

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

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

k111552

**B. Purpose for Submission:**

New device

**C. Measurand:**

Assayed control materials for L-3,3,5-Triiodothyronine (T3)

**D. Type of Test:**

Quality control materials

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

Elecsys T3 CalCheck 5

**G. Regulatory Information:**

| Product Code | Classification       | Regulation Section                          | Panel                   |
|--------------|----------------------|---|-------------------------|
| JJX          | Class I,<br>reserved | 21 CFR 862.1660<br>Quality Control Material | Clinical Chemistry (75) |

**H. Intended Use:**

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) for use:

The Elecsys T3 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 T3 quantitative assay reagent on the indicated Elecsys and cobas e immunoassay analyzers, for in vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Elecsys and cobas e immunoassay analyzers including the Elecsys 2010, MODULAR ANALYTICS E170, **cobas e 411**, **cobas e 601**, and **cobas e 602** analyzer platforms.

Note: **cobas e 411** share the same analytical core as Elecsys 2010; **cobas e 601**, and **cobas e 602** share the same analytical core as E170.

**I. Device Description:**

The Elecsys T3 CalCheck 5 is a lyophilized product consisting of L-3,3,5-Triiodothyronine (T3) in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. The sponsor declared in the labeling that all products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Target Values and Ranges for Elecsys T3 CalCheck 5

| Level   | Target Value (ng/mL) | Target Value (nmol/L) | Target Range (ng/mL) | Target Range (nmol/L) |
|---------|----------------------|-----------------------|----------------------|-----------------------|
| Check 1 | ≤ .13                | < 0.2                 | -                    | -                     |
| Check 2 | 1.30                 | 2.0                   | 1.11-1.50            | 1.7-2.3               |
| Check 3 | 3.26                 | 5                     | 2.93-3.58            | 4.5-5.5               |
| Check 4 | 5.21                 | 8                     | 4.69-5.73            | 7.2-8.8               |
| Check 5 | 6.51                 | 10                    | 5.79-7.16            | 8.9-11.0              |

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Elecsys T3 CalCheck

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

K963167

3. Comparison with predicate:

| Characteristic                       | Elecsys T3 CalCheck 5<br>(New Device)  | Elecsys T3 CalCheck<br>(Predicate Device)  |
|--------------------------------------|--|--|
| Similarities                         |  |  |
| Intended Use/<br>Indications for use | Same   | For use in the verification of the calibration established by the Elecsys T3 reagent on Indicated Elecsys and Cobas e immunoassay analyzers. |
| Format                               | Same   | Lyophilized  |
| Matrix                               | Same   | Human serum  |
| Handling                             | Same   | Reconstitute with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.           |
| Unopened Stability                   | Same   | Store at 2-8°C until expiration date   |
| Assay Measuring Range                | Same   | 0.19 – 6.51 ng/mL  |
| Differences                          |  |  |
| Levels                               | 5  | 3  |
| Reconstituted Stability              | 20-25 °C, 4 hours  | 15-25 °C, 4 hours  |
| Target Values                        | Check 1: < 0.13 ng/mL<br>Check 2: 1.3 ng/mL<br>Check 3: 3.26 ng/mL<br>Check 4: 5.21 ng/mL<br>Check 5: 6.51 ng/mL | Check 1: 0 ng/mL<br>Check 2: 1.6 ng/mL<br>Check 3: 5.8 ng/mL   |

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

None were 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):*

### Traceability

The assayed value of each CalCheck level was standardized against reference standards by weighing T3 into an analyte-free human serum matrix. The reference standard used was T3, BCR® certified Reference Material, from a commercial vendor. BCR is a registered trademark of the European Commission.

### Value Assignment:

For each Elecsys T3 CalCheck 5 lot manufactured, the CalChecks are assayed in duplicate on four E170 analyzers. The assigned value of each CalCheck is defined as the median value obtained from 8 determinations of the respective CalCheck. The assigned range is  $\pm 18\%$  of assigned value, in which 10% was allotted for between-analyzer platform tolerance, 4% for stability tolerance and 4% for precision of the assay.

Values are assigned for each lot of Elecsys T3 CalCheck 5 in combination with each Elecsys T3 reagent lot available.

For additional analyzers (Elecsys 2010), The Elecsys T3 CalCheck 5 was run once a day on 8 Elecsys 2010 analyzers for a total of 1 day. The assigned values obtained on Elecsys 2010 are compared to those obtained on the E170. Differences between the analyzer platforms are within the 10% tolerance, therefore, the values assigned to the E170 (and **cobas e 601, e602**) are transferred to and valid for the Elecsys 2010 (and **cobas e 411**).

### Stability:

The stability studies for T3 CalCheck 5 were performed on Elecsys 2010. Because these studies are not analyzer-dependent, these results, in addition to real-time stability study results, can be applied to the MODULAR ANALYTICS E170, cobas e 411, cobas e 601 and cobas e 602. The stability protocol and the acceptance criteria have been reviewed and found to be acceptable.

- Shelf-life stability:  
The accelerated stability testing performed at 35°C supports an initial shelf-life claim of 24 months at 2-8°C. Real-time testing at 2-8°C is on-going to support a claim of 36 months.
- Open-vial stability after reconstitution :  
Real time testing was performed and the data support the package insert claim that reconstituted Elecsys T3 CalCheck 5 is stable up to 4 hours at 20-25°C.
- On-board stability:  
The T3 CalCheck 5 products are not stored on-board the analyzer, therefore no on-board stability claims is made.

### *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:

Not applicable

**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.