

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

A. 510(k) Number:

k051185

B. Purpose for Submission:

New device

C. Measurand:

Quality Control Material (assayed for CA 19-9)

D. Type of Test:

Calibration Verification Material for CA 19-9

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

Elecsys® CA 19-9 CalCheck™

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX

4. Panel:

75 – Clinical Chemistry

H. Intended Use:

1. Intended use:

Elecsys® CA 19-9 Cal Check™ is intended for use in the verification of the calibration established by the Elecsys® CA 19-9 reagent on the Elecsys® 1010/2010/MODULAR E170 immunoassay analyzers.

2. Indications for use:

Same as intended use.

3. Special conditions for use statement(s):

None.

4. Special instrument requirements:

Elecsys® 1010, 2010 and MODULAR ANALYTICS E170

I. Device Description:

The Elecsys® CA 19-9 CalCheck™ is a lyophilized product consisting of CA 19-9 in a buffered human serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentrations.

J. Substantial Equivalence Information:

1. Predicate device name:

Elecsys® C-Peptide CalCheck™

2. Predicate 510(k) number:

k040157

3. Comparison with predicate:

Similarities		
Characteristic	Elecsys CA 19-9 CalCheck	Predicate device Elecsys C-Peptide CalCheck
Intended Use	Elecsys® CA 19-9 Cal Check™ is intended for use in the verification of the calibration established by the Elecsys® CA 19-9 reagent on the Elecsys® 1010/2010/MODULAR E170 immunoassay analyzers	Elecsys® C-Peptide CalCheck™ is intended for use in the verification of the calibration established by the Elecsys® C-Peptide reagent on the Elecsys® immunoassay systems.
Levels	Three	same
Format	Lyophilized	same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mixing gently.	same
Stability	<u>Unopened:</u> Store at 2 - 8°C until expiration date <u>Reconstituted:</u> 20 - 25°C: 4 hours	same

Differences		
Characteristic	Elecsys CA 19-9 CalCheck	Predicate device Elecsys C-Peptide CalCheck
Matrix	Human serum with added human CA 19-9	Buffered horse serum with added C-Peptide

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

None 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: - There is no reference material for CA 19-9. The values for the CA 19-9 master calibrators are calibrated against Enzygum Test CA 19-9.

Values are assigned using four Elecsys® MODULAR ANALYTICS E170 Immunoassay Analyzers, four ELECSYS® 2010 Immunoassay Analyzers and four ELECSYS® 1010 Immunoassay Analyzers. Two independent series of analyses are performed on each instrument. Each sample is tested in duplicate. The target value is then calculated as the median of the determined values. Approximate target values are found in the following table. Lot-specific target values may differ slightly after value assignment.

CA 19-9 CalCheck™ Level	CA 19-9 Target Values IU/mL
Check 1 (low)	<5
Check 2 (medium)	179
Check 3 (high)	676

Stability: Two studies were performed in order to verify the stability claims for the Elecsys® CA 19-9 CalCheck™.

Stability	Unopened	Reconstituted
CA 19-9 CalCheck™	Store at 2 - 8°C until expiration date	20 – 25°C: 4 hrs

Study 1: Accelerated Stability. The CA 19-9 CalCheck™ on-test material was stored at 35° C for 3 weeks. At the end of three weeks, it was analyzed in duplicate with a reference material (master calibrators stored at 4-8° C). The product met the acceptance criterion (90%-110% of the reference value). The sponsor will test for real-time stability.

Study 2: Reconstituted Material: Stability of the reconstituted product and reconstituted reference material are tested in duplicate. The product is reconstituted, stored for four hours at 25° C. The reference is a freshly reconstituted set of CA 19-9 CalCheck materials. The product met the stated acceptance criterion (90%-110% of the reference value) to support the stability claim of 4 hours at 20-25° C.

Expected Values: Representative Assigned Values of One Lot of Product

Level	Value	Range	Unit
Check 1	>5	<5	U/MI
Check 2	158	125-191	U/mL
Check 3	617	487-747	U/mL

- d. *Detection limit:*
Not applicable.

