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

A. 510(k) Number:

k112104

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Osteocalcin

D. Type of Test:

Quality control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys N-MID Osteocalcin 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:

   Single (specified) analyte controls (assayed and unassayed) (JJX)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Elecsys N-MID Osteocalcin 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 N-MID Osteocalcin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. For in vitro diagnostic use.

3. Special conditions for use statement(s):

   For prescription use.

   Limitations: Elecsys N-MID Osteocalcin CalCheck 5 is not intended to be used as primary calibrator or control material.

4. Special instrument requirements:

   Elecsys and cobas e immunoassay analyzers including the Elecsys 2010, MODULAR ANALYTICS E170, cobas e 411, cobas e 601, and cobas e 602 analyzer platforms.

I. Device Description:

The Elecsys N-MID Osteocalcin CalCheck 5 is a lyophilized product consisting of osteocalcin in a human serum matrix. During the manufacture, the analyte is spiked into the matrix at the desired concentration levels. This solution is used to verify the calibration established with the Elecsys N-MID Osteocalcin CalSet and to verify the assay range established by the Elecsys N-MID Osteocalcin Reagent on the indicated Elecsys and cobas e immunoassay analyzers. The labeling states: 'All products derived from human blood are 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.'

Target values listed below for Elecsys N-MID Osteocalcin CalCheck 5 provided on the value sheet are reagent lot-specific, and are based on and established using results from multiple analyzers and assay runs.

Level	Target Value (ng/dL)
Check 1	≤ 2.00
Check 2	10.5
Check 3	130
Check 4	208
Check 5	271

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Elecsys DHEA-S CalCheck 5

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

   k103402

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Characteristics	**Elecsys N-MID Osteocalcin CalCheck 5 (Candidate Device)**	**Elecsys DHEA-S CalCheck 5 (K103402)**
Intended Use	An assayed control for use in calibration verification and for use in the verification of the assay range.	Same
Levels	Five	Same
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4 and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, and then mix gently by inversion.	Same
Stability	Unopened: Store at 2-8°C until expiration date (18 months)	Same
Matrix	Human serum	Same
Differences		
Analyte	Osteocalcin	DHEA-S
Stability	Reconstituted: 20-25°C, 5 hours	Reconstituted: 20-25°C, 4 hours

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: The Elecsys N-MID Osteocalcin CalCheck5 is traceable to the in-house reference standard which is osteocalcin in analyte-free human serum matrix to generate a master calibrator curve on the cobas e 601 analyzer.

Value Assignment: For each Elecsys N-MID Osteocalcin CalCheck5 lot manufactured, the CalChecks are run in duplicate on at least three cobas e 601 analyzers. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range for each CalCheck is ± 30% of assigned value. Reagent lot-specific values are assigned for each lot of Elecsys N-MID Osteocalcin CalCheck5 in combination with each Elecsys N-MID Osteocalcin reagent lot available. For additional analyzers, the same value assignment procedure is performed. The assigned values obtained on additional analyzers are compared to those obtained on the cobas e 601.

Stability: The shelf life for the Elecsys N-MID Osteocalcin CalCheck5 is determined to be 18 months when stored at 2-8°C on the cobas e 601 analyzer in an accelerated study. Real time shelf life stability is on-going. The reconstituted (open vial) Elecsys N-MID Osteocalcin CalCheck5 when stored at 20-25°C has a 5 hour stability claim. The CalCheck products are not stored on-board the analyzers, therefore no on-board stability claims are made. Stability study protocols and acceptance criteria were described and found to be acceptable.

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.