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


**A. 510(k) Number:**

k113382

**B. Purpose for Submission:**

New device

**C. Measurand:**

Alanine Aminotransferase activity
Aspartate Aminotransferase activity
Gamma-glutamyltransferase activity

**D. Type of Test:**

Quantitative, photometric assay

**E. Applicant:**

Alfa Wasserman Diagnostic Technologies, LLC

**F. Proprietary and Established Names:**

ACE ALT Reagent
ACE AST Reagent
ACE γ-GT Reagent

**G. Regulatory Information:**

1. Regulation section:

   21 CFR § 862.1030, Alanine Aminotransferase (ALT/SGPT) test system
   21 CFR § 862.1035, Aspartate Aminotransferase (AST/SGOT) test system
   21 CFR § 862.1360, Gamma-glutamyltranspeptidase and isoenzymes test system

2. Classification:

   Class I  meets limitations of exemptions in 862.9(c)(9), for ALT and GGT
   Class II for AST

3. Product code:

CKA
CIT
JPZ

4. Panel:

75 (Clinical Chemistry)

## H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) 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.

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:

   ACE Axcel Clinical Chemistry System

**I. Device Description:**

The ACE reagent kits, used with the ACE Axcel Clinical Chemistry System, consist of natural or brown plastic bottles containing liquid-stable reagents. The reagents are side-labeled to identify them to the user and have a dot code label applied to the bottom of the bottle to identify each bottle to the ACE Axcel via cameras, located in the bottom section of the reagent compartment. Reagent kits typically have either one reagent (R1) or sometimes two (R1, R2) or more different reagent bottles per kit. For example, the AST Reagent kit has both R1 (buffer) and R2 (substrate) bottles (three R1 and three R2 bottles) in each kit.

The ACE ALT Reagent consists of two reagent bottles (Substrate and Coenzyme). The combined AST Reagent consist of L-Alanine, $\alpha$-Ketoglutarate, Nicotinamide adenine dinucleotide, reduced (NADH), Lactate dehydrogenase (rabbit muscle), Tris, Preservative and Stabilizers

The ACE AST Reagent consists of two reagent bottles (Substrate and Coenzyme). The combined AST Reagent consists of L-Asprutate, α-Ketoglutarate, Nicotinamide adenine dinucleotide, reduced (NADH), Malate dehydrogenase (microbial), Lactate dehydrogenase (Porcine), Tris, Preservative and Stabilizers.

The ACE γ-GT Reagent consists of two reagent bottles (Buffer and Substrate). The Buffer Reagent (R1) contains Glycylglycine, Preservative and stabilizers. The Substrate Reagent (R2) contains L-y-glutamyl-3-carboxy-4-nitroanilide, Buffer, Preservative and Stabilizers.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

   ACE Clinical Chemistry System, ACE ALT Reagent
   ACE Clinical Chemistry System, ACE AST Reagent
   ACE Clinical Chemistry System, ACE γ-GT Reagent

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

   k931786

3. Comparison with predicate:

| Item | ACE plus ISE/Clinical Chemistry System, ACE ALT Reagent (Candidate Device – k113382) | ACE plus ISE/Clinical Chemistry System, ACE ALT Reagent (Predicate Device – k931786) |
|---|---|---|
| Intended Use/Indications for Use | It is intended for the quantitative determination of alanine aminotransferase activity in serum. | Same |
| Instrument | ACE Axcel Clinical Chemistry System | ACE and ACE *Alera*® Clinical Chemistry Systems |
| Sample type | Serum | Same |
| Reagent type | Two part liquid | Same |
| Reaction type | Kinetic | Same |
| Measuring range | 5 to 480 U/L | Same |
| On-Board Stability | 30 Days | Same |
| Shelf life | Stable until expiration date on box when stored at 2-8ºC | Same |

| Item | ACE Axcel Clinical Chemistry System, ACE AST Reagent (Candidate Device – k113382) | ACE plus ISE/Clinical Chemistry System, ACE AST Reagent (Predicate Device – k931786) |
|---|---|---|
| Intended Use/Indications for Use | It is intended for the quantitative determination of aspartate aminotransferase activity in serum. | Same |
| Instrument | ACE Axcel Clinical Chemistry System | ACE and ACE *Alera*® Clinical Chemistry Systems |
| Sample type | Serum | Same |
| Reagent type | Two part liquid | Same |
| Reaction type | Kinetic | Same |
| Measuring range | 7 to 450 U/L | Same |
| On-Board Stability | 30 Days | Same |
| Shelf life | Stable until expiration date on box when stored at 2-8ºC | Same |

| Item | ACE Axcel Clinical Chemistry System, ACE γ-GT Reagent (Candidate Device – k113382) | ACE plus ISE/Clinical Chemistry System, ACE γ-GT Reagent (Predicate Device – k931786) |
|---|---|---|
| Intended Use/Indications for Use | It is intended for the quantitative determination of gamma-glutamyltransferase activity in serum | Same |
| Instrument | ACE Axcel Clinical Chemistry System | ACE and ACE *Alera*® Clinical Chemistry Systems |
| Sample type | Serum | Same |
| Reagent type | Two part liquid | Same |
| Reaction type | Kinetic | Same |
| Measuring range | 7 to 950 U/L | 3 to 950 U/L |
| On-Board Stability | 30 Days | Same |
| Shelf life | Stable until expiration date on box when stored at 2-8ºC | Same |

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

- CLSI EP6-A: Evaluation of Linearity of Quantitative Analytical Methods
- CLSI EP7-A2: Method Comparison and Bias Estimation Using Patient Samples
- CLSI EP5-A2: Evaluation of Precision Performance of Clinical Chemistry Devices
- CLSI EP10-A3: Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures
- CLSI EP-A2-IR: Method Comparison and Bias Estimation Using Patient Samples, CLSI EP17-A: Protocols for Determination of Limits of Detection

**L. Test Principle:**

ACE ALT Reagent
Alanine aminotransferase in serum converts the L-alanine and α-ketoglutarate substrates, contained in the reagent, to L-glutamate and pyruvate. The pyruvate formed reacts with reduced nicotinamide adenine dinucleotide (NADH) in the presence of lactate dehydrogenase to form lactic acid and oxidized nicotinamide adenine dinucleotide (NAD+). The rate of conversion of the reduced cofactor to the oxidized cofactor results in a decrease in absorbance at 340 nm.

ACE AST Reagent
Aspartate aminotransferase in serum converts the L-aspartate and α-ketoglutarate substrates, contained in the reagent, to L-glutamate and oxalacetate. The oxalacetate formed reacts with reduced nicotinamide adenine dinucleotide (NADH) in the presence of malate dehydrogenase to form malate and oxidized nicotinamide adenine dinucleotide (NAD+). The rate of conversion of the reduced cofactor to the oxidized cofactor results in a decrease in absorbance at 340 nm. This rate of conversion is a proportional to the activity of AST in the sample.

ACE γ-GT Reagent
γ-GT in serum catalyzes the transfer of the γ-glutamyl group from the L-γ-glutamyl-3-carboxy-4-nitroanilide substrate to the glycylglycine product in the reagent. The product, 5-amino-2-nitrobenzoate, absorbs strongly at 408 nm. The rate of increase in absorbance is directly proportional to the γ-GT activity in the sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

   a. *Precision/Reproducibility:*

   In house: ACE ALT Reagent
   Within-Run and Total precision evaluations were determined following CLSI EP5-A2. Four levels, three serum based pool and one normal human serum sample, were tested on the ACE Axcel Clinical Chemistry System analyzer in

two runs per day, with two replicates of each level per run for 22 days.

| Sample 1<br>Mean 30.0 U/L ALT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 2.1 | 0.0 | 0.0 | 2.1 |
| Coefficient of Variation | 6.9% | 0.0% | 0.0% | 6.9% |

| Sample 2<br>Mean 265.3 U/L ALT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 5.5 | 0.0 | 1.2 | 5.7 |
| Coefficient of Variation | 2.1% | 0.0% | 0.4% | 2.1% |

| Sample 3<br>Mean 389.2 U/L ALT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 3.2 | 2.3 | 2.2 | 4.5 |
| Coefficient of Variation | 0.8% | 0.6% | 0.6% | 1.1% |

| Sample 4*<br>Mean 55.3 U/L ALT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 0.4 | 0.6 | 1.1 | 1.3 |
| Coefficient of Variation | 0.8% | 1.2% | 2.0% | 2.4% |

*Data collected for 21 days.

Point of Care Laboratory: ACE ALT Reagent
Point of care precision evaluations were determined following CLSI EP10-A3.
Three serum based pools were tested on the ACE Axcel Clinical Chemistry
System analyzer in one run per day, with three replicates of each level per run for
5 days.

| ALT | | | Within-Run | | Total | |
|---|---|---|---|---|---|---|
| Lab | Sample | Mean | SD | %CV | SD | %CV |
| POL 1 | 1 | 28.9 | 2.3 | 7.9 | 2.3 | 7.9 |
| POL 2 | 1 | 29.8 | 2.6 | 8.7 | 2.6 | 8.7 |
| POL 3 | 1 | 30.9 | 1.7 | 5.4 | 1.7 | 5.4 |
| | | | | | | |
| POL 1 | 2 | 256.5 | 5.9 | 2.3 | 5.9 | 2.3 |
| POL 2 | 2 | 263.3 | 5.4 | 2.1 | 6.1 | 2.3 |
| POL 3 | 2 | 261.4 | 2.1 | 0.8 | 4.4 | 1.7 |
| | | | | | | |
| POL 1 | 3 | 474.9 | 7.4 | 1.6 | 7.4 | 1.6 |
| POL 2 | 3 | 383.9 | 3.7 | 1.0 | 4.9 | 1.3 |
| POL 3 | 3 | 380.1 | 3.8 | 1.0 | 5.5 | 1.4 |

In house: ACE AST Reagent

Within-Run and Total precision evaluations were determined following CLSI EP5-A2. Four levels, three serum based pool and one normal human serum sample, were tested on the ACE Axcel Clinical Chemistry System analyzer in two runs per day, with two replicates of each level per run for 22 days.

| Sample 1<br>Mean 23.9 U/L AST | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 1.7 | 1.1 | 0.0 | 2.0 |
| Coefficient of Variation | 7.1% | 4.8% | 0.0% | 8.5% |

| Sample 2<br>Mean 219.6 U/L AST | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 6.0 | 0.0 | 0.0 | 6.0 |
| Coefficient of Variation | 2.7% | 0.0% | 0.0% | 2.7% |

| Sample 3<br>Mean 398.4 U/L AST | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 5.2 | 0.4 | 2.1 | 5.7 |
| Coefficient of Variation | 1.3% | 0.1% | 0.5% | 1.4% |

| Sample 4*<br>Mean 115.2 U/L AST | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 1.1 | 0.8 | 1.8 | 2.3 |
| Coefficient of Variation | 0.9% | 0.7% | 1.6% | 2.0% |

*Data collected for 21 days.

Point of Care Laboratory: ACE AST Reagent
Point of care precision evaluations were determined following CLSI EP10-A3.
Three serum based pools were tested on the ACE Axcel Clinical Chemistry
System analyzer in one run per day, with three replicates of each level per run for
5 days.

| AST | | | Within-Run | | Total | |
|---|---|---|---|---|---|---|
| Lab | Sample | Mean | SD | %CV | SD | %CV |
| POL 1 | 1 | 23.3 | 2.6 | 11.3 | 2.6 | 11.3 |
| POL 2 | 1 | 25.5 | 2.2 | 8.7 | 2.2 | 8.7 |
| POL 3 | 1 | 23.7 | 1.8 | 7.6 | 2.3 | 9.6 |
| | | | | | | |
| POL 1 | 2 | 211.0 | 3.4 | 1.6 | 3.4 | 1.6 |
| POL 2 | 2 | 218.7 | 5.2 | 2.4 | 5.2 | 2.4 |
| POL 3 | 2 | 220.3 | 4.4 | 2.0 | 4.6 | 2.1 |
| | | | | | | |
| POL 1 | 3 | 383.7 | 4.3 | 1.1 | 7.5 | 2.0 |
| POL 2 | 3 | 397.3 | 4.8 | 1.2 | 4.8 | 1.2 |
| POL 3 | 3 | 394.5 | 6.5 | 1.6 | 8.3 | 2.1 |

In house: ACE γ-GT Reagent
Within-Run and Total precision evaluations were determined following CLSI
EP5-A2. Four levels, three serum based pool and one normal human serum
sample, were tested on the ACE Axcel Clinical Chemistry System analyzer in
two runs per day, with two replicates of each level per run for 22 days.

| Sample 1*<br>Mean 23.0 U/L γ-GT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 0.7 | 0.9 | 0.9 | 1.4 |
| Coefficient of Variation | 3.0% | 3.7% | 3.8% | 6.1% |

*Data collected for 21 days

| Sample 2<br>Mean 401.9 U/L γ-GT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 5.0 | 4.4 | 0.0 | 6.7 |
| Coefficient of Variation | 1.2% | 1.1% | 0.0% | 1.7% |

| Sample 3<br>Mean 751.8 U/L γ-GT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|

| | | | |
|---|---|---|---|
| Standard Deviation, U/L | 7.3 | 3.7 | 0.0 | 8.2 |
| Coefficient of Variation | 1.0% | 0.5% | 0.0% | 1.1% |

| Sample 4*<br>Mean 28.9 U/L γ-GT | Within Run | Between Run | Between Day | Total |
|---|---|---|---|---|
| Standard Deviation, U/L | 0.7 | 1.0 | 0.8 | 1.5 |
| Coefficient of Variation | 2.3% | 3.6% | 2.9% | 5.2% |

*Data collected for 21 days

Point of Care Laboratory: ACE γ-GT Reagent
Point of care precision evaluations were determined following CLSI EP10-A3.
Three serum based pools were tested on the ACE Axcel Clinical Chemistry
System analyzer in one run per day, with three replicates of each level per run for
5 days.

| γ-GT | | | Within-Run | | Total | |
|---|---|---|---|---|---|---|
| Lab | Sample | Mean | SD | %CV | SD | %CV |
| POL 1 | 1 | 17.7 | 2.2 | 12.4 | 2.3 | 13.0 |
| POL 2 | 1 | 19.9 | 2.4 | 12.1 | 2.5 | 12.5 |
| POL 3 | 1 | 18.2 | 2.1 | 11.5 | 2.3 | 12.5 |
| | | | | | | |
| POL 1 | 2 | 415.5 | 4.8 | 1.2 | 8.9 | 2.1 |
| POL 2 | 2 | 412.7 | 4.5 | 1.1 | 14.7 | 3.6 |
| POL 3 | 2 | 421.3 | 4.5 | 1.1 | 10.0 | 2.4 |
| | | | | | | |
| POL 1 | 3 | 786.9 | 8.4 | 1.1 | 10.9 | 1.4 |
| POL 2 | 3 | 795.2 | 5.4 | 0.7 | 17.9 | 2.2 |
| POL 3 | 3 | 811.2 | 6.4 | 0.8 | 10.6 | 1.3 |

b. *Linearity/assay reportable range:*

ACE ALT Reagent
Linearity studies were carried out using dilutions of a spiked serum samples. Ten
concentrations were prepared by mixing spiked serum samples in known portions
of saline. All samples were measured in triplicate. The sample range tested was
4.7 to 480.3 U/L.

| Claimed Measuring Range | Intercept | Slope | $r^2$ |
|---|---|---|---|
| 5 U/L - 480 U/L | 0.477 | 1.030 | 0.9988 |

Based on the linearity data, the measuring range claimed from 5 U/L - 480 U/L

was supported.

ACE AST Reagent
Linearity studies were carried out using dilutions of a spiked serum samples. Ten concentrations were prepared by mixing spiked serum samples in known portions of saline. All samples were measured in triplicate. The sample range tested was 4.0 to 453.7 U/L.

| Claimed Measuring Range | Intercept | Slope | $r^2$ |
|---|---|---|---|
| 7 U/L - 450 U/L | 1.9 | 1.013 | 0.9990 |

Based on the linearity data, the measuring range claimed from 7 U/L - 450 U/L. was supported.

ACE g-GT Reagent
Linearity studies were carried out using dilutions of a spiked serum samples. Twelve concentrations were prepared by mixing spiked serum samples in known portions of saline. All samples were measured in triplicate. The sample range tested was 0.3 to 984.7 U/L.

| Claimed Measuring Range | Intercept | Slope | $r^2$ |
|---|---|---|---|
| 7 U/L - 950 U/L | 2.5 | 1.012 | 0.9991 |

Based on the linearity data, the measuring range claimed from 7 U/L - 950 U/L was supported.

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

   ACE ALT Reagent
   Traceable to another commercially available FDA cleared assay by method comparison.

   ACE AST Reagent
   Traceable to another commercially available FDA cleared assay by method comparison.

   ACE γ-GT Reagent
   Traceable to another commercially available FDA cleared assay by method comparison.

d. *Detection limit:*

   Studies were carried out in accordance with CLSI Guidance Document EP17-A. Detection Limits (LoB and LoD) were performed using 60 blank and 60 low serum samples and LoQ were performed using 40 low serum samples according to the recommendations of CLSI EP 17A protocol. Sponsor defined

LoQ as the value with precision <20%. LoB, LoD and LoQ were calculated to be: <u>ALT</u>: LoB =2.9 U/L, LoD = 3.1 U/L, LoQ = 3.1 U/L; <u>AST</u>: LoB = 1.4 U/L, LoD = 1.5 U/L, LoQ = 4.0 U/L; <u>γ–GT</u>: LoB = 2.4 U/L, LoD = 2.7 U/L, LoQ = 7.0 U/L.

The claimed measuring range of ALT is 5 - 480 U/L, AST is 7 - 450 U/L, and <u>γ–GT is 7 - 950 U/L.</u>

e. *Analytical specificity:*

Studies were carried out in accordance with CLSI Guidance Document EP7-A2.

<u>ACE ALT Reagent</u>
Interference studies were performed by using serum pools containing approximately 30 U/L and 350 U/L of ALT with individual interferents at a range of concentrations. The sera were assayed for ALT (n = 3 replicates) and the mean result calculated. Interference was considered to be significant by the sponsor if the analyte recovery changed by > ± 10%. The results reported were obtained on ACE Axcel Clinical Chemistry System analyzer using fresh ACE ALT Reagent.

Interferents Claim

| Interferents | No Significant Interference At or Bellow |
|---|---|
| Unconjugated Bilirubin | 30 mg/dL |
| Hemolysis | 1000 mg/dL |
| Lipemia (Intralipid) | 502 mg/dL |
| Ascorbic Acid | 6 mg/dL |

<u>ACE AST Reagent</u>
Interference studies were performed by using serum pools containing approximately 30 U/L and 230 U/L of AST with individual interferents at a range of concentrations. The sera were assayed for AST (n = 3 replicates) and the mean result calculated. Interference was considered to be significant by the sponsor if the analyte recovery changed by > ± 10%. The results reported were obtained on ACE Axcel Clinical Chemistry System analyzer using fresh ACE AST Reagent.

Interferents Claim

| Interferents | No Significant Interference At or Bellow |
|---|---|
| Unconjugated Bilirubin | 58 mg/dL |
| Hemolysis | * |
| Lipemia (Intralipid) | 526 mg/dL |
| Acorbic Acid | 6 mg/dL |

\* Use clear, unhemolyzed serum. Because erythrocytes contain high levels of AST activity, hemolyzed samples should not be used

ACE γ-GT Reagent
Interference studies were performed by using serum pools containing approximately 30 U/L and 400 U/L of γ-GT with individual interferents at a range of concentrations. The sera were assayed for γ-GT (n = 3 replicates) and the mean result calculated. Interference was considered to be significant by the sponsor if the analyte recovery changed by $> \pm 10\%$. The results reported were obtained on ACE Axcel Clinical Chemistry System analyzer using fresh ACE γ-GT Reagent.

Interferents Claim

| Interferents | No Significant Interference At or Bellow |
|---|---|
| Unconjugated Bilirubin | 18 mg/dl |
| Hemolysis | 62.5 mg/dl\* |
| Lipemia (Intralipid) | 1310 mg/dl |
| Acorbic Acid | 6 mg/dl |

Because hemolysis interferes with the GGT assay, the sponsor put the following limitations in the labeling for GGT:
"\* Specimens showing any indication of hemolysis should not be analyzed."

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Studies are carried out according to CLSI EP9-A2-IR.

In house: ACE ALT Reagent
ACE ALT Reagent was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System. One hundred two serum samples were assayed in parallel by both the test and predicate methods and the results compared by Deming regression. The range tested was 5 to 472 U/L. Seven samples were altered.
The comparison by Deming regression resulted in a slope of 1.041 (95%CI = 1.035 to 1.047), an intercept of 0.3 (95%CI = -0.3 to 0.9), correlation coefficient of $R2 = 0.9996$, and a std. error of 2.4.

Point of Care Laboratory: ACE ALT Reagent

ACE Clinical Chemistry System, ACE ALT Reagent (k931786) was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE ALT Calibrators. Results compared by Deming regression. Eighteen samples were altered.

| POL | n | Range | Regression Equation | Correlation Coefficient | Standard Error | Confidence Interval Slope | Confidence Interval Intercept |
|---|---|---|---|---|---|---|---|
| 1 | 40 | 6-457 | y = 1.014x + 1.5 | 0.9999 | 2.4 | 1.009 to 1.019 | 0.6 to 2.4 |
| 2 | 49 | 5-476 | y = 1.019x - 0.1 | 0.9997 | 2.9 | 1.012 to 1.027 | -1.1 to 0.9 |
| 3 | 40 | 6-453 | y = 1.026x + 1.1 | 0.9997 | 3.1 | 1.018 to 1.035 | 0.0 to 2.2 |

In house: ACE AST Reagent

ACE AST Reagent was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System. One hundred seventeen serum samples were assayed in parallel by both the test and predicate methods and the results compared by Deming regression. The range tested was 8 to 440 U/L. Seven samples were altered.

The comparison by Deming regression resulted in a slope of 1.007 (95%CI = 1.002 to 1.012), an intercept of 2.3 (95%CI = 1.9 to 2.8), correlation coefficient of $R^2 = 0.9996$, and a std. error of 2.2.

Point of Care Laboratory: ACE AST Reagent

ACE Clinical Chemistry System, ACE AST Reagent (k931786) was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE AST Calibrators. Results compared by Deming regression. Twenty one samples were altered.

| POL | n | Range | Regression Equation | Correlation Coefficient | Standard Error | Confidence Interval Slope | Confidence Interval Intercept |
|---|---|---|---|---|---|---|---|
| 1 | 51 | 7-409 | y = 1.010x - 0.6 | 0.9998 | 2.5 | 1.005 to 1.015 | -1.4 to 0.3 |
| 2 | 50 | 8-391 | y = 1.030x + 0.4 | 0.9996 | 2.8 | 1.021 to 1.038 | -0.6 to 1.3 |
| 3 | 42 | 7-383 | y = 1.030x + 1.1 | 0.9997 | 2.9 | 1.021 to 1.038 | 0.1 to 2.1 |

In house: ACE γ-GT Reagent

ACE γ-GT Reagent was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System. One hundred twenty eight serum samples were assayed in parallel by both the test and predicate methods and the results compared by Deming regression. The range tested was 7 to 902 U/L. Four samples were altered.

The comparison by Deming regression resulted in a slope of 0.984 (95%CI = 0.981 to 0.988), an intercept of 0.1 (95%CI = -0.6 to 0.8), correlation coefficient of R2 = 0.9998, and a std. error of 3.4.

Point of Care Laboratory: ACE γ-GT Reagent
ACE Clinical Chemistry System, ACE γ-GT Reagent (k931786) was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE γ-GT Calibrators. Results compared by Deming regression. Twenty five samples were altered.

| POL | n | Range | Regression Equation | Correlation Coefficient | Standard Error | Confidence Interval Slope | Confidence Interval Intercept |
|-----|-----|--------|---------------------|-------------------------|----------------|---------------------------|-------------------------------|
| 1 | 62 | 7-814 | y = 0.970x - 0.6 | 0.9999 | 3.7 | 0.967 to 0.973 | -1.7 to 0.5 |
| 2 | 52 | 13-848 | y = 0.981x + 2.0 | 0.9992 | 8.8 | 0.970 to 0.992 | -0.8 to 5.0 |
| 3 | 49 | 8-912 | y = 1.046x - 0.5 | 0.9997 | 3.6 | 1.039 to 1.053 | -1.6 to 0.7 |

b.  *Matrix comparison:*

   Not applicable

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):*

4. Clinical cut-off:

   Not Applicable

5. Expected values/Reference range:

   ALT expected values are: 10-40 U/L (Males), 7-35 U/L (Females) [1]

   AST expected values are: 5-34 U/L [2]

γ-GT expected values are: 13-68 U/L (Males), 11-48 U/L (Females) [3]

1. Tietz, N. W. (Ed.), Clinical Guide to Laboratory Tests, 3rd Edition, W.B. Saunders Co., Philadelphia, PA (2005).

2. Kaplan L.A., Pesce, A.J., Clinical Chemistry, St. Louis, C.V. Mosby, 911-912 (1989).

3. Reference Intervals-UNC Hospitals, McLendon Clinical Laboratories http://unchealthcare.org/labtestinfo

## 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.