

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

A. 510(k) Number:

k100594

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for cardiac troponin I

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Troponin I 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:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to indications for use below

2. Indication(s) for use:

The Elecsys Troponin I 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 Troponin I 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 only. The Elecsys Troponin I Cal Check 5 is not intended to be used as a primary calibrator or routine control material.

4. Special instrument requirements:

The labeling states that the CalChecks are for use with the Elecsys Troponin I reagent on the Elecsys 2010/cobas e411 and Modular Analytics E170/cobas e601 test systems.

I. Device Description:

The Elecsys Troponin I CalCheck 5 is a lyophilized product consisting of recombinant human Troponin I in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. CalCheck Level 1 contains no analyte.

Elecsys Troponin I CalCheck	Target Value (ng/mL)
Level 1	< 0.3
Level 2	0.8
Level 3	5.0
Level 4	20.0
Level 5	25.0

The human source materials were prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

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 (k100594)	Predicate (k092168)
Indications for use	For use in calibration verification and for use in the verification of the assay range for the Elecsys and cobas e immunoassay analyzers.	Same
Format	Lyophilized	Same
Matrix	Human serum	Same
Handling	Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Stability	<u>Unopened</u> Store at 2-8°C until expiration date. <u>Reconstituted</u> 20-25°C for 4 hours.	Same
Levels	5	Same

Differences		
Item	Device (k100594)	Predicate (k092168)
Analyte	Elecsys Troponin I reagent	Elecsys HCG+β reagent
Reactive Component	Recombinant human Troponin I	hCG purified from human urine

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

The Troponin I used in the Elecsys Troponin I CalCheck 5 is traceable to an internal reference material assayed with a commercially available Troponin I assay. The Elecsys Troponin I CalCheck 5 material is analyzed on the sponsor's reference analyzers and recovered values must fall within pre-determined acceptance criteria.

Expected Values and Value Ranges

Expected values for the Elecsys Troponin I CalCheck 5 are determined by duplicate analyses of levels 1 to 5 using $N \geq 3$ analyzers (i.e. Elecsys 2010, E170, and cobas e 601). Pre-determined acceptance criteria for Troponin I recovery must be met for each control lot. The target value for each CalCheck is the median of the observed values. Troponin I expected values and value ranges are lot dependent and are listed in the lot-specific value sheet. Test results must fall within the range printed on the lot-specific value sheet. The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability

The manufacturer claims CalCheck 5 is stable until the expiration date printed on the vial when stored unopened at 2-8°C. Accelerated stability testing supports the target shelf life claim of 18 months. The reconstituted vials are stable for four hours at 20-25°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.