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

A. 510(k) Number:

k103601

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Free T3 and Free T4

D. Type of Test:

Not applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit MicroCV™ FreeT4/FreeT3 Linearity Set

G. Regulatory Information:

1. Regulation section:

   21CFR 862.1660, Quality control material

2. Classification:

   Class I, reserved

3. Product code:

   JJY, multi-analyte controls, all kinds

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   The Audit™ MicroCV™ Free T4 / Free T3 Linearity Set consists of five levels of human and bovine albumin based matrix. Each level contains the following analytes: Free T4 and Free T3. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments.

   This product may also be used as a quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on automatic analyzers. The Audit™ Free T4 / Free T3 Linearity Set is "For In Vitro Diagnostic Use Only".

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Performance testing was conducted on the Biomerieux V12 Compact Mini-Vidas Immunoassay Analyzer (for Free T4) and the Siemens Centaur XP (for Free T3)

I. Device Description:

The Audit™ MicroCV™ Free T4 / Free T3 Linearity Set is a 5 level quality control solution set containing Free T4 / Free T3 analytes as the messurand. The base matrix is a human and bovine based serum albumin and the free T4 and free T3 in each control are the endogenous levels found in the human and bovine serum used to make each control. The linearity set is used to confirm the proper calibration, linear operating range, and reportable range of Free T4 / Free T3 analytes. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

All human source materials used to produce this product have been tested for HbsAg, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA cleared/approved tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Audit™ MicroCV™ Immunoassay Linearity Set

2. Predicate K number(s):

   k062668

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	The Audit™ MicroCV™ Free T4 / Free T3 Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples to detect systematic analytical deviations of laboratory testing procedures	Same
Number of levels per set	5	Same
Kit Contents	5 x 5 mL	Same
Matrix	Human and Bovine Albumin Serum	Same
Form	Lyophilized	Same
Storage	2 – 8 ºC for 24 months	Same
Open Bottle Stability	2 – 8 ºC for 5 days	Same

Differences		
Item	Device	Predicate
Analytes	Free T4 and Free T3	Cortisol. Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4, TSH, and Vitamin B12

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

CLSI EP6-A: evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

The Audit™ Micro CV™ Free T4 / Free T3 Linearity Set is prepared such that a linear relationship exists among all five levels (Levels A through E). Level A has a concentration near the lower limit level and Level E has concentrations near the upper limit level of instruments. Levels B-D are related by linear dilution of Level A and Level E using dilution schemes based on guidelines provided by CLSI EP6-A.

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

Traceability and Value Assignment

All components of the Audit™ Micro CV™ Free T4 / Free T3 Linearity Set are obtained from a commercial vendor and inspected in-house.

Value assignment for each analyte was conducted by repeat analyses on the Biomerieux Mini-Vidas analyzer (Free T4) or the Siemens Centaur analyzer (Free T3). All control material levels for both analytes were measured 4 times (1 lot) and the mean values were used to assign the target concentration values for each of the five linearity set levels. The target ranges were calculated as ± 15% of the target value. The mean concentration values of each level were plotted (concentration value vs. assigned level) and a linear regression value obtained. If the five-point linear regression R^2 value was greater that 0.95 and if the plots are linear, the product passed the linearity test. Values may change depending on lot, instrumentation, methodology, and assay temperature. Lot-specific expected value ranges are provided in the package insert. Expected value ranges for each level of the linearity set are summarized in the table below.

Target Values:

Analyte	**Units**	**A**	**B**	**C**	**D**	**E**
Free T4	pmol/L	$\leq$ 10	30	50	70	90
Free T3	pg/mL	$\leq$ 5	13.75	17.5	21.25	25

Stability

Stability studies have been performed to determine the open vial stability and shelf life for the Audit™ MicroCV™ Free T4 / Free T3 Linearity Set. Real time studies are ongoing to support the shelf life of this product. Stability claims meet the stated acceptance criteria of recovery from unstressed material values of ± 15%, and are as follows:

Open Vial Stability: Once a vial has been reconstituted, all analytes will be stable for 5 days when stored tightly capped at 2-8 C.

Shelf Life: 24 months at 2 - 8º C.

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.