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

A. 510(k) Number:

k051687

B. Purpose for Submission:

Marketing of a laboratory control

C. Measurand:

Control material for AFP, Cortisol, DHEAS, Estradiol, Ferritin, Folate, FSH, FT3, FT4, hCG, IgE, Insulin, LH, Progesterone, Prolactin, SHBG, Testosterone, T3, T4, TSH, T-Uptake, and Vitamin B12

D. Type of Test:

The product is used as a quality control to monitor the precision of laboratory testing procedures.

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys® PreciControl Universal

G. Regulatory Information:

1. Regulation section:

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

2. Classification:

   Class I

3. Product code:

   JJY

4. Panel:

   (75) Chemistry

H. Intended Use:

1. Intended use:

   See indications for use below.

2. Indications for use:

   Elecsys® PreciControl Universal is used for quality control of the Elecsys® immunoassays on the Elecsys® immunoassay systems.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   Elecsys Immunoassay systems

I. Device Description:

The Elecsys® PreciControl Universal is a lyophilized product consisting of added antigens in human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentrations.

J. Substantial Equivalence Information:

1. Predicate device name:

   Elecsys PreciControl MultiAnalyte

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

   k033937

3. Comparison with predicate:

Similarities		
Characteristics	**Elecsys PreciControl Universal**	**Predicate device Elecsys PreciControl MultiAnalyte**
Intended Use	Elecsys® PreciControl Universal is used for quality control of Elecsys® immunoassays on the Elecsys® immunoassay systems.	Elecsys® PreciControl MultiAnalyte is used for quality control of the Elecsys® C-Peptide and Elecsys® Insulin immunoassays on the Elecsys® immunoassay systems.
Levels	Two	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 3.0 mL distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Reconstitute with exactly 2.0 mL distilled water and allow to stand closed for 15 minutes to reconstitute, and then mix gently.
Stability	Unopened: Store at 2 - 8ºC until expiration date Reconstituted (except for Insulin): • 20 - 25ºC: up to 8 hours • on the analyzers at 20 - 25ºC: up to 8 hours • at 2-8ºC: 3 days • at -20ºC: 1 month (freeze only once) Reconstituted Insulin: • on the analyzers at 20 - 25ºC: up to 5 hours • 20 - 25ºC: up to 5 hours • at -20ºC: 1 month (freeze only once)	Unopened: Store at 2 - 8ºC until expiration date Reconstituted: • on the analyzers at 20 - 25ºC: up to 3 hours • at -20ºC: 1 month (freeze only once) • after thawing: use only once

Differences		
Characteristic	**Elecsys PreciControl Universal**	**Predicate device Elecsys PreciControl MultiAnalyte**
Matrix	Human serum with added antigens	Equine serum with added C-Peptide and insulin

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

None were referenced in the submission.

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):

Roche Diagnostics maintains a set of master calibrators for each assay that have values assigned that are traceable to the various method "gold standards." Elecsys® PreciControl products are assayed and compared to these reference preparations and target values and ranges are assigned.

Values are assigned using a total of 12 analyzers e*xcept for hCG; hCG* values were assigned using 8 analyzers. Two independent series of analyses are performed on each instrument for each analyte. Each sample is tested in duplicate. The target value is calculated as the median of the determined values.

Four studies were performed on reconstituted material to verify the stability claims.

Elecsys PreciControl Universal material and reference material are evaluated in triplicate. The Elecsys PreciControl Universal material is stressed. The reference material is an unstressed set of Elecsys PreciControl Universal. One

bottle of Elecsys PreciControl Universal material was used per each stability testing. Each result is reported as the average of three samples. The acceptance criterion is recovery of 90%-110% of the concentration based on unstressed material. The results are presented below.

Stability	**Reconstituted**	
Elecsys PreciControl Universal	***Except for Insulin*** ◦on the analyzers at 20 - 25ºC: up to 5 hours ◦20 - 25ºC: up to 8 hours ◦at 2-8ºC: 3 days ◦at -20ºC: 1 month (freeze only once)	***Insulin*** ◦on the analyzers at 20-25ºC: up to 5 hours ◦20º-25ºC: up to 5 hours ◦-20ºC: 1 month (freeze only once)

Unopened vial stability: 2-8ºC until the expiration date.

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.