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

A. 510(k) Number:
k111506

B. Purpose for Submission:
New Device – Combining two previously cleared devices (k082340 and k051543) into one new device

C. Measurand:
Quality Control Material

D. Type of Test:
Not applicable

E. Applicant:
Roche Diagnostics

F. Proprietary and Established Names:
Elecsys PreciControl Varia 3

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY Multi-Analyte Controls, All Kinds (Assayed)	Class I, reserved	21 CFR § 862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   Elecsys PreciControl Varia 3 is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers. See the package insert for the list of all analytes claimed.

3. Special conditions for use statement(s):
   This device is intended for prescription use only.

4. Special instrument requirements:
   Elecsys 2010 and cobas e 601 analyzers.

I. Device Description:

Elecsys PreciControl Varia 3 is a lyophilized product consisting of analytes spiked into human serum matrix at desired concentration levels. Specifically, the kit is comprised of control material for β-CrossLaps, Ferritin, Folate, Osteocalcin, Parathyroid Hormone and Vitamin B_{12}. 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 or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

J. Substantial Equivalence Information:

Elecsys PreciControl Varia 3 is a multi-analyte control that combines the analytes in the Elecsys PreciControl Anemia (k082340) and Elecsys PreciControl Bone (k051543) multi-analyte controls.

Predicate devices name	Predicate 510(k) number
Elecsys PreciControl Bone	k051543
Elecsys PreciControl Anemia	k082340

Comparison with predicate:

Similarities and Differences			
Item	Proposed Device	Predicate Device (k082340)	Predicate Device (k051543)
Intended Use	Same	Used for quality control of specified Elecsys immunoassays.	Used for quality control of specified Elecsys immunoassays.
Analyzer	Elecsys 2010, Modular Analytics E170 or Cobas e immunoassay analyzers	Elecsys 1010/2010, Modular Analytics E170 or Cobas e immunoassay analyzers	Elecsys 1010/2010, Modular Analytics E170 or Cobas e immunoassay analyzers
Analyte Concentration	β-CT_x: ~320 pg/mL β-CT_x: ~750 pg/mL Ferritin: ~14 ng/mL Ferritin: ~150 ng/mL Ferritin: ~1000 ng/mL Folate: ~3.9 ng/mL Folate: ~12 ng/mL Osteocalcin: ~20 ng/mL Osteocalcin: ~100 ng/mL PTH: ~25 pg/mL PTH: ~60 pg/mL PTH: ~200 pg/mL	β-CT_x: N/A β-CT_x: N/A Ferritin: ~15 ng/mL Ferritin: ~500 ng/mL Ferritin: ~1500 ng/mL Folate: ~3 ng/mL Folate: ~8 ng/mL Folate: ~14 ng/mL Osteocalcin: N/A Osteocalcin: N/A PTH: N/A PTH: N/A PTH: N/A	β-CT_x: ~315 pg/mL β-CT_x: ~750 pg/mL β-CT_x: ~3000 pg/mL Ferritin: N/A Ferritin: N/A Ferritin: N/A Folate: N/A Folate: N/A Osteocalcin: ~20 ng/mL Osteocalcin: ~100 ng/mL Osteocalcin: ~205 ng/mL PTH: ~60 pg/mL PTH: ~205 pg/mL PTH: ~850 pg/mL

	Vitamin B_{12}: ~230 pg/mL Vitamin B_{12}: ~500 pg/mL Vitamin B_{12}: ~1000 pg/mL	Vitamin B_{12}: ~350 pg/mL Vitamin B_{12}: ~700 pg/mL Vitamin B_{12}: ~1500 pg/mL	Vitamin B_{12}: N/A Vitamin B_{12}: N/A Vitamin B_{12}: N/A
Format	Same	Same	Lyophilized
Volume after Reconstitution	3.0 mL	2.0 mL	2.0 mL
Stability	-20°C: 31 days 2–8°C: 72 hours 20-25°C: 5 hours	-20°C: 1 month 2–8°C: 3 days 20-25°C: 5 hours	-20°C: 1 month 2–8°C: 5 days 20-25°C: 8 hours

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 and Value Assignment:
Elecsys PreciControl Varia 3 assigned values are determined with respective Elecsys assays on the cobas e 601 and Elecsys 2010 analyzers. For each assay, a master calibrator set is available, which is traceable to external or internal reference material. The assigned values for Elecsys PreciControl Varia 3 are read from the master calibration curve. The traceability of the external or internal material used is described in the table below.

Analyte	Reference Material or Reference Method
β-CrossLaps [pg/mL]	Gravimetry
Ferritin [ng/mL]	1st International Standard-NIBSC 80/062
Folate [ng/mL]	Elecsys Folate II Assay
Osteocalcin [ng/mL]	In-house reference standards: Commercially available osteocalcin enzyme immuno/radio-binding assay

Parathyroid Hormone [pg/mL]	In-house reference standards: Commercially available PTH radio-binding assay
Vitamin B12 [pg/mL]	In-house reference standards: Commercially available radio-binding assay

Value assignment for Elecsys PreciControl Varia on the cobas e 601 analyzer or Elecsys 2010 analyzer was performed in the following manner. The assigned value of each control level was determined by the median value obtained from eight determinations (duplicate runs on four cobas e 601 analyzers or four Elecsys 2010 analyzers). The ranges are determined based upon a specified ± percentage of the assigned value for each analyte.

Stability:
Stability testing protocols (carried out on the cobas e 601 analyzer) and acceptance criteria were described and found to be acceptable. Elecsys PreciControl Varia 3 is stable for 15 months when stored unopened at 2 – 8° C. Reconstituted Elecsys PreciControl Varia 3 vials are stable for 5 hours on the analyzers at 20 - 25°C, 72 hours at 2 – 8°C, and 31 days at -20°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 analyte for each specific lot.

N. Proposed Labeling:
The labeling is sufficient and 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.