

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

A. 510(k) Number:

k102269

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification and assay range verification material for IgE

D. Type of Test:

Not applicable

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Elecsys IgE CalCheck 5

G. Regulatory Information:

1. Regulation section:

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

2. Classification:

Class I, reserved

3. Product code:

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

4. Panel:

Immunology

H. Intended Use:

1. Intended use(s):

The Elecsys IgE 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 IgE II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

2. Indication(s) for use:

See Intended Use

3. Special conditions for use statement(s):

For prescription use only. For *in vitro* diagnostic use. The Elecsys IgE CalCheck 5 is not intended to be used as a primary calibrator or control material.

4. Special instrument requirements:

MODULAR ANALYTICS E170, cobas e 601, Elecsys 2010, cobas e 411 analyzers

I. Device Description:

The Elecsys IgE CalCheck 5 is a lyophilized product consisting of human Immunoglobulin E (IgE) in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels. Each set contains 5 lyophilized levels: Each bottle, reconstituted to 1.0 mL; Reactive ingredient (after reconstitution): IgE (human) in human serum matrix. Level 1 contains no analyte.

Level	Target Value [IU/mL]	Target Range [IU/mL]
Check 1	≤ 0.1	–
Check 2	100	79 - 121
Check 3	1225	968 - 1482
Check 4	2000	1580 - 2420
Check 5	2500	1975 - >2500

All human material should be considered potentially infectious. 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. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient specimen.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Elecsys IgE CalCheck
2. Predicate K number(s):
k984419
3. Comparison with predicate:

Similarities		
Item	New Device (k102269)	Predicate (k984419)
Intended Use	For use in calibration verification and for use in the verification of the assay range established by the Elecsys IgE II reagent on the indicated Elecsys and cobas e immunoassay analyzers	For use in the verification of the calibration established by the Elecsys IgE reagent and CalSet on Elecsys 1010 or 2010 immunoassay analyzers.
Analyte Measured	Human Immunoglobulin E	Same
Format of Reagent	Lyophilized	Same
Matrix	Human Serum	Same

Differences		
Item	New Device (k102269)	Predicate (k984419)
Number of Levels	5 levels	3 levels
Reagent Handling Instructions	Reconstitute the contents of Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow the bottles to	Reconstitute the contents of Check 1 with exactly 1 mL distilled or deionized water. Allow the bottle to stand closed for 15 minutes. Mix

Differences		
Item	New Device (k102269)	Predicate (k984419)
	stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	gently by inversion to ensure homogeneity. Prepare Checks 2 and 3 in the same manner as for Check 1 above.
Stability of Reagent	<u>Unopened:</u> •Store at 2-8°C until expiration date <u>Reconstituted:</u> •20-25°C: 4 hours	<u>Unopened:</u> •Store at 2-8°C until expiration date <u>Reconstituted:</u> •15-25°C: 4 hours

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

Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

L. Test Principle:

Calibration verification is not a requirement of the Elecsys and cobas e immunoassay systems based on the manufacturer’s recommendations.

However, in instances where such a test procedure is required by certification agencies, or where the user wishes to document calibration verification, these CalCheck 5 solutions are used for such testing.

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:

This method has been standardized against the 2nd IRP WHO Reference Standard 75/502.

Expected Values and Value Ranges

For each Elecsys IgE CalCheck 5 lot manufactured, the CalChecks are run in duplicate on at least three E170 analyzers. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzers) of the respective CalCheck. (i.e. Elecsys 2010 and E170). Pre-determined acceptance criteria for IgE recovery must be met for each control lot. The target value for each CalCheck is the median of the observed values. IgE expected values and value ranges are lot dependent and are listed in the lot-specific value sheet. Test results must fall within the range printed on the lot-specific value sheet. The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Value Assignment

Level	Target Value (IU/mL)	Assigned Value (IU/mL)
Check 1	≤ 0.1	< 0.1
Check 2	100	98.4
Check 3	1225	1130
Check 4	2000	1880
Check 5	2500	2460

Stability

Open-Vial Stability Studies

The on-test and reference materials were tested in duplicate. The on-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 CalChecks. The on-test recovery was calculated as a percentage of the reference value. The reconstituted vials are stable for four hours at 20-25°C

Accelerated Stability:

The on-test material was stored lyophilized (as supplied to the user) 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 on-test recovery was calculated as a percentage of the reference value. Accelerated stability testing supports the target shelf life claim of 18 months

Real-Time Stability:

In the on-going real-time stability study, the Elecsys IgE CalCheck 5 test material is stored at 2-8°C. The CalChecks are tested at T=0 and at specified intervals over the shelf life of the device up to the planned shelf life plus one month. The manufacturer claims CalCheck 5 is stable until the expiration date printed on the vial when stored unopened at 2 – 8° C.

Dilution Study:

To demonstrate that the values are within the assay's measuring range of 0.100 – 2500 IU/mL after mixing, the following dilution study was performed on Elecsys IgE CalCheck 5 Levels 1 and 5: Check 1 & Check 2 and Check 4 & Check 5 were mixed in a 1:1 ratio and measured in two-fold determination. The average was then calculated.

Sample	Value after 1:1 Dilution [IU/mL]	Average 1:1 Dilution [IU/mL]
E170/e 601		
Check 1 + Check 2	48.7	48.6
Check 1 + Check 2	248.4	
Check 4 + Check 5	2246	2274
Check 4 + Check 5	2302	
2010/e 411		
Check 1 + Check 2	50.7	49.4

Check 1 + Check 2	48.0	
Check 4 + Check 5	2274	2250
Check 4 + Check 5	2225	

- 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:
The expected values are provided in the labeling for each specific lot.

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.