

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k102086

B. Purpose for Submission:

New Device

C. Measurand:

Calibration verification and assay range verification material for CA 125

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys CA 125 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):
The Elecsys CA 125 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 CA 125 II assay reagent on the indicated Elecsys and cobas e immunoassay analyzers. For *in vitro* diagnostic use only.
2. Indication(s) for use:
Same as intended use
3. Special conditions for use statement(s):
Prescription use only.
4. Special instrument requirements:
For use with Elecsys CA 125 II assay reagent on the Elecsys 2010, MODULAR ANALYTICS E170, cobas e 601, and cobas e 411

I. Device Description:

The Elecsys CA 125 II CalCheck 5 set contains one lyophilized level of equine serum and four lyophilized levels of CA 125 II antigen in human serum matrix. During manufacture, the analyte is spiked into the matrix at the target concentrations. CalCheck Level 1 is free of analyte. Sponsor recommends using Check level 2, 3 and 4 for calibration verification only; and Check 1, 2, 3, 4 and 5 for verification of the assay range only or verification of the assay range and calibration verification. Target values and approximate concentration target ranges are listed below:

Level	Target Value[U/mL]	Approximate Target Range [U/mL]
Check 1	≤ 3.00	≤ 3.00
Check 2	35.0	27.7 - 42.4
Check 3	2500	1975 - 3025
Check 4	4000	3160 - 4840
Check 5	5000	3950 - > 5000

All human source materials were prepared exclusively from the blood of donors tested individually and found to be free from HBsAg, antibodies to HCV and HIV. The testing methods 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 CA 125 II CalCheck
2. Predicate 510(k) number(s):
k003967
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Elecsys CA 125 II CalCheck 5	Elecsys CA 125 II CalCheck
Intended Use	The Elecsys CA 125 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 CA 125 II quantitative assay reagent on the indicated Elecsys and cobas e immunoassay analyzers. For <i>in vitro</i> diagnostic use only.	Same
Analyte	CA 125	Same
Format	Lyophilized	Same
Handling	Reconstitute each level of CalCheck 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> Store at 2-8°C until expiration date <u>Reconstituted:</u> 4 hours at 20-25°C	Same
Matrix	Level 1: Equine serum Other levels: Human serum matrix	Same
Measuring range	0.6-5000 U/mL	Same

Differences		
Item	Device	Predicate
	Elecsys CA 125 II CalCheck 5	Elecsys CA 125 II CalCheck
Levels	Five	Three
Check Target Values	Check 1: ≤ 3 U/mL Check 2: 35 U/mL Check 3: 2500 U/mL Check 4: 4000 U/mL Check 5: 5000 U/mL	Check 1: 0.6 U/mL Check 2: 1500 U/mL Check 3: 4500 U/mL

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

Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

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 sponsor claims the assayed value of each CalCheck level was standardized against the Enzymun-Test CA 125 II method. This assay was in turn calibrated against CA 125 II RIA from Fujirebio.

Value assignment:

For each Elecsys CA 125 II CalCheck 5 kit manufactured, value assignment for each level was tested once a day on two Modular Analytics E170 analyzers for a total of eight runs on two days. The Modular Analytics E170 master calibration curve was used to calculate U/mL from counts. The assigned target value of each CalCheck is the median of the observed values. The assigned values and assigned range for lot that was used in the submission on the E170 are listed below.

Level	Target Value [U/mL]	Assigned Value [U/mL]	Assigned Range
Check 1	≤ 3	≤ 3	-
Check 2	35	31.2	24.6 – 37.8
Check 3	2500	2440	1928 – 2952
Check 4	4000	3870	3057 – 4683
Check 5	5000	4840	3824 - 5856

Additionally, the same value assignment procedure was performed on the

Elecsys 2010 analyzers. The assigned values obtained on the Elecsys 2010 analyzers were compared to those obtained on the E170. Results showed that the values assigned to the E170 are valid for the Elecsys 2010.

The labeling states that obtained values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability:

Stability studies were performed in order to verify the stability claims for the Elecsys CA 125 II CalCheck 5.

Open vial stability:

One Elecsys CA 125 II CalCheck 5 lot was evaluated in duplicate on the Elecsys E170. The test material was reconstituted and stored for 4 hours at 20-25°C (in an open vial). The reference material was a freshly reconstituted set of CalChecks. The recovery of test material was calculated as a percent of the reference value. The data support the claimed stability - Elecsys CA125 II CalCheck 5 is stable up to 4 hours at 20-25°C.

On-Board Stability:

Not applicable

Accelerated stability:

One Elecsys CA 125 II CalCheck 5 lot was evaluated in duplicate on the Elecsys E170. The test material was stored lyophilized at 35°C for 3 weeks. The reference material was a freshly reconstituted set of CalChecks (stored at 2-8°C). After 3 weeks, the test and reference materials were tested in duplicate. The recovery of test material was calculated as a percent of the reference value.

Real time stability:

The real time stability is on-going. The test material is stored at 2-8°C. Sample at time-points at 0, 13, 19 and 37 months will be tested in duplicate and the recovery value will be calculated by comparing to the unstressed reference value (stored at -20°C).

The results from the Accelerated stability and on-going Real time stability support an initial shelf-life claim of 18 months when the Elecsys CA 125 II CalCheck 5 is stored under normal storage conditions of 2-8°C.

c. *Dilution Study:*

A study is suggested in the package insert to analyze diluted samples in the event CalCheck level 1 or 5 produce results that exceed the reportable measuring range of the assay. To demonstrate that the values are within the assay's measuring range of 0.6 U/mL – 5000 U/mL, the dilution study was performed. Check 1&2 and Check 4&5 were mixed in a 1:1 ratio and measured in duplicates. Results are summarized in the following table and both CalCheck dilution values are within the assay's measuring range after dilution.

Sample	Value after 1:1 Dilution [U/mL]	Average 1:1 Dilution [U/mL]
E170/e 601		
Check 1 + Check 2	16.8	16.5
Check 1 + Check 2	16.3	
Check 4 + Check 5	4520	4475
Check 4 + Check 5	4430	
2010/e 411		
Check 1 + Check 2	17.2	16.6
Check 1 + Check 2	16.1	
Check 4 + Check 5	4397	4456
Check 4 + Check 5	4515	

- e. *Detection limit:*
Not applicable
 - f. *Analytical specificity:*
Not applicable
 - g. *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 a value sheet 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.