

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

A. 510(k) Number: K031698

B. Analyte: Sex Hormone-Binding Globulin (SHBG)

C. Type of Test: N/A

D. Applicant: Roche Diagnostics Corporation

E. Proprietary and Established Names: Elecsys® SHBG CalCheck

F. Regulatory Information:

1. Regulation section: §862.1660, Single (Specified) Analyte Controls
(Assayed and Unassayed)
2. Classification: Class I
3. Product Code: JJX
4. Panel: 75

G. Intended Use:

1. Indication(s) for use:

For use in the verification of the calibration established by the Elecsys SHBG reagent on Elecsys 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

2. Special condition for use statement(s): None
3. Special instrument Requirements: None

H. Device Description:

Elecsys® SHBG CalCheck calibration verification solution comprises three levels – low, mid, and high – each with a defined SHBG concentration. The low solution concentration is near the lower detection limit of the assay. The middle solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® SHBG CalCheck is a lyophilized product manufactured using SHBG in human serum/ horse serum matrix. The analyte is appropriately spiked into the CalCheck matrix to the correct concentration levels.

I. Substantial Equivalence Information:

1. Predicate device name(s): Elecsys® proBNP CalCheck.
2. Predicate K number(s): K020883
3. Comparison with predicate:

The Elecsys® SHBG CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® proBNP CalCheck (K020883)

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

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials”.

K. Test Principle: NA**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
 - a. *Precision/Reproducibility:* NA
 - b. *Linearity/assay reportable range:* NA
 - c. *Traceability (controls, calibrators, or method):*
The values were standardized against the 1st International Standard for SHBG from the National Institute for Biological Standards and Control (NIBSC) code 95/560.
 - d. *Detection limit:* NA
 - e. *Analytical specificity:* NA
 - f. *Assay cut-off:* NA
2. Comparison studies:
 - a. *Method comparison with predicate device:* NA
 - b. *Matrix comparison:* NA
3. Clinical studies:
 - a. *Clinical sensitivity:* NA
 - b. *Clinical specificity:* NA
 - c. *Other clinical supportive data (when a and b are not applicable):*
NA

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

Proposed Mean and Target Ranges

Target Values given below are target values for each level of the Elecsys SHBG CalCheck solutions. These values are valid for all lots of CalCheck solutions listed. Lots: 12345600, 12345601, 12345602

Level	Value	Range	Unit
Check 1	20.0	15.8 – 24.2	nmol/l
Check 2	81.1	64.1 – 98.1	nmol/l
Check 3	163	128.8 -197.2	nmol/l

M. Conclusion:

Based on the information provided, I recommend that the Roche Diagnostics Corporation Elecsys® SHBG CalCheck, be found substantially equivalent to the predicate device (K020883) Elecsys ® proBNP CalCheck.