

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k103171

B. Purpose for Submission:

Modified device (from liquid to lyophilized material)

C. Measurand:

Calibrator for Thyroid Autoantibody

D. Type of Test:

Not Applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys® Anti-TPO CalSet

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX: Calibrator, Multi-analyte Mixture	Class II	21 CFR § 862.1150, Calibrator	Chemistry (75)

H. Intended Use:

1. Intended use(s):

Elecsys® Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay 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 Analyzer (k961481)

MODULAR ANALYTICS E170 (k961481/A003)

Cobas e 411 Analyzer (k062279)

Cobas e 601 Analyzer (k060373)

I. Device Description:

The Elecsys® Anti-TPO CalSet is a lyophilized product consisting of sheep anti-TPO antibodies in a human serum matrix in two concentration ranges (approximately 35 IU/mL and 350 IU/mL). The CalSet includes a barcode card, calibrator barcode sheet, 4 empty labeled snap-cap bottles, 2X6 bottle labels. The exact lot-specific calibrator values are encoded in the barcode as well as printed in the enclosed (or electronically available) calibrator barcode sheet. The CalSet package consists 4 bottles (reconstitution volume: 1.5 mL/ bottle): 2 bottles for calibrator 1, and 2 bottles for calibrator 2, and can be used with all reagent lots.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Elecsys[®] Anti-TPO test system [Includes the calibrator, Elecsys Anti-TPO CalSet (liquid form)]
2. Predicate 510(k) number(s):
k051890
3. Comparison with predicate:

Similarities		
Item	New Device	Predicate Device
	k103171	k051890
	Elecsys [®] Anti-TPO CalSet	Elecsys [®] Anti-TPO test system (includes the Anti-TPO CalSet calibrator)
Technology	Electrochemiluminescence	Same
Analyte	Anti-TPO antibodies (sheep)	Same
International Reference standard material	Traceable to NIBSC (National Institute for Biological Standards and Controls) 66/387 International Standard	Same
Matrix	Human serum	Same
Levels and Corresponding Concentrations	Two Calibrator 1: approx. 35.0 IU/mL Calibrator 2: approx. 350 IU/mL	Same

Differences		
Item	New Device	Predicate
	k103171	k051890
	Elecsys [®] Anti-TPO CalSet	Elecsys [®] Anti-TPO test system (includes the Anti-TPO CalSet calibrator)
Intended Use	Elecsys Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and cobas e immunoassay analyzers.	The Elecsys Anti-TPO immunoassay is for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.

Differences		
Item	New Device	Predicate
Calibrator Material Form (Format)	Lyophilized	Liquid
Stability and storage	<p><u>Unopened:</u></p> <ul style="list-style-type: none"> Store at 2-8°C until expiration date <p><u>Reconstituted:</u></p> <ul style="list-style-type: none"> at 2-8°C: 7 days at -20 °C: 8 weeks (freeze only once) on the analyzers at 20-25 °C: use only once 	<p><u>Unopened:</u></p> <ul style="list-style-type: none"> Store at 2-8°C until expiration date <p><u>Opened:</u></p> <ul style="list-style-type: none"> at 2-8°C: 6 weeks at 20-25 °C on Elecsys 1010/2010: up to 5 hours MODULAR ANALYTICS E170: use only once
Analyzer	Roche Elecsys 2010, MODULAR ANALYTICS E170 (Elecsys module), and cobas e immunoassay platforms (cobas e 411 and cobas e 601 analyzers).	Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.
Handling	<p>Dissolve carefully the contents of one bottle by adding exactly 1.5 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottles supplied.</p> <p>Elecsys 2010 and cobas e 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25°C. Perform only one</p>	<p>The reagents in the kit are ready for use and supplied in the bottles compatible with the system.</p> <p>Elecsys 1010/2010 analyzers: The Elecsys calibrators Cal1 and Cal2 and the Elecsys controls PC A-TPO1 and PC A-TPO2 should only be left on the analyzers at 20-25°C during calibration/quality control. After use, close the bottles as soon as possible and store at 2-8°C.</p> <p>Ensure that no calibration</p>

Differences		
Item	New Device	Predicate
	<p>calibration procedure per aliquot. If necessary, freeze in aliquots; see section on MODULAR ANALYTICS E170 and cobas e 601 analyzers.</p> <p>MODULAR ANALYTICS E170 and cobas e 601 analyzers: Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the reconstituted calibrator into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots for later use at -20°C. Perform only one calibration procedure per aliquot.</p>	<p>and control solution is trapped in the opened snap-cap. Because of possible evaporation effects, not more than 5 calibration/quality control procedures per bottle set should be performed.</p> <p>MODULAR ANALYTICS E170 analyzer: Unless the entire volume is necessary for calibration and quality control on the analyzer, transfer aliquots of the ready-for-use calibrators and controls into empty snap-cap bottles (CalSet Vials/Control Set Vials). Attach the supplied labels to these additional bottles. Store the aliquots for later use at 2-8°C. Perform only one calibration or control procedure per aliquot.</p> <p>All information required for correct operation is read in via the respective reagent barcodes.</p>
Packaged and sold	Packaged and sold separately	Packaged as part of the Elecsys [®] Anti-TPO Test System

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

Not applicable

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):*

The calibrator is traceable to the reference material NIBSC (National Institute for Biological Standards and Controls) 66/387 International Standard.

Stability

Studies for unopened lyophilized, opened reconstituted and opened on-board stability testings supports the following CalSet expiration date claims:

Unopened calibrator lyophilized bottles: 18 months at 2-8°C (real time stability testing is on-going to support future 36 months claim)

Opened reconstituted calibrator: 7 days at 2-8°C; 8 weeks (freeze only once) at -20 °C; and use only once on the analyzers at 20-25 °C up to 5 hours.

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 and specificity:*

Not applicable.

b. *Other clinical supportive data (when a. is 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.