

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

K090311

**B. Purpose for Submission:**

New calibration test system

**C. Measurand:**

Rubella-specific IgG in human serum and plasma

**D. Type of Test:**

Calibration verification material for Rubella IgG

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

Elecsys Rubella IgG CalCheck; Rubella IgG CalCheck

**G. Regulatory Information:**

1. Regulation section:

21CFR §862.1660, Quality Control Material (Assayed and Unassayed)

21CFR §866.3510, Rubella Virus Serological Reagents

2. Classification:

Class I reserved (quality control)

Class II (Rubella IgG)

3. Product code:

JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

LFX, Enzyme Linked Immunoabsorbent Assay, Rubella

4. Panel:

Clinical Chemistry (75)

Microbiology (83)

**H. Intended Use:**

1. Intended use(s):

The Elecsys Rubella IgG CalCheck is an assayed calibrator control intended for use in the verification of the calibration established by the Elecsys Rubella IgG reagent on the Elecsys 2010, the MODULAR ANALYTICS E170, and **cobas e** immunoassay analyzers.

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

For prescription use only. To be used with the Elecsys Rubella IgG assay

4. Special instrument requirements:

Elecsys 2010, MODULAR ANALYTICS E170, or **cobas e** analyzers

**I. Device Description:**

The Elecsys Rubella IgG CalCheck is a lyophilized product consisting of human anti-Rubella IgG antibodies in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Elecsys C-Peptide CalCheck

2. Predicate K number(s):

K040157

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device Elecsys Rubella IgG CalCheck</b>	<b>Predicate Elecsys C-Peptide CalCheck</b>
Intended Use	For use in the verification of the calibration established by the Elecsys Rubella IgG reagent on the Elecsys 2010, the MODULAR ANALYTICS E170, and <b>cobas e</b> immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys C-Peptide reagent on the Elecsys and cobas e immunoassay analyzers
Levels	Three	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mix gently.	Same
Stability	<u>Unopened:</u> Store at 2-8°C until expiration date <u>Reconstituted:</u> 20 - 25°C: 4 hrs	Same

<b>Differences</b>		
<b>Item</b>	<b>Device Elecsys Rubella IgG CalCheck</b>	<b>Predicate Elecsys C-Peptide CalCheck</b>
Matrix	Human Serum	equine serum matrix

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

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material (<http://www.fda.gov/cdrh/oivd/guidance/2231.html>)

**L. Test Principle:**

“Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument kit or test system has remained stable throughout the laboratory’s reportable range for patient test results.” (42 Code of U.S. Federal Regulations. Part 493.1217. Standard; Calibration and calibration verification procedures.) (sic.)

Calibration verification is not a requirement of the Elecsys and cobas e immunoassay systems based on the manufacturer's recommendations. However, CalCheck solutions can be used in instances where such a test procedure is required by certification agencies, or where the user wishes to document calibration verification.

**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:*

Elecsys Rubella IgG CalCheck is Standardized against the NIBSC 1<sup>st</sup> International Standard for Anti-Rubella Immunoglobulin, Human. The NIBSC standard is reconstituted and a serial dilution set is created from it. A master curve is derived using the NIBSC dilution set. The master calibrators are assigned values using the master curve. From the master calibrators a master curve is derived. In turn the CalChecks are assigned values using the master curve based on the master calibrators. Values are assigned using a minimum of,

- 4 Elecsys 2010 / cobas e 411 analyzers,
- 4 MODULAR ANALYTICS E170/ cobas e 601 analyzers.

Six independent series of analyses are performed on each instrument. Each sample is tested in duplicate. The target value is then calculated as the median of the determined values. Approximate target values are given in the table below. Lot-specific target values may differ slightly after value assignment.

<b>Rubella IgG CalCheck Level</b>	<b>Rubella IgG Target Values (IU/mL)</b>
Check 2 (low)	10
Check 3 (medium)	250
Check 4 (high)	400

<b>Rubella IgG CalCheck Level</b> (Lots 151729, 179243, 179244)	<b>Rubella IgG Assigned Values and Ranges</b>
Check 2 (low)	9.52 IU/mL (5.81-13.2)
Check 3 (medium)	270 IU/mL (165-375)
Check 4 (high)	421 IU/mL (257-585)

*Stability:*

Two studies were performed in order to verify the stability claims for the Elecsys Rubella IgG CalCheck. The data was generated using Rubella IgG master calibrators, which have the same composition and target values as Rubella IgG CalCheck.

Study 1: Accelerated Stability: Reference and on-test material are tested in duplicate. The on-test material is stored at 35°C for 3 weeks, the reference material at 2-8°C. The on-test recovery is calculated as a percent of the reference value. The acceptance criterion was recovery of 90-110 % of the reference value. The unopened Rubella IgG CalCheck is stable up to the stated expiration date.

**Accelerated Stability**

<b>Sample</b>	<b>Mean [IU/mL]</b>	<b>On-test as a % of Reference</b>
<b>Reference:</b>	<b>Stores at 4°C</b>	
Low	9.65	-
Medium	239	-
High	398	-
<b>On-Test:</b>	<b>3 weeks at 35°C</b>	
Low	9.52	99%
Medium	232	97%
High	383	96%

Study 2: Open Vial Stability: The Elecsys Rubella IgG CalCheck test material and reference material are tested in duplicate. The test material is reconstituted, stored for four hours at 25°C (in open vial). The reference material is a freshly reconstituted set of Elecsys Rubella IgG CalChecks. The acceptance criterion was recovery of 90-110% of the reference value.

The reconstituted Elecsys Rubella IgG is stable up to 4 hours at 20-25°C.

**Reconstituted (Open Vial) Stability for Elecsys Rubella IgG CalCheck**

<b>Sample</b>	<b>Mean [IU/mL]</b>	<b>On-test as a % of Reference</b>
<b>Reference:</b>	<b>Stores at 4°C</b>	
Low	9.64	-
Medium	240	-
High	390	-
<b>On-Test:</b>	<b>4 hours open at 25°C</b>	
Low	9.47	98%
Medium	241	100%
High	399	102%

*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:

Representative values assigned to three lots: 151729, 179243, and 179244 of the product.

<b>Level</b>	<b>Value</b>	<b>Range</b>	<b>Unit</b>
Check 1	9.52	5.81 -13.2	IU/mL
Check 2	270	165 -375	IU/mL
Check 3	421	257 -> 500	IU/mL

**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.