

**SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k112113

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for myoglobin

D. Type of Test:

Quality control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Myoglobin CalCheck 5

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material

2. Classification:

Class I (reserved)

3. Product code:

JJX – Single (Specified) Analyte Controls

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication for use below

1. Indication(s) for use:

The Elecsys Myoglobin 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 Myoglobin reagent on the indicated Elecsys and cobas e immunoassay analyzers.

2. Special conditions for use statement(s):

For prescription use, for *in vitro* diagnostic use

4. Special instrument requirements:

Roche Elecsys 2010 / cobas e 411 and MODULAR ANALYTICS E170 / cobas e 601 / Cobas 602 immunoassay analyzers as shown in the table below.

Assay Application	MODULAR ANALYTICS E170	Elecsys 2010	cobas e 411	cobas e 601	cobas e 602
Myoglobin (18 minutes)	X	X	X	X	X
Myoglobin STAT (9 minutes)		X	X	X	X

Note: **cobas e 411** share the same analytical core as Elecsys 2010; **cobas e 601**, and **cobas e 602** (both are part of the **cobas 6000** Analyzer series cleared in k060373) share the same analytical core as E170.

I. Device Description:

Elecsys Myoglobin CalCheck 5 set is an *in vitro* diagnostic device that contains 5 levels of Myoglobin in a HEPES buffer/protein (bovine serum) matrix. The vials contain 1.0 mL each and are packaged in sets of 5.

Level	Target Value (ng/mL)	Approximate Target Range (±10% Target Range)
Check 1	<21.0	<21.0
Check 2	70	63-77
Check 3	1000	900 - 1100

Check 4	2400	2160 - 2640
Check 5	3000	2100 - 3300

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys Digoxin CalCheck 5

2. Predicate 510(k) number(s):

k102044

3. Comparison with predicate:

Items	Elecsys Myoglobin CalCheck 5 (Candidate Device)	Elecsys Digoxin CalCheck 5 (Predicate Device)
Similarities		
Intended Use	Same	For use in the verification of the calibration on the indicated Elecsys and cobas e immunoassay analyzers
Levels per Kit	Same	Five
Format	Same	Liquid
Handling	Same	Mix gently by inversion to ensure homogeneity
Matrix	Same	BSA/buffer matrix
Differences		
Analytes	Myoglobin	Digoxin
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration Opened: • 20-25°C: 6 hours

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:

The five levels of the CalCheck 5 kit are assigned based on the measuring range of the assay. Each level was standardized using the Elecsys Myoglobin STAT assay, which was standardized against an in-house reference preparation as follow: 1) There is no international standard for myoglobin. A stock solution of Myoglobin antigen is prepared by weighing in myoglobin antigen purchased from a commercial vendor and then dissolving it in Human sera (buffered to pH 7.0). 2) The different master calibrators are prepared by weighing in the necessary amount of stock solution and diluting it accordingly with the buffered human serum. 3) Finally, bottles are filled with the master calibrators and lyophilized.

Once the produced CalChecks are determined to meet the specifications, the Elecsys Myoglobin CalCheck 5 is released for the value assignment utilizing the Elecsys 2010 master calibration curve to calculate ng/mL from corresponding magnitudes of chemiluminescent emission detected by a photomultiplier.

Value Assignment:

For each Elecsys Myoglobin CalCheck 5 lot manufactured, the CalChecks are assayed in duplicate on at least three Elecsys 2010 analyzers. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzers) of the respective CalCheck. The assigned range is defined as $\pm 27\%$ of the assigned value for levels 2 (7% CV) and $\pm 30\%$ of the assigned value for level 3-5 (10% CV).

Reagent-specific value assignments were performed for each lot of Elecsys Myoglobin CalCheck 5 in combination with each Elecsys Myoglobin 18-minute assay and Elecsys Myoglobin STAT (9-minute assay, k083260) reagent lot using 8 Elecsys 2010 analyzers once a day in a total of 8 runs. To ensure the values assigned using the master platform are transferrable and valid for the other instrument platforms, the same value assignment procedure is performed separately using cobas e 411, cobas e 601 / Cobas e 602 immunoassay analyzers. For MODULAR ANALYTICS

E170, only 18-minute reagent was performed because no STAT (9-minute) functionality is available on this analyzer. The assigned values obtained on the additional analyzers are compared to those obtained on the Elecsys 2010.

Acceptance criteria for all stages of the process were met. It is stated in the package inserts that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

Stability:

Opened-vial and accelerated Shelf-life stability studies were performed to verify the stability claims for the Elecsys Myoglobin CalCheck 5 on the cobas e 411. Since these studies are not analyzer-dependent, these results can be applied to the MODULAR ANALYTICS E170, Elecsys 2010, cobas e 601, and cobas e 602.

- 1) Open-Vial Stability: Real-time testing was performed for the Elecsys Myoglobin CalCheck 5. The data support the package insert claims that reconstituted Elecsys Myoglobin CalCheck 5 is stable up to 4 hours at 20-25°C.
- 2) Shelf-life stability: The accelerated stability testing performed supports an initial shelf-life claim of 15 months when the Elecsys Myoglobin CalCheck 5 are stored under normal storage conditions of 2-8°C. Real-time testing at 2-8°C is on-going to support a claim of 24 months.

d. Matrix effect:

No applicable

e. Detection limit:

Not applicable

f. Analytical specificity:

Not applicable

g. Assay cut-off:

Not applicable

2. Comparison studies:

Not applicable

3. Clinical studies:

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.