

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

A. 510(k) Number:

K092888

B. Purpose for Submission:

For 510(k) clearance of a modification of calibration test system to include reportable range verification as an intended use

C. Measurand:

Toxoplasma gondii (T. gondii)

D. Type of Test:

Calibration Verification and Reportable Range Verification Material for *Toxoplasma* IgG

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Toxo IgG CalCheck 5; Toxo IgG CalCheck 5

G. Regulatory Information:

1. Regulation section:

862.1660- Quality control material (assayed and unassayed)

2. Classifications:

Class I

3. Product codes:

JJX- Quality Control Material (assayed and unassayed)

4. Panel:

75- Clinical Chemistry

H. Intended Use:

1. Intended use(s):

The Elecsys Toxo IgG CalCheck, an assayed calibrator control, is intended for use in calibration verification and for use in the verification of the reportable range established by the Elecsys Toxo IgG reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

2. Indication(s) for use:

The Elecsys Toxo IgG CalCheck, an assayed calibrator control, is intended for use in calibration verification and for use in the verification of the reportable range established by the Elecsys Toxo IgG reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

3. Special condition for use statement(s):

To be used with the Elecsys Toxo IgG assay

4. Special instrument requirements:

Elecsys 2010, MODULAR ANALYTICS E170 or cobas e (411 and 601) analyzers

I. Device Description:

The Elecsys Toxo IgG CalCheck 5 set contains five lyophilized levels of human anti-Toxo IgG antibodies in a solution of human serum protein and has the appropriate matrix characteristics for the analyte. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. Upon reconstitution, the control material is used in the verification of calibration as well as the verification of the reportable range for Elecsys Toxo IgG on the Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411 and **cobas e** 601 immunoassay analyzers.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys Toxo IgG CalCeck

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

K083655

3. Comparison with predicate:

Similarities		
Item	Proposed Device (K092888)	Predicate (K083655)
Matrix/Format	Human Serum/Lyophilized	Same
Reactive Component	Anti-Toxo IgG antibody	Same
Handling	Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water. Allow bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Stability	<u>Unopened:</u> Store at 2-8 ⁰ C until expiration date <u>Reconstituted:</u> Store at 20 – 25 ⁰ C for up to 4 hours	Same

Differences		
Item	Proposed Device (K092888)	Predicate (K083655)
Intended Use	Verification of calibration and verification of the reportable range established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and the cobas e (411 and 601) immunoassay analyzer	Verification of calibration established by the Elecsys Toxo IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and the cobas e immunoassay analyzer
Levels	Five	Three

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

This 510(k) Premarket Notification was prepared and referenced the guidance document, “Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material: (June 7, 2007)”

I. Test Principle:

Not applicable – Calibrator

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

To verify the reportable range of the Elecsys 2010, MODULAR ANALYTICS E170 or cobas e analyzers using Elecsys Toxo IgG CalCheck 5, a dilution study was performed using the Elecsys Toxo IgG CalCheck Levels 1 and 5.

Dilution Study

CalCheck 1, CalCheck 2, CalCheck 4 and CalCheck 5 were mixed in a 1:1 ratio and measured in two-fold determination. The average was then calculated. The predetermined specification was that the diluted value had to fall within the measuring range.

Results showed that CalCheck dilution values were within the assay’s measuring range after dilution, as follows:

Sample	Value after 1:1 Dilution [IU/mL]	Average 1:1 Dilution [IU/mL]
CalCheck 1 + CalCheck 2	1.72	1.68
CalCheck 1 + CalCheck 2	1.64	
CalCheck 4 + CalCheck 5	545	527.5
CalCheck 4 + CalCheck 5	510	

Both CalCheck dilution values are within the assay’s measuring range after dilution.

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

The Elecsys Toxo IgG CalCheck is standardized against the same master calibration curve as the calibrators used for the Elecsys Toxo IgG test system (Elecsys Toxo IgG Reagent and Calibrators, k073501). Serum/plasma comparisons performed demonstrate equivalency of the specimen types. Please refer to pages 62-71 of the original Elecsys Toxo IgG Test System submission, K073501, for this information.

Analyte Value Assignment

Values for Toxo IgG CalCheck 5 were calibrated against the WHO anti-Toxoplasma serum (TOXM), 3rd International Standard for *T. gondii* from the National Institute for Biological Standards and Control (NIBSC), UK. Values are assigned using a minimum of four Elecsys 2010/ cobas e 411 analyzers and four MODULAR ANALYTICS E170/ cobas e601 analyzers. Two independent series of analyses are performed for each instrument. The target value of each CalCheck is the median over 6 -8 series (i.e., 0.175 - 650 IU/mL) of the respective CalCheck.

Stability

Open Vial Stability and Accelerated stability studies were performed in order to verify the stability claims for the Elecsys Toxo IgG CalCheck 5. The data was generated using Toxo IgG master calibrators, which have the same composition and target values as Toxo IgG CalCheck 5.

Open Vial Stability:

The Elecsys Toxo IgG CalCheck 5 test material and reference material were tested in duplicate. The 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 Elecsys Toxo IgG CalCheck 5. The recovery was calculated as a percent of the reference value.

The acceptance criterion is recovery of 90-110% of the reference material value.

The results for the Reconstituted (Open Vial) Stability for Elecsys Toxo IgG CalCheck 5 were as follows:

Sample	Mean (IU/mL)	Percent of Reference
Reference:		
Level 1	0.0	-
Level 2	2.83	-
Level 3	326	-
Level 4	504	-
Level 5	605	-
Test Material:	5 hours open at 25°C	
Level 1	0.0	-
Level 2	2.88	102
Level 3	318	98
Level 4	494	98
Level 5	615	102

The data support the package insert claims that reconstituted Elecsys Toxo IgG CalCheck 5 is stable up to 4 hours at 20-25°C.

Accelerated Stability

The Elecsys Toxi IgG CalCheck 5 test material was stored at 35°C for 3 weeks. The reference material was a freshly reconstituted set of CalChecks stored at 2-8°C. After 3 weeks, the test and reference materials were tested in duplicate. The recovery was calculated as a percent of the reference value. The acceptance criterion was recovery of 90-110% of the reference material value.

Results for accelerated stability studies were as follows:

Sample	Mean (IU/mL)	Percent of Reference
Reference:	3 weeks at 2-8°C	
Level 1	0.06	-
Level 2	2.79	-
Level 3	319	-
Level 4	497	-
Level 5	622	-

Test Material:	3 weeks at 35°C	
Level 1	0.12	-
Level 2	2.85	102
Level 3	320	100
Level 4	497	100
Level 5	607	98

The accelerated stability model employed supports a shelf-life claim of 29 months when the Toxo IgG CalCheck 5 materials are stored under normal storage conditions of 2-8°C.

d. Detection limit:

Not applicable, Calibrator material with assigned values..

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

The assay cut-off was determined using master calibrators for the assay that has values assigned that are traceable to the World Health Organizations (WHO) standards. The sponsor used the WHO anti-Toxoplasma serum (TOXM), 3rd International Standard for *T. gondii* from NIBSC, UK. Two independent series of analyzes were performed on the Elecsys 2010, cobas e 411, and the MODULAR ANALYTICS E170/ cobas e601 analyzers. The samples were run in duplicate and the target values were calculated as the median of the determined values. This fulfils the requirements of demonstrating a target values for the Toxo IgG CalCheck levels calibrators.

Instruments Used in Value Assignment	> 3 Elecsys 2010 analyzers > 6 series per analyzer platform	
Procedure	Toxo IgG CalCheck 5 Level	Toxo IgG Target Value (IU/mL)
Specified Target Values	Level 1	0
Assigned Target Values and Ranges	Level 2	3
	Level 3	325
	Level 4	520
	Level 5	650
	Level 1 (Lot 179227)	≤ 1
	Level 2 (Lot 152734)	2.73 (1.91 α 3.55)
	Level 3 (Lot 179229)	315 (221 α 410)
	Level 4 (Lot 179230)	500 (350 α 650)
	Level 5 (Lot 179231)	610 (427 α 793)

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 were assigned to the product. The Anti HBs CalCheck is composed of calibration verification solutions consisting of five CalCheck solutions; very low, low, medium, high and very high, each with a defined Toxo IgG CalCheck level (as shown in the table below). This information is included in the package insert.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The information submitted in this premarket notification is complete and supports a substantial equivalent decision.

