



ALKO Diagnostic Corporation

A Life Sciences International Company

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510(k) Summary

ISE Reagents

for BMD Hitachi Clinical Chemistry 700 Series and 911 Systems

All product(s) encompassed by this 510(k) submission are Class I (75JJG) and Class II (75JIX) In Vitro Diagnostic Solutions manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The ISE Reagents are intended for use on the ISE Module of the BMD Hitachi Clinical Chemistry Systems. The ISE High and Low Calibrators are intended to provide calibration points for the Na +, K+, and Cl- Electrodes on the ISE Subsystem. The 1N KCl Solutions are intended to provide stable reference potential for the Na +, K+, and Cl- Electrodes. The ISE Diluent dilutes all measured patient samples for the quantitative determination of Na +, K+, and Cl- in Serum, Plasma and Urine by ISE. The ISE Internal Reference Solutions are intended as a means of compensating for calibration drift in the quantitative determination of Na +, K+, and Cl- in Serum, Plasma and Urine samples on the BMD Hitachi Clinical Chemistry Systems. Boehringer Mannheim Diagnostics is the original equipment manufacturer (OEM) of the analyzer(s) and of predicate ISE Reagents which are necessary for the continued operation and use of ISE Subsystem on the analyzer.

The ISE Hitachi Reagents are intended to serve as direct replacement to like named product manufactured by Boehringer Mannheim Diagnostic. Listed below are ALKO products and their OEM equivalents.

<u>ALKO #</u>	<u>OEM</u>	<u>Description</u>	<u>Models</u>	<u>Class</u>
A858-044	820637	ISE Diluent	704	1
A820-636	820638	ISE Diluent	717,736,737,747	1
A450-043	450043	ISE Diluent	911	1
A820-644	836246	ISE Internal Reference Solution	704,717,737,747	1
A836-244	836245	ISE Internal Reference Solution	736	1
A450-042	450042	ISE Internal Reference Solution	911	1
A820-652	820639	ISE 1N KCl Solution	704,717,736,737,747	1
A450-041	450041	ISE 1N KCl Solution	911	1
A620-428	620428	ISE Low Standard	704,717,736,737,747,911	2
A620-427	620427	ISE High Standard	704,717,736,737,747,911	2

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

- Through a comparative analysis where results obtained on BMD Hitachi Clinical Chemistry Systems calibrated with ALKO products were compared with results obtained on the same system calibrated with BMD Hitachi products; and
- Through a precision study where ALKO products were installed on BMD Hitachi Clinical Chemistry Systems and samples were measured over 20 runs.

A summary of the results of these studies follows:

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PERFORMANCE CHARACTERISTICS**Correlation with BMD Reagents - Urine Samples**

1. Correlation data collected from urine samples measured on Hitachi 736, 704, 737 and 911 System, calibrated with ALKO and BMD products separately. The study compares values obtained using ALKO products as compared BMD products wherein Linear Regression Analyses were performed using ALKO Data as the Dependent Y Variable and BMD Data as the Independent X Variable in the equation $Y = a + bX$.

Hitachi 736 System

Analyte	(N)	Slope	Intercept	R Sq.	Range
Na	40	1.0076	1.5483	0.9995	9-253
K	40	1.0028	0.4064	0.9995	5.7-81.1
Cl	40	1.0419	-2.5008	0.9986	13-214

Hitachi 704 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	40	1.0798	-5.1321	0.9985	10.0-258.8
K	40	1.0436	-0.4654	0.9904	5.1- 83.2
Cl	40	1.0769	-5.9423	0.9988	10.8-237.7

Hitachi 737 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	42	1.0239	-2.0167	0.9992	6-190
K	42	0.9828	-0.0362	0.9996	3.3-102.5
Cl	42	1.0243	-2.0894	0.9978	7-235

Hitachi 911 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	42	1.0368	-4.2943	0.9997	2-187
K	42	0.9574	0.1334	0.9992	3.2-101.5
Cl	42	1.0295	-1.5562	0.9993	14-231

R Sq = Correlation Coefficient Squared

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Correlation with BMD Reagents - Plasma Samples

2. Correlation data collected from plasma samples measured on Hitachi 736, 704, 737 and 911 Clinical Chemistry Systems, calibrated with ALKO and BMD products separately. The study compares values obtained using ALKO products as compared BMD products wherein Linear Regression Analyses were performed using ALKO Data as the Dependent Y Variable and BMD Data as the Independent X Variable in the equation $Y = a + bX$.

Hitachi 736 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	59	1.0141	-1.6476	0.9955	86-178
K	59	0.9747	0.1266	0.9990	3.0-11.9
Cl	59	0.9968	-0.4270	0.9955	64-154

Hitachi 704 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	57	0.9705	3.64833	0.9913	84.6-180.9
K	57	0.9704	0.1084	0.9982	2.9-12.2
Cl	59	1.0023	-1.3518	0.9946	63.6-150.0

Hitachi 737 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	59	1.0331	-7.4335	0.9949	85-180
K	59	0.9843	-0.04915	0.9991	3.0-12.2
Cl	59	1.0185	-4.5429	0.9976	62-156

Hitachi 911 System

Analyte	(N)	Slope	Intercept	R Sq	Range
Na	59	1.0096	-1.2435	0.9930	86-179
K	59	0.9553	-0.2228	0.9992	3.0-12.2
Cl	59	0.9574	5.8746	0.9917	67-154

R Sq = Correlation Coefficient Squared

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Precision of ALKO Reagents - Urine Samples

3. Precision data collected from urine samples measured on Hitachi 704, 717, 736 and 737 Clinical Chemistry Systems, over a period of four to six days using all ALKO reagents.

Hitachi 704 System

Level	Analyte	(N)	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na	20	88.43	2.38	2.69	0.42	0.47
	K	20	28.73	0.48	1.67	0.34	1.19
	Cl	20	80.28	3.05	3.80	0.32	0.39
Level 2	Na	20	188.39	2.32	1.23	0.73	0.39
	K	20	73.29	4.01	5.47	3.02	4.12
	Cl	20	190.09	5.58	2.94	1.86	0.98

Hitachi 717 System

Level	Analyte	(N)	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na	20	83.28	1.77	2.13	0.57	0.68
	K	20	29.64	0.59	1.98	0.55	1.85
	Cl	20	77.53	3.91	5.04	1.13	1.46
Level 2	Na	20	180.05	2.26	1.26	1.00	0.56
	K	20	77.73	3.91	5.04	1.13	1.46
	Cl	20	182.78	6.71	3.67	1.82	1.00

Hitachi 736 System

Level	Analyte	(N)	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na	20	81.25	2.00	2.47	0.87	1.07
	K	20	29.25	0.46	1.46	0.35	1.20
	Cl	20	80.38	4.32	5.38	2.37	2.95
Level 2	Na	20	179.05	2.63	1.47	2.53	1.41
	K	20	94.90	1.99	2.09	0.44	0.46
	Cl	20	159.48	6.44	4.04	1.75	1.10

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Hitachi 737 System

Level	Analyte	(N)	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na	20	27.83	1.39	4.99	0.69	2.48
	K	20	7.57	0.11	1.45	0.09	1.24
	Cl	20	26.75	4.03	15.08	1.83	6.84
Level 2	Na	20	57.33	1.59	2.78	0.52	0.91
	K	20	15.85	0.17	1.07	0.04	0.28
	Cl	20	56.55	2.29	4.05	0.59	1.05

Conclusion

ALKO manufactures products that serve as functional equivalents to consumable distributed by Original Equipment Manufacturer. All such products are manufactured with the intent of complying with the Good Manufacturing Practice Regulations.

As previously stated the product encompassed by this request serves as a functional equivalent to the product currently manufactured and marketed by Boehringer Mannheim Diagnostics. We believe that BMD has received 510 (k) market approval given that they are currently distributing the instruments and related consumable domestically. The previously described labeling and performance verification should provide adequate documentation as to the equivalence of the ALKO Product.

I hope you find the documentation provided informative and helpful.

 Janet A. McGrath
 Regulatory Affairs