

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

A. 510(k) Number:

k092168

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for hCG+ β

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys hCG+ β 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

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Elecsys HCG+ β 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 HCG+ β reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

3. Special conditions for use statement(s):

The Elecsys HCG+ β CalCheck 5 is not intended to be used as a primary calibrator or routine control material.

4. Special instrument requirements:

The labeling states that the CalChecks are for use with the Elecsys HCG+ β reagent on the Elecsys 2010/cobas e411 and Modular Analytics E170/cobas e601 test systems.

I. Device Description:

The Elecsys HCG+ β CalCheck 5 is a lyophilized product consisting of human chorionic gonadotropin (hCG) purified from human urine in human serum matrix. During manufacture, the hCG is spiked into the matrix at the target concentrations listed below. CalCheck Level 1 contains no analyte.

Elecsys HCG+β CalCheck level	Target Value (mIU/mL)
Level 1	≤ 0.2
Level 2	5
Level 3	5,000
Level 4	8,000
Level 5	10,000

The human source materials were 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 HCG+β CalCheck

2. Predicate K number(s):

k010237

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Composition	Same	Lyophilized human serum matrix spiked with hCG purified from human urine
Stability	Same	Unopened: Store at 2-8°C until expiration date Reconstituted: 4 hrs at 20 – 25°C.

Differences		
Item	Device	Predicate
Intended use	For use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+β reagent on the indicated Elecsys and cobas e immunoassay analyzers.	For use in the calibration verification established by the Elecsys HCG+β reagent on the indicated Elecsys 1010 or 2010 analyzers
Levels	5	3
Preparation and handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Reconstitute Check 1 and Check 2 with exactly 1.0 mL distilled or deionized water. Reconstitute Check 3 with exactly 1.5 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.

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 and value assignment

Elecsys HCG+ β CalCheck 5 is standardized using internally produced master calibrators which are traceable to the 4th International Standard for HCG (NIBSC) 75/589.

Each of the five CalCheck levels is value assigned using a minimum of three Elecsys 2010/cobas e411 analyzers and four MODULAR ANALYTICS E140/cobas e 601 analyzers. Each sample is tested in duplicate. The target value for each CalCheck is the median of the observed values.

The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability

Real time and accelerated stability testing protocols and acceptance criteria were described and found to be adequate. CalCheck 5 is stable until the expiration date printed on the vial when stored unopened at 2 – 8° C. The reconstituted vials are stable for four hours at 20-25°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:

The expected values are provided in the labeling 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.