

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

A. 510(k) Number:

K083655

B. Purpose for Submission:

New calibration test system

C. Measurand:

Toxoplasma gondii (T. gondii)

D. Type of Test:

Calibration Verification Material for *Toxoplasma* IgG

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys Toxo IgG CalCheck; Toxo IgG CalCheck

G. Regulatory Information:

1. Regulation section:

862.1660- Quality control material (assayed and unassayed)

866.3780 - *Toxoplasma gondii* serological reagents

2. Classification:

Class I

Class II

3. Product code:

JJX- Quality Control Material (assayed and unassayed)

LGD- *Toxoplasma gondii* serological reagents

4. Panel:

75- Clinical Chemistry

83- Microbiology

H. Intended Use:

1. Intended use(s):

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

2. Indication(s) for use:

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

I. Device Description:

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

J. Substantial Equivalence Information:

1. Predicate device name(s):

- Elecsys C-Peptide CalCheck

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

- K040157

3. Comparison with predicate:

Similarities		
Item	Device Elecsys Toxo IgG CalCheck	Predicate Elecsys C-Peptide CalCheck (K040157)
Intended Use	For use in the verification of the calibration established by the Elecsys Toxo IgG reagent on the Elecsys and cobas e 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.
Indications for Use	For use in the verification of the calibration established by the Elecsys Toxo IgG reagent on the Elecsys and cobas e 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	Same	Three
Format	Same	Lyophilized
Handling	Same	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mix gently.
Stability	Same	<u>Unopened:</u> Store at 2-8°C until expiration date <u>Reconstituted:</u> 20 - 25°C : 4 hrs

Differences		
Item	Device Elecsys Toxo IgG CalCheck	Predicate Elecsys C-Peptide CalCheck (K040157)
Matrix Analyte	Human Serum anti- Toxo IgG	equine serum matrix anti- CCP

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

This 510(k) Premarket Notification was prepared and referenced the following guidance documents and recognized standards:

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material (DRAFT final: June 7, 2007)

No Standard document was 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):

Values for Toxo IgG CalCheck are 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 3 Elecsys 2010/ cobas e 411 analyzers, 3 MODULAR ANALYTICS E170/ cobas e601 analyzers. Two independent series of analyses are performed for each instrument. The target value is then calculated as the median of the determined values.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

The assay cut-off was determined using a 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.

Toxo IgG CalCheck Level	Toxo IgG Target Values (IU/mL)
Check 1 (low)	3
Check 2 (medium)	325
Check 3 (high)	520

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 are assigned to lots 15273499, 17922999, and 17923099 of the product. Composition: The Anti HBs CalCheck calibration verification solutions consists of 3 CalCheck solutions; low, medium and high, each with a defined Toxo IgG CalCheck level. This information is included in the package insert.

Toxo IgG CalCheck Level	Toxo IgG Assigned Values and Ranges
Check 1 (low)	2.73 IU/mL (1.91- 3.55)
Check 2 (medium)	315 IU/mL (189-441)
Check 3 (high)	500 IU/mL (300-700)

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.