

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

A. 510(k) Number:

K092585

B. Purpose for Submission:

Clearance of new device for the Calibration control 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 5; Rubella IgG CalCheck 5

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 II (Rubella IgG)

3. Product code:

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

LFX, Enzyme Linked Immunoabsorbent Assay, Rubella

H. Intended Use:

1. Intended use(s): The Elecsys Rubella IgG 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 Rubella IgG reagent on the Elecsys 2010, 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 5 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 Rubella IgG CalCheck

2. Predicate K number(s):

K090311

3. Comparison with predicate:

Comparison		
Item	Predicate Elecsys Rubella IgG CalCheck (K090311)	Device Elecsys Rubella IgG CalCheck 5
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 cobas e immunoassay analyzers.	For use in the verification of the reportable range established by the Elecsys Rubella IgG reagent on the Elecsys and cobas e immunoassay analyzers
Levels	Three	Five

Comparison		
Item	Predicate Elecsys Rubella IgG CalCheck (K090311)	Device Elecsys Rubella IgG CalCheck 5
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
Matrix	Human Serum	Same

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 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 range:*

Verification of Assay Range: To demonstrate that after dilution of Rubella IgG CalCheck 1 and 5 values are within the assay’s measuring range of 0.21 - 500 IU/mL, the following dilution study was performed:

CalCheck 1 & CalCheck 2, CalCheck 4 & CalCheck 5, and CalCheck 5 & CalCheck 3 were mixed in a 1:1 ratio and measured in two-fold determination. Then the average was calculated.

Result: Both CalCheck 1 & CalCheck 2 and CalCheck 3 & CalCheck 5 dilution values are within the assay's measuring range after dilution. CalCheck 4 & CalCheck 5 dilution values were outside of the assay's measuring range, however, CalCheck 3 & CalCheck 5 dilution was within the assay's measuring range.

Sample	Value after 1:1 Dilution [IU/mL]	Average 1:1 Dilution [IU/mL]
CalCheck 1 + CalCheck 2	4.80	4.82
CalCheck 1 + CalCheck 2	4.84	
CalCheck 4 + CalCheck 5	511.0	515.3
CalCheck 4 + CalCheck 5	519.6	
CalCheck 3 + CalCheck 5	435.3	436.3
CalCheck 3 + CalCheck 5	437.2	

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

Elecsys Rubella IgG CalCheck 5 is standardized against the NIBSC 1st 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 Elecsys2010/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.

Assigned Target Values and Ranges

Rubella IgG CalCheck 5 Level	Rubella IgG Assigned Values and Ranges
Level 1 (Lot 179241)	< 2
Level 2 (Lot 151729)	9.52 IU/mL (5.81-13.2)
Level 3 (Lot 179243)	270 IU/mL (165-375)
Level 4 (Lot 179244)	421 IU/mL (257-585)
Level 5(Lot 179245)	514 IU/mL (314-714)

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 5. The acceptance criterion was recovery of 90-110 % of the reference value, which was accomplished. The reconstituted Elecsys Rubella IgG CalCheck 5 is stable up to 4 hours at 20-25°C.

Expected Range:

The approximate target ranges were included in the Package Insert as given below in the table. It was recommended to refer to the value sheet on www.MyLabOnline.com for lot-specific range.

Level	Approximate Target Range	Unit
Check 1	< 2.00	IU/mL
Check 2	6.10 - 13.9	IU/mL
Check 3	153 - 348	IU/mL
Check 4	244 - >500	IU/mL
Check 5	300 - > 500	IU/mL

- 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 five lots: 179241, 151729, 179243, 179244, and 179245 of the product.

Level	Value	Range	Unit
Level 1	< 2.00	< 2.00	IU/mL
Level 2	9.52	5.81 -13.2	IU/mL
Level 3	270	165 -375	IU/mL
Level 4	421	257 - > 500	IU/mL
Level 5	> 500	314 - > 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.