K113382

510(k) SUMMARY

JUL 19 2012

ACE ALT, AST, γ-GT Reagents on the ACE Axcel Clinical Chemistry System

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	July 13, 2012	
Device:	Trade Name:	ACE ALT Reagent
	Classification:	Class 1
	Common/Classification Name:	NADH Oxidation/NAD Reduction, ALT/SGPT (21 C.F.R. § 862.1030) Product Code CKA
	Trade Name:	ACE AST Reagent
	Classification:	Class 2
	Common/Classification Name:	NADH Oxidation/NAD Reduction, AST/SGOT (21 C.F.R. § 862.1100) Product Code CIT
	Trade Name:	ACE γ-GT Reagent
	Classification:	Class 1
		Common/Classification Name: Colorimetric Method, Gamma-Glutamyl Transpeptidase (21 C.F.R. § 862.1360) Product Code JPZ
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Reagents (K931786)	

Device Descriptions:	In the ACE ALT Reagent assay, alanine aminotransferase in serum converts the L-alanine and α-ketoglutarate substrates in the reagent to L-glutamate and pyruvate. Lactate dehydrogenase (LDH) catalyzes the oxidation of the reduced cofactor to the cofactor. The rate of conversion of the reduced cofactor to the cofactor can be determined by monitoring the decrease in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from the reduced cofactor to the cofactor is a function of the activity of ALT in the sample. In the ACE AST Reagent assay, aspartate aminotransferase in serum converts the L-aspartate and α-ketoglutarate in the reagent to oxalacetate and L-glutamate. The oxalacetate undergoes reduction with simultaneous oxidation of NADH to NAD^+ in the malate dehydrogenase catalyzed indicator reaction. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. Therefore, the rate of conversion of NADH to NAD^+ can be determined by monitoring the decrease in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from NADH to NAD^+ is a function of the activity of AST in the sample. Lactate dehydrogenase is added to prevent interference from endogenous pyruvate, which is normally present in serum. In the ACE γ-GT Reagent assay, γ-GT in serum catalyzes the transfer of the γ-glutamyl group from L-γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine in the reagent. The product, 5-amino-2-nitrobenzoate, absorbs strongly at 408 nm. The rate of increase in absorbance, monitored bichromatically at 408 nm/486 nm, is directly proportional to the γ-GT activity in the sample.
Intended Use:	Indications for Use: The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity in serum using the ACE Axcel Clinical Chemistry System. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity in serum using the ACE Axcel Clinical Chemistry System. Measurements of aspartate aminotransferase are used in the diagnosis and treatment of certain types of liver and heart disease. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE γ-GT Reagent is intended for the quantitative determination of gamma-glutamyltransferase activity in serum using the ACE Axcel Clinical Chemistry System. Gamma-glutamyltransferase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The ACE ALT Reagent consists of two reagent bottles (Substrate and Coenzyme). The reagents contain L-alanine, α-ketoglutarate, nicotinamide adenine dinucleotide, reduced (NADH), lactate dehydrogenase and Tris buffer. The ACE AST Reagent consists of two reagent bottles (Substrate and Coenzyme). The reagents contain L-aspartate, α-ketoglutarate, nicotinamide adenine dinucleotide, reduced (NADH), malate dehydrogenase, lactate dehydrogenase and Tris buffer. The ACE γ-GT Reagent consists of two reagent bottles (Buffer and Substrate). The Buffer Reagent (R1) contains: glycylglycine. The Substrate Reagent (R2) contains: L-γ-glutamyl-3-carboxy-4-nitroanilide and buffer.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. <u>ACE ALT Reagent</u> <u>Precision</u>: In testing conducted at four ALT levels for 22 days, the within-run CV ranged from 0.8 to 6.9%, and total CV ranged from 1.1 to 6.9% In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.8 to 8.7% and total CV ranged from 1.3 to 8.7%. <u>Accuracy</u>: In the correlation study, 102 samples with ALT values ranging from 4 to 472 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9996, a standard error estimate of 2.4, a confidence interval slope of 1.035 to 1.047, and a confidence interval intercept of -0.3 to 0.9. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9997 to 0.9999, standard error estimates of 2.4 to 3.1, confidence interval slopes of 1.009 to 1.035, and a confidence interval intercepts of -1.1 to 2.4. <u>Detection limit</u>: The detection limit was 3.1 U/L. <u>ACE AST Reagent</u> <u>Precision</u>: In testing conducted at four AST levels for 22 days, the within-run CV ranged from 0.9 to 7.1%, and total CV ranged from 1.4 to 8.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.1 to 11.3% and total CV ranged from 1.2 to 11.3%. <u>Accuracy</u>: In the correlation study, 117 samples with AST values ranging from 8 to 440 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9996, a standard error estimate of 2.2, a confidence interval slope of 1.002 to 1.012, and a confidence

	interval intercept of 1.9 to 2.8. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9996 to 0.9998, standard error estimates of 2.5 to 2.9, confidence interval slopes of 1.005 to 1.038, and a confidence interval intercepts of -1.4 to 2.1. Detection limit: The detection limit was 1.5 U/L. ACE γ-GT Reagent Precision: In testing conducted at four γ-GT levels for 22 days, the within-run CV ranged from 1.0 to 3.0%, and total CV ranged from 1.1 to 6.1%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.7 to 12.4% and total CV ranged from 1.3 to 13.0%. Accuracy: In the correlation study, 128 samples with γ-GT values ranging from 7 to 902 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9998, a standard error estimate of 3.4, a confidence interval slope of 0.981 to 0.988, and a confidence interval intercept of -0.6 to 0.8. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9992 to 0.9999, standard error estimates of 3.6to 8.8, confidence interval slopes of 0.967 to 1.053, and a confidence interval intercepts of -1.7 to 4.8. Detection limit: The detection limit was 2.7 U/L.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Alfa Wassermann Diagnostic Technologies, LLC
c/o Hyman Katz, Ph.D.
4 Henderson Drive
West Caldwell, NJ 07006

JUL 19 2012

Re: k113382
Trade Name: ACE AST Reagent
ACE ALT Reagent
ACE y-GT Reagent
Regulation Number: 21 CFR §862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system
Regulatory Class: Class II
Product Codes: CIT, CKA, JPZ
Dated: June 19, 2012
Received: June 20, 2012

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.

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/Medical Devices/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

510(k) Number: k113382

Device Name: ACE ALT Reagent

Indications for Use: The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity in serum using the ACE Axcel Clinical Chemistry System. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases. 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 Devices (OIVD)

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

510(k) K113382

Indications for Use

510(k) Number: k113382

Device Name: ACE AST Reagent

Indications for Use: The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity in serum using the ACE Axcel Clinical Chemistry System. Measurements of aspartate aminotransferase are used in the diagnosis and treatment of certain types of liver and heart disease. 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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Evaluation and Safety

510(k) K113382

Indications for Use

510(k) Number: k113382

Device Name: ACE γ-GT Reagent

Indications for Use: The ACE γ-GT Reagent is intended for the quantitative determination of gamma-glutamyltransferase activity in serum using the ACE Axcel Clinical Chemistry System. Gamma-glutamyltransferase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

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