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

A. 510(k) Number:

k051111

B. Purpose for Submission:

Obtain clearance to market a reagent pack for Abbott analyzers. The reagent pack is used to measure the unsaturated iron-binding capacity in serum and plasma.

C. Measurand:

Iron

D. Type of Test:

Quantitative spectrophotometric

E. Applicant:

Sentinel

F. Proprietary and Established Names:

Sentinel UIBC Liquid

G. Regulatory Information:

1. Regulation section:

    CFR 862.1415

2. Classification:

    Class I, reserved

3. Product code:

    JMO

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The Sentinel UIBC Liquid (Unsaturated Iron Binding Capacity) assay is intended to measure the unsaturated iron-binding capacity in serum and plasma. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Abbott AEROSET and Abbott ARCHITECT c8000

I. Device Description:

The reagent pack consists of 3 solutions, solid tablets, and a set of plastic tweezers. The solid tablets contain 85 mg. of ascorbic acid. These tablets are dissolved in the first solution. Tablets must be handled with plastic tweezers to avoid iron contamination. The first solution is a 0.25 M Tris buffer, pH 8.6. The second solution contains the iron sequestering chromophor, Ferene-S, at a concentration 22.0 mM. The third solution is the iron standard, 90 µM Fe^{+3} in HCl, pH = 3.0.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche UIBC

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

K770748

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3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample Matrix	Human Serum or Plasma	Same
Calibration	Aqueous Iron standard	Same
Measurement Method	i) Saturation of available binding capacity with a known standard ii) Determination of capacity by difference	Same

Differences		
Item	Device	Predicate
Chromophore	Ferene-S	FerroZine
Measurement Range	30-500 ug/dL	10-500 ug/dL

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:

Transferrin is the carrier protein in blood, normally 20% to 50% saturated in its two iron-binding sites. The additional amount of iron that can potentially be bound is the unsaturated iron-binding capacity (UIBC). UIBC is usually determined directly by saturating the transferrin at an alkaline pH with a known excess of iron.

The product under submission is used by laboratory professionals to measure the unsaturated iron-binding capacity in serum and plasma. Serum or plasma is added to an alkaline buffer/reductant solution containing a known concentration of iron. The remaining free iron after binding to transferrin is reduced and complexed by an iron-selective chromophore. The unsaturated iron binding capacity (UIBC) of Transferrin is determined from the decrease in known free iron concentration in the reagent.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*

    Intra-assay imprecision was tested using 20 replicates each of two control materials assayed in one run on one day. Intra-assay imprecision was found to be less than 3%.

    Inter-assay imprecision was determined using replicates of two control materials assayed in two runs per day for 10 days (n = 40 samples total). Total imprecision on the Aeroset was found to vary from approximately 7% to 9.6% depending on the concentration measured. Total imprecision on the Architect was found to vary from approximately 4% to 6% depending on the concentration measured.

    b. *Linearity/assay reportable range:*

    Linearity was established with various dilutions of a stock solution over the assay range; saline was the diluting agent. Percent recovery was within 4% of the expected value for all points over the range of the assay.

    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. Measured stability of unopened product met the stated acceptance criteria. Onboard stability is claimed as 30 days if contamination is avoided.

    d. *Detection limit:*

    Lower detection limit of the assay was established by averaging 20 replicates of a saline blank and adding three standard deviations. The lower limit of detection of the assay was determined to be 30 ug/dL.

e. Analytical specificity:

Interference from hemoglobin, triglycerides, and bilirubin, was evaluated using a significance criterion of >10% variance from control. The samples used for testing interference had a clinically low iron binding capacity, 125-140 ug/dL. Concentrations of hemoglobin up to 200 mg/dL did not interfere with the assay at the 10% level. Up to 50 mg/dL bilirubin did not interfere with the assay. Triglycerides did not impact the assay at concentrations up 1000 mg/dL.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The company compared the performance of their assay to the predicate by testing duplicate measurements of clinical samples across the range of the assay on the Aeroset and on an Architect c8000.

Their assay demonstrated a linear correlation with the predicate as a function of iron binding capacity. On the Architect platform, using 59 clinical samples, the assay demonstrated a goodness of fit value was 0.999 with a slope of 0.997 and intercept of -4.34. On the Aeroset platform, using 60 clinical samples, the assay demonstrated a goodness of fit value of 0.9144 with a slope of 1.0236 and intercept of 14.642. The slight offset shown in this comparison was well within the error claimed for this and the predicate assay.

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. <u>Clinical cut-off</u>**:**

   Not applicable

5. <u>Expected values/Reference range:</u>
   Unsaturated iron-binding capacity (UIBC):   110 - 370 µg/dL
                       or equivalently: 19.7 - 66.2 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.