

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

A. 510(k) Number:

k053291

B. Purpose for Submission:

Clearance of new calibrator for ferritin

C. Measurand:

Not Applicable

D. Type of Test:

Calibrator material

E. Applicant:

Reference Diagnostics, Inc.

F. Proprietary and Established Names:

RDI Ferritin Calibrator Set

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1150, Calibrator
2. Classification:
Class II
3. Product code:
JIT, Calibrator, Secondary
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
The RDI Ferritin Calibrator Set is intended for medical purposes for use with the RDI Ferritin Kit to establish points of reference that are used in the quantitative determination of Ferritin in human serum or plasma by immunoturbidimetric measurement.
3. Special conditions for use statement(s):
For Prescription Use
4. Special instrument requirements:
Automated chemistry analyzer systems specified in the package insert.

I. Device Description:

The RDI Ferritin Calibrator Set is made from human ferritin antigen, which has full biological and immunochemical properties, in TBS, containing stabilizers and preservative. All human source material was tested and found non-reactive for HBsAg, HCV, and HIV-1/2 by an FDA-approved method.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Ferritin Calibrator
2. Predicate 510(k) number(s):
k983548
3. Comparison with predicate:

| Similarities | | |
|---------------------|---|---|
| Item | Device | Predicate |
| Value Assignment | The assigned values are referenced to WHO 3rd International Standard for Ferritin, Recombinant, (94/572). | The assigned values are referenced to WHO 3rd International Standard for Ferritin, Recombinant, (94/572). |

| Differences | | |
|--------------------|--------|-----------|
| Item | Device | Predicate |
| Levels | 6 | 5 |

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

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators (Guidance for Industry - 2/22/1999)

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not Applicable
 - b. *Linearity/assay reportable range:*
Not Applicable
 - 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. In each case, the RDI Ferritin calibrators recovered within +/- 5% of the NIBSC material. The accuracy of the Ferritin calibrator set was substantiated by use in the RDI Ferritin kit (k053211) comparison to the predicate, ADVIA Centaur Ferritin.

Based upon initial accelerated stability studies, an expiration date of 12 months after manufacture will be applied until real-time, 4°C, testing is complete.

- d. *Detection limit:*
Not Applicable
 - e. *Analytical specificity:*
Not Applicable
 - f. *Assay cut-off:*
Not Applicable
2. Comparison studies:
- a. *Method comparison with predicate device:*
Not Applicable
 - b. *Matrix comparison:*
Not Applicable
3. Clinical studies:
- a. *Clinical Sensitivity:*
Not Applicable
 - b. *Clinical specificity:*
Not Applicable
 - c. *Other clinical supportive data:*
Not Applicable
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:

Not Applicable

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.