

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

A. 510(k) Number:

k111349

B. Purpose for Submission:

New device

C. Measurand:

Assayed control materials for Sex Hormone –Binding Globulin (SHBG)

D. Type of Test:

Quality control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys SHBG CalCheck 5

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) for use:

The Elecsys SHBG 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 SHBG quantitative assay reagent on the indicated Elecsys and cobas e immunoassay analyzers, for in vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Elecsys and cobas e immunoassay analyzers including the Elecsys 2010, MODULAR ANALYTICS E170, **cobas e 411**, **cobas e 601**, and **cobas e 602** analyzer platforms.

Note: **cobas e 411** share the same analytical core as Elecsys 2010; **cobas e 601**, and **cobas e 602** share the same analytical core as E170.

I. Device Description:

The Elecsys SHBG CalCheck 5 is a lyophilized product consisting of SHBG in human and equine (horse) serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. The sponsor declared in the labeling that all products derived from human blood are 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.

During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Target Values and Ranges for Elecsys hGH CalCheck 5

Level	Target Value (nmol/L)	Target Range (nmol/L)
Check 1	< 5	-
Check 2	20	10-30
Check 3	80	70-90
Check 4	150	130-170
Check 5	200	180-220

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys SHBG CalCheck

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

K031698

3. Comparison with predicate:

Characteristic	Elecsys SHBG CalCheck 5 (New Device)	Elecsys SHBG CalCheck (Predicate Device)
Similarities		
Intended Use/ Indications for use	Same	For use in the verification of the calibration established by the Elecsys SHBG reagent on Elecsys analyzers.
Format	Same	Lyophilized
Matrix	Same	Human serum/Horse serum matrix
Handling	Same	Reconstitute with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Unopened Stability	Same	Store at 2-8°C until expiration date
Reconstituted Stability	Same	20-25 °C, 4 hours
Differences		
Levels	5	3
Assay Measuring Range	0.800– 200 nmol/L	0.350 - 200 nmol/L
Target Values	Check 1: < 5 nmol/L Check 2: 20 nmol/L Check 3: 80 nmol/L Check 4: 150 nmol/L Check 5: 200 nmol/L	Check 1: 20 nmol/L Check 2: 80 nmol/L Check 3: 150 nmol/L

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

The Elecsys SHBG CalCheck 5 is traceable to the NIBSC 95/560 international standard.

Value Assignment:

For each Elecsys SHBG CalCheck 5 lot manufactured, the CalChecks are assayed in duplicate on at least three E170 analyzers. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range is $\pm 30\%$ of assigned value, in which 10% was allotted for between-analyzer platform tolerance, 10% for stability tolerance and 10% for precision of the assay.

Values are assigned for each lot of Elecsys SHBG CalCheck 5 in combination with each Elecsys SHBG reagent lot available.

For additional analyzers (Elecsys 2010), the same value assignment procedure is performed. The assigned values obtained on 2010 are compared to those obtained on the E170. Differences between the analyzer platforms are within the 10% tolerance, therefore, the values assigned to the E170 (and **cobas e 601, e602**) are transferred to and valid for the Elecsys 2010 (and **cobas e 411**).

Stability:

The stability studies for SHBG CalCheck 5 were performed on the cobas e 601. Because these studies are not analyzer-dependent, these results, in addition to real-time stability study results, can be applied to the Elecsys 2010, MODULAR ANALYTICS E170, cobas e 411 and cobas e 602. The stability protocol and the acceptance criteria have been reviewed and found to be acceptable.

- Shelf-life stability:
The accelerated stability testing performed at 35°C supports an initial shelf-life claim of 18 months at 2-8°C. Real-time testing at 2-8°C is on-going to support a claim of 36 months.
- Open-vial stability after reconstitution :
Real time testing was performed and the data support the package insert claim that reconstituted Elecsys SHBG CalCheck 5 is stable up to 4 hours at 20-25°C.
- On-board stability:
The SHBG CalCheck 5 products are not stored on-board the analyzer, therefore no on-board stability claims is made.

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:

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.