510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

A. 510(k) Number:
K053211

B. Purpose for Submission:
Clearance of new assay for ferritin

C. Measurand:
Ferritin

D. Type of Test:
Turbidimetric immunoassay

E. Applicant:
Reference Diagnostics, Inc.

F. Proprietary and Established Names:
Proprietary Name: RDI Ferritin
Established Name: Ferritin, antigen, antiserum, control

G. Regulatory Information:
1. Regulation section:
   21 CFR § 866.5340 Ferritin Immunological test system.
2. Classification:
   Class II
3. Product code:
   DBF
4. Panel:
   Immunology

H. Intended Use:
1. Intended use(s):
   The RDI Ferritin kit is for quantitative measurement of ferritin in human serum or plasma. Measurement of ferritin is useful in assessing iron stores and in the evaluation of iron deficiency anemia and hemochromatosis.
2. Indication(s) for use:
   The RDI Ferritin kit is for quantitative measurement of ferritin in human serum or plasma. Measurement of ferritin is useful in assessing iron stores and in the evaluation of iron deficiency anemia and hemochromatosis.
3. Special conditions for use statement(s):
   Prescription Use
4. Special instrument requirements:
   Hitachi 911 analyzer.

I. Device Description:
The RDI Ferritin is a immunoturbidimetric assay. Serum ferritin in the presence of anti-ferritin attached to latex microparticles and glycine buffer (pH 8.3) forms an antigen-antibody reaction resulting in agglutination of latex microparticles. The agglutination is measured turbidimetrically by an absorbance change at a wave length of 600 nm. The magnitude of the absorbance change is proportional to the ferritin concentration in the sample. A standard curve is generated with known concentrations

of ferritin to calculate the values.

J. Substantial Equivalence Information:
1. Predicate device name(s):
   Bayer Health Care Corporation- ADVIA Centaur Ferritin
2. Predicate 510(k) number(s):
   K905770
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indication for use	Quantitative measurement of ferritin in human serum/plasma as an aid in assessing iron deficiency anemia, hemochromatosis.	Same

Differences		
Item	Device	Predicate
Calibrator Levels	6 – in liquid form	5 lyophilized powder
Reference material	The assigned values are referenced to WHO 3rd International Standard for Ferritin, Recombinant, (94/572).	Reference material WHO 80/58-recombinant ferritin
Assay method	Turbidimetric immunoassay	2 site sandwich – chemiluminescent immunoassay
Matrix	Serum/heparinized plasma	Serum/heparinized plasma/EDTA plasma
Analyzer	911 Hitachi	ADVIA Centaur
Minimum detectable concentration	7.6ng/ml	0.5ng/ml

K. Standard/Guidance Document Referenced (if applicable):
   None referenced
L. Test Principle:
   Turbidimetric immunoassay
M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*
      Precision studies were performed using 3 concentrations.

Within Run (n=20)			
Pool	1	2	3
Mean mg/ml	29.5	182.7	395.7
SD	1.3	2.2	2.6
CV (%)	4.5	1.2	0.6

Between Run (n=20)			
Pool	1	2	3
Mean mg/ml	31.4	183.0	400.7
SD	2.0	10.1	19.7
CV (%)	6.5	5.5	4.9

b. *Linearity/assay reportable range:*
   A serum pool with high concentration of ferritin was diluted with normal saline and assayed by the RDI ferritin method. Results are as described by the sponsor.

	Undiluted sample	1:5 dilution	1:10 dilution
Hitachi 911	> 1200 ng/ml	587.8 ng/ml	3136 ng/ml
Calculated		2939 ng/ml	3136 ng/ml
% recovery		103.7 %	110.6%

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
   The RDI Ferritin calibrators were prepared by diluting a stock solution of human ferritin liver antigen purchased from a commercial source with non-fat dry milk in TBS to achieve the following target concentrations: 0 (blank), 25, 50, 200, 800, and 1200 ng/ml.

   Ferritin calibrators were prepared using the 3rd International Standard for Ferritin, Recombinant, NIBSC code 94/572 (6.3 micrograms/mL) diluted to the respective levels as the RDI Ferritin calibrators. They were used to calibrate the RDI Ferritin assay on the Roche Hitachi 911 and the RDI Ferritin calibrators were assayed in triplicate along with the NIBSC calibrators. In order to avoid potential errors introduced by mathematical curve-fitting, the absolute absorbance of each RDI calibrator and the absorbance obtained for the corresponding concentration of NIBSC reference material were compared.

d. *Detection limit:*
   Minimum detectable concentration is stated as 7.6ng/ml

e. *Analytical specificity:*
   Not provided

f. *Assay cut-off:*
   Not provided. However, the reference range is supposed to be used.

2. Comparison studies:
   a. *Method comparison with predicate device:*
      RDI ferritin assay using Hitachi 911 was Bayer ADVIA Centaur ferritin assay using 117 patient samples ranging from 9-1055 ng/ml. Linear regression analysis showed y=0.982 x +11.5ng/ml with a correlation coefficient (r) of 0.997.

b. *Matrix comparison:*
   Serum vs. sodium heparin plasma : y =1.0134x – 4.1985
   $R^2 = 0.9993$ (n = 25)
   Serum vs. lithium heparin plasma: y =1.016x -6.3405
   $R^2 = 0.9996$ (n = 25)
3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not provided
   b. *Clinical specificity:*
      Not provided
   c. Other clinical supportive data:
      Not provided
4. Clinical cut-off:
   Not provided
5. Expected values/Reference range:
   Reference intervals for serum ferritin are stated as 20-250ng/ml for men and 10-120 ng/ml for women.

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.