

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

A. 510(k) Number:

k052002

B. Purpose for Submission:

New device; originally sold as part of an Unsaturated Iron Binding Capacity (UIBC) assay kit which was pre-amendment. Currently, the Iron Standard is marketed separately from the assay and Roche Diagnostics is submitting a retrospective submission.

C. Measurand:

Calibrator for Iron

D. Type of Test:

Calibrator

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Iron Standard

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1150

2. Classification:

Class II

3. Product code:

JIT

4. Panel:

H. Intended Use:

1. Intended use:

See Indications for use

2. Indications for use:

Iron Standard is for use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers.

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

Roche clinical chemistry analyzers

I. Device Description:

The Iron Standard is a single level product consisting of a gravimetrically prepared aqueous solution of Ferrous Ammonium Sulfate Hexahydrate.

J. Substantial Equivalence Information:

1. Predicate device name:

Elecsys C-Peptide Calset

2. Predicate 510(k) number:

k033873

3. Comparison with predicate:

Similarities		
Characteristic	Iron Standard	Predicate device Elecsys C-Peptide Calset
Intended Use	For use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers	For calibrating the quantitative Elecsys C-Peptide assay on the Elecsys immunoassay systems.

Similarities		
Characteristic	Iron Standard	Predicate device Elecsys C-Peptide Calset
Levels	One	Two

Differences		
Characteristic	Iron Standard	Predicate device Elecsys C-Peptide Calset
Format	Aqueous solution	Lyophilized
Handling	Ready to use	Add exactly 1.0 mL distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.
Stability	<u>Unopened:</u> Store at 15-25°C until expiration date <u>Opened:</u> 15-25°C until expiration date	<u>Unopened:</u> Store at 2-8°C until expiration date <u>Reconstituted:</u> -20°C: 1 month (freeze only once) On the analyzers at 20-25°C: use only once
Matrix	Gravimetrically prepared aqueous solution of Ferrous Ammonium Sulfate Hexahydrate.	Equine serum with added synthetic C-Peptide

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

None referenced

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):*

A master calibrator is developed that has values assigned that are traceable to the method “gold standard”. Iron Standard is a gravimetrically prepared product with a target value of 500 µg/dL. This product is assayed and compared to a NIST standard prepared from SRM 937, Iron Metal (Clinical).

Values are confirmed on Hitachi analyzers using the Iron or UIBC reagent kit. The reagent is calibrated using the 500 µg/dL NIST standard. Replicates of the new batch of Iron Standard are run, followed by replicates of the NIST standard and replicates of a previously released lot of Iron Standard. The new product, the NIST Standard, and the previously released lot of Iron Standard met the sponsor’s acceptance criteria.

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Two studies were performed in order to verify the stability claims for the new Iron Standard.

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Stability	Unopened	Opened
Iron Standard	Store at 15– 25°C until expiration date	15–25°C: until expiration date

Study 1: Real Time Stability. The Iron product is stored at 15-25C° for 6 months, 9 months and 12 months. The Iron reagent is calibrated using the 500 µg/dL NIST standard. Using a Hitachi 917, testing is performed at 6, 9 and 12 months on replicates of the new batch of Iron Standard, followed by replicates of the NIST standard and replicates of a previously released lot of Iron Standard. The new product, the NIST Standard, and the previously released lot of Iron Standard met the sponsor’s acceptance criteria.

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Study 2: Accelerated Stability: At the 11th month of a 12 month shelf life, the Iron product is incubated for 5 days at 45° C and equilibrated to the labeled storage temperature, 15-25C°. The Iron reagent is calibrated using 500 µg/dL NIST standard. Using a Hitachi 917, replicates of the new batch of Iron Standard are run, followed by replicates of the NIST standard and replicates of a previously released lot of Iron Standard. The new product, the NIST Standard, and the previously released lot of Iron Standard met the sponsor’s acceptance criteria.

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The results of the real time and accelerated stability studies support the claim of a 12 month expiration date.

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d. *Detection limit:*

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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

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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

5. Expected values/Reference range:

Not applicable

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N. Proposed Labeling:

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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.

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