

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

A. 510(k) Number:

k102267

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification for Elecsys Ferritin Reagent

D. Type of Test:

Assayed quality control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Ferritin CalCheck 5

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to indications for use below

2. Indication(s) for use:

The Elecsys Ferritin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and cobas e immunoassay analyzers.

3. Special conditions for use statement(s):

For in vitro diagnostic use

For prescription use

4. Special instrument requirements:

For use with Elecsys Ferritin reagent on the Modular Analytics E170/cobas e 601 and Elecsys 2010/cobas e 411 analyzers.

I. Device Description:

The Elecsys Ferritin CalCheck 5 set contains five levels of ferritin from human liver in a human serum matrix. During manufacture, human ferritin is spiked into the matrix at the target concentrations listed below. CalCheck Level 1 is free of analyte.

Elecsys Ferritin CalCheck Level	Target Value (ng/mL)
Level 1	Less than 2
Level 2	27.5
Level 3	915
Level 4	1550
Level 5	1970

All human source materials were prepared exclusively from the blood of donors tested individually and found to be nonreactive for HBsAg, antibodies to HCV and HIV. The testing methods were FDA approved or cleared in compliance with the European Directive 98/79/EC.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys CalCheck Ferritin

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

k981281 (Elecsys Ferritin)

3. Comparison with predicate

	Candidate Device	Predicate - Elecsys CalCheck Ferritin (k981281)
Indications for Use	The Elecsys Ferritin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Ferritin reagent on the indicated Elecsys and cobas e immunoassay analyzers.	Same
Analyte	Ferritin	Same
Matrix	Human serum	Same
Format	Aqueous	Same
Number of levels per set	5	3
Stability	Unopened: Store at 2 to 8°C until expiration date Opened: 4 hours at 20 to 25°C	Unopened: Same Opened: 5 hours at 20 to 25°C

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

None were 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):

Traceability

The sponsor claims traceability of ferritin used in this quality control set to National Institute for Biological Standards and Controls (NIBSC) reagent for Ferritin (human liver) 80/602. The Elecsys Ferritin assay was standardized against the Enzymun-Test Ferritin method.

Value Assignment

For each Elecsys Ferritin CalCheck 5 lot manufactured, value assignment for each level of CalCheck was performed by duplicate runs on at least three Elecsys Modular Analytics E170/cobas e 601 analyzers. Additionally, the same value assignment procedure was performed on the Elecsys 2010/cobas e 411 analyzers. The assigned target value of each CalCheck is the median of the observed values. The labeling states that obtained values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Closed (unopened) vial shelf life of 2 years at the recommended storage temperature (2 to 8°C) was demonstrated based on accelerated stability studies. Real-time closed-vial stability studies for the Elecsys Ferritin CalCheck 5 solutions are ongoing. Open vial stability of 4 hours was demonstrated at the recommended storage temperature of 20 to 25°C. Storage recommendations are provided in the labeling.

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 (when a. and b. are not applicable):
Not applicable
- 4. Clinical cut-off:
Not applicable
- 5. Expected values/Reference range:
The expected values are provided in the labeling for each specific lot.

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 substantial equivalence decision.