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

Traceability and Value Assignment:

All standards contained within this submission are traceable to either NIST reference method materials or to equivalent primary standards if NIST is not available. Values are assigned by gravimetric preparations using a standard source of materials of known purity.

Stability:

Carbon Dioxide Standard Kit:

Five (5) lots of carbon dioxide standards (5 levels, A through E) were evaluated at t=15 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 15 months. The results of this study support the sponsor's claimed stability of 15 months when stored at 2-8°C.

Urine Chemistry Standard Kit:

Five (5) lots of urine chemistry standards (5 levels, A through E) were evaluated at t= 19 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 19 months. The results of this study support the sponsor's claimed stability of 19 months when stored at 2-8°C.

Electrolyte Standard Kit:

Five (5) lots of sodium, potassium, chloride, and lithium standards (5 serum levels of each analyte and 5 urine levels of sodium, potassium, and chloride) and five (5) lots of carbon dioxide standards (5 levels) were evaluated and compared to a reference control. The standards used for the study were freshly prepared for each standard type. The results of this study support a stability of 24 months for serum, 19 months for urine, and 15 months for CO₂ when stored at 2-8 °C.

Additionally, five (5) lots of ionized calcium standards were evaluated at five (5) concentration levels and compared to a reference control. The standards used for the study were freshly prepared from storage. The results of this study supports a stability of 20 months when stored at 2-8°C.

Cholesterol Standard Kit:

Five (5) lots of cholesterol standards (5 levels, 40 – 500 mg/dL) were evaluated at t=30 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 30 months. The results of this study support the sponsor's claimed stability of 30 months when stored at 2-8°C.

Uric Acid Standard Kit:

Five (5) lots of uric acid standards (5 levels, 2.0 – 22.0 mg/dL) were evaluated at t=26 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 26 months. The

results of this study support the sponsor's claimed stability of 26 months when stored at 2-8°C.

ISE Standard Kit:

Five (5) lots of sodium, potassium, chloride, lithium, magnesium, and calcium standards (5 levels of each analyte) were evaluated at t=24 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 24 months. The results of this study support the sponsor's claimed stability of 24 months when stored at 2-8°C.

ISE Standard (S4):

One (1) lot of sodium, potassium, chloride, and CO₂ (1 level at a single concentration of each analyte) were evaluated at t=16 months and compared to a reference control. The standards used for the study were freshly prepared using standards stored for 16 months. The results of this study support the sponsor's claimed stability of 16 months when stored at 2-28°C.

Multi Chemistry Standard Kit:

Five (5) lots of standard kits containing five levels of the following analytes: creatinine, glucose, magnesium, phosphorus, potassium, sodium, triglyceride, and urea nitrogen at t=24 months for each analyte except for phosphorus (t=21 months) and compared to a reference control. The results of this study support the sponsor's claimed stability of 21 months for when stored at 2-8°

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

- b. Matrix comparison:*
Not Applicable
- 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:
See each individual package insert.

N. Proposed Labeling:

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

O. Conclusion:

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