

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

A. 510(k) Number:

k101365

B. Purpose for Submission:

New Device

C. Measurand:

Calibration verification and assay range verification material for CA 19-9

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys CA 19-9 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 19-9 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 19-9 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):
For prescription use only. The Elecsys IgE CalCheck 5 is not intended to be used as a primary calibrator or routine control material.
4. Special instrument requirements:
Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 411

I. Device Description:

The Elecsys CA 19-9 CalCheck 5 kit consist of 5 levels of human CA 19-9, each with the appropriate lyophilized level of human CA 19-9 in human serum matrix. During manufacture, the analyte CA 19-9 is spiked into the matrix at the desired concentration levels. Level 1 contains no analyte. Sponsor recommends using Check levels 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	-
Check 2	35	27.7 - 42.4
Check 3	500	395 - 605
Check 4	800	362 - 968
Check 5	1000	790 - > 1000

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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Elecsys CA 19-9
2. Predicate 510(k) number(s):
k050231
3. Comparison with predicate:

	New Device	Predicate
Item	Elecsys CA 19-9 CalCheck 5	Predicate Elecsys CA 19-9 CalCheck
Similarities		
Intended Use	The Elecsys CA 19-9 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 19-9 quantitative assay reagent on the indicated Elecsys and cobas e immunoassay analyzers, for in vitro diagnostic use only.	Same
Format	Lyophilized	Same
Handling	Reconstitute 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> : 20-25°C: 4 hours	Same
Analyte	CA 19-9	Same

Assay Measuring Range	0.600 – 1000 U/mL	Same
Matrix	Human serum matrix	Same
Differences		
Check Target Values	Check 1: ≤ 3 U/mL Check 2: 35 U/mL Check 3: 500 U/mL Check 4: 800 U/mL Check 5: 1000 U/mL	Check 1: < 5 U/mL Check 2: 179 U/mL Check 3: 676 U/mL

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

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

L. Test Principle:

Per sponsor: Calibration verification is not a requirement of the Elecsys and cobas e immunoassay systems based on the manufacturer’s recommendations.

However, in instances where such a test procedure is required by certification agencies, or where the user wishes to document calibration verification, these CalCheck 5 solutions provide an appropriate material for such testing.

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 CA 19-9 CalCheck 5 was initially standardized against the Enzymun Test CA 19-9.

Value assignment:

The five levels of the CalCheck 5 kit are assigned based on the measuring range of the assay. Samples were run in duplicates on 4 E170 analyzers for a total of 8 runs on 2 days, and on 3 Elecsys 2010 analyzers on one day and 4 Elecsys 2010 analyzers on one day for a total of 7 runs on 2 days. The Modular Analytics E170 master calibration curve is used to calculate U/mL from counts. The table below summarizes the assigned values and ranges for Elecsys CA 19-9 CalCheck 5 lot that was used in this submission on the E170:

Level	Target Value [U/mL]	Assigned Value [U/mL]
Check 1	≤ 3	<5
Check 2	35	30.7
Check 3	500	460
Check 4	800	746
Check 5	1000	955

Stability:

Opened-vial and accelerated stability studies were completed on the MODULAR ANALYTICS E170.

Open Vial Stability:

One lot of Elecsys CA 19-9 CalCheck 5 (Check 1-5) was evaluated in duplicate on the E170. The test material was reconstituted and stored for 4 hours at 25°C and compared to reference material that was a freshly reconstituted set of CalChecks. The claimed stability for reconstituted Elecsys CA 19-9 CalCheck 5 is up to 4 hours at 20-25°C.

On-Board Stability

Not applicable

Accelerated Stability % Real time Stability:

One Elecsys CEA 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 4°C. After 3 weeks, the test and reference materials were tested in duplicate and compared.

Real-time stability study is ongoing. The shelf life stability is based on the accelerated stability study of the CalCheck 5 and the real-time stability studies of three-level CalCheck (because of the identical composition of the 3-level and 5-level CalChecks). The initial shelf life stability claim is 18 months when stored at 2-8°C.

d. *Dilution Study*

A study is suggested in the package insert in the event CalCheck Levels 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 0.600–1000 U/mL, the following dilution study was performed: Check 1&2 and Check 4&5 were mixed in a 1:1 ratio and measured in duplicates. Per the sponsor specification, the diluted value must fall within the assay's measuring range: 0.6 – 1000U/mL. Results of a dilution study are summarized in the table below:

Sample	Value after 1:1 Dilution [U/mL]	Average 1:1 Dilution [U/mL]
E170/e 601		
Check 1 + Check 2	17.7	17.1
Check 1 + Check 2	16.5	
Check 4 + Check 5	874.0	824.0
Check 4 + Check 5	774.0	
2010/e 411		
Check 1 + Check 2	15.7	15.7
Check 1 + Check 2	15.7	
Check 4 + Check 5	834.0	840.0
Check 4 + Check 5	847.0	

- 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.