

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

A. 510(k) Number:

k091601

B. Purpose for Submission:

New device

C. Measurand:

Human IgG autoantibodies to cyclic citrullinated peptides (CCP)

D. Type of Test:

Calibration verification material for the Elecsys Anti-CCP reagent

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

Elecsys Anti-CCP CalCheck

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 indication(s) for use below.
2. Indication(s) for use:
For use in the verification of the calibration established by the Elecsys Anti-CCP reagent on the indicated Elecsys and cobas e immunoassay analyzers.
3. Special conditions for use statement(s):
For *In Vitro* Diagnostic Use; For Prescription Use Only; To be used with the Elecsys Anti-CCP reagent only
4. Special instrument requirements:
Elecsys 2010, MODULAR ANALYTICS E170, **cobas e 411** and **cobas e 601** analyzers

I. Device Description:

The Elecsys Anti-CCP CalCheck is a lyophilized product consisting of human antibodies to CCP (derived from human serum) in a human serum matrix containing preservatives. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. Each Elecsys Anti-CCP CalCheck is calibrated against master calibrators standardized against a commercially available FDA-cleared second-generation Anti-CCP assay.

All human source materials used in the preparation of the proposed device were tested using FDA-approved methods and shown to be free from Hepatitis B Surface Antigen, and antibodies to Hepatitis C and HIV.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Diagnostics, Elecsys C-Peptide CalCheck
2. Predicate 510(k) number(s):
k040157
3. Comparison with predicate:

Item	Device	Predicate (k040157)
Similarities		
Intended use	For use in the verification of the calibration established by the Elecsys Anti-CCP reagent on the indicated Elecsys and cobas e immunoassay analyzers.	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 to stand closed for 15 minutes, then mix gently by inversion.	Same
Stability	<u>Unopened:</u> Store at 2 to 8 °C until expiration date. <u>Reconstituted:</u> 20 to 25 °C; 4 hours	Same
Differences		
Matrix	Human serum	Equine serum

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: There is no recognized standard for CCP. Therefore, the CCP CalCheck material is traceable to a commercially available FDA-cleared second-generation Anti-CCP assay.

Value assignment: Each of the three CalCheck levels is value assigned using a minimum of three Elecsys 2010/cobas e411 analyzers and three MODULAR ANALYTICS E140/cobas e 601 analyzers. A minimum of six independent series of analyses are performed on each instrument platform. Each sample is tested in duplicate. The target value is then calculated as the median of the determined values. The target values are given in the table below:

Anti-CCP CalCheck Level	Anti-CCP Target Values (U/mL)
Check 1 (low)	20
Check 2 (medium)	300
Check 3 (high)	375

Stability: The unopened stability of the CalChecks was determined using accelerated studies. Based on the accelerated studies, the unopened shelf-life was estimated to be 24 months. The sponsor is currently performing real-time studies to support the unopened stability claim predicted from accelerated studies.

The open vial stability was determined using real-time studies. The data supports the claim that the reconstituted product is stable up to 4 hours when stored at 20 to 25 °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:*
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:

Target values and acceptable ranges for pilot lot are listed below:

For the Elecsys 2010/**cobas e 411** analyzers

Level	Value	Range	Units
Check 1	21.2	17.0 – 25.4	U/mL
Check 2	261	209 – 313	U/mL
Check 3	347	260 - 434	U/mL

For the MODULAR ANALYTICS E170/**cobas e 601** analyzers

Level	Value	Range	Units
Check 1	18.7	15.0 – 22.4	U/mL
Check 2	267	214 – 320	U/mL
Check 3	350	263 - 438	U/mL

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.