K-960085

510(k) Summary
ALKO Calibrators and ISE Liquid Reagent
for Baxter Diagnostics Paramax^R CLiNaK™ 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 calibrators are intended for use in calibrating the electrodes of Paramax^R CLiNaK™ Analyzers. The ISE Liquid Reagent is used to dilute samples measured on the Paramax^R CLiNaK™ Analyzers. Baxter Diagnostics, Inc. is the original equipment manufacturer (OEM) of the analyzer and of predicate Calibrators and ISE Liquid Reagent which are necessary for the continued operation and use of the analyzer.

The ALKO calibrators and ISE Liquid Reagent are intended to serve as direct replacements to like named products manufactured by Baxter Diagnostics, Inc. (currently Dade International). ALKO Product A611-151 (ALKO Calibrant A) is equivalent to Baxter Diagnostics Product B6110-151 (ISE Calibrant A). ALKO Product A611-152 (ALKO Calibrant B) is equivalent to Baxter Diagnostics Product B6110-152 (ISE Calibrant B). ALKO Product A611-153 (ALKO ISE Liquid Reagent) is equivalent to Baxter Diagnostics Product B6110-153 (ISE Liquid Reagent).

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

o   Through a method comparison where results obtained on a Paramax^R CLiNaK™ Analyzer calibrated with ALKO products were compared with results obtained on the same analyzer calibrated with Baxter products; and

o   Through a precision study where ALKO products were installed on a Paramax^R CLiNaK™ Analyzer and samples were measured over 20 runs.

A summary of the results of these studies follows:

Accuracy by Correlation with Baxter (Dade) ISE Reagents

Correlation data was collected from 60 pooled serum samples with Na+, K+, Cl- and Li+ values adjusted using NaCl, KCl and LiCl salts. The correlation study was performed on a Baxter CLiNaK^{TM} ISE module, calibrated with ALKO and Baxter reagents separately. A Linear Regression Analysis was performed using OEM data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation Y = a + bX. One outlier for K+ and one outlier for Cl- data were excluded from the comparison. Outliers were excluded using a formula where if the individual value of the difference between the two methods is greater than four times the average absolute difference of all measurements then the individual value is excluded.

Analyte	N	Slope	Intercept	R Sq	Range
Na+	60	1.002	-0.174	0.993	63 - 203
K+	58	1.002	0.007	0.998	0.9 - 14.3
Cl-	59	0.969	2.798	0.996	41 - 170
Li+	57	0.999	0.022	0.998	0.0 - 5.93

R Sq = Correlation Coefficient Squared

Precision Data

Na+, K+, Cl- and Li+ electrolyte precision data was collected from the analysis of two levels of controls measured on a Baxter CLiNaK^{TM} ISE module (calibrated with all ALKO reagents) 3 times per run for a total of 20 runs. A separate calibration was performed prior to each run.

Na+

Level		N	Mean	STD	CV%	Min	Max
1	Total	60	146.2	1.077	0.74	144	149
	Run to Run	20	146.2	0.957	0.65	144.7	148.0
2	Total	60	126.3	1.118	0.89	124	129
	Run to Run	20	126.3	0.719	0.57	125.3	127.7

K+

Level		N	Mean	STD	CV%	Min	Max
1	Total	60	6.98	0.102	1.46	6.8	7.3
	Run to Run	20	6.98	0.085	1.22	6.83	7.17
2	Total	60	3.95	0.090	2.28	3.7	4.2
	Run to Run	20	3.95	0.065	1.63	3.83	4.10
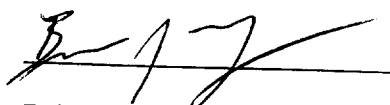
Cl-

Level		N	Mean	STD	CV%	Min	Max
1	Total	60	107.0	1.080	1.01	105	109
	Run to Run	20	107.0	0.906	0.85	105.3	108.7
2	Total	60	86.8	1.501	1.73	83	90
	Run to Run	20	86.8	1.337	1.54	84.3	89.3

Li+

Level		N	Mean	STD	CV%	Min	Max
1	Total	60	0.446	0.021	4.66	0.40	0.50
	Run to Run	20	0.446	0.016	3.63	0.423	0.487
2	Total	60	1.726	0.0355	2.06	1.65	1.81
	Run to Run	20	1.726	0.0244	1.41	1.680	1.790

I hope that you find this information useful and informative.

Brian J. Young
Director, Design and
Regulatory Affairs

1/4/96
(date prepared)

SHEET 5 OF 76