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

A. 510(k) Number:

k093836

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for TSH (thyroid stimulating hormone)

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys TSH CalCheck 5

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 - Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   The Elecsys TSH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys TSH reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

3. Special conditions for use statement(s):

   - Not intended to be used as a primary calibrator or routine control material
   - For *in vitro* diagnostic use
   - For prescription use only

4. Special instrument requirements:

   The labeling states that the CalChecks are for use with the Elecsys TSH reagent on the Elecsys 2010/cobas e411 and Modular Analytics E170/cobas e601 test systems.

I. Device Description:

The Elecsys TSH CalCheck 5 is a lyophilized product consisting of human TSH in equine serum matrix. During manufacture, the TSH is spiked into the matrix at the target concentrations listed below.

Elecsys TSH CalCheck level	**Target Value (µg/mL)**
Level 1	< 0.1
Level 2	2
Level 3	50
Level 4	83
Level 5	100

The human source materials were 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Elecsys CalCheck TSH

2. Predicate K number(s):

   k963147

3. Comparison with predicate:

Characteristic	Elecsys CalCheck TSH (k963147)	Elecsys TSH CalCheck 5
Indications for use	Verification of the calibration curve established by the Elecsys TSH reagents	Same
Intended Use	Elecsys CalCheck TSH is intended for use in the quantitative verification of the calibration curve established by the Elecsys TSH reagents and calibrators on Elecsys 1010 and 2010 immunoassay analyzers.	The Elecsys TSH CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys TSH reagent on the indicated Elecsys **cobas e** immunoassay analyzers.
Analyzers	Elecsys 1010 and 2010	Elecsys cobas e
Levels	Three	Five
Format	Lyophilized	Same
Handling	Reconstitute the contents of Check 1, Check 2 and Check 3 with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Stability	Unopened: • Store at 2-8^{o}C until expiration date Reconstituted: • 20 – 25^{o}C : 4 hrs	Same
Matrix	Equine serum matrix	Same

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 and value assignment
Elecsys TSH CalCheck 5 is standardized using internally produced master calibrators which are traceable to the World Health Organization's Second International Reference Preparation (WHO 2nd IRP 80/558) human recombinant standardization material.

Value assignment testing is conducted and pre-defined acceptance criteria are applied. Specifically, each of the five CalCheck levels is value assigned using a minimum of three Elecsys 2010/cobas e411 analyzers and MODULAR ANALYTICS E170/cobas e 601 analyzers. Each sample is tested in duplicate. The target value for each CalCheck is the median of the observed values.

The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability
Real time and accelerated stability testing protocols and acceptance criteria were described and found to be adequate. CalCheck 5 is stable for 24 months when stored unopened at 2 – 8° C. The reconstituted vials are stable up to four hours at 20-25°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:

The expected values are provided in the labeling for each specific lot.

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.