

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

A. 510(k) Number:

k110613

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for Prolactin

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Prolactin II 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 (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Elecsys Prolactin II 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 Prolactin II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

3. Special conditions for use statement(s):

The Elecsys Prolactin II CalCheck 5 is not intended to be used as a primary calibrator or routine control material.

4. Special instrument requirements:

The labeling states that the Elecsys Prolactin II CalCheck 5 are for use with the Elecsys Prolactin II reagent on the Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601, and **cobas e** 602 test systems

I. Device Description:

The Elecsys Prolactin II CalCheck 5 is a lyophilized product consisting of prolactin in an equine serum matrix. During manufacture, the analyte is spiked at the target concentrations listed below.

Level	Target Value [μIU/mL]
Check 1	< 10
Check 2	500
Check 3	5000
Check 4	7500
Check 5	10000

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys DHEA-S CalCheck 5

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

k103402

3. Comparison with predicate:

Characteristic	Elecsys Prolactin II CalCheck 5 (Candidate Device)	Elecsys DHEA-S CalCheck 5 (K103402)
Intended Use	The Elecsys Prolactin II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the assay on the indicated Elecsys and cobas e immunoassay analyzers.	Same
Analyte	Prolactin	DHEA-S
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 hours	<u>Unopened:</u> <ul style="list-style-type: none">• Same <u>Reconstituted:</u> <ul style="list-style-type: none">• Same
Matrix	Equine serum matrix	Human 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

CalCheck 5 is standardized using internally produced master calibrators which are traceable to the 3rd IRP WHO 84/500 international standard.

Each of the five CalCheck levels is value assigned using a minimum of three **cobas e 601**. Each sample is tested in duplicate. The target value for each CalCheck is the median of the observed values.

The sponsor experimentally confirmed the values assigned were transferrable to Elecsys 2010/cobas e 411 analyzers. For Elecsys 2010/cobas e 411 analyzers, the same value assignment procedure was performed. The assigned values obtained on these additional analyzers were shown to meet the same acceptance criteria as the E170/e 601/e 602. Additionally, the acceptance criteria for differences between the master platform and additional analyzer platforms (e) were also met. Therefore, the values assigned to the cobas e 601 analyzer/s are transferred and valid for the Elecsys 2010 analyzer/s.

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 until the expiration date printed on the vial when stored unopened at 2 – 8° C. The reconstituted vials are stable for four hours at 20-25°C. The real time studies are ongoing.

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.