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

A. 510(k) Number:
k092320

B. Purpose for Submission:
New device

C. Measurand:
Quality control materials for Thyroid Stimulating Hormone Receptor (TSHR), Thyroperoxidase, (TPO), Thyroglobulin (TG)

D. Type of Test:
The product is used as a quality control serum to monitor the precision of laboratory testing procedures

E. Applicant:
Roche Diagnostics

F. Proprietary and Established Names:
Elecsys PreciControl ThyroAB

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY (Multi-analyte controls)	Class I, reserved	21 CFR§ 862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):
   Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsys and **cobas e** immunoassay analyzers.

2. Indication(s) for use:
   Same as Intended use

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   Elecsys 2010, MODULAR ANALYTICS E170, cobas e 411, cobas e 601

I. Device Description:

The Elecsys PreciControl ThyroAB is a lyophilized product consisting of human serum with added anti-TSHR antibody (human), anti-TPO antibody (sheep) and anti-TG antibody (sheep) in two level ranges each. During manufacture, the antibodies are spiked into the matrix at the desired concentration levels.

Reagents - working solutions

• PC Thyro1: 2 bottles for 2 x 2.0 mL of control serum (human)
• PC Thyro2: 2 bottles for 2 x 2.0 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 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(s):
   Elecsys Anti-TSHR Immunoassay and Elecsys PreciControl ThyroAB

2. Predicate 510(k) number(s):
   k080092

3. Comparison with predicate:

Similarities		
Intended use	Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsys and cobas e immunoassay analyzer.	Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR immunoassay on the Elecsys and cobas e immunoassay analyzers.
Characteristics	Elecsys PreciControl ThyroAB (Candidate device)	Elecsys PreciControl ThyroAB (Predicate device – k080092)
Analyzers	Elecsys and cobas e immunoassay analyzers: - Elecsys 2010 -MODULAR ANALYTICS E170 -cobas e 411 -cobas e 601	Same

Matrix	Human serum	Same
Format	Lyophilized	Same

Differences		
Characteristics	Elecsys PreciControl ThyroAB (Candidate device)	Elecsys PreciControl ThyroAB (Predicate device – k080092)
Analyte concentration	Anti-TSHR (IU/L) Level 1 = 4 Level 2 = 16 Anti-TPO (IU/mL) Level 1 = 35 Level 2 = 100 Anti-TG (IU/mL) Level 1 = 100 Level 2 = 200	Anti-TSHR (IU/L) Level 1 = 4 Level 2 = 16
Antibody source and type	Anti-TSR Human monoclonal Anti-TPO: Sheep polyclonal Anti-TG: Sheep polyclonal	Anti-TSR: Human monoclonal
Stability	Unopened: Store at 2-8^{o}C until expiration date Reconstituted: On the analyzer at 20-25^{o}C up to 5 hrs At -20^{o}C: 1 month (freeze only once) or at 2-8^{o}C for 3 days (for Anti-TPO and Anti-TG only)	Unopened: Store at 2-8^{o}C until expiration date Reconstituted: On the analyzer at 20-25^{o}C up to 3 hrs At -20^{o}C: 3 months (freeze only once) After thawing: use only once.
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes

	for 30 minutes to reconstitute. Mix carefully, avoiding formation of foam.	to reconstitute. Mix carefully, avoiding formation of foam.

K. Standard/Guidance Document Referenced (if applicable):
None were 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):

Roche Diagnostics maintains a set of master calibrators for each assay that have values assigned that are traceable to the National Institute of Biological Standard and Control (NIBSC) standards. The Elecsys PreciControl products are assayed and compared to these reference preparations and target values and ranges are assigned. Anti-TSHR is standardized against NIBSC 1st IS 60/972 Standard. Anti-TPO is standardized against the NIBSC 66/387 Standard. Anti-TG is standardized against the NIBSC 65/93 Standard.

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 15 months at normal storage conditions of 2-8°C. Reconstituted Elecsys PreciControl ThyroAB for anti-TPO and anti-TG is stable: one month at -20°C, 3 days at 2-8°C and up to 5 hours at 20-25°C. Reconstituted Elecsys PreciControl ThyroAB for anti-TSHR is stable: one month at -20°C and up to 5 hrs at 20-25°C. Protocol for real time stability and 15 month data are provided. Shelf life will be increased to 18, 21 and 24 months after stability data at additional time points is available.

Each control level was tested on a total of twelve Elecsys immunoassay analyzers (4 Elecsys 1010 analyzers, 4 Elecsys 2010/cobas e 411 analyzers, and 4 Elecsys MODULAR ANALYTICS E170/cobas e 601 analyzers) using Elecsys reagents.
Samples were assayed in two independent series using duplicate testing on each analyzer for each analyte. The target value for each analyte in the

PreciControl material is calculated from 8 measurements of each of the respective PreciControl.

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 presented in the labeling.

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.