

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

**A. 510(k) Number:**

k051543

**B. Purpose for Submission:**

Modification of PreciControl Bone to add Osteocalcin to previously cleared quality control material

**C. Measurand:**

Quality control material for Osteocalcin

**D. Type of Test:**

Quality control material

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

Elecsys PreciControl Bone

**G. Regulatory Information:**

1. Regulation section:

21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds (assayed and unassayed)

4. Panel:

(75) Chemistry

**H. Intended Use:**

1. Intended use(s):

Elecsys PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.

2. Indication(s) for use:

PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay systems

**I. Device Description:**

PreciControl Bone contains lyophilized control serum based on equine serum in three concentration ranges: BONE 1, BONE 2 and BONE 3. Each level is supplied as 2 bottles, each for 2.0 mL of control serum.

Materials of human origin were tested for HIV, HBV, and HCV infection and found to be negative.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Elecsys PreciControl Bone

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

k993706

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Analyzer system	Elecsys immunoassay analyzers	same
Reagent format	Lyophilized, based on equine serum	same
Stability	2-8° C - unopened until expiration date Reconstituted/thawed : @ 20-25° C – 8 hours @ 2-8° C – 5 days @ -20° C (4 freeze thaw cycles possible) – 1 month	same

<b>Differences</b>		
Item	Device	Predicate
Intended Use	Elecsys PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.	PreciControl Bone is used for quality control of the Elecsys $\beta$ -CrossLaps/serum ( $\beta$ -CTX), and PTH (parathyroid hormone) immunoassays on Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay systems.
Analyte composition	$\beta$ -CTX, PTH and N-MID Osteocalcin	$\beta$ -CTX, PTH
Analyte target concentrations	$\beta$ -CTX (synthetic): approximately 0.315, 0.75 and 3.0 ng/mL PTH (synthetic): approximately 60, 205 and 850 pg/mL Osteocalcin (synthetic): approximately 20, 100 and 205 ng/mL	$\beta$ -CTX (synthetic): approximately 0.315, 0.75 and 3.0 ng/mL PTH (synthetic): approximately 60, 205 and 850 pg/mL

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

None 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):*

Each control level is tested on a total of twelve Elecsys immunoassay analyzers. Two series of measurements are performed on each instrument with samples tested in duplicate. The method has been standardized against an in-house reference standard: osteocalcin in analyte-free human serum matrix. The target values for Osteocalcin are set at approximately 20, 100 and 205 ng/mL. Lyophilized control material is stable up to the stated expiration date.

Reconstituted control material is stable at 2-8° C for 5 days. Stability data at 5 days supports the package insert claim of 5 days. Percent recoveries at 5 days meet the sponsor's acceptance criteria of 90 – 110 % of concentration based on unstressed material.

Reconstituted control material is stable frozen at -20° C for 1 month. Stability data at one month supports the package insert claim of stability frozen at -20° C for 1 month. Percent recoveries at 1 month meet the sponsor's acceptance criteria of 90 – 110 % of concentration based on unstressed material.

Reconstituted control material is stable for up to 8 hours at 20-25° C. Stability data supports the package insert claim that the control is stable for up to 8 hours at 20-25° C. Percent recoveries meet the sponsor's acceptance criteria of 90-110%.

*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):*

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.