

**510(k) SUMMARY
MULTI-ANALYTE CHEMISTRY STANDARDS**

MAR 28 2012

Page 1

The assigned 510k number is: k112834

Manufacturer's Name, Address, Telephone, Contact Person and Date of Preparation:

Manufacturer: Verichem Laboratories Inc.
90 Narragansett Avenue
Providence, R.I. 02907

Contact Information: Verichem Laboratories Inc.
90 Narragansett Avenue
Providence, R.I. 02907

Attn: Anthony Di Monte
Tel: 401-461-0180
Fax: 401-467-1540

Date prepared: September 22, 2011

Analytes:

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

Type of Test:

Calibrators

Proprietary and Established Names:

See table below under Indications for Use (G2) for proprietary names.

Regulatory Information:

1. Regulation section:
21 CFR§ 862.1150 - Calibrator
2. Classification:
Class II
3. Product Code:
JIX - Calibrator, Multi-Analyte Mixture
4. Panel:
Clinical Chemistry (75)

Intended Use:

1. Intended use(s): See below.

**510(k) SUMMARY
MULTI-ANALYTE CHEMISTRY STANDARDS**

2. Indication(s) for use:

The nine Verichem Diagnostic standard solutions appear in the table below, along with their intended use.

Part Number	Product Name	Intended Use
9210	Carbon Dioxide Standard Kit	The Carbon Dioxide Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of carbon dioxide test systems.
9000	Urine Chemistry Standard Kit	The Urine Chemistry Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9020	Urine Uric Acid Standard Kit	The Urine Uric Acid Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9200	Electrolyte Standard Kit	The Electrolyte Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of serum electrolyte test systems.
9110	Cholesterol Standard Kit	The Cholesterol Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9010	Uric Acid Standard Kit	The Uric Acid Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9240	ISE Standard Kit	The ISE Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9207	ISE Standard (S4)	The ISE Standard (S4) is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.
9100	Multi-Chemistry Standard Kit	The Multi-Chemistry Standard Kit is an in vitro diagnostic product intended for calibration or calibration verification of clinical chemistry test systems.

3. Special condition for use statement(s):

These devices are for in vitro diagnostic use.

Device Description:

All calibrator materials included in this submission are aqueous, primary standards containing known amounts of each component for in vitro diagnostic use. Standardization is achieved by gravimetric procedure. Verification is performed using available NIST Standard Reference materials.

Substantial Equivalence Information:

1. Predicate device name(s):

**510(k) SUMMARY
MULTI-ANALYTE CHEMISTRY STANDARDS**

Substantial Equivalence Table & Trade Names

#	Product Description	Predicate Device	510k	Cleared Date
1	Carbon Dioxide Standard Kit	pHoenix Diagnostics ISE Standards	K023268	November 15, 2002
2	Urine Chemistry Standard Kit	Multi-Chemistry Linearity Standard	K875285	Sept. 2, 1988
3	Urine Uric Acid Standard Kit	Beckman - Synchron Multi-Calibrator	K110251	May 25, 2011
4	Electrolyte Standard Kit	pHoenix Diagnostics ISE Standards	K023268	November 15, 2002
5	Cholesterol Standard Kit	Beckman - Synchron Multi-Calibrator	K110251	May 25, 2011
6	Uric Acid Standard Kit	Beckman - Synchron Multi-Calibrator	K110251	May 25, 2011
7	ISE Standard Kit	pHoenix Diagnostics ISE Standards	K023268	November 15, 2002
8	ISE Standard (S4)	pHoenix Diagnostics ISE Standards	K023268	November 15, 2002
9	Multi-Chemistry Primary Standards	Multi-Chemistry Linearity Standard	K875285	Sept. 2, 1988

2. Predicate K number(s):

See the table in section I, 1, above.

3. Comparison with predicate:

See Exhibits 5 – 7: Comparative Information

Standard/Guidance Document Reference (if applicable):

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

Test Principle:

Not applicable.

Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision performance specifications are defined in the individual quality control test protocols. These are typically less than 3.0 % coefficient of variation. Precision performance for the lowest concentration set is based on resolution of the analyzer at that level.

**510(k) SUMMARY
MULTI-ANALYTE CHEMISTRY STANDARDS**

Page 4

b. Linearity/assay reportable range:

Not applicable.

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

See each individual Comparative Information Table for the specific NIST Standard Reference materials used.

d. Methodology for Concentration Verification: Each product Certificate of Analysis includes a description of the methodology used to verify the gravimetric concentration. This document is included in each kit.

VALUE ASSIGNMENT:

Assigned concentrations are primary standard values. These standard values are assigned by gravimetric procedure and indicate weight per volume composition using standard source materials of known purity. The gravimetric concentrations are verified and lot certified using NIST Standard Reference materials or equivalent primary standards if NIST is not available. Reference method verification is used when available.

STABILITY:

Real time stability studies are conducted according to Verichem Standard Operating Procedure number 40. Acceptance criteria for multi-level components are identical to the Verichem Quality Control End Test Procedure. Our real time stability testing utilizes a freshly prepared identical product as a reference to determine change in analyte concentration over time. NIST material is included in the stability testing.

e. Detection limit:

Not applicable.

f. Analytical specificity:

Not applicable.

g. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

**510(k) SUMMARY
MULTI-ANALYTE CHEMISTRY STANDARDS**

Page 5

3. Clinical studies:
Not applicable.

4. Clinical cut-off:
Not applicable.

5. Expected values/Reference range:
See each individual product insert.

Conclusion: We have shown that these Verichem devices are similar to the predicate devices in terms of analytes, intended use, performance characteristics, value assignment, matrix and stability. I recommend that this device be found substantially equivalent in terms of safety and effectiveness to the predicate device(s).



10903 New Hampshire Avenue
Silver Spring, MD 20993

Verichem Laboratories
c/o Anthony James Dimonte
90 Narragansett Avenue
Providence, RI 02907 USA

MAR 28 2012

Re: k112834
Trade Name: 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)
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: March 16, 2012
Received: March 20, 2012

Dear Mr. Dimonte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 112834

Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

Device Name: Urine Uric Acid Standard Kit

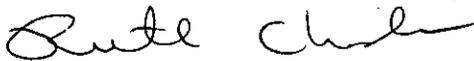
Indications for Use:

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

Device Name: Carbon Dioxide Standard Kit

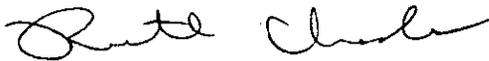
Indications for Use:

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

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.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use Form

510(k) Number (if known): k112834

Device Name: ISE Standard (S4)

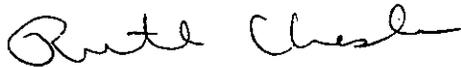
Indications for Use:

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.

Prescription Use X AND/OR Over-The-Counter Use _____
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