K072142

510(k) SUMMARY

JUN 26 2008

510(k) Owner:	Alfa Wassermann Diagnostic Technology, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237	
Date Summary Prepared:	June 19, 2008	
Device:	Trade Name:	S-Test ALP; S-Test AMY; S-Test AST Reagent cartridge (21 C.F.R. § 862.1050, Product code CJI; 21 C.F.R. § 862.1070, Product code JFJ; 21 C.F.R. § 862.1100, Product code CIT)
	Classification:	Class II
	Common/Classification Name:	Alkaline phosphatase; amylase; aspartate aminotransferase test systems
Predicate Devices	Manufacturers for analyzer/reagent system predicates are: 1. <u>ACE plus ISE/ Clinical Chemistry System</u> ACE Alkaline Phosphatase Reagent (K931786) ACE Amylase Reagent (K931786) ACE Aspartate Aminotransferase Reagent (K931786) 2. <u>Olympus AU640 Clinical Chemistry Analyzer</u> Alkaline Phosphatase Reagent (K961274) Amylase Reagent (K961274) Aspartate Aminotransferase Reagent (K961274) 3. <u>Piccolo® xpress Chemistry Analyzer</u> Alkaline Phosphatase Reagent (K942782) Amylase Reagent (K942782) Aspartate Aminotransferase Reagent (K942782)	

Device Description:	The S-Test alkaline phosphatase (ALP) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of ALP activity in serum or heparin plasma based on an enzymatic photometric test using *p*-nitrophenyl phosphate as a substrate. The S-Test amylase (AMY) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of amylase activity in serum or heparin plasma based on an enzymatic photometric test using 2-chloro-4-nitrophenyl-α-galactopyranosyl maltoside (Gal-G2-CNP) as a substrate. The S-Test aspartate aminotransferase (AST) reagent cartridge used with the S40 Clinical Analyzer is intended for quantitative *in vitro* diagnostic determination of AST in serum or heparin plasma based on an enzymatic photometric test using L-aspartate and α-ketoglutarate as substrates.
Intended Use:	The S-Test Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test Amylase Reagent is intended for the quantitative determination of amylase activity in serum or heparin plasma using the S40 Clinical Analyzer. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The S-Test Aspartate Aminotransferase Reagent is intended for the quantitative determination of aspartate aminotransferase activity in serum or heparin plasma using the S40 Clinical Analyzer. Aspartate aminotransferase measurements 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.

Technological Characteristics:	The S-Test ALP is a bi-reagent cartridge. Reagent 1 is ethyl amino ethanol buffer and magnesium chloride. Reagent 2 is p-nitrophenyl phosphate (46 mmol/L). The S-Test AMY is a bi-reagent cartridge. Reagent 1 contains: sodium chloride, calcium chloride, and Good's buffer (pH 6.0). Reagent 2 contains: α-2-chloro-4-nitrophenyl galactopyranosyl maltoside, potassium thiocyanate, and Good's buffer (pH 6.0). The S-Test AST reagent is a bi-reagent cartridge. Reagent 1 contains: nicotinamide-adenine dinucleotide (reduced form), malate dehydrogenase (derived from Thermus), 2-amino-2-hydroxymethyl-1,3-propanediol buffer (pH 7.8, 30°C), and L-aspartic acid. Reagent 2 contains: L-aspartic acid, ά-ketoglutaric acid, and 2-amino-2-hydroxymethyl-1,3-propanediol buffer (pH 7.8, 30°C).
Performance Data:	Performance data on the S-Test ALP, S-Test AMY, and S-Test AST, and included precision, accuracy, and sensitivity data. **S-Test ALP** Precision: In testing conducted at three ALP levels for 22 days, the within-run CV ranged from 2.2 to 3.5%, and total CV ranged from 5.4 to 5.7%. In precision studies at three separate Physician Office Laboratories (POL) sites and in-house over five days, the within-run CV ranged from 1.5 to 4.4%, and the total CV ranged from 1.5 to 4.9%. Accuracy: In the correlation study, 180 samples with ALP values ranging from 28 to 733 U/L were assayed on the S40 Clinical Analyzer using S-Test-ALP reagent and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.997, a standard error estimate of 10.9, a confidence interval slope of 0.929 to 1.009, and a confidence interval intercept of -4.43 to 2.02. In patient correlation studies at four separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients ranging from 0.996 to 0.998, standard error estimates of 10.4 to 14.3, confidence interval slopes of 0.963 to 1.011, and confidence interval intercepts of -2.5 to 15.6. Sensitivity: The detection limit was 20 U/L. **S-Test AMY** Precision: In testing at three amylase levels for 22 days, the within-run CV ranged from 1.7 to 2.4%, and total CV ranged from 6.4 to 8.2%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 1.0 to 6.4%, and the total CV ranged from 1.0 to 6.6% Accuracy: In the correlation study, 196 samples with amylase values ranging from 9 to 1461 U/L were assayed on the S40 Clinical Analyzer using S-Test Amylase and a comparison method. Least-squares regression analysis yielded

	a correlation coefficient of 0.997, a standard error estimate of 21.0, a confidence interval slope of 0.932 to 1.005, and a confidence interval intercept of 0.56 to 5.81. In patient correlation studies at four separate POL sites using the S40 Clinical Analyzer and a comparison method, least-squares regression analysis yielded correlation coefficients of 0.997, standard error estimates of 35.6 to 37.0, confidence interval slopes of 0.914 to 0.960, and confidence interval intercepts of -7.4 to 21.6. Sensitivity: The detection limit was 8 U/L. **S-Test AST** Precision: In testing at three AST levels for 22 days, the within-run CV ranged from 0.8 to 2.5%, and total CV ranged from 4.4 to 4.9%. In precision studies at three separate POL sites and in-house over five days, the within-run CV ranged from 0.8 to 4.8%, and the total CV ranged from 0.9 to 7.0%. Accuracy: In the correlation study, 177 samples with AST values ranging from 10 to 333 U/L were assayed using S-Test AST and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.998, a standard error estimate of 4.5, a confidence interval slope of 0.986 to 1.042, and confidence interval intercept of -1.75 to 0.09. In patient correlation studies at four separate POL sites over five days using the S40 Clinical Analyzer and a comparison method, least-squares regression analysis yielded correlation coefficients of 0.998, standard error estimates of 6.3 to 6.7, confidence interval slopes of 1.041 to 1.110, and confidence interval intercepts of -7.7 to 4.9. Sensitivity: The detection limit was 8 U/L.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 6 2008

Alfa Wassermann Diagnostic Technologies, Inc.
c/o Mr. Daivd Slavin
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k072142
Trade/Device Name: S Test Alkaline Phosphatase (ALP) Reagent cartridge, S Test Amylase (AMY) Reagent cartridge and S Test Aspartate Aminotransferase (AST) Reagent cartridge
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline Phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CKF, CIJ, CIT
Dated: June 16, 2008
Received: June 17, 2008

Dear Mr. Slavin

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Alfa Wassermann Diagnostic Technology, Inc.
510(k) Submission K072142

S40 Clinical Analyzer
S-Test ALP
S-Test AMY
S-Test AST

Indications for Use

510(k) Number (if known): K072142

Device Name: S-Test Alkaline Phosphatase (ALP)

Indications for Use: The S-Test Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in serum or heparin plasma using the S40 Clinical Analyzer. Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K072142

Alfa Wassermann Diagnostic Technology, Inc.
510(k) Submission K072142

S40 Clinical Analyzer
S-Test ALP
S-Test AMY
S-Test AST

Indications for Use

510(k) Number (if known): K072142

Device Name: S-Test Amylase (AMY)

Indications for Use: The S-Test Amylase Reagent is intended for the quantitative determination of amylase activity in serum or heparin plasma using the S40 Clinical Analyzer. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

Alfa Wassermann Diagnostic Technology, Inc.
510(k) Submission K072142

S40 Clinical Analyzer
S-Test ALP
S-Test AMY
S-Test AST

Indications for Use

510(k) Number (if known): K072142

Device Name: S-Test Aspartate Aminotransferase (AST)

Indications for Use: The S-Test Aspartate Aminotransferase Reagent is intended for the quantitative determination of aspartate aminotransferase activity in serum or heparin plasma using the S40 Clinical Analyzer. Aspartate aminotransferase measurements 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 _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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