

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

A. 510(k) Number:

k103402

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for Dehydroepiandrosterone Sulfate (DHEA-S).

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys DHEA-S CalCheck 5

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1660, Quality Control Material
2. Classification:
Class I, reserved
3. Product code:
JJX - Single (Specified) Analyte Controls
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
The Elecsys DHEA-S 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 DHEA-S 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:

Elecsys 2010/cobas e411 and Modular Analytics E170/cobas e601/cobas e602 immunoassay analyzers.

I. Device Description:

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

Elecsys DHEA-S CalCheck level	Target Value [$\mu\text{g/dL}$]
Level 1	≤ 2
Level 2	100
Level 3	500
Level 4	800
Level 5	1000

The human source materials were prepared exclusively from the blood of donors tested individually and shown to be negative for 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 C-Peptide CalCheck 5

2. Predicate K number(s):

k100810

3. Comparison with predicate:

Characteristic	Elecsys DHEA-S CalCheck 5	Elecsys C-Peptide CalCheck 5 (k100810)
Intended Use	Elecsys CalCheck DHEA-S is intended for use in the quantitative verification of the calibration curve established by the Elecsys DHEA-S reagents and calibrators on Elecsys and cobas e immunoassay analyzers.	Same
Analyte	DHEA-S	C-Peptide
Analyzers	Elecsys 2010, Modular Analytics 170, cobas e 411, cobas e 601 and cobas e 602	Elecsys 2010, Modular Analytics 170, cobas e 411, and cobas e 601
Levels	Five	Same
Format	Lyophilized	Same
Handling	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.	Same
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 	Same
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 and value assignment

DHEA-S is of synthetic origin and purchased from a commercially available source. The Elecsys DHEA-S CalCheck 5 is traceable to internal master calibrators where DHEA-S has been added gravimetrically into human serum matrix.

Value assignment testing is conducted and must pass pre-defined acceptance criteria. 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 for total of at least 6 measurements (duplicate runs on at least 3 analyzers). The target value for each CalCheck is the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range is calculated as $\pm 24\%$ of the assigned value for levels 3-5 and $\pm 30\%$ of the assigned value for level 2. The % CV is 4% for levels 3-5 and 10% for level 2. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

To ensure the values assigned using the master platform are transferrable and valid for the other instrument platforms, each Elecsys DHES-A CalCheck 5 level is assayed once a day on 8 Elecsys 2010 / cobas e 411 and 8 MODULAR ANALYTICS E170/cobas e 601/cobas e 602 analyzers. The median value for the 8 analyses must be within 10% of the master platform assigned value (10% for between analyzer platform tolerances). After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the Elecsys 2010 / cobas e 411 and MODULAR ANALYTICS E170/cobas e 601/cobas e 602 immunoassay analyzers.

Stability

Real time and accelerated stability testing protocols and acceptance criteria were described and found to be adequate. CalCheck 5 is stable for 18 months when stored unopened at 2 – 8° C. The expiration date listed on each CalCheck bottle label reflects this stability time of 18 months. The reconstituted vials are stable up to four hours at 20-25°C, as supported by the data and stated in the label.

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.