510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k131351

B. Purpose for Submission:

New reagents (Alkaline Phosphatase, Amylase, Alanine amino transferase, Aspartate amino transferase) added onto ACE Alera instrument (k123018)

Addition of lithium heparin plasma samples to already cleared reagents on the ACE (k930104) and ACE Axcel (k113389) instruments.

C. Measurand:

Alkaline Phosphatase, Amylase, Alanine Amino Transferase (ALT/SGPT), Aspartate Amino Transferase (AST/SGOT)

D. Type of Test:

Quantitative, photometric/colorimetric methods

E. Applicant:

Alfa Wassermann Diagnostic Technologies, LLC

F. Proprietary and Established Names:

ACE Alkaline Phosphatase Reagent
ACE Amylase Reagent
ACE ALT Reagent
ACE AST Reagent

G. Regulatory Information:

Product Code	Classification	Regulation	Panel
CJE	Class II	21 CFR 862.1050 Alkaline Phosphatase or Isoenzymes Test System	Clinical Chemistry (75)
CIJ	Class II	21 CFR 862.1, Amylase Test System	Clinical Chemistry (75)

CKA	Class I, meets limitations of exemption per 862.9(c)(9)	21 CFR 862.1030 Alanine amino transferase (ALT/SGPT) Test System	Clinical Chemistry (75)
CIT	Class II	21 CFR 862.1100, Aspartate amino transferase (AST/SGOT) Test System	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use.

2. Indication(s) for use:

   The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. 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 and physician office laboratories. For *in vitro* diagnostic use only.

   The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. 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 and physician office laboratories. For *in vitro* diagnostic use only.

   The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. 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 and 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 and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. 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 and physician office laboratories. For *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use only

   For prescription use and point-of-care settings

4. Special instrument requirements:

   For use on the ACE, ACE Axcel and ACE Alera Clinical Chemistry Systems.

I. Device Description:

The ACE Alkaline Phosphatase Reagent is composed of two reagent bottles (Buffer and Substrate Reagent). The reagents contain AMP Buffer (pH 10.45), magnesium acetate, p-nitrophenyl phosphate.

The ACE Amylase Reagent is composed of a single reagent bottle. The reagents contain 2-chloro-p-nitrophenyl-α-D-maltotrioside, sodium chloride, calcium acetate, potassium thiocyanate and MES buffer (pH 6.0).

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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACE Alkaline Phosphatase Reagent
   ACE Amylase Reagent
   ACE ALT Reagent
   ACE AST Reagent

2. Predicate 510(k) number(s):

   K931786 (ACE Alkaline Phosphatase Reagent and ACE Amylase Reagent)
   K930104 (ACE ALT Reagent and ACE AST Reagent)

3. Comparison with predicate:

1. ACE Alkaline Phosphatase Reagent:

ALP	Candidate Device	Predicate Device K931786
Intended Use/ Indications for Use	The ACE Alkaline Phosphatase Reagent is intended for the quantitative determination of alkaline phosphatase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	SA2002: 20 Days RX2002: 7 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	4 µL	Same
Reaction Volume	169 µL	Same
Expected Values	44 - 147 U/L	Same
Measuring Range	9 - 1400 U/L	Same

2. ACE Amylase Reagent:

AMYLASE	Candidate Device	Predicate Device K931786
Intended Use/ Indications for Use	The ACE Amylase Reagent is intended for the quantitative determination of α-amylase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	168 µL	Same
Expected Values	20 - 104 U/L	Same
Measuring Range	9 - 1900 U/L	Same

3. ACE ALT Reagent:

ALT	Candidate Device	Predicate Device K930104
Intended Use/ Indications for Use	The ACE ALT Reagent is intended for the quantitative determination of alanine aminotransferase activity	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	13 µL	Same
Reaction Volume	185 µL	Same
Expected Values	5 - 30 U/L	Same
Measuring Range	4 - 480 U/L	Same

4. ACE AST Reagent:

AST	Candidate Device	Predicate Device K930104
Intended Use/ Indications for Use	The ACE AST Reagent is intended for the quantitative determination of aspartate aminotransferase activity.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	13 µL	Same
Reaction Volume	185 µL	Same
Expected Values	7 - 31 U/L	Same
Measuring Range	4 - 450 U/L	Same

K. Standard/Guidance Document Referenced (if applicable):

Evaluation of Precision Performance of Quantitative Measurement Methods (CLSI EP5-A2)

Method Comparison and Bias Estimation Using Patient Samples (CLSI EP9-A2IR)

Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures (CLSI EP17-A2)

Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach CLSI EP6-A)

Interference Testing in Clinical Chemistry (CLSI EP7-A2)

L. Test Principle:

In the ACE Alkaline Phosphatase Reagent assay, alkaline phosphatase catalyzes the hydrolysis of colorless p-nitrophenyl phosphate to p-nitrophenol and inorganic phosphate. In an alkaline solution (pH 10.5), p-nitrophenol is in the phenoxide form and has a strong absorbance at 408 nm. The rate of increase in absorbance, monitored bichromatically at 408 nm/486 nm, is directly proportional to the alkaline phosphatase activity in the sample.

In the ACE Amylase Reagent assay, α-amylase hydrolyzes the 2-chloro-p-nitrophenyl-α-D-maltotrioside substrate to release 2-chloro-p-nitrophenol and form 2-chloro-pnitrophenyl-α-D-maltoside, maltotriose and glucose. The rate of increase in absorbance, monitored bichromatically at 408 nm/ 647 nm, is directly proportional to the α-amylase activity in the sample.

In the ACE ALT Reagent assay, alanine Aminotransferase 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 converts the L-aspartate and α-ketoglutarate in the reagent to oxaloacetate and L-glutamate. The oxaloacetate 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 blood.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were conducted in house and at three Physician Office Laboratories (POL) with trained operators typically found in these settings, following CLSI guidance document EP5-A2. Three samples each of low, mid and high analyte serum were run on the ACE Alera Clinical Chemistry System in duplicate, for at least 20 days at 2 runs per day (N=80). Results are summarized below:

Serum POL precision study:

ALP		**ACE Alera**				
Lab	**Sample**	**Mean (U/L)**	**Within-Run**		**Total**	
			SD	**%CV**	**SD**	**%CV**
In-House	1	60	1.1	1.8%	1.3	2.1%
POL 1	1	56	0.8	1.4%	1.7	3.0%
POL 2	1	59	1.2	2.0%	2.1	3.5%
POL 3	1	56	1.4	2.5%	3.0	5.4%
In-House	2	653	4.5	0.7%	7.0	1.1%
POL 1	2	626	7.4	1.2%	16.7	2.7%
POL 2	2	659	4.2	0.6%	18.0	2.7%
POL 3	2	640	5.9	0.9%	21.9	3.4%
In-House	3	1192	9.4	0.8%	13.4	1.1%
POL 1	3	1135	19.0	1.7%	25.0	2.2%
POL 2	3	1209	9.6	0.8%	29.3	2.4%
POL 3	3	1165	6.6	0.6%	37.2	3.2%

AMY		**ACE Alera**				
Lab	**Sample**	**Mean (U/L)**	**Within-Run**		**Total**	
			SD	**%CV**	**SD**	**%CV**
In-House	1	39	0.8	2.1%	1.4	3.5%
POL 1	1	38	0.9	2.4%	1.7	4.4%
POL 2	1	40	1.3	3.2%	1.3	3.2%
POL 3	1	39	1.0	2.5%	1.1	2.8%
In-House	2	747	4.4	0.6%	7.3	1.0%
POL 1	2	723	4.7	0.6%	7.0	1.0%
POL 2	2	770	4.3	0.6%	6.1	0.8%
POL 3	2	747	5.8	0.8%	7.4	1.0%
In-House	3	1437	11.6	0.8%	12.8	0.9%
POL 1	3	1388	19.5	1.4%	21.6	1.6%
POL 2	3	1500	10.3	0.7%	11.7	0.8%
POL 3	3	1435	8.4	0.6%	14.4	1.0%

ALT		ACE Alera				
Lab	**Sample**	**Mean (U/L)**	**Within-Run**		**Total**	
			SD	**%CV**	**SD**	**%CV**
In-House	1	32	1.1	3.5%	1.2	3.9%
POL 1	1	28	1.4	5.1%	2.4	8.4%
POL 2	1	26	0.9	3.6%	2.1	8.2%
POL 3	1	29	2.1	7.5%	2.4	8.4%
In-House	2	190	4.0	2.1%	4.1	2.1%
POL 1	2	193	1.7	0.9%	2.0	1.0%
POL 2	2	194	2.2	1.1%	2.5	1.3%
POL 3	2	195	3.5	1.8%	5.0	2.6%
In-House	3	307	4.0	1.3%	4.1	1.3%
POL 1	3	309	3.1	1.0%	3.6	1.2%
POL 2	3	314	2.3	0.7%	2.6	0.8%
POL 3	3	310	8.5	2.8%	9.1	3.0%

AST		ACE Alera				
Lab	**Sample**	**Mean (U/L)**	**Within-Run**		**Total**	
			SD	**%CV**	**SD**	**%CV**
In-House	1	28	1.2	4.5%	1.7	6.0%
POL 1	1	26	1.0	3.8%	1.3	5.1%
POL 2	1	27	2.0	7.5%	2.4	8.9%
POL 3	1	29	2.9	9.9%	2.9	9.9%
In-House	2	222	4.8	2.2%	7.1	3.2%
POL 1	2	220	2.0	0.9%	3.2	1.5%
POL 2	2	233	3.8	1.6%	5.0	2.1%
POL 3	2	229	5.3	2.3%	7.2	3.2%
In-House	3	406	2.9	0.7%	6.8	1.7%
POL 1	3	416	7.8	1.9%	9.2	2.2%
POL 2	3	428	5.1	1.2%	5.6	1.3%
POL 3	3	417	8.2	2.0%	12.1	2.9%

Additional precision studies were performed in-house using 3 concentrations of lithium heparin plasma samples over a period of 3 or more days (n=20). All samples were tested twice a day in duplicate on the ACE, ACE Axcel, and ACE Alera Clinical Chemistry Systems. The within-run and total precision results are summarized in the tables below.

Plasma in-house precision study:

Precision (SD, %CV)									
ALP U/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Plasma Low	76	1.9, 2.5%	2.8, 3.7%	75	0.8, 1.1%	3.4, 4.6%	74	1.1, 1.5%	3.7, 5.1%
Plasma Mid	614	5.8, 0.9%	24.4, 4.0%	609	5.1, 0.8%	20.2, 3.3%	613	3.4, 0.6%	20.5, 3.3%
Plasma High	1163	6.8, 0.6%	33.5, 2.9%	1149	5.9, 0.5%	32.9, 2.9%	1155	7.6, 0.7%	35.7, 3.1%

Precision (SD, %CV)									
AMY U/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Plasma Low	41	0.7, 1.8%	1.3, 3.2%	42	0.5, 1.3%	1.5, 3.5%	41	1.0, 2.5%	2.5, 6.0%
Plasma Mid	806	8.1, 1.0%	12.5, 1.5%	801	4.4, 0.5%	13.1, 1.6%	805	5.3, 0.7%	12.2, 1.5%
Plasma High	1604	15.4, 1.0%	29.3, 1.8%	1596	18.8, 2.1%	33.8, 2.1%	1604	21.6, 1.3%	25.0, 1.6%

Precision (SD, %CV)									
ALT U/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Plasma Low	32	0.9, 2.7%	1.3, 4.0%	32	0.8 2.6%	1.5, 4.7%	34	1.0, 2.9%	1.4, 4.1%
Plasma Mid	112	1.1, 1.0%	1.5, 1.4%	112	0.9, 0.8%	1.1, 1.0%	113	1.0, 0.9%	1.5, 1.4%
Plasma High	219	1.1, 0.5%	1.6, 0.7%	219	2.1, 0.9%	3.0, 1.4%	222	1.7, 0.7%	2.7, 1.2%

Precision (SD, %CV)									
AST U/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Plasma Low	26	0.8, 3.2%	1.4, 5,4%	26	0.6, 2.5%	1.0, 3.7%	26	0.9, 3.5%	1.0, 4.0%
Plasma Mid	157	1.6, 1.0%	2.3, 1.4%	157	1.5, 0.9%	1.7, 1.1%	158	1.4, 0.9%	2.0, 1.3%
Plasma High	304	3.5, 1.2%	4.5, 1.5%	303	2.6 0.9%	3.9, 1.3%	305	3.2, 1.1%	4.3, 1.4%

b. Linearity/assay reportable range:

Serum samples were spiked with the appropriate analyte and used to determine linearity on the ACE Alera Clinical Chemistry System. The assigned values of the highest and lowest sample were set to their mean values. The assigned values of the other levels were calculated by multiplying the mean value by the dilution proportions used. All samples were run in triplicate. The linear regression correlation between the expected values and the measured values is summarized below:

ACE Reagents	Low level tested	Upper level tested	Linear Regression Equation	R^2
ALP	4 U/L	1401 U/L	y = 0.998x – 0.5	0.9993
Amylase	4 U/L	2012 U/L	y = 1.013x + 0.2	0.9974
ALT	3.1 U/L	503.8U/L	y = 1.007x - 0.17	0.9992
AST	3 U/L	491.3 U/L	y = 1.013x + 0.24	0.9992

The linearity data provided by the sponsor support the following reportable range claims:

Analyte tested	Assay range
ALP (U/L)	9 - 1400
Amylase (U/L)	9 - 1900
ALT (U/L)	4 - 480
AST (U/L)	4 - 450

Automatic Dilution Study:

Sponsor performed additional auto-dilution studies to confirm the auto-dilution function (1:2 for ALP and 1:4 for Amylase, ALT and AST) on the ACE Alera analyzer for plasma and serum samples by comparing the auto-diluted results to the manual dilution results. ALT, AST, ALP and Amylase samples recovered within ±10% bias.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The ALP assay and the Amylase assay are traceable to an IFCC traceable method. The ALT assay is traceable to ERM-AD454 and the AST assay is traceable to ERM-AD457.

Calibration is not needed for these four assays.

d. Detection limit:

The Limit of blank (LoB), limit of detection (LoD), and limit of quantification (LoQ) were determined according to CLSI EP17-A with the ACE Alera Clinical Chemistry System. For the LoB and LoD studies, five low samples and five blanks (n=60 reps, 20 reps per day) were tested over three days on two ACE Alera Clinical Chemistry Systems. For the LoQ studies, five samples (n = 40 reps, 8 reps per run) were tested in five separate runs over five days. LoQ values are based on inter-assay precision of ≤20% CV. The results are as follows:

ACE *Alera*	ALP	Amylase	ALT	AST
LoB (U/L)	2.8	0.2	1.6	2.2
LoD (U/L)	4.8	0.9	3.1	3.3
LoQ (U/L)	4.8	5.6	4.1	3.3

Sponsor claims the following measuring ranges for the assays:

Analyte	Assay range
ALP (U/L)	9 - 1400
Amylase (U/L)	9 - 1900
ALT (U/L)	4 - 480
AST (U/L)	4 - 450

e. Analytical specificity:

Interference studies were performed to determine the effects from potential interferents. The various concentration of interferent was spiked into serum pools containing analytes at normal and abnormal concentrations. All samples were tested in triplicate. Six interferent levels and the control samples were tested for each interferent (n=7). For lipemia interference studies, Intralipid was used as the added interferent with ALP and Amylase, while avian triglycerides concentrate was used with ALT and AST. Bias greater than +/- 10% defines significant interference by the sponsor. The results of the highest concentration tested without significant interference are as follows:

Interferents on ACE *Alera*	No Significant Interference at or below:			
	ALP	**Amylase**	**ALT**	**AST**
Icterus	70.6 mg/dL	30.0 mg/dL	50 mg/dL	50 mg/dL
Hemolysis	62.5 mg/dL	62.5 mg/dL	500 mg/dL	62.5 mg/dL
Lipemia	1000 mg/dL	1000 mg/dL	419 mg/dL	439 mg/dL
Ascorbic Acid	6 mg/dL	6 mg/dL	6 mg/dL	6 mg/dL

Limitations are included in the package insert to reflect these results. Since hemolysis affects ALP, Amylase, and AST results, the sponsor has the following limitations in the labeling:

"Specimens showing any indication of hemolysis should not be analyzed."

For a comprehensive list of drugs and other substances which can affect assay in serum please refer to the literature given by Young, et. Al.

Young, D.S., et.al., Effects of drugs on Clinical Laboratory Tests, 5th edition, AACC press, Washington D.C. (2000).

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were completed at 3 POC sites following CLSI document EP9-A2. Samples were run on the ACE Clinical Chemistry System at Alfa Wassermann and the results were compared against those gathered on ACE Alera Clinical Chemistry Systems at 3 Physician Office Labs. For each test method, at least 40 determinations were made in singlicate for serum samples drawn from the same individuals on each platform. To test across the assay reportable ranges, 5-6 samples were spiked per analyte. No samples were diluted with saline.

The following chart summarizes the POL method comparison studies:

ALP	ACE (in-house) vs. ACE Alera (POL)		
	POL 1	POL 2	POL 3
N	50	50	50
Range (mg/dL)	58 to 1199	58 to 1199	58 to 1199
Slope	0.997	1.029	1.010
Intercept	-4.6	-4.1	-6.6
Correlation Coefficient	0.9992	0.9991	0.9986

AMY	ACE (in-house) vs. ACE Alera (POL)		
	POL 1	POL 2	POL 3
N	51	51	51
Range (mmol/L)	28 to 1732	28 to 1732	28 to 1732
Slope	0.960	1.010	0.990
Intercept	3.0	5.8	3.7
Correlation Coefficient	0.9991	0.9995	0.9995

ALT	ACE (in-house) vs. ACE Alera (POL)		
	POL 1	POL 2	POL 3
N	50	50	50
Range (mmol/L)	6 to 442	6 to 442	6 to 442
Slope	1.019	1.012	0.970
Intercept	-0.5	-3.5	2.4
Correlation Coefficient	0.9986	0.9985	0.9977

AST	ACE (in-house) vs. ACE Alera (POL)		
	POL 1	POL 2	POL 3
N	50	50	50
Range (mmol/L)	6 to 413	6 to 413	6 to 413
Slope	1.028	1.040	1.004
Intercept	1.4	0.5	1.8
Correlation Coefficient	0.9995	0.9992	0.9995

b. Matrix comparison:

A matrix comparison study was performed using paired serum/lithium heparin plasma samples, with levels of each analyte that cover the measuring ranges of the assays, in singlicate on the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. To cover the assay range, 4-5 spiked samples were tested per analyte and 6 diluted samples were tested for ALP. Linear regression analyses (Deming) were performed using serum (x) and lithium heparin plasma (y), with the following results:

Matrix Comparison Studies

Reagent	**Results**		
	ACE	**ACE *Alera***	**ACE Axcel**
ALP (U/L)	Pairs: 108 Range: 9-1274 Slope: 0.998 Intercept: -8.3 Correlation: 0.9980	Pairs: 108 Range: 9-1202 Slope: 0.9952 Intercept: -6.4 Correlation: 0.9952	Pairs: 62 Range: 11-1222 Slope: 0.9982 Intercept: -6.5 Correlation: 0.9982
Amylase (U/L)	Pairs: 104 Range: 11-1766 Slope: 0.977 Intercept: 1.7 Correlation: 0.9995	Pairs: 101 Range: 11-1703 Slope: 0.979 Intercept: 0.9 Correlation: 0.9994	Pairs: 52 Range: 10-1890 Slope: 0.994 Intercept: -1.76 Correlation: 0.9996
ALT (U/L)	Pairs: 54 Range: 4-460 Slope: 1.003 Intercept: -3.6 Correlation: 0.9994	Pairs: 52 Range: 5-463 Slope: 1.000 Intercept: -3.6 Correlation: 0.9986	Pairs:56 Range: 6-469 Slope: 0.985 Intercept: -3.35 Correlation: 0.9993
AST (U/L)	Pairs: 53 Range: 4-404 Slope: 0.981 Intercept: 0.7 Correlation: 0.9992	Pairs: 52 Range: 4-396 Slope: 0.999 Intercept: -0.6 Correlation: 0.9989	Pairs: 52 Range: 4-408 Slope: 1.001 Intercept: 0.22 Correlation: 0.9989

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Reference values for serum and plasma are provided in the labeling according to literature as follows:

ALP[1]:	44 - 147 U/L
Amylase[2]:	20 - 104 U/L
ALT[2]:	5 - 30 U/L
ASP[2]:	7 - 31 U/L

1. Dugdale, D., Zieve, D. (05/30/2011). ALP- blood test: MedlinePlus Medical Encyclopedia.
2. Wu, A.H.B. (Ed.), *Tietz Clinical Guide to Laboratory Tests*, 4th Edition, Saunders Elsevier, S. Louis, Mo (2006).

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.