

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

A. 510(k) Number:

k092169

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for Elecsys proBNP II Reagent

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys proBNP II CalCheck 5

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660 Quality Control Material

2. Classification:

Class I, reserved

3. Product code:

JJX – single (specified) analyte controls

4. Panel:

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Elecsys proBNP II 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 proBNP II reagent on the indicated Elecsys and cobas e immunoassay analyzers.

3. Special conditions for use statement(s):

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

4. Special instrument requirements:

For use with Elecsys proBNP II reagent on the Elecsys 2010/cobas e411, and MODULAR ANALYTICS E 170/cobas e 601 test systems.

I. Device Description:

Elecsys ProBNP II CalCheck 5 set contains 5 lyophilized levels of NT-proBNP (synthetic) in a solution of human serum and has the appropriate matrix characteristics for the analyte. The reactive ingredient after reconstitution is NT-proBNP (synthetic) in human serum/buffer matrix. 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 were FDA approved or cleared in compliance with the European Directive 98/79/EC.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys proBNP II CalCheck

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

k080147

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For use in calibration verification and for use in the verification of the assay range established by the Elecsys proBNP II reagent on the indicated Elecsys and cobas e immunoassay analyzers	For use in the verification of the calibration established by the Elecsys proBNP II reagent on the Elecsys and cobas e immunoassay analyzers
Format	same	Lyophilized
Matrix	same	Human serum
Stability	same	Unopened: Store at 2-8 °C until expiration date Reconstituted: 4 hours at 20-25 °C

Differences		
Item	Device	Predicate
Levels	Five	Three

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 and Value Assignment

The assayed value of each CalCheck level was standardized against reference standards by weighing pure synthetic NT-proBNP (1-76) amide into a human serum matrix.

Value assignment is performed for each Elecsys proBNP II CalCheck5 lot. Values are assigned for each lot of proBNP II CalCheck 5 in combination with each Elecsys proBNP II reagent lot available. Values are assigned using four Elecsys MODULAR ANALYTICS E170/cobas e601 analyzers and three Elecsys 2010/cobas e411 analyzers. Each sample is tested in duplicate. 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. CalCheck 5 is stable until the expiration date printed on the vial when stored unopened at 2 – 8 ° C. 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.