

K982501

SEP 1 1998

# 510(k) Summary for ALKO Reagents on Beckman CX® Series and Equivalent Analyzers

The products encompassed by this 510(k) submission are Class II (75JIX) In Vitro Diagnostic Solutions manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The Reagents are intended for use on equivalent Beckman Analyzers. Beckman Instrument is the original equipment manufacturer (OEM) of the analyzers and of predicate reagents which are necessary for the continued operation and use of the analyzers.

Information herein will support ALKO's position for the intended use of these products to the equivalent Beckman Chemistry Analyzers. The Beckman Chemistry Analyzers perform a broad array of tests. ALKO manufactures the ISE Reagents, wherein samples are analyzed for quantitative determinations of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub> by ISE method. These Reagents are intended to be used with equivalent Beckman Chemistry Analyzers. As such, ALKO products are intended to serve as direct replacements to like named products manufactured by Beckman Instrument Inc.

The Electrolyte Buffer is intended to provide constant ionic strength for measuring electrolytes in the samples. As such, it is diluted with Wash Solution and introduced into the sample and/or calibrator, for quantitative determination of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub>. The Electrolyte Reference Reagent is to provide reference points for Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub>. The CO<sub>2</sub> Acid Reagent is to release CO<sub>2</sub> from serum and plasma samples and/or calibrators. The CO<sub>2</sub> Alkaline Buffer is to provide a constant CO<sub>2</sub> concentration as reference for the CO<sub>2</sub> Electrode. The Wash Concentrate is intended to be diluted with de-ionized water. The prepared Wash Solution is used to wash the systems sample probe and to dilute reagents on equivalent Beckman CX® Systems.

- ALKO product A443-325 (Electrolyte Buffer) is equivalent to Beckman Instrument product 443325 (Electrolyte Buffer).
- ALKO product A443-315 (Electrolyte Reference Reagent), is equivalent to Beckman Instrument product 443315 (Electrolyte Reference Reagent).
- ALKO product A443-330 (CO2 Acid Reagent), is equivalent to Beckman Instrument product 443330 (CO2 Acid Reagent).
- ALKO product A443-320 (CO2 Alkaline Buffer), is equivalent to Beckman Instrument product 443320 (CO2 Alkaline Buffer).
- ALKO product A443-335 (Wash Concentrate), is equivalent to Beckman Instrument product 443335 (Wash Concentrate).

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**SHEET 11 OF 111**

ALKO uses a similar composition, description and packaging design as that used by Beckman Instrument Inc. in its products. ALKO has shown performance equivalence of its products to Beckman Instrument products in the following manner:

- Through a method comparison where results obtained on an equivalent Beckman Chemistry Analyzer, calibrated with ALKO products and compared with results obtained on the same Analyzer calibrated with Beckman Instrument products; and
- Through a precision study where ALKO products were installed on an equivalent Beckman Chemistry Analyzer and samples were measured one run per day for a defined period as stated below. A summary of the results of these studies follows:

**PERFORMANCE CHARACTERISTICS**

**Precision Data**

Precision data were collected from the analysis of two levels of serum and urine controls, measured in triplicate per run, one run per day for a total of 20 runs over 30 days on the ISE Module of Beckman CX<sup>®</sup>3, calibrated with all ALKO reagents.

**Serum Level : Normal**

		N	Mean	STD	CV%	Min	Max
Na <sup>+</sup>	Total	60	137.4	1.3186	0.9596	135.1	140.0
	Run to Run	20	137.4	1.2477	0.9080	135.5	139.7
K <sup>+</sup>	Total	60	4.17	0.0461	1.1071	4.08	4.28
	Run to Run	20	4.17	0.0430	1.0323	4.11	4.24
Cl <sup>-</sup>	Total	60	100.5	1.2705	1.2643	97.0	103.1
	Run to Run	20	100.5	1.0149	1.0099	98.5	102.3
CO <sub>2</sub>	Total	60	15.1	0.6136	4.0549	14.1	16.6
	Run to Run	20	15.1	0.5805	3.8425	14.3	16.4

**Serum Level : Abnormal**

		N	Mean	STD	CV%	Min	Max
Na <sup>+</sup>	Total	60	151.2	1.1638	0.7698	147.5	153.1
	Run to Run	20	151.2	1.0763	0.7119	148.7	152.7
K <sup>+</sup>	Total	60	7.32	0.0620	0.8462	7.12	7.42
	Run to Run	20	7.32	0.0594	0.8120	7.14	7.40
Cl <sup>-</sup>	Total	60	112.1	0.9476	0.8451	109.6	113.9
	Run to Run	20	112.1	0.8375	0.7468	110.4	113.4
CO <sub>2</sub>	Total	60	25.5	0.4917	1.9268	24.5	26.8
	Run to Run	20	25.5	0.4393	1.7214	24.9	26.4

**Urine Level 1**

		N	Mean	STD	CV%	Min	Max
Na <sup>+</sup>	Total	60	81.0	1.0163	1.2544	79.4	83.6
	Run to Run	20	81.0	0.9591	1.1838	79.7	82.9
K <sup>+</sup>	Total	60	30.2	0.3910	1.2944	29.3	30.9
	Run to Run	20	30.2	0.3799	1.2576	29.5	30.9
Cl <sup>-</sup>	Total	60	81.3	1.1310	1.3918	78.5	83.4
	Run to Run	20	81.3	0.9046	1.1133	79.6	82.7

**Urine Level 2**

		N	Mean	STD	CV%	Min	Max
Na <sup>+</sup>	Total	60	175.5	1.8021	1.0267	171.8	179.6
	Run to Run	20	175.5	1.7356	0.9888	172.3	179.1
K <sup>+</sup>	Total	60	100.4	1.2619	1.2567	97.0	103.2
	Run to Run	20	100.4	1.2280	1.2229	97.1	102.9
Cl <sup>-</sup>	Total	60	203.4	2.1740	1.0690	199.5	209.0
	Run to Run	20	203.4	2.0802	1.0228	200.5	208.7

**Correlation with Beckman Reagents**

Linear Regression Analyses were performed using the Beckman data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation  $Y = a + bX$ .

**Serum(Plasma) Samples (Beckman CX<sup>®</sup>3):**

Correlation data were collected from 68+ serum and plasma samples for Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>/CO<sub>2</sub>, measured on the ISE Module of the Beckman CX<sup>®</sup>3 System, calibrated with ALKO as compared with Beckman reagents separately.

	Na	K	Cl	CO <sub>2</sub>
N	72	74	77	68
Slope	1.0048	0.9840	0.9801	0.9738
Intercept	-0.6344	0.0846	1.5534	0.6117
R Squared	0.9992	0.9995	0.9991	0.9956
Range	100 - 200	1 - 15	50 - 200	5 - 40

**Serum (Plasma) Samples (Beckman CX<sup>®</sup>5):**

Correlation data were collected from 34+ serum samples for Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>/CO<sub>2</sub>, measured on the ISE Module of the Beckman CX<sup>®</sup>5 System, calibrated with ALKO as compared with Beckman reagents separately.

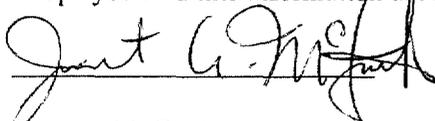
	Na	K	Cl	CO <sub>2</sub>
N	38	40	34	38
Slope	0.9727	0.9807	0.9369	0.9885
Intercept	3.7055	0.0447	5.0960	0.2429
R Squared	0.9961	0.9993	0.9991	0.9988
Range	100 - 200	1 - 15	50 - 200	5 - 40

**Urine Samples (Beckman CX<sup>®</sup>3):**

Correlation data were collected from 54+ urine samples for Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>, measured on the ISE Module of the Beckman CX<sup>®</sup>3 System, calibrated with ALKO as compared with Beckman reagents separately.

	Na	K	Cl
N	54	54	55
Slope	0.9984	0.9602	0.9764
Intercept	0.0968	1.0587	1.7695
R Squared	0.9997	0.9991	0.9978
Range	10 - 200	2 - 200	15 - 300

I hope you find this information useful and informative.



7/16/98  
(date prepared)

Janet A. McGrath  
Regulatory Affairs



SEP | 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Janet A. McGrath  
• Regulatory Affairs Specialist  
Alko Diagnostic Corporation  
333 Fiske Street  
Holliston, Massachusetts 01746

Re: K982501  
Electrolyte Buffer A443-325, and Reference Reagent  
Regulatory Class: II  
Product Code: JIX  
Dated: July 16, 1998  
Received: July 20, 1998

Dear Ms. McGrath:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

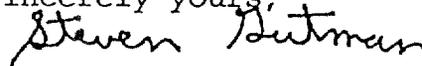
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Reagents on Equivalent Beckman Chemistry Analyzers

**Indication For Use:**

The products encompassed by this request are intended for in vitro diagnostic use and are intended for use in the quantitative determinations of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and CO<sub>2</sub>. Beckman Instrument is the Original Equipment Manufacturer of the Chemistry Analyzers and of the predicate Reagents. The Beckman Chemistry Analyzers perform a broad array of tests. ALKO manufactures the ISE Reagents, wherein samples are analyzed for quantitative determinations of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub> by ISE method. These Reagents are intended to be used with equivalent Beckman Chemistry Analyzers. As such, ALKO products are intended to serve as direct replacements to like named products manufactured by Beckman Instrument Inc.

The Electrolyte Buffer is intended to provide constant ionic strength for measuring electrolytes in the samples. As such, it is diluted with Wash Solution and introduced into the sample and/or calibrator, for quantitative determination of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub>. The Electrolyte Reference Reagent is intended to provide reference points for Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> and CO<sub>2</sub>. The CO<sub>2</sub> Acid Reagent is intended to release CO<sub>2</sub> from serum and plasma samples and/or calibrators. The CO<sub>2</sub> Alkaline Buffer is to provide a constant CO<sub>2</sub> concentration as reference for the CO<sub>2</sub> Electrode. The Wash Concentrate is intended to be diluted with de-ionized water. The prepared Wash Solution is used to wash the systems sample flow path and to dilute reagents on equivalent Beckman CX<sup>®</sup> Systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K98 2501

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)