510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k140112

B. Purpose for Submission:

New Device

C. Measurand:

Calibration material for human CA 125

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostic

F. Proprietary and Established Names:

CA 125 II CalSet II

G. Regulatory Information:

1. Regulation section:

   21 CFR§862.1150, Calibrator

2. Classification:

   Class II

3. Product code:

   JIT – Calibrator, Secondary

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II assay on the Elecsys and **cobas e** immunoassay analyzers.

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 411, cobas e 601, and cobas e 602 immunoassay analyzers.

   Note: cobas e 411 share the same analytical core as Elecsys 2010; cobas e 601, and cobas e 602 share the same analytical core as E170.

I. Device Description:

CA 125 II CalSet II consists of lyophilized equine serum matrix (CA 125 II Cal1) and human serum matrix with added human CA 125 antigen (CA 125 II Cal2). The device contains the following materials:

- CA 125 II Cal1: 0 U/mL human CA 125 in an equine serum matrix with preservative, 2 bottles (1.0 mL/bottle after reconstitution)
- CA 125 II Cal2: ~500 U/mL human CA 125 in human matrix with preservative, 2 bottles (1.0 mL/bottle after reconstitution).

The exact lot specific calibrator values are encoded in the barcode as well as printed on the enclosed (or electronically available) calibrator barcode sheet.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Elecsys CA 125 II CalSet (k003969)

2. Comparison with predicate:

Similarities		
Item	Device CA 125 II CalSet II	Predicate Elecsys CA 125 II CalSet
Intended Use	For calibrating the quantitative Elecsys CA 125 II assay on the Elecsys and cobas e immunoassay analyzers	Same
Analyte	CA 125	Same
Matrix	Cal2: Human serum	Same
Levels	Two	Same
Target ranges	Cal2: 500 U/mL	Same
Analyzer	Elecsys 2010, MODULAR ANALYTICS 170, cobas e 411, cobas e 601, and cobas e 602	Same
Stability–Unopened	Store at 2-8°C until expiration date	Same
Stability – On-board	On Elecsys 2010/cobas e 411: 20 – 25°C: 5 hours On MODULAR ANALYTICS E170, cobas e 601 and cobas e 602: 20 – 25°C: Use only once.	Same

Differences		
Item	Device CA 125 II CalSet II	Predicate Elecsys CA 125 II CalSet
Format	Lyophilized	Liquid
Matrix	Cal1: Equine serum	Cal1: Human serum
Target ranges	Cal1: 0 U/mL	Cal1: 35 U/mL
Stability – Reconstituted	2 – 8°C: 12 weeks -20°C: 20 weeks (freeze only once)	2-8°C: 12 weeks
Handling Instruction	Reconstituted volume: 1 mL Reconstituted time: 15 minutes	Ready to use

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

None

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:

There is no international standard available for CA 125. The Elecsys CA 125 II assay has been standardized against the Boehringer Mannheim Enzymun Test CA 125 II method. This in turn was standardized against the CA 125 II RIA from Fujirebio Diagnostics.

Value Assignment:

For each Elecsys CA 125 II CalSet II manufactured, the calibrators are run in duplicate on at least three (3) cobas e 411 analyzers and at least three (3) Modular Analytics E170 analyzers with all the CA 125 II assay reagent lots available at that time using the master calibrators as the reference values. The assigned value of each calibrator is defined as the median value obtained over at least six (6) runs on at least three (3) analyzers of the respective calibrator.

The target value and target range for CA 125 II CalSet II is shown in the following table:

Level	Target Value (U/mL)	Target Range (U/mL)
Calibrator 1	0	<1500 counts
Calibrator 2	500	450-550

Stability:

Stability studies were performed on cobas e 411 in order to verify the stability claims for the Elecsys CA 125 II CalSet II. For each study, both the test and reference materials were tested in duplicate and the acceptance criteria that the value for test material is within 93 – 107% of the reference value.

Open vial (after reconstitution) stability: Stability of the Elecsys CA 125 II CalSet II

after reconstitution was evaluated. The test materials were reconstituted and kept in closed vials at storage condition: 2 – 8°C for 15 weeks, and -15 to -25°C for 21 weeks (with or without freeze/thaw cycles). A freshly reconstituted CalSet was used as the reference material for the study. The results support the following stability claim for the reconstituted CA 125 II CalSet: 12 weeks at 2 – 8°C, 20 weeks at -15 to -25°C with one freeze/thaw cycle.

Open vial/On-board stability: The test material was reconstituted and tested when stored at 20 – 25°C for six hours in open vial. A freshly reconstituted set of CalSet II was used as reference. The results support the claimed stability: CA 125 II CalSet II is stable up to five hours at 20-25°C.

According to the sponsor, the reconstituted calibrators should only be left on the Elecsys 2012 and cobas e 411 analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store upright at 2 – 8°C. For MODULAR ANALYTICS, cobas e 601 and cobas e 602 analyzers, CA 125 II CalSet II should only be used once.

Closed vial stability: The stability for the CA 125 II CalSet II was evaluated with both the accelerated and an on-going real-time stability study. For the real time stability study, three lots of test materials are stored at 2 – 8°C. Samples at time-points 0, 3, 6, 9, 12, 13, 19, 25, and 31 months are tested and the recovery value is calculated by comparing to the value from the reference material (stored at -20°C). For the accelerated stability study, the on-test material was stored at 35°C for three weeks; the value of testing material was evaluated by comparing to the value of the reference. The results generated from the on-going real-time stability studies support a claim of 12 months when the CA 125 II CalSet II is stored at 2-8°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 and Specificity:

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.