

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

A. 510(k) Number:

k101075

B. Purpose for Submission:

New Device

C. Measurand:

Calibration verification and assay range verification material for Insulin

D. Type of Test:

Not Applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Insulin Calheck 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 Control (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 Insulin 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 Insulin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers

3. Special conditions for use statement(s):

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

4. Special instrument requirements:

The label states that Elecsys Insulin CalCheck 5 are for use with the Elecsys Insulin reagent on MODULAR ANALYTICS E170, Elecsys 2010, **cobas e** 601, and **cobas e** 411 immunoassay analyzers.

I. Device Description:

The Elecsys Insulin CalCheck 5 is a lyophilized product consisting of recombinant human insulin in bovine serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

J. Substantial Equivalence Information:

1. Predicate device

Elecsys HCG+ β CalCheck 5

2. Predicate K number

k092168

3. Comparison with predicate

Similarities

Characteristic	Elecsys HCG+ β CalCheck 5 (K092168)	Elecsys Insulin CalCheck 5
Indications for use	For use in calibration verification and for use in the verification of the assay range	Same
Levels	Five	Same
Format	Lyophilized	Same
Handling Instructions	Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Stability	Unopened: Store at 2-8°C until expiration date. Reconstituted: 20-25°C: 4 hours	Same

Differences

Characteristic	Elecsys HCG+ β CalCheck 5 (k092168)	Elecsys Insulin CalCheck 5
Analyte	HCG+B	insulin
Matrix	Human Serum	Bovine Serum

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

None were 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

The Elecsys Insulin assay is standardized against the WHO Reference Reagent, 1st IRP, code 66/304 (NIBSC).

For each Insulin CalCheck 5 lot manufactured, the CalChecks were assayed in duplicate on the Elecsys MODULAR ANALYTICS E170, Elecsys 2010, **cobas e 601**, and **cobas e 411** immunoassay 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.

Stability studies

Open-Vial Stability:

The on-test material was reconstituted and stored for 5 hours at 25°C (in an open vial).

The reference material was a freshly reconstituted set of CalChecks. The on-test and reference materials were tested in duplicate. On-test recovery was calculated as a percent of the reference. The protocol, data and acceptance criteria were found to be adequate.

The data supported the package insert claims that reconstituted Insulin CalCheck 5 is stable up to 4 hours at 20-25°C.

Accelerated Stability:

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was freshly reconstituted set of CalChecks (stored at 4°C). After 3 weeks, the test and reference materials are tested in duplicate. The on-test recovery is calculated as a percent of the reference. The protocol, data and acceptance criteria were found to be adequate.

One Elecsys Insulin CalCheck 5 lot was evaluated in duplicate on the Elecsys 2010.

Real-Time Stability:

In addition to open-vial and accelerated stability, real-time stability was evaluated. In the on-going real-time stability study, the Elecsys Insulin CalCheck 5 test material is stored at 2-8°C. The CalChecks were tested at T=0 and at specified intervals over the shelf life of the device up to the planned shelf life plus one month.

The shelf life claim is 18 months. This is based on the accelerated stability results.

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.

Level	Target Value, $\mu\text{U/mL}$	Target Range, $\mu\text{U/mL}$
Check 1	≤ 5	NA
Check 2	20	15-20
Check 3	500	450-550
Check 4	800	720-880
Check 5	1000	900-1000

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.