

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

A. 510(k) Number:

k102157

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for C-peptide, insulin, adrenocorticotrophic hormone (ACTH), and human growth hormone (hGH)

D. Type of Test:

Quality control material

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys PreciControl Multimarker

G. Regulatory Information:

1. Regulation section:

21 CFR 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:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and cobas e immunoassay analyzers

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Roche Elecsys 2010 / cobas e 411 and MODULAR ANALYTICS E170 / cobas e 601 immunoassay analyzers

I. Device Description:

Elecsys PreciControl Multimarker is an *in vitro* diagnostic device that contains lyophilized control serum based on equine serum matrix in two concentration ranges. The vials contain 2.0 mL each, and are packed in sets of 6 (3 of each level).

Analyte (in equine serum matrix)	Target Concentration		Unit
	Level 1	Level 2	
C-Peptide	2	10	ng/mL
Insulin	25	80	µU/mL
ACTH	50	1000	pg/mL
hGH	1	10	ng/mL

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys PreciControl MultiAnalyte

2. Predicate K number(s):

k033937

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Same	Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and cobas e immunoassay analyzers
Analyzer System	Same	Elecsys and cobas e immunoassay analyzers
Analyte Concentration	Same	C-Peptide (ng/mL): Level 1 = 2 Level 2 = 10
Format	Same	Lyophilized
Matrix	Same	Equine serum
Levels	Same	Two

Differences		
Item	Device	Predicate
Analyte Concentration	Insulin (μU/mL): Level 1 = 25 Level 2 = 80 ACTH (pg/mL): Level 1 = 50 Level 2 = 1000 hGH (ng/mL): Level 1 = 1 Level 2 = 10	Insulin (μU/mL): Level 1 = 20 Level 2 = 100
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • on the analyzer at 20-25°C: up to 5 hours • at -20 °C: 31 days (freeze only once) After Thawing: • use only once	Unopened: • Store at 2-8°C until expiration date Reconstituted: • on the analyzer at 20-25°C: up to 3 hours • at -20 °C: 3 months (freeze only once) • or at 2-8°C for 72 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

Each level of the Elecsys PreciControl Multimarker is assigned analyte-specific values with the respective Elecsys assay using master calibrators. The master calibrator for ACTH is traceable to an internal reference material based on gravimetry, for C-Peptide is traceable to NIBCS reference material, and for hGH and Insulin the master calibrators are traceable to respective WHO reference materials. The Elecsys PreciControl products are assayed and compared to these reference preparations and target values and ranges are assigned.

For lot-specific value assignment, each level of quality control is tested in duplicate on at least three Elecsys MODULAR ANALYTICS E170 / cobas e 601 immunoassay analyzers (master platform). The assigned value of each control level is defined as the median value obtained from at least six determinations (duplicate runs on at least three analyzers), with an assigned range calculated from the assigned value. Acceptance criteria including precision of control determinations and percent difference between assigned and target values must be met for lot value assignment.

To ensure the values assigned to the Elecsys PreciControl Multimarker on the master platform are transferrable to the additional instrument platforms, the same value assignment procedure is performed on the Elecsys 2010 / cobas e 411 immunoassay analyzer and the assigned values are compared to those obtained on the master platform. The analyzer-to-analyzer variability must be less than 10% difference to meet acceptance criteria. The assigned value from the master platform is then valid on the Elecsys 2010 / cobas e 411 immunoassay analyzer.

Stability

As stability studies are not analyzer dependent, all stability studies were performed on the cobas e 601 / MODULAR ANALYTICS E170 immunoassay analyzer and can be applied to the Elecsys 2010 / cobas e 411 analyzer. An accelerated stability study was performed to simulate a shelf life of 15 months at normal storage conditions of 2-8 °C. Stability data supports this package insert claim and percent recoveries at 15 months meet the stated acceptance criteria of 90-110% of concentration based on unstressed material. A real-time stability study is ongoing.

Reconstituted control material is stable at 2-8 °C for 72 hours. Stability data supports this package insert claim and percent recoveries at 72 hours meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

Reconstituted control material is stable frozen at -20 °C for 31 days. Stability data supports this package insert claim and percent recoveries at 31 days meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

Reconstituted control material is stable sitting on the analyzers at 20-25 °C for 5 hours. Stability data supports this package insert claim and percent recoveries at 5 hours meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

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.