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

A. 510(k) Number:

k090541

B. Purpose for Submission:

New device

C. Measurand:
Multiple constituents listed in the package insert

Control material for AFP, Cortisol, DHEAs, Estradiol, FSH, fT3, fT4, hCG, IgE, Insulin, LH, Progesterone, Prolactin, SHBG,T3, T4, Testosterone, Thyroglobulin, TSH, T-Uptake approx, CEA, and tPSA.

D. Type of Test:

Not applicable

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, reserved

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 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:

   Elecsys and cobas e immunoassay analyzers

I. Device Description:

The Elecsys PreciControl Universal is a lyophilized product consisting of added antigens in a human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.
Reagents - working solutions
• PC U1: 2 bottles for 2 x 3.0 mL of control serum (human)
• PC U2: 2 bottles for 2 x 3.0 mL of control serum (human)
Safety data sheet available for professional user on request.
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 initial thyroid glandular tissue extract containing the human thyroglobulin has 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. Disposal of all waste material should be in accordance with local guidelines.

J. Substantial Equivalence Information:

1. Predicate device name:

   Elecsys PreciControl Universal (PCU)

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

   k051687

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 and cobas immunoassay analyzers.	Elecsys PreciControl Universal is used for quality control of the Elecsys immunoassays on Elecsys immunoassay systems.
Reagent Format	Same	Lyophilized, based on human serum in two concentration ranges.
Matrix	Same	Human serum matrix
Handling	Same	Reconstitute with exactly 3.0 mL distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.

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 standards such as WHO, NIST, or in-house developed standards. The Elecsys PreciControl products are assayed and compared to these reference preparations and target values and ranges are assigned.

Each control level was tested on a multiple analyzers using Elecsys reagents. Two series of measurements were performed on each instrument. Samples were tested in duplicate and concentrations were read against the respective master calibrator curve. The target value is then calculated for each analyzer platform and set as the median of the determined values.

The protocols for establishing shelf-life and open-vial stability were reviewed and adequate. An accelerated stability study was performed to simulate a shelf life of 24 months at normal storage conditions of 2-8°C. Data supports the package insert claims that reconstituted Elecsys PreciControl Universal is stable: on the analyzer up to 5 hours at 20-25°C; after thawing, 3 days at 2-8°C; after reconstitution, -20°C for one month. Data supports the package insert claims that insulin within the reconstituted Elecsys PreciControl Universal is stable: on the analyzer up to 5 hours at 20-25°C; and after reconstitution, -20°C for one month. Protocol for real time stability and 9 month data are provided.

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.