

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

**A. 510(k) Number:**

k101856

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Calibration verification and assay range verification material for CEA

**D. Type of Test:**

Not applicable

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

Elecsys CEA 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 CEA 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 CEA CalCheck quantitative 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):

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:

MODULAR ANALYTICS E170, cobas e 601, Elecsys 2010, cobas e 411 analyzers.

**I. Device Description:**

The Elecsys CEA CalCheck 5 kit consist of 5 levels of human CEA, each with the appropriate lyophilized level of human CEA antigen in human serum matrix. During manufacture, the analyte CEA 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 (ng/mL)	Target Range (ng/mL)
Level 1	≤ 0.5	<0.500
Level 2	5.0	3.95 – 6.05
Level 3	500	395 - 605
Level 4	800	632 - 968
Level 5	1000	790 – >1000

All human source materials were prepared exclusively from the blood of donors tested individually and found nonreactive for HBsAg, antibodies to HCV and HIV. The testing methods were FDA approved or cleared in compliance with the European Directive 98/79/EC.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Elecsys CalCheck CEA
2. Predicate 510(k) number(s):  
K970452
3. Comparison with predicate:

	New Device	Predicate
Item	Elecsys CEA CalCheck 5	Elecsys CEA CalCheck
<b>Similarities</b>		
Intended Use	The Elecsys CEA 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 CEA reagent on the indicated Elecsys and <b>cobas e</b> immunoassay analyzers.	Same
Format	Lyophilized	Same
Matrix	Human serum matrix	Same
Control for Analyte	CEA	Same

Handling	Reconstitute with 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Diferences		
Levels	5	3
Target values (ng/mL)	Check 1 - <0.5 ng/mL Check 2 - 5.0 ng/mL Check 3 - 500 ng/mL Check 4 - 800 ng/mL Check 5 - 1000 ng/mL	Low - <0.2 ng/mL Medium - 104 ng/mL High - 874 ng/mL
Assay measuring range	0.2 – 1000 ng/mL	0.0 – 1000 ng/mL
Stability	<u>Unopened:</u> Store at 2-8 °C until expiration date  <u>Reconstituted:</u> 20-25 °C: 4 hours	Same  <u>Reconstituted:</u> 15-25 °C: 4 hours

**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):*  
All testing and information for CalCkeck 5 were done on the modular Analytics E170, and on the Elecsys 2010.

Traceability:

Elecsys CEA is standardized against the 1<sup>st</sup> IRP WHO Reference Standard 73/601

Value Assignment:

The five levels of the CalCheck 5 kit are assigned based on the measuring

range of the assay. Samples from each level was run 1 time a day on 4 MODULAR ANALYTICS E170 and 4 Elecsys 2010 analyzers for a total of 2 days. The difference between the target and assigned value was less than 10%. A master calibration curve is generated on the E170 master calibration curve and used to calculate ng/mL from counts. The table below summarizes the Assigned Values and Ranges for Elecsys CA 19-9 CalCheck 5 on the E170 :

Level	Target Value (ng/mL)	Assigned Value (ng/mL)
Check 1	≤ 0.5	< 0.5
Check 2	5.0	4.67
Check 3	500	513
Check 4	800	831
Check 5	1000	1040

Stability:

Stability studies were done on the Elecsys E170.

*Open vial stability:*

One Elecsys CEA CalCheck 5 lot was evaluated in duplicate on the Elecsys E170. The claimed reconstituted Elecsys CEA CalCheck 5 is stable for 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:

The CEA CalCheck 5 package insert instructs the customer to analyze diluted samples 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 0.2-1000 ng/mL after mixing, the following dilution study was performed: Check 1&2 and Check4 &5 were mixed in a 1:1 ratio and measured in duplicate. Results of a dilution study are summarized in the table below:

Sample	Value after 1:1 Dilution [ng/mL]	Average 1:1 Dilution [ng/mL]
<b>E170/e 601</b>		
Check 1 + Check 2	2.5	2.4
Check 1 + Check 2	2.4	
Check 4 + Check 5	1026	984
Check 4 + Check 5	943	
<b>2010/e 411</b>		
Check 1 + Check 2	2.4	2.4
Check 1 + Check 2	2.4	
Check 4 + Check 5	901	887
Check 4 + Check 5	873	

- 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:  
The assigned 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.