

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

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

k113438

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Total iron-binding capacity  
Iron  
Lipase

**D. Type of Test:**

Quantitative, colorimetric assay

**E. Applicant:**

Alfa Wassermann Diagnostic Technologies, LLC

**F. Proprietary and Established Names:**

ACE Direct Total Iron-Binding capacity (TIBC) Reagent  
ACE Serum Iron Reagent  
ACE Lipase Reagent

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
JMO	Class I, reserved	21 C.F.R. §862.1415 Iron-Binding Capacity Test	Clinical Chemistry (75)
JIY	Class I, reserved	21 C.F.R. §862.1410 Iron (non-heme) Test System	Clinical Chemistry (75)
CHI	Class I (meets the limitations of exemptions in 21 CFR 862.9(c)(9))	21 C.F.R. § 862.1465 Lipase Test System	Clinical Chemistry (75)

## H. Intended Use:

1. Intended use(s):

Please see indication use below.

2. Indication(s) for use:

ACE TIBC Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the ACE Axcel Clinical Chemistry System. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

The ACE Serum Iron Reagent is intended for the quantitative determination of iron concentration in serum using the ACE Axcel Clinical Chemistry System. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofusion, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

The ACE Lipase Reagent is intended for the quantitative determination of lipase activity in serum using the ACE Axcel Clinical Chemistry System. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. 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 prescription Use.

4. Special instrument requirements:

ACE Axcel Clinical Chemistry System

## I. Device Description:

ACE Direct Total Iron-Binding capacity (TIBC) Reagent assay consists of the Direct TIBC Color Reagent (R1) and the Direct TIBC Buffer (R2). The Direct TIBC Color Reagent contains chromazurol B, cetrimide, ferric chloride and acetate buffer. The Direct TIBC Buffer contains sodium bicarbonate buffer. Both reagents are added to the serum sample.

ACE Serum Iron Reagent is composed of two reagent bottles, Buffer (R1) and Color Reagent (R2). The Buffer contains hydroxylamine hydrochloride, acetate buffer (pH 4.5) and surfactant. The Color Reagent contains ferrozine and hydroxylamine hydrochloride.

ACE Lipase Reagent is composed of two reagents, the Lipase Reagent (R1) and the Lipase Activator Reagent (R2). The Lipase Reagent contains 1, 2-dyglyceride, monoglyceride lipase, glycerol kinase, glycerol-3-phosphate oxidase, N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-

toluidine, ATP, peroxidase and cholic acid. The Lipase Activator Reagent contains deoxycholate and 4-Aminoantipyrene.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

ACE Clinical Chemistry System, ACE TIBC Reagent  
 ACE Clinical Chemistry System, ACE Serum Iron Reagent  
 ACE Clinical Chemistry System, ACE Lipase Reagent

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

k931786

3. Comparison with predicate:

Attribute	ACE Direct Total Iron-Binding Capacity (TIBC) Reagent (Candidate Device – k113438)	ACE Clinical Chemistry System, ACE TIBC Reagent (Predicate – k931786)
Indication for use / Intended Use	It is intended for the quantitative determination of Total Iron Binding Capacity in serum	Same
Instrument	ACE Axcel Clinical Chemistry System	ACE and ACE Alera <sup>®</sup> Clinical Chemistry Systems
Sample	Serum	Same
Reagent type	Two part liquid	Same
Reaction Type/Test Methodology	Delta/ Measurement of the capacity of serum protein to bind to iron using a dye.	Same
Measuring range	42 - 700 µg/dL	Same
Storage Temperature after opening	10-14°C for 8 hrs per day / capped and refrigerated at 2-8 °C when not in use	Same
Onboard Stability Claim	30 days	Same
Shelf life	Stable until expiration date on box when stored at 2-8°C	Same

Attribute	ACE Serum Iron Reagent (Candidate Device – k113438)	ACE Clinical Chemistry System, ACE Serum Iron Reagent (Predicate – k931786)
Indication for use / Intended Use	It is intended for the quantitative determination of Iron in serum	Same
Instrument	ACE Axcel Clinical Chemistry System	ACE and ACE Alera <sup>®</sup> and NExCT Clinical Chemistry Systems

Sample	serum	Same
Reagent type	Two part liquid	Same
Reaction Type/Test Methodology	Endpoint/Ferrachrome/Ferrozine without protein removal	Same
Linearity range	12 - 600µg/dL	Same
Storage Temperature after opening	10-14°C	Same
Onboard Stability Claim	30 days	Same
Shelf life	Stable until expiration date on box when stored at 2-8°C	Same

Attribute	ACE Lipase Reagent (Candidate Device – k113438)	ACE Clinical Chemistry System, ACE Lipase Reagent (Predicate – k931786)
Indication for use / Intended Use	The ACE Lipase Reagent is intended for the quantitative determination of lipase activity in serum	Same
Instrument	ACE Axcel Clinical Chemistry System	ACE and ACE Alera <sup>®</sup> Clinical Chemistry Systems
Sample	Serum	Same
Reagent type	Two part liquid	Same
Reaction Type/Test Methodology	Delta / Colorimetric method	Same
Linearity range	15 – 700U/L	11 – 700U/L
Storage Temperature after opening (onboard)	10-14°C	1 week @ 25°C 3 weeks @ 2-8°C
Onboard Stability Claim	20 days	20 days
Shelf life	Stable until expiration date on box when stored at 2-8°C	Same

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

Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (CLSI EP6-A)

Interference Testing in Clinical Chemistry; Approved Guidelines- Second edition (CLSI EP7-A2)

Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- Second Edition (CLSI EP5-A2)

Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures – Third Edition (CLSI EP10 –A3)

Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition (CLSI EP9-A2-IR)

Protocols for Determination of Limits of Detection; Approved Guideline (CLSI EP17-A)

**L. Test Principle:**

ACE Direct Total Iron-Binding capacity (TIBC) Reagent

The Direct TIBC Color reagent releases iron from transferrin, forming a color complex with the dye. Then the Direct TIBC Buffer is added, shifting the pH and resulting in a large affinity of transferrin for iron. The serum transferrin rapidly binds the iron by abstracting the iron from the dye-iron complex. The decrease in absorbance is directly proportional to the total iron binding capacity of the serum sample. The absorbance is measured at 647 nm.

ACE Serum Iron Reagent

The transferrin-bound iron in serum is released at a pH and reduced from ferric to ferrous iron. These ions react with ferrozine to form a violet color complex, which is measured bichromatically at 554 nm/692 nm. The intensity of color produced is directly proportional to the serum iron concentration.

ACE Lipase Reagent

Serum lipase acts on a natural substrate, 1, 2-diglyceride, to liberate 2-monoglyceride. A series of redox reactions take place leading to the formation of a quinone dye. The rate of formation of the dye, determined bichromatically at an absorbance of 573nm/692 nm, is proportional to the lipase activity in the sample.

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

1. Analytical performance:

*a. Precision/Reproducibility:*

In house: ACE Direct Total Iron-Binding capacity (TIBC) 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 Mean 176.3 µg/dL TIBC	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	3.9	1.7	4.1	5.9
Coefficient of Variation	2.2%	1.0%	2.3%	3.3%

Sample 2 Mean 342.8 µg/dL TIBC	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	3.5	2.5	5.2	6.8
Coefficient of Variation	1.0%	0.7%	1.5%	2.0%

Sample 3 Mean 444.9 µg/dL TIBC	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	7.4	0.0	7.4	10.5
Coefficient of Variation	1.7%	0.0%	1.7%	2.4%

Sample 4 Mean 320.3 µg/dL TIBC	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	2.9	3.9	4.5	6.7
Coefficient of Variation	0.9%	1.2%	1.4%	2.1%

Point of Care Laboratory: ACE Direct Total Iron-Binding capacity (TIBC) 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.

TIBC			Within Run		Total	
Lab	Sample	Mean µg/dL	SD	%CV	SD	%CV
POL 1	1	177.3	2.3	1.3	3.2	1.8
POL 2	1	175.2	5.6	3.2	6.7	3.8
POL 3	1	180.1	6.1	3.4	7.4	4.1
POL 1	2	340.2	2.2	0.6	3.1	0.9
POL 2	2	334.2	4.1	1.2	9.7	2.9
POL 3	2	338.6	3.3	1.0	9.2	2.7
POL 1	3	439.7	6.9	1.6	8.2	1.9
POL 2	3	422.9	6.7	1.6	11.6	2.8
POL 3	3	433.6	8.9	2.1	12.0	2.8

In house: ACE Serum Iron 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 one ACE Axcel Clinical Chemistry System analyzer in two runs per day, with two replicates of each level per run for 22 days.

Sample 1 Mean 70.2 µg/dL Total Iron	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	3.7	0.0	1.0	3.8
Coefficient of Variation	5.2%	0.0%	1.5%	5.4%

Sample 2 Mean 269.6 µg/dL Total Iron	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	6.3	0.0	1.6	6.5
Coefficient of Variation	2.3%	0.0%	0.6%	2.4%

Sample 3 Mean 457.1 µg/dL Total Iron	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	5.5	2.6	0.7	6.1
Coefficient of Variation	1.2%	0.6%	1.2%	1.3%

Sample 4 Mean 58.8 µg/dL Total Iron	Within Run	Between Run	Between Day	Total
Standard Deviation, µg/dL	2.7	0.0	1.5	3.1
Coefficient of Variation	4.7%	0.0%	2.5%	5.3%

Point of Care Laboratory: ACE Serum Iron 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.

Total Iron			Within Run		Total	
Lab	Sample	Mean µg/dL	SD	%CV	SD	%CV
POL 1	1	71.3	2.9	4.1	2.9	4.1
POL 2	1	72.5	2.5	3.4	2.6	3.6
POL 3	1	79.5	2.1	2.6	3.3	4.2
POL 1	2	269.2	4.4	1.6	4.4	1.6

POL 2	2	272.5	4.2	1.5	4.2	1.5
POL 3	2	281.7	3.9	1.4	4.7	1.7
POL 1	3	457.0	5.6	1.2	5.6	1.2
POL 2	3	458.8	7.8	1.7	7.8	1.7
POL 3	3	473.3	6.3	1.3	6.3	1.3

In house: ACE Lipase Reagent

Within-Run and Total precision evaluations were determined following CLSI EP5-A2. Four serum based levels of lipase 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 Mean 38.5 U/L Lipase	Within Run	Between Run	Between Day	Total
Standard Deviation, U/L	2.5	2.8	1.7	4.1
Coefficient of Variation	6.5%	7.3%	4.4%	10.7%

Sample 2 Mean 248.35 U/L Lipase	Within Run	Between Run	Between Day	Total
Standard Deviation, U/L	3.62	2.53	15.13	15.76
Coefficient of Variation	1.5%	1.0%	6.1%	6.3%

Sample 3 Mean 403.27 U/L Lipase	Within Run	Between Run	Between Day	Total
Standard Deviation, U/L	4.61	3.53	24.40	25.08
Coefficient of Variation	1.1%	0.9%	6.1%	6.2%

Sample 4 Mean 56.0 U/L Lipase	Within Run	Between Run	Between Day	Total
Standard Deviation, U/L	2.6	2.7	2.6	4.5
Coefficient of Variation	4.6%	4.8%	4.6%	8.1%

Point of Care Laboratory: ACE Lipase Reagent

Point of care precision evaluations were determined following CLSI EP10-A3. Three serum based samples containing varying levels of lipase 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.

Lipase			Within Run		Total	
Lab	Sample	Mean µg/dL	SD	%CV	SD	%C V
POL 1	1	39.13	1.97	5.0	2.70	6.9
POL 2	1	33.96	2.49	7.3	2.49	7.3
POL 3	1	33.20	2.14	6.4	2.14	6.4
POL 1	2	257.75	3.56	1.4	6.14	2.4
POL 2	2	267.93	5.31	2.0	9.62	3.6
POL 3	2	261.65	3.85	1.5	6.64	2.5
POL 1	3	416.27	4.96	1.2	7.89	1.9
POL 2	3	432.68	5.97	1.4	11.97	2.8
POL 3	3	426.92	3.14	0.7	9.73	2.3

b. *Linearity/assay reportable range:*

ACE Direct Total Iron-Binding capacity (TIBC) 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 29.7 to 742 µg/dL.

Claimed Measuring Range	Intercept	Slope	r <sup>2</sup>
42-700 µg/dL	0.3	1.016	0.9966

Based on the linearity data, the measuring range claimed from 42-700 µg/dL was supported.

ACE Serum Iron 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 11.7 to 606.0 µg/dL.

Claimed Measuring Range	Intercept	Slope	r <sup>2</sup>
12-600µg/dL	3	0.990	0.9996

Based on the linearity data, the measuring range claimed from 12-600µg/dL was supported.

ACE Lipase Reagent

Linearity studies were carried out using dilutions of a spiked serum samples. Thirteen samples with increasing lipase concentrations were measured in triplicate. The sample range tested was 14.5 to 757.7 U/L.

Claimed Measuring Range	Intercept	Slope	r <sup>2</sup>
15-700 U/L	0.294	1.000	1.000

Based on the linearity data, the measuring range claimed from 15-700 U/L was supported.

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

Traceability

ACE Direct Total Iron-Binding capacity (TIBC) Reagent

Traceable to another commercially available FDA cleared assay by method comparison. The calibrator was previously cleared under k060264.

ACE Serum Iron Reagent

Traceable to NIST SRM 937. The calibrator was previously cleared under k961588.

ACE Lipase Reagent

Traceable to another commercially available FDA cleared assay by method comparison. The calibrator was previously cleared under k897150.

d. *Detection limit:*

Detection Limits (LoB and LoD) were performed using 60 blank and 60 low serum samples as per the recommendations of CLSI EP 17A protocol. LoB and LoD were calculated to be: TIBC: LoB = 35 µg/dL, LoD = 42 µg/dL; Total Iron: LoB = 2 µg/dL, LoD = 5 µg/dL; Lipase: LoB = 8.44 U/L, LoD = 10.63 U/L.

e. *Analytical specificity:*

ACE Direct Total Iron-Binding capacity (TIBC) Reagent

Interference studies were performed by using serum pools containing 258.0 µg/dL to 296.6 µg/dL and 600 µg/dL of TIBC with individual interferents at a range of concentrations. The sera were assayed for TIBC (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 Direct Total Iron-Binding capacity (TIBC) Reagent.

#### Interferents Claim

Interferents	No Significant Interference At or Below
Unconjugated Bilirubin	55 mg/dL
Hemolysis	250 mg/dL
Lipemia (Intralipid)	1000 mg/dL
Ascorbic Acid	3 mg/dL

#### ACE Serum Iron Reagent

Interference studies were performed by using two serum pools containing 70µg/dL and 220µg/dL with individual interferents at a range of concentrations. The sera were assayed for Iron (n = 3 replicates) and the mean result calculated. Interference was considered to be significant by the sponsor if the analyte recovery changed by more than  $\pm 10\%$ . The results reported were obtained on ACE Axcel Clinical Chemistry System analyzer using fresh ACE Serum Iron Reagent.

#### Interferents Claim

Interferents	No Significant Interference At or Below
Unconjugated Bilirubin	56 mg/dL
Hemolysis	62.5 mg/dL
Triglycerides	500 mg/dL
Ascorbic Acid	6 mg/dL

#### ACE Lipase Reagent

Interference studies were performed by using two serum pools containing 40U/L and 380U/L lipase with individual interferents at a range of concentrations. The sera were assayed for lipase (n = 3 replicates) and the mean result calculated. Interference was considered to be significant by the sponsor if the analyte recovery changed by more than the least detectable or  $> 10\%$ . The results reported were obtained on ACE Axcel Clinical Chemistry System analyzer using fresh ACE Lipase Reagent.

Interferents Claim

Interferents	No Significant Interference At or Below
Unconjugated Bilirubin	8 mg/dL
Hemolysis	1000 mg/dL
Triglycerides	693 mg/dL
Ascorbic Acid	6 mg/dL

Because hemolysis interferes with the above assays, therefore, the sponsor put the following limitations in the labeling for TIBC and Iron:

“Do not use hemolyzed sample.”

f. *Assay cut-off:*  
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Studies were carried out according to CLSI EP09-A2-IR.

In house: ACE Direct Total Iron-Binding capacity (TIBC) Reagent

ACE Clinical Chemistry System, ACE TIBC Reagent (k931786) was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE Direct TIBC Calibrators. One hundred and nine serum samples were assayed in parallel by both the candidate and predicate methods and the results compared by Deming regression. The range tested was 96 to 598 µg/dL. Two samples were altered.

The comparison by Deming regression resulted in a slope of 0.979 (95%CI = 0.961 to 0.9998), an intercept of 2.5 (95%CI = -9.2 to 4.3), correlation coefficient of R2 = 0.9950, and a std. error of 9.1.

Point of Care Laboratory: ACE Direct Total Iron-Binding capacity (TIBC) Reagent

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

POL	n	Range µg/dL	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
1	55	59 - 659	$y = 0.982x + 4.2$	0.9987	6.2	0.968 to 0.996	-0.8 to 9.3
2	46	53 - 621	$y = 0.978x + 9.2$	0.9980	6.1	0.960 to 0.997	3.1 to 15.2
3	45	135 - 615	$y = 0.964x + 5.6$	0.9902	11.2	9.923 to 1.006	-8.2 to 19.4

#### In house: ACE Serum Iron Reagent

ACE Serum Iron Reagent was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE Serum Iron Calibrators. One hundred thirty serum samples were assayed in parallel by both the candidate and predicate methods and the results compared by Deming regression. The range tested was 13 to 550 µg/dL. Nine samples were altered.

The comparison by Deming regression resulted in a slope of 1.006 (95%CI = 1.000 to 1.012), an intercept of 1.8 (95%CI = -2.7 to -1.0), correlation coefficient of R<sup>2</sup> = 0.9995, and a std. error of 3.3.

#### Point of Care Laboratory: ACE Serum Iron Reagent

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

POL	n	Range µg/dL	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
1	63	31 - 578	$y = 1.002x - 1.8$	0.9998	3.0	0.997 to 1.007	-2.7 to -0.6
2	54	12 - 548	$y = 1.007x + 2.0$	0.9993	4.9	0.997 to 1.017	0.1 to 3.9
3	49	33 - 575	$y = 1.028x + 7.2$	0.9992	4.6	1.016 to 1.041	5.3 to 9.2

#### In house: ACE Lipase Reagent

ACE Lipase Reagent was used as the predicate method, using recommended applications and procedures on the ACE Clinical Chemistry System analyzer and calibrating with ACE Lipase Calibrators. One hundred eleven serum samples were assayed in parallel by both the test and predicate methods and the results compared by Deming regression. The range tested was 15.6 to 697.5 U/L. Four samples were altered.

The comparison by Deming regression resulted in a slope of 0.982 (95%CI = 0.970 to 0.994), an intercept of 3.97 (95%CI = 1.97 to 5.97), correlation coefficient of R2 = 0.9980, and a std. error of 9.06.

Point of Care Laboratory: ACE Lipase Reagent

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

POL	n	Range U/L	Regression Equation	Correlation Coefficient	Standard Error	Confidence Interval Slope	Confidence Interval Intercept
1	51	15.9-664.7	$y = 1.013x + 1.89$	0.9997	4.44	1.006 to 1.020	0.36 to 3.41
2	52	15.1 – 674.3	$y = 1.013x + 1.98$	0.9993	7.89	1.002 to 1.023	-4.74 to 0.79
3	45	16.1 – 684.2	$y = 1.038x + 1.22$	0.9996	4.64	1.030 to 1.047	-2.89 to 0.44

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:  
TIBC expected values are 250-450µg/dL<sup>1</sup>.

Total Iron expected values are: Male 65-175µg/dL and female 50-170µg/dL<sup>1</sup>.

Lipase Reagent expected values are: 21 – 67 International Units (U/L) at 37 °C<sup>1</sup>

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

**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.