K123322

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510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hkatz@AlfaWassermannUS.com Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	May 14, 2013	
Device:	Trade Name:	ACE BUN/Urea Reagent
	Classification:	Class 2
	Common/Classification Name:	Urease, Photometric, Urea Nitrogen (21 C.F.R. § 862.1770) Product Code CDN
	Trade Name:	ACE Creatinine Reagent
	Classification:	Class 2
	Common/Classification Name:	Alkaline Picrate, Colorimetry, Creatinine (21 C.F.R. § 862.1225) Product Code CGX
	Trade Name:	ACE Uric Acid Reagent
	Classification:	Class 1, reserved
	Common/Classification Name:	Acid, Uric, Uricase (Colorimetric) (21 C.F.R. § 862.1775) Product Code KNK
	Trade Name:	ACE CK Reagent
	Classification:	Class 2
	Common/Classification Name:	NAD Reduction/NADH Oxidation, CPK Or Isoenzymes (21 C.F.R. § 862.1215) Product Code CGS

Predicate Devices:	Alfa Wassermann ACE BUN/Urea Reagent, ACE Creatinine Reagent, ACE Uric Acid Reagent, and ACE CK Reagents (K930104)
Device Descriptions:	In the ACE BUN/Urea Reagent assay, urea in serum is hydrolyzed in the presence of urease to yield ammonia and carbon dioxide. The ammonia formed then reacts in the presence of glutamate dehydrogenase with 2-oxoglutarate and NADH to yield glutamate and NAD. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. The initial rate of decrease in absorbance, monitored bichromatically at 340 nm/647 nm, is proportional to the urea concentration in the sample. In the ACE Creatinine Reagent assay, creatinine reacts with picric acid in an alkaline medium to form a red-orange colored complex, which absorbs strongly at 505 nm. The rate of complex formation, determined by measuring the increase in absorbance bichromatically at 505 nm/573 nm during a fixed time interval, is directly proportional to the creatinine concentration in the sample. In the ACE Uric Acid Reagent assay, uric acid in serum is oxidized by uricase to allantoin and hydrogen peroxide. The hydrogen peroxide then acts to oxdatively couple dichlorohydroxybenzene sulfonic acid and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex, which absorbs strongly at 505 nm. The amount of chromogen formed is determined by measuring the increase in absorbance bichromatically at 505 nm/610 nm, and is directly proportional to the uric acid concentration in the sample. In the ACE CK Reagent assay, serum creatine kinase initiates the conversion of creatine phosphate to creatine with the transfer of a phosphate group to adenosine diphosphate (ADP), forming ATP. The ATP is then used in the phosphorylation of D-glucose to form D-glucose-6-phosphate and ADP. This reaction is catalyzed by hexokinase. The enzyme glucose-6-phosphate dehydrogenase catalyzes the reduction of D-glucose-6-phosphate and nicotinamide adenine dinucleotide phosphate ($NADP^+$). The series of reactions triggered by serum creatine kinase and ending in the formation of NADPH. NADPH strongly absorbs at 340 nm, whereas $NADP^+$ does not. Therefore, the rate of conversion of $NADP^+$ to NADPH can be determined by monitoring the increase in absorbance bichromatically at 340 nm/378 nm. This rate of conversion from $NADP^+$ to NADPH is a function of the activity of CK in the sample.

Intended Use:	Indications for Use:
	The ACE BUN/Urea Reagent is intended for the quantitative determination of blood urea nitrogen (BUN) concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. BUN measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Creatinine Reagent is intended for the quantitative determination of creatinine concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Uric Acid Reagent is intended for the quantitative determination of uric acid concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytotoxic drugs. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE CK Reagent is intended for the quantitative determination of creatine kinase activity in **serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Measurement of creatine kinase is used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The ACE BUN/Urea Reagent consists of a single reagent bottle. The reagent contains α-ketoglutarate, urease, glutamate dehydrogenase, adenosine diphosphate (ADP), nicotinamide adenine dinucleotide and reduced (NADH). The ACE Creatinine Reagent consists of two reagent bottles. The Sodium Hydroxide Reagent (R1) contains sodium hydroxide. The Picric Acid Reagent (R2) contains picric Acid. The ACE Uric Acid Reagent consists of a single reagent bottle. The reagent contains 4-aminoantipyrine, dichlorohydroxybenzene sulfonic acid, peroxidase and uricase. The ACE CK Reagent consists of two reagent bottles. The Buffer Reagent (R1) contains: imidazole buffer, glucose, N-acetyl-cysteine, magnesium acetate, EDTA, NADP and hexokinase. The Substrate Reagent (R2) contains: creatine phosphate, ADP, AMP, diadenosine pentaphosphate, EDTA and glucose-6-phosphate dehydrogenase.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE BUN/Urea Reagent

BUN/Urea	Candidate Device	Predicate Device K930104 (ACE BUN/Urea)
Intended Use/ Indications for Use	The ACE BUN/Urea Reagent is intended for the quantitative determination of blood urea nitrogen (BUN) concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	7 days	Same
On-Board Stability	30 days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	333 µL	Same
Expected Values	6 - 20 mg/dL	Same
Measuring Range	3 - 100 mg/dL	Same
Sample Stability	Samples may be stored for 7 days at 4-8°C and for 1 year at -20 °C.	Same

Device Comparison with Predicate

ACE Creatinine Reagent

Creatinine	Candidate Device	Predicate Device K930104 (ACE Creatinine)
Intended Use/ Indications for Use	The ACE Creatinine Reagent is intended for the quantitative determination of creatinine concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	2 days	Same
On-Board Stability	10 days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	20 µL	Same
Reaction Volume	240 µL	Same
Expected Values	Female: 0.6-1.1 mg/dL Male: 0.9-1.3 mg/dL	Same
Measuring Range	0.33 - 25.0 mg/dL	Same
Sample Stability	Creatinine is stable for 7 days when refrigerated at 4-8°C and for 3 months frozen at -20°C.	Same

ACE Uric Acid Reagent

Uric Acid	Candidate Device	Predicate Device K930104 (ACE Uric Acid)
Intended Use/ Indications for Use	The ACE CK Reagent is intended for the quantitative determination of creatine kinase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	243 µL	Same
Expected Values	Female: 2.6-6.0 mg/dL Male: 3.5-7.2 mg/dL	Same
Measuring Range	1.5 - 16.0 mg/dL	
Sample Stability	Separated from cells, uric acid is stable for 3-5 days at 4 °C and for 6 months frozen at -20°C.	Same

Device Comparison with Predicate

ACE CK Reagent

Creatinine Kinase	Candidate Device	Predicate Device K930104 (ACE CK)
Intended Use/ Indications for Use	ACE Magnesium Reagent is intended for the quantitative determination of magnesium.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not Applicable	Same
On-Board Stability	25 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	5 µL	Same
Reaction Volume	170 µL	Same
Expected Values	Female: 26-140 U/L Male: 38-174 U/L	Same
Measuring Range	11 - 1350 U/L	
Sample Stability	Serum magnesium is stable for 7 days at 4-8°C and 1 year at -20 °C if the serum is separated from the erythrocytes.	Same

Performance Data:

In-House Precision - Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Precision: Serum vs. Plasma – ACE BUN/Urea Reagent

	Precision (SD, %CV)								
BUN mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	5	0.5, 11.1%	0.6, 12.4%	5	0.4, 7.9%	0.6, 13.6%	4	0.4, 8.1%	0.5, 12.1%
Serum Mid	46	0.7, 1.4%	0.9, 1.8%	46	0.4, 0.9%	0.7, 1.5%	45	0.6, 1.2%	0.7, 1.5%
Serum High	85	2.4, 2.8%	2.7, 3.2%	85	1.4, 1.6%	1.8, 2.1%	85	1.3, 1.5%	1.7, 2.0%
Plasma Low	4	0.4, 10.7%	0.5, 12.8%	4	0.0, 0.0%	0.0, 0.0%	4	0.3, 6.3%	0.3, 6.3%
Plasma Mid	46	0.4, 0.9%	0.7, 1.5%	45	0.5, 1.1%	0.9, 1.9%	45	0.6, 1.4%	0.6, 1.4%
Plasma High	85	2.9, 3.4%	3.2, 3.8%	85	1.3, 1.5%	1.6, 1.9%	84	1.8, 2.2%	1.9, 2.3%

In-House Precision: Serum vs. Plasma – ACE Creatinine Reagent

	Precision (SD, %CV)								
Creatinine mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	0.67	0.04, 5.8%	0.06, 8.5%	0.70	0.02, 3.2%	0.04, 5.6%	0.70	0.04, 6.0%	0.06, 8.1%
Serum Mid	9.32	0.28, 3.0%	0.28, 3.0%	9.24	0.21, 2.3%	0.22, 2.4%	9.31	0.16, 1.7%	0.19, 2.1%
Serum High	18.25	0.13, 0.7%	0.35, 1.9%	17.96	0.18, 1.0%	0.22, 1.2%	17.97	0.14, 0.8%	0.23, 1.3%
Plasma Low	0.65	0.04, 6.3%	0.06, 9.0%	0.66	0.04, 5.5%	0.05, 7.8%	0.64	0.04, 6.6%	0.06, 9.3%
Plasma Mid	9.47	0.23, 2.5%	0.25, 2.7%	9.41	0.23, 2.5%	0.23, 2.5%	9.42	0.19, 2.0%	0.25, 2.6%
Plasma High	18.38	0.20, 1.1%	0.45, 2.4%	18.04	0.19, 1.0%	0.22, 1.2%	18.13	0.31, 1.7%	0.43, 2.4%

Performance Data:

In-House Precision – Serum vs. Plasma

In-House Precision: Serum vs. Plasma – ACE Uric Acid Reagent

	Precision (SD, %CV)								
Uric Acid mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	4.5	0.1, 2.6%	0.2, 4.5%	4.5	0.1, 3.0%	0.2, 4.6%	4.5	0.1, 1.5%	0.2, 4.4%
Serum Mid	9.3	0.1, 1.3%	0.2, 2.5%	9.2	0.1, 0.8%	0.2, 2.6%	9.3	0.1, 0.9%	0.3, 2.8%
Serum High	15.0	0.3, 1.8%	0.3, 2.0%	14.8	0.3, 1.9%	0.3, 2.1%	14.9	0.2, 1.1%	0.3, 1.8%
Plasma Low	4.3	0.2, 3.6%	0.2, 5.5%	4.3	0.1, 3.3%	0.2, 5.5%	4.3	0.1, 2.8%	0.2, 4.5%
Plasma Mid	9.0	0.1, 0.7%	0.2, 1.9%	8.9	0.2, 2.1%	0.2, 2.6%	9.0	0.1, 1.0%	0.2, 2.0%
Plasma High	14.7	0.2, 1.2%	0.2, 1.4%	14.5	0.3, 1.8%	0.3, 1.9%	14.5	0.2, 1.2%	0.2, 1.3%

In-House Precision: Serum vs. Plasma – ACE CK Reagent

	Precision (SD, %CV)								
CK mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	79	3.2, 4.0%	3.2, 4.0%	81	3.8, 4.7%	4.1, 5.0%	85	1.5, 1.7%	2.3, 2.7%
Serum Mid	636	7.7, 1.2%	30.9, 4.9%	615	9.4, 1.5%	28.6, 4.6%	682	3.7, 0.5%	31.4, 4.6%
Serum High	1176	17.4, 1.5%	56.1, 4.8%	1125	7.9, 0.7%	55.5, 4.9%	1255	7.2, 0.6%	58.4, 4.7%
Plasma Low	61	2.8, 4.6%	3.1, 5.1%	65	1.8, 2.8%	2.8, 4.4%	66	1.8, 2.8%	2.1, 3.2%
Plasma Mid	619	11.1, 1.8%	25.8, 4.2%	605	8.8, 1.5%	32.4, 5.4%	666	13.0, 2.0%	36.5, 5.5%
Plasma High	1140	16.1, 1.4%	57.1,5.0%	1111	14.4, 1.3%	51.1, 4.6%	1221	11.7, 1.0%	54.7, 4.5%

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Matrix Comparison: Serum vs. Plasma – ACE BUN/Urea Nitrogen Reagent

System	Range	Results - Serum vs. Plasma
ACE 95 pairs	3-91 mg/dL	Slope: 0.979 Intercept: 0.4 Correlation: 0.9980 Std. Error Est: 1.2 Confidence Interval Slope: 0.966 to 0.992 Confidence Interval Intercept: 0.0 to 0.7
ACE Alera 96 pairs	3-96 mg/dL	Slope: 1.009 Intercept: -0.1 Correlation: 0.9976 Std. Error Est: 1.4 Confidence Interval Slope: 0.995 to 1.023 Confidence Interval Intercept: -0.5 to 0.4
ACE Axcel 51 pairs	3-100 mg/dL	Slope: 1.007 Intercept: 0.3 Correlation: 0.9944 Std. Error Est: 2.4 Confidence Interval Slope: 0.977 to 1.038 Confidence Interval Intercept: -0.7 to 1.4

In-House Matrix Comparison: Serum vs. Plasma – ACE Creatinine Reagent

System	Range	Results - Serum vs. Plasma
ACE 102 pairs	0.37-22.12 mg/dL	Slope: 1.014 Intercept: -0.003 Correlation: 0.9974 Std. Error Est: 0.279 Confidence Interval Slope: 1.000 to 1.029 Confidence Interval Intercept: -0.068 to 0.062
ACE Alera 102 pairs	0.41-23.15 mg/dL	Slope: 1.050 Intercept: -0.077 Correlation: 0.9984 Std. Error Est: 0.197 Confidence Interval Slope: 1.038 to 1.062 Confidence Interval Intercept: -0.124 to -0.029
ACE Axcel 55 pairs	0.37-23.45 mg/dL	Slope: 1.003 Intercept: 0.005 Correlation: 0.9993 Std. Error Est: 0.197 Confidence Interval Slope: 0.993 to 1.013 Confidence Interval Intercept: -0.058 to 0.069

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

In-House Matrix Comparison: Serum vs. Plasma – ACE Uric Acid Reagent

System	Range	Results - Serum vs. Plasma
ACE 97 pairs	2.5-14.0 mg/dL	Slope: 1.008 Intercept: -0.14 Correlation: 0.9906 Std. Error Est: 0.35 Confidence Interval Slope: 0.980 to 1.036 Confidence Interval Intercept: -0.34 to 0.06
ACE Alera 95 pairs	2.5-14.4 mg/dL	Slope: 1.028 Intercept: -0.29 Correlation: 0.9836 Std. Error Est: 0.48 Confidence Interval Slope: 0.989 to 1.066 Confidence Interval Intercept: -0.57 to -0.01
ACE Axcel 55 pairs	1.8-15.6 mg/dL	Slope: 1.025 Intercept: -0.09 Correlation: 0.9879 Std. Error Est: 0.42 Confidence Interval Slope: 0.981 to 1.069 Confidence Interval Intercept: -0.39 to 0.21

In-House Matrix Comparison: Serum vs. Plasma – ACE CK Reagent

System	Range	Results - Serum vs. Plasma
ACE 94 pairs	11-1234 U/L	Slope: 0.997 Intercept: -0.5 Correlation: 0.9965 Std. Error Est: 23.5 Confidence Interval Slope: 0.980 to 1.014 Confidence Interval Intercept: -6.3 to 5.2
ACE Alera 96 pairs	14-1211 U/L	Slope: 0.978 Intercept: 0.1 Correlation: 0.9960 Std. Error Est: 22.1 Confidence Interval Slope: 0.960 to 0.996 Confidence Interval Intercept: -5.2 to 5.5
ACE Axcel 55 pairs	17-1315 U/L	Slope: 1.006 Intercept: -0.50 Correlation: 0.9990 Std. Error Est: 13.24 Confidence Interval Slope: 0.993 to 1.019 Confidence Interval Intercept: -4.74 to 3.74

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

(Note: Refer to previously cleared submission k113389 for ACE Axcel POL data)

BUN/Urea			ACE Result mg/dL SD, %CV		Mean	ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	8	0.00 SD	0.30 SD	8	0.40 SD	0.60 SD
			0.0%	4.0%		5.5%	7.7%
POL 1	1	8	0.30 SD	0.30 SD	9	0.40 SD	0.50 SD
			3.9%	3.9%		4.5%	6.2%
POL 2	1	8	0.40 SD	0.50 SD	8	0.20 SD	0.40 SD
			4.4%	5.6%		2.8%	4.9%
POL 3	1	8	0.30 SD	0.30 SD	9	0.30 SD	0.70 SD
			3.9%	3.9%		3.6%	8.3%
In-House	2	41	1.90 SD	2.00 SD	42	1.30 SD	1.60 SD
			4.7%	5.0%		3.2%	3.9%
POL 1	2	43	0.40 SD	0.80 SD	43	1.40 SD	1.70 SD
			1.0%	1.9%		3.4%	4.0%
POL 2	2	42	0.30 SD	1.40 SD	41	1.10 SD	1.80 SD
			0.7%	3.3%		2.7%	4.4%
POL 3	2	42	1.00 SD	1.10 SD	44	0.70 SD	1.40 SD
			2.4%	2.6%		1.7%	3.3%
In-House	3	74	1.10 SD	2.40 SD	75	0.40 SD	2.00 SD
			1.5%	3.2%		0.5%	2.6%
POL 1	3	75	1.30 SD	1.30 SD	76	1.20 SD	1.80 SD
			1.8%	1.8%		1.6%	2.4%
POL 2	3	73	1.30 SD	2.30 SD	74	1.70 SD	2.80 SD
			1.8%	3.1%		2.3%	3.7%
POL 3	3	76	1.20 SD	1.40 SD	76	1.10 SD	2.20 SD
			1.6%	1.9%		1.4%	2.9%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Creatinine			ACE Result mg/dL SD, %CV			ACE Alera Result mg/dL SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**	**Mean**	**Within-Run**	**Total**
In-House	1	0.58	0.04 SD	0.05 SD	0.58	0.02 SD	0.03 SD
			6.4%	8.8%		3.2%	5.3%
POL 1	1	0.51	0.03 SD	0.04 SD	0.53	0.03 SD	0.05 SD
			5.6%	8.4%		6.0%	9.3%
POL 2	1	0.54	0.04 SD	0.05 SD	0.56	0.02 SD	0.03 SD
			6.9%	9.8%		4.2%	4.4%
POL 3	1	0.53	0.04 SD	0.04 SD	0.55	0.02 SD	0.04 SD
			6.6%	7.5%		4.3%	6.3%
In-House	2	8.29	0.09 SD	0.32 SD	8.08	0.11 SD	0.28 SD
			1.0%	3.9%		1.3%	3.5%
POL 1	2	7.97	0.08 SD	0.20 SD	7.84	0.08 SD	0.15 SD
			1.0%	2.5%		1.1%	1.9%
POL 2	2	7.60	0.11 SD	0.43 SD	8.21	0.14 SD	0.23 SD
			1.4%	5.7%		1.7%	2.8%
POL 3	2	7.89	0.11 SD	0.13 SD	7.98	0.09 SD	0.23 SD
			1.4%	1.7%		1.1%	2.9%
In-House	3	12.92	0.18 SD	0.46 SD	12.65	0.07 SD	0.42 SD
			1.4%	3.5%		0.5%	3.3%
POL 1	3	12.42	0.23 SD	0.37SD	12.32	0.10 SD	0.42 SD
			1.9%	3.0%		0.9%	3.4%
POL 2	3	11.67	0.22 SD	0.53 SD	12.81	0.31 SD	0.50 SD
			1.9%	4.5%		2.4%	3.9%
POL 3	3	12.28	0.17 SD	0.18 SD	12.27	0.12 SD	0.44 SD
			1.4%	1.5%		1.0%	3.6%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Uric Acid			ACE Result mg/dL SD, %CV		Mean	ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	2.9	0.19 SD	0.19 SD	2.9	0.10 SD	0.13 SD
			6.5%	6.5%		3.5%	4.5%
POL 1	1	3.0	0.05 SD	0.09 SD	3.0	0.15 SD	0.16 SD
			1.7%	3.1%		5.2%	5.3%
POL 2	1	2.8	0.10 SD	0.11 SD	2.9	0.09 SD	0.10 SD
			3.5%	4.0%		3.1%	3.6%
POL 3	1	2.9	0.06 SD	0.14 SD	3.2	0.05 SD	0.09 SD
			2.2%	5.0%		1.6%	2.9%
In-House	2	8.0	0.13 SD	0.15 SD	8.0	0.05 SD	0.17 SD
			1.6%	1.9%		0.7%	2.1%
POL 1	2	7.7	0.05 SD	0.11 SD	7.6	0.13 SD	0.21 SD
			0.6%	1.4%		1.7%	2.8%
POL 2	2	7.5	0.13 SD	0.16 SD	7.5	0.08 SD	0.13 SD
			1.7%	2.2%		1.0%	1.8%
POL 3	2	7.9	0.10 SD	0.13 SD	7.9	0.07 SD	0.25 SD
			1.2%	1.7%		0.9%	3.1%
In-House	3	12.5	0.35 SD	0.38 SD	12.7	0.18 SD	0.22 SD
			2.8%	3.0%		1.4%	1.7%
POL 1	3	12.0	0.13 SD	0.28 SD	11.9	0.14 SD	0.26 SD
			1.1%	2.4%		1.2%	2.2%
POL 2	3	11.8	0.29 SD	0.32 SD	11.6	0.27 SD	0.27 SD
			2.5%	2.7%		2.4%	2.4%
POL 3	3	12.3	0.11 SD	0.12 SD	12.2	0.15 SD	0.35 SD
			0.9%	1.0%		1.2%	2.9%

Performance Data at POL:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

CK			ACE Result mg/dL SD, %CV			ACE Alera Result mg/dL SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**	**Mean**	**Within-Run**	**Total**
In-House	1	77	3.20 SD	4.00 SD	75	2.50 SD	3.30 SD
			4.2%	5.2%		3.3%	4.4%
POL 1	1	70	1.40 SD	2.90 SD	73	1.40 SD	2.60 SD
			2.0%	4.1%		1.9%	3.6%
POL 2	1	69	1.90 SD	3.00 SD	70	2.20 SD	3.50 SD
			2.7%	4.4%		3.2%	5.0%
POL 3	1	79	2.60 SD	2.70 SD	70	2.10 SD	4.10 SD
			3.2%	3.4%		3.0%	5.9%
In-House	2	521	6.70 SD	7.20 SD	516	8.00 SD	8.10 SD
			1.3%	1.4%		1.5%	1.6%
POL 1	2	568	4.90 SD	6.90 SD	567	10.00 SD	14.00 SD
			0.9%	1.2%		1.8%	2.5%
POL 2	2	526	3.90 SD	9.20 SD	514	6.50 SD	8.80 SD
			0.7%	1.8%		1.3%	1.7%
POL 3	2	540	4.00 SD	4.30 SD	559	6.90 SD	14.10 SD
			0.7%	0.8%		1.2%	2.5%
In-House	3	907	10.90SD	14.60SD	905	9.50 SD	14.00 SD
			1.2%	1.6%		1.1%	1.6%
POL 1	3	967	22.00SD	22.70SD	995	7.60 SD	14.40 SD
			2.3%	2.3%		0.8%	1.4%
POL 2	3	929	18.60SD	18.90SD	899	11.40SD	11.60SD
			2.0%	2.0%		1.3%	1.3%
POL 3	3	950	7.80 SD	9.90 SD	977	13.00SD	19.60 SD
			0.8%	1.0%		1.3%	2.0%

Performance Data:

Method Comparison - POL on ACE

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	In-House ACE (x) vs. POL 1 ACE (y)	In-House ACE (x) vs. POL 2 ACE (y)	In-House ACE (x) vs. POL 3 ACE (y)
BUN	n	53	54	54
	Range	3 to 88	3 to 88	3 to 88
	Regression	y = 1.034x – 0.1	y = 1.025x + 0.0	y = 1.031x + 0.0
	Correlation	0.9989	0.9985	0.9990
	Std. Error Est.	0.9	1.1	0.9
	CI Slope	1.020 to 1.047	1.010 to 1.040	1.018 to 1.044
	CI Intercept	-0.5 to 0.2	-0.4 to 0.5	-0.3 to 0.4
Creatinine	n	51	51	51
	Range	0.34 to 22.57	0.34 to 22.57	0.34 to 22.57
	Regression	y = 1.032x – 0.010	y = 1.010x – 0.046	y = 0.986x – 0.017
	Correlation	0.9994	0.9997	0.9999
	Std. Error Est.	0.148	0.100	0.060
	CI Slope	1.022 to 1.042	1.003 to 1.016	0.982 to 0.990
	CI Intercept	-0.057 to 0.037	-0.078 to -0.014	-0.036 to 0.002
Uric Acid	n	49	49	49
	Range	1.7 to 14.5	1.7 to 14.5	1.7 to 14.5
	Regression	y = 0.988x + 0.23	y = 1.018x – 0.06	y = 1.009x + 0.03
	Correlation	0.9939	0.9957	0.9969
	Std. Error Est.	0.27	0.23	0.19
	CI Slope	0.956 to 1.020	0.991 to 1.046	0.985 to 1.032
	CI Intercept	0.01 to 0.45	-0.25 to 0.13	-0.13 to 0.19
Creatinine kinase	n	50	48	49
	Range	11 to 1204	11 to 1204	11 to 1204
	Regression	y = 1.010x – 7.7	y = 0.989x – 8.0	y = 0.986x – 1.8
	Correlation	0.9976	0.9987	0.9996
	Std. Error Est.	19.2	13.9	7.7
	CI Slope	0.990 to 1.031	0.974 to 1.004	0.978 to 0.995
	CI Intercept	-14.7 to -0.7	-13.2 to -2.8	-4.6 to 1.1

Performance Data at POL:

Method Comparison - POL on ACE *Alera*

POL – Method Comparison for ACE *Alera* Clinical Chemistry System

Reagent	Statistic	In-House ACE (x) vs. POL 1 Alera (y)	In-House ACE (x) vs. POL 2 Alera (y)	In-House ACE (x) vs. POL 3 Alera (y)
BUN	n	53	53	53
	Range	3 to 88	3 to 88	3 to 88
	Regression	y = 1.039x + 0.3	y = 1.011x + 0.2	y = 1.019x + 1.0
	Correlation	0.9987	0.9990	0.9972
	Std. Error Est.	0.9	0.8	1.4
	CI Slope	1.024 to 1.053	0.998 to 1.023	0.997 to 1.040
	CI Intercept	-0.1 to 0.6	-0.1 to 0.6	0.4 to 1.6
Creatinine	n	51	51	51
	Range	0.34 to 22.57	0.34 to 22.57	0.34 to 22.57
	Regression	y = 0.987x – 0.012	y = 1.041x – 0.038	y = 1.000x – 0.013
	Correlation	0.9993	0.9994	0.9986
	Std. Error Est.	0.149	0.149	0.220
	CI Slope	0.977 to 0.998	1.031 to 1.051	0.985 to 1.015
	CI Intercept	-0.059 to 0.036	-0.085 to 0.010	-0.083 to 0.057
Uric acid	n	49	49	49
	Range	1.7 to 14.5	1.7 to 14.5	1.7 to 14.0
	Regression	y = 0.967x + 0.37	y = 0.964x + 0.21	y = 0.994x + 0.29
	Correlation	0.9941	0.9951	0.9909
	Std. Error Est.	0.26	0.23	0.33
	CI Slope	0.936 to 0.998	0.936 to 0.992	0.955 to 1.034
	CI Intercept	0.16 to 0.58	0.02 to 0.40	0.02 to 0.56
Creatinine Kinase	n	50	49	50
	Range	11 to 1204	11 to 1204	11 to 1204
	Regression	y = 1.043x – 6.4	y = 0.971x – 2.3	y = 0.983x – 8.7
	Correlation	0.9994	0.9995	0.9968
	Std. Error Est.	9.8	7.5	21.5
	CI Slope	1.032 to 1.053	0.962 to 0.980	0.960 to 1.006
	CI Intercept	-9.9 to -2.8	-5.1 to 0.5	-16.5 to -0.9

Performance Data:

ACE *Alera*

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE *Alera* Clinical Chemistry Systems

Detection Limits - ACE *Alera* Clinical Chemistry System

ACE *Alera*	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)	CK (U/L)
LoB	1.53	0.14	1.11	4.68
LoD	1.97	0.18	1.34	8.30
LoQ (claimed)	3.0	0.33	1.50	11.0

Linearity - ACE *Alera* Clinical Chemistry System

ACE Reagents	Low level tested	Upper level tested	Linear to:	Linear Regression Equation	Correlation Coefficients R^2
BUN (mg/dL)	0.7	108.7	100.0	y=1.011x + 0.1	0.9991
Creatinine (mg/dL)	0.2	32.4	25.0	y=1.002x + 0.06	0.9981
Uric Acid (mg/dL)	1.1	17.3	16.0	y=0.994x – 0.10	0.9939
CK (U/L)	10.0	1416.7	1350.0	y=1.053x – 2.6	0.9975

Performance Data:

ACE *Alera*

Interferences - ACE *Alera* Clinical Chemistry System

ACE Alera	Icterus	Hemolysis	Lipemia (Intralipid)/ Triglycerides	Ascorbic Acid
BUN	No significant interference at or below 70 mg/dL	No significant interference at or below 500 mg/dL	No significant interference at or below 2080 mg/dL Triglycerides	No significant interference at or below 6 mg/dL
Creatinine	No significant interference at or below 6.0 mg/dL	No significant interference at or below 1000 mg/dL	No significant interference at or below 2080 mg/dL Triglycerides	No significant interference at or below 6 mg/dL
UA	No significant interference at or below 16.9 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 893 mg/dL Triglycerides	No significant interference at or below 1.313 mg/dL
CK	No significant interference at or below 30 mg/dL	No significant interference at or below 125 mg/dL	No significant interference at or below 2372 mg/dL Triglycerides	No significant interference at or below 6 mg/dL

Performance Data:

ACE *Alera*

Precision - ACE *Alera* Clinical Chemistry System

on ACE *Alera*		*Precision (SD, %CV)*		
		Mean	**Within-Run**	**Total**
BUN mg/dL	Low	15	0.3, 2.1%	0.5, 3.1%
	Mid	42	0.7, 1.7%	1.3, 3.0%
	High	74	1.5, 2.0%	2.3, 3.2%
Creatinine mg/dL	Low	0.9	0.03, 3.9%	0.08, 9.8%
	Mid	1.7	0.04, 2.4%	0.12, 7.5%
	High	5.4	0.13, 2.5%	0.22, 4.1%
Uric Acid mg/dL	Low	3.5	0.10, 3.0%	0.18, 5.2%
	Mid	6.0	0.14, 2.3%	0.25, 4.1%
	High	11.6	0.32, 2.8%	0.55, 4.7%
CK U/L	Low	128	2.2, 1.7%	3.8, 3.0%
	Mid	378	6.8, 1.8%	11.5, 3.0%
	High	865	8.5, 1.0%	16.2, 1.9%

Performance Data:

ACE *Alera*

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) vs. In-House ACE *Alera* (y)

	BUN (mg/dL)	Creatinine (mg/dL)	Uric Acid (mg/dL)	CK (U/L)
n	53	51	50	49
Range	3 - 88	0.34 – 22.57	1.7 – 14.5	11 - 1204
Slope	1.000	1.016	0.992	0.991
Intercept	0.1	-0.002	0.05	-1.3
Correlation Coefficient	0.9988	0.9997	0.9978	0.9999
Std. Error	0.9	0.111	0:17	-1.3
CI Slope	0.986 to 1.014	1.008 to 1.023	0.973 to 1.010	0.987 to 0.995
CI Intercept	-0.3 to 0.4	-0.038 to 0.0.34	-0.09 to 0.18	-2.6 to 0.0

Conclusions:

Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. These data indicate substantial equivalence for lithium heparin plasma sample collection tubes to the predicate device's use of serum sample collection tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

Alfa Wassermann Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K123322
Trade/Device Name: ACE BUN/Urea Reagent, ACE Creatinine Reagent, ACE Uric Acid Reagent, ACE CK Reagent
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: II
Product Code: CDN, CGX, KNK, CGS
Dated: March 07, 2013
Received: March 20, 2013

Dear Dr. Katz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director, Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123322

Device Name: ACE BUN/Urea Reagent

Indications for Use: The ACE BUN/Urea Reagent is intended for the quantitative determination of blood urea nitrogen (BUN) concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. BUN measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Creatinine Reagent

Indications for Use: The ACE Creatinine Reagent is intended for the quantitative determination of creatinine concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR)

Yung W. Chan -S

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

510(k) k123322

Indications for Use

510(k) Number (if known): k123322

Device Name: ACE Uric Acid Reagent

Indications for Use: The ACE Uric Acid Reagent is intended for the quantitative determination of uric acid concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytotoxic drugs. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE CK Reagent

Indications for Use: The ACE CK Reagent is intended for the quantitative determination of creatine kinase activity in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Measurement of creatine kinase is used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

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

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Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR)

Yung W. Chan -S

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

510(k) k123322