

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

A. 510(k) Number:

k103221

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and assayed control materials for human growth hormone (hGH)

D. Type of Test:

Calibrator and quality control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

The Elecsys hGH CalSet

The Elecsys hGH CalCheck 5

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT	Class II	21 CFR 862.1150 Calibrator	Clinical Chemistry (75)
JJX	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) for use:

Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and cobas e immunoassay analyzers.

The Elecsys hGH 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 hGH reagent on the indicated Elecsys and cobas e immunoassay analyzers.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Elecsys and cobas e immunoassay analyzers including the Elecsys 2010, MODULAR ANALYTICS E170, **cobas e 411**, **cobas e 601**, and **cobas e 602** analyzer platforms.

I. Device Description:

The Elecsys hGH CalSet and hGH CalCheck 5 are lyophilized products consisting of human growth hormone (hGH) in human serum matrix. The sponsor declared in the labeling that 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.

During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Target Values and Ranges for Elecsys hGH CalSet

Level	Target Value (ng/mL)
Calibrator 1	0.00
Calibrator 2	10.00

Target Values and Ranges for Elecsys hGH CalCheck 5

Level	Target Value (ng/mL)	Target Range (ng/mL)
Check 1	≤ 0.09	≤ 0.09
Check 2	10	9-11
Check 3	25	22-28
Check 4	40	36-44
Check 5	48	46-50

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys C-Peptide CalSet; Elecsys C-Peptide CalCheck 5

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

Elecsys C-Peptide CalSet (k033873)

Elecsys C-Peptide CalCheck 5 (k100810)

3. Comparison with predicate:

Characteristic	Elecsys hGH CalSet (New Device)	Elecsys C-Peptide CalSet (Predicate Device) k033873
Similarities		
Intended Use/ Indications for use	Same	Used for calibrating the quantitative Elecsys assay on the Elecsys and cobas e immunoassay analyzers
Format	Same	Lyophilized
Levels	Same	2
Handling	Same	Reconstitute with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Unopened Stability	Same	Store at 2-8°C until expiration date
Differences		
Analyte	Human growth hormone (hGH)	C-Peptide
Matrix	Human serum matrix	Equine serum matrix
Reconstituted Stability	-20°C: 28 days (freeze only once) On MODULAR ANALYTICS E170, cobas e 601, and cobas e 602: Perform only one calibration procedure per aliquot. On Elecsys 2010 and cobas e 411 (20-25°C): Perform no more than 5 calibration procedures per bottle set, up to 5 hours.	-20°C: 1 month (freeze only once) On analyzers (20-25°C): Perform only one calibration procedure per aliquot.

Characteristic	Elecsys hGH CalCheck 5 (New Device)	Elecsys C-Peptide CalCheck 5 (Predicate Device) k100810
Similarities		
Intended Use/Indications for use	Same	Assayed quality control material for use in calibration verification and verification of the assay range established by the Elecsys reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Format	Same	Lyophilized
Levels	Same	5
Handling	Same	Reconstitute with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Stability	Unopened: • Same Reconstituted: • 20-25°C: 5 hours	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 4 hours
Differences		
Analyte	Human growth hormone (hGH)	C-Peptide
Matrix	Human serum matrix	Equine serum matrix

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):

Traceability

The Elecsys hGH CalSet and CalCheck 5 are traceable to the NIBSC 98/574 international standard.

Value Assignment:

The Elecsys hGH CalSet assigned values are determined with the Elecsys hGH assay. A master calibrator set is available and traceable to NIBSC 98/574. The assigned values for Elecsys hGH CalSet are read from the master calibration curve. Kit Calibrator (CalSet) values are assigned for each instrument platform (Elecsys 2010/cobas e 411 and E170/cobas e 601/cobas e 602). The assigned lot-specific value is the median over a minimum of 6 measurements (two runs on each analyzer, minimal of 3 analyzers of each instrument platform).

For each Elecsys hGH CalCheck 5 lot manufactured, the CalChecks are assayed in duplicate on at least three E170 analyzer measuring cells. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range is $\pm 30\%$ of assigned value, in which 10% was allotted for between-analyzer platform tolerance, 10% for stability tolerance and 10% for precision of the assay. For additional analyzers, the same value assignment procedure is performed.

Stability:

The stability study for CalSet was performed on **cobas e 411**. The stability study for CalCheck was performed on **E170**. The stability protocol and the acceptance criteria have been reviewed and found to be acceptable.

- Shelf-life stability:
The accelerated stability testing at 35°C supports an initial shelf-life claim of 18 months at 2-8°C for CalSet and CalCheck. Real-time testing at 2-8°C is on-going.
- Stability after reconstitution and freeze/thaw cycles:
Real time testing was performed and supports the following claims:
Reconstituted Elecsys hGH CalSet is stable for up to 7 days at 2 to 8°C; up to 28 days at -15 to -25°C and 1 freeze/thaw cycle.
Reconstituted Elecsys hGH CalCheck 5 is stable for up to 5 hours at 20-25°C.
- On-board stability:
Real-time testing supports on-board stability of reconstituted CalSet for up to 5 hours at 20-25°C.
The CalCheck products are not stored on-board the analyzer, therefore no on-board stability claims are made.

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.