

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

A. 510(k) Number:

k080643

B. Purpose for Submission:

Notification of intent to manufacture and market new devices for the verification of calibration of Anti-TSHR on the Elecsys and Cobas e.

C. Measurand:

Control material for Anti-Thyroid-Stimulating Hormone Receptor

D. Type of Test:

Quality Control for the Elecsys Anti-TSHR test system

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Proprietary – Elecsys Anti-TSHR CalCheck
Established – Quality Control

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJX

4. Panel:

75

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

For use in the verification of calibration established by the Elecsys Anti-TSHR reagent on the indicated Elecsys and cobas e immunoassay analyzers.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

For use on the Elecsys and cobas e immunoassay analyzers.

I. Device Description:

The Elecsys Anti-TSHR CalCheck is a lyophilized product consisting of human anti-TSHR antibodies in human serum matrix. During manufacture, the antibody is spiked into the matrix at the desired concentration levels. The control material is provided at three levels of 1ml each.

All components of the control are tested individually and shown to be free of HBsAG and antibodies to HCV and HIV. The testing methods used were FDA approved or cleared with the European Directive 98/79/EC Annex II List A.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys C-Peptide CalCheck

2. Predicate K number(s):

k040157

3. Comparison with predicate:

Similarities		
Characteristic	Predicate device Elecsys C-Peptide CalCheck	Elecsys Anti-TSHR CalCheck
Intended Use	For use in the verification of the calibration established by the Elecsys C-Peptide reagent on the indicated Elecsys and cobas e immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys Anti-TSHR reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Levels	Three	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mixing gently.	Same

Differences		
Feature	Predicate	New Device
Stability	<u>Unopened:</u> <ul style="list-style-type: none"> • Store at 2-8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none"> • 20 – 25 °C : 4 hrs 	<u>Unopened:</u> <ul style="list-style-type: none"> • Store at 2-8°C until expiration date <u>Reconstituted:</u> <ul style="list-style-type: none"> • 15 - 25 °C : 5 hrs
Matrix	equine serum matrix	Human serum matrix

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

None 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):*

Traceability: Standardized against NIBSC 1st IS 90/672 Standard

Value Assignment: Values are assigned using a minimum of three Elecsys 2010 / cobas e 411 and three MODULAR ANALYTICS E170 / cobas e 601 Immunoassay Analyzers. Six independent series of analyses are performed on each instrument platform. The target value is calculated as the median of the determined values. Approximate target values are found in the following table. Lot-specific target values may differ slightly after value assignment.

Anti-TSHR CalCheck Level	Anti-TSHR Target Values (IU/L)
Check 1 (low)	< 1.0
Check 2 (medium)	10
Check 3 (high)	38

Stability: Stability testing protocols and acceptance criteria were described and found to be acceptable. The CalCheck is stable until the expiration date printed on the vial when stored unopened at 2 – 8° C. Reconstituted vials are stable for five hours at 15 - 25°C.

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.