

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

A. 510(k) Number:

k051517

B. Purpose for Submission:

New device

C. Measurand:

Quality Control Material (assayed for Ferritin, Folate, and Vitamin B12)

D. Type of Test:

Quality Control Materials for Ferritin, Folate, and Vitamin B12

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys® PreciControl Anemia

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1660 Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product code:
JJX
4. Panel:
75 – Clinical Chemistry

H. Intended Use:

1. Intended use:

See Indications for use below.

2. Indications for use:

Elecsys® PreciControl Anemia is used for quality control of the Elecsys® Ferritin, Folate II, and Vitamin B12 immunoassays on the Elecsys® immunoassay systems.

3. Special conditions for use statement: N/A

4. Special instrument requirements:

Elecsys® immunoassay systems

I. Device Description:

The Elecsys® PreciControl Anemia is a lyophilized product consisting of added ferritin and aprotinine in human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentrations.

J. Substantial Equivalence Information:

1. Predicate device name:

Elecsys® PreciControl MultiAnalyte

2. Predicate 510(k) number:

k033937

3. Comparison with predicate:

Similarities		
Characteristic	Elecsys PreciControl Anemia	Predicate device - Elecsys PreciControl MultiAnalyte
Intended Use	Elecsys® PreciControl Anemia is used for quality control of the Elecsys® Ferritin, Folate II, and Vitamin B12 immunoassays on the Elecsys® immunoassay systems.	Elecsys® PreciControl MultiAnalyte is used for quality control of the Elecsys® C-Peptide and Elecsys® Insulin immunoassays on the Elecsys® immunoassay systems.
Levels	Three	Two
Format	Lyophilized	Same
Handling	Reconstitute with exactly 2.0 mL distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Reconstitute with exactly 2.0 mL distilled water and allow to stand closed for 15 minutes to reconstitute, and then mix gently.

Similarities		
Characteristic	Elecsys PreciControl Anemia	Predicate device - Elecsys PreciControl MultiAnalyte
Stability	<u>Unopened:</u> Store at 2 - 8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none"> • 20 - 25°C: up to 8 hours • on the analyzers at 20 - 25°C: up to 5 hours • at 2-8°C: 3 days • at -20°C: 1 month (freeze only once) • after thawing: use only once 	<u>Unopened:</u> Store at 2 - 8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none"> • on the analyzers at 20 - 25°C: up to 3 hours • at -20°C: 1 month (freeze only once) • after thawing: use only once

Differences		
Characteristic	Elecsys PreciControl Anemia	Predicate device Elecsys PreciControl MultiAnalyte
Matrix	Human serum with added Ferritin (human origin) and Aprotinine (bovine origin)	Equine serum with added C-Peptide and insulin

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:

N/A

b. Linearity/assay reportable range: N/A

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

Traceability: Roche Diagnostics maintains a set of master calibrators for each assay that have values assigned that are traceable to the various method “gold standards”. These standards can either be WHO, NIST or in-house developed

standards. The Elecsys® PreciControl products are assayed and compared to these reference preparations and target values and ranges are assigned. Values are assigned using Elecsys® MODULAR ANALYTICS E170, Elecsys® 2010 and Elecsys® 1010 Immunoassay Analyzers. Two independent series of analyses are performed on each instrument for each analyte. Each sample is tested in duplicate. The target value is calculated as the median of the determined values.

Stability: Five studies were performed to verify the stability claims for Elecsys® PreciControl Anemia. The acceptance criterion for Ferritin and Vitamin B12 is recovery of 90%-110% of the concentration based on unstressed material. The acceptance criterion for Folate II is for samples with concentrations of ≤ 5 ng/mL, a SD ≤ 0.5 ng/mL and for concentrations > 5 ng/mL is recovery of $\pm 10\%$.

Stability	Unopened	Reconstituted
Elecsys PreciControl Anemia	Store at 2 - 8°C until expiration date	<ul style="list-style-type: none"> ◦ 20 - 25°C: up to 8 hours ◦ on the analyzers at 20 - 25°C: up to 5 hours ◦ at 2-8°C: 3 days ◦ at -20°C: 1 month (freeze only once) ◦ after thawing: use only once

- d. *Detection limit:* N/A
- e. *Analytical specificity:* N/A
- f. *Assay cut-off:* N/A

2. Comparison studies:

- a. *Method comparison with predicate device:*

N/A

- b. *Matrix comparison:*

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Lot specific target values for Elecsys® 2010 analyzer are presented in the following table:

	PC Anemia I Low	PC Anemia II Medium	PC Anemia III High
Folate II (ng/mL)	2.89	7.74	16.2
Ferritin (ng/mL)	11.9	431	1320
Vitamin B12 (pg/mL)	287	773	1610

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.