

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

A. 510(k) Number:

k080147

B. Purpose for Submission:

Modification to QC/control material

C. Measurand:

proBNP control

D. Type of Test:

Quality control material for proBNP

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys proBNP II CalCheck

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:

For use in the verification of the calibration established by the Elecsys proBNP II reagent on the Elecsys and cobas e immunoassay analyzers.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on the Elecsys and cobas e immunoassay analyzers.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Elecsys or Cobas e immunoassay analyzer

I. Device Description:

The Elecsys proBNP II CalCheck is a lyophilized product consisting of NT-proBNP (1-76) amide human serum and potassium phosphate buffered matrix. During manufacture the analytes are spiked into the matrix at the desired concentration levels. In the labeling the sponsor states that each donor unit was tested for hepatitis B surface antigen, antibodies to hepatitis C and antibodies to HIV and found to be negative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys proBNP CalCheck

2. Predicate K number(s):

k020883

3. Comparison with predicate:

Similarities		
Item	Elecsys proBNP II CalCheck (Device)	Elecsys proBNP CalCheck (Predicate)
Levels	Three	Three
Format	Lyophilized	Lyophilized
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow to stand closed for 15 minutes, then mix gently.	Reconstitute with exactly 1.0 mL distilled or deionized water and allow to stand closed for 15 minutes, then mix gently.
Storage	2 - 8°C	2 - 8°C
Matrix	Level 1: NT-proBNP free human serum Levels 2/3: synthetic NT-proBNP in human serum/buffer matrix	Level 1: NT-proBNP free human serum Levels 2/3: synthetic NT-proBNP in human serum/buffer matrix

Differences		
Item	Elecsys proBNP II CalCheck (Device)	Elecsys proBNP CalCheck (Predicate)
Intended use	Intended for use in the verification of the calibration established by the Elecsys proBNP II reagent on the Elecsys and cobas e analyzers	Intended for use in the verification of the calibration established by the Elecsys proBNP reagent on the Elecsys and cobas e analyzers

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

Not applicable

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):

Values are assigned by multiple analyses on multiple analyzers. Runs are calibrated against reference standards produced by weighing in pure synthetic NT-proBNP (1-76) amide in a human serum matrix. The target value is calculated as the median of the determined values.

Stability testing protocols and acceptance criteria were described and found to be acceptable. The CalCheck is stable until the expiration date printed on the vial when stored unopened at 2 – 8° C. 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:

Not applicable

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.