

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

A. 510(k) Number:

k102044

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification for Elecsys Digoxin CalCheck 5

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Digoxin 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 Digoxin 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 Digoxin reagent on the indicated Elecsys and cobas e immunoassay analyzers

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Roche Elecsys 2010 / cobas e 411 and MODULAR ANALYTICS E170 / cobas e 601 immunoassay analyzers

I. Device Description:

Elecsys Digoxin CalCheck 5 set is an *in vitro* diagnostic device that contains 5 levels of Digoxin in a buffer/protein (bovine serum) matrix. The vials contain 2.0 mL each and are packaged in sets of 5.

Level	Target Value (ng/mL)	Target Range (ng/mL)
Check 1	≤ 0.3	≤ 0.3
Check 2	1.5	1.35 - 1.65
Check 3	2.5	2.25 - 2.75
Check 4	4	3.8 - 4.2
Check 5	5	4.8 - 5.2

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys Digoxin CalCheck

2. Predicate K number(s):

k973973

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Same	For use in the verification of the calibration established by the Elecsys Digoxin reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte Reagent	Same	Digoxin
Format	Same	Liquid
Handling	Same	Mix gently by inversion to ensure homogeneity
Matrix	Same	Bovine serum matrix

Differences		
Item	Device	Predicate
Levels	Five	Three
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 6 hours	Unopened: • Store at 2-8°C until expiration date Opened: • 15-25°C: 5 hours

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 generated on the Elecsys 2010 analyzer is used to calculate ng/mL digoxin in each CalCheck for value assignment. Each master calibrator is standardized by weighing USP Digoxin reference material into analyte-free bovine serum.

For each Elecsys Digoxin CalCheck 5 lot manufactured, the CalChecks are assayed in duplicate on at least three MODULAR ANALYTICS E170 / cobas e 601 analyzers (master platform). The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzers) of the respective CalCheck. The assigned range is calculated as $\pm 27\%$ of the assigned value for levels 2-4 and $\pm 30\%$ of the assigned value for level 5. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

To ensure the values assigned using the master platform are transferrable and valid for the other instrument platforms, each Elecsys Digoxin CalCheck 5 level is assayed once a day on 8 Elecsys 2010 / cobas e 411 analyzers for 1 day. The median value for the 8 analyses must be within 10% of the master platform assigned value. After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the Elecsys 2010 / cobas e 411 immunoassay analyzers.

Stability

Open-vial and accelerated stability study protocols and acceptance criteria were described. As stability studies are not analyzer dependent, all stability studies were performed on the Elecsys 2010 / cobas e 411 immunoassay analyzer and can be applied to the MODULAR ANALYTICSE170 / cobas e 601 analyzers. The data support the package insert claims that open-vial Elecsys Digoxin CalCheck 5 is stable for up to 6 hours at 20-25°C, and that storage at 2-8°C provides stability for 18 months. The expiration date listed on each CalCheck bottle label reflects this stability time of 18 months. A real-time stability study is ongoing.

- 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:

There are 5 levels of the CalCheck 5 kit which span the 0-5 ng/mL measuring range of the Digoxin assay (see Device Description under section I). The final assigned values are lot specific and are provided in the labeling.

Dilution Studies were performed where CalCheck 1 & CalCheck 2, and CalCheck 4 & CalCheck 5 were mixed in a 1:1 ratio (as instructed in the draft package insert for dilutions) and measured in two-fold determination. The Digoxin CalCheck 5 dilution values were within the assay measuring range after dilution.

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.