

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

A. 510(k) Number:

k051115

B. Purpose for Submission:

Obtain clearance to market a reagent pack for Abbott analyzers. The reagent pack is used to determine iron present in transferrin in serum and plasma.

C. Measurand:

Iron

D. Type of Test:

Quantitative, spectrophotometric

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E. Applicant:

Sentinel

F. Proprietary and Established Names:

Sentinel Iron Liquid

G. Regulatory Information:

1. Regulation section:

CFR 862.1410, Iron (non-heme) test system.

2. Classification:

Class I, reserved

3. Product code:

J1Y

4. Panel:

H. Intended Use:

1. Intended use(s):

The Sentinel Iron Liquid is a direct colorimetric in vitro diagnostic assay for the quantitative determination of Iron without deproteinization in human serum and plasma (heparin salts, only).

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 hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

2. Indication(s) for use:

The Sentinel Iron Liquid is a direct colorimetric in vitro diagnostic assay for the quantitative determination of Iron without deproteinization in human serum and plasma (heparin salts, only).

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 hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Abbott AEROSET and Abbott ARCHITECT c8000

I. Device Description:

Transferrin is the carrier protein in blood, normally 20% to 50% saturated in its two iron-binding sites. This assay determines the amount of iron carried in by transferrin in a serum or plasma sample.

Components of the kit and initial concentration of reactive components:

The reagent pack consists of three solutions. The first is a concentrated acetate buffer, 1.4 M, and a pH of 4.8 containing 4.5 M of guanidine hydrochloride and 65 mM thiourea. The second solution contains Ferene-S at concentrations in excess of

20 mM and 0.5 M ascorbic acid. The iron standard is 17.9 μM in Fe^{+3} in an HCl solution, pH = 3.

J. Substantial Equivalence Information:

1. Predicate device name(s):

IL Test Iron

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

k972363

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample Matrix	Human Serum or Plasma	Same
Calibration	Aqueous Iron standard	Same
Measurement Method	Direct colorimetric measurement	Same
Chromophore	Ferene-S	Same

Differences		
Item	Device	Predicate
Instrument	Abbott AEROSET, ARCHITECT c8000	IL Lab 600/900/1800 Plus Chemistry system

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

CLSI EP05-A2: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline-Second

CLSI EP06-A: Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline

L. Test Principle:

The product under submission is used by laboratory professionals to measure the iron in serum and plasma. Serum or plasma is added to an acidic denaturing buffer that triggers the release of iron from carrier proteins. The released iron is reduced and complexed with an iron-specific chromophore.

M. Performance Characteristics (if/when applicable):

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1. Analytical performance:

a. *Precision/Reproducibility:*

Imprecision was assessed by measuring twenty replicates at two different concentrations, 110 ug/dL and 173 ug/dL, for a total of forty measurements. Inter-assay imprecision was determined by sampling both concentration levels twice a day for 10 days. The Aeroset and Architect tests both demonstrated an intra-assay imprecision of less than 1.2%. Inter-assay imprecision was less than 4% for the Aeroset test system and less than 2% for the Architect test system.

b. *Linearity/assay reportable range:*

The company conducted linearity studies using nineteen different concentrations spanning the entire range of the assay, 5 - 1000 µg/dL. Each concentration was measured five times over a time course of fourteen days. For both platforms, the observed values of the assay correlated with the expected values with a correlation coefficient for regressions exceeding 0.999. Deviations from theoretical values were randomly distributed and below 4% CV.

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

The calibration standard packaged with the assay is traceable to gravimetric preparations made by the company. The company verifies the standard value against a NIST (National Institute of Standards and Technology) standard, SRM 3126a.

Reagent stability was established by real-time performance studies. "Reagent on board" stability was established through real-time measurement on control samples. Stability claims were substantiated by following three separate samples at each of three separate concentrations beyond the claimed shelf or calibration lifetime of the product. Actual measured stability exceeded the stability claimed in the product insert by at least 20%.

d. *Detection limit:*

The company established the lower detection limit of the assay by determining three times the standard deviation of 20 replicate measurements of their zero value. The lower limit of the assay was 5 uM/dL.

e. *Analytical specificity:*

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The company tested 58 clinical samples in duplicate spanning the clinically relevant concentration range of 40 - 160 µg/dL and showed that their device was substantially equivalent to the previously cleared device. The correlation coefficient of the fit on the AEROSET was greater than 0.999 with a slope of 0.9584 and intercept of 2.8900. The correlation coefficient of the fit on the ARCHITECT was greater than 0.998 with a slope of 1.002 and intercept of -0.401.

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):

Not applicable

4. Clinical cut-off:

Not applicable

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5. Expected values/Reference range:

Male: 60 - 160 µg/dL (10.7 - 28.6 µmol/L)
Female: 40 - 145 µg/dL (7.2 - 25.9 µmol/L)

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.