

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k094031

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification for Elecsys Folate III Reagent.

D. Type of Test:

Not applicable.

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Folate III CalCheck 5

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Elecsys Folate III 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 Folate III reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

3. Special conditions for use statement(s):

For prescription use only. The Elecsys Folate III CalCheck 5 is not intended to be used as a primary calibrator or routine control material.

4. Special instrument requirements:

For use with Elecsys Folate III reagent on the Modular Analytics E170/cobas e 601 analyzers.

I. Device Description:

Elecsys Folate III CalCheck 5 is a lyophilized product consisting of folic acid in human serum buffer matrix. During manufacture, folate is spiked into the matrix at the target concentrations listed below. CalCheck Level 1 contains no analyte.

Elecsys Folate III CalCheck Level	Target Value (ng/mL)
Level 1	0
Level 2	3.8
Level 3	10.0
Level 4	16.0
Level 5	19.0

All human source materials were prepared exclusively from the blood of donors tested individually and found nonreactive for HBsAg, antibodies to HCV and HIV-1/2. 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 HCG+β CalCheck 5

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

k092168

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for use	for use in the calibration verification and assay range verification	Same
Levels	Same	Five
Format	Same	Lyophilized
Stability	Same	Unopened: Store at 2-8 °C until expiration date. Opened: 4 hours at 20-25 °C
Matrix	Same	Human serum

Differences		
Item	Device	Predicate
Analyte reagent	Elecsys Folate III Reagent	Elecsys HCG+β Reagent
Handling	Reconstitute Checks 1, 2, 3, 4 and 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 30 minutes, and then mix gently by inversion.	Reconstitute Checks 1, 2, 3, 4 and 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, and then mix gently by inversion.

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

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material.

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 and Value Assignment

A master calibration curve is generated on an Elecsys Modular Analytics E170 /cobas e 601 analyzer by standardizing the Folate III assay against internal reference samples. The master calibration curve is used to calculate ng/mL for the respective CalChecks. For each Elecsys Folate III CalCheck 5 lot manufactured, value assignment is performed as follows. Each CalCheck is tested in duplicate using at least three Elecsys Modular Analytics E170 /cobas e 601 analyzers. The target value for each CalCheck is the median of the observed values.

The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability

Real time and accelerated stability testing protocols and acceptance criteria were described and found to be adequate. The current closed vial stability claim is 18 months at 2° to 8°C. The reconstituted vials are stable for four hours at 25 ° C.

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 a substantial equivalence decision.