

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

A. 510(k) Number:

k062668

B. Purpose for Submission:

New device

C. Measurand:

Quality control set for Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4, TSH, and Vitamin B12.

D. Type of Test:

Quality control material

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit™ MicroCV™ Immunoassay Linearity Set

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660, Quality control material (assayed and unassayed).

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds (assayed and unassayed)

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™ Immunosassay Linearity Set consists of five levels in Human and Bovine serum albumin matrix. Each level contains the following analytes: cortisol, digoxin, estradiol, ferritin, folate, free T4, FSH, hCG, LH, progesterone, prolactin, testosterone, total PSA, total T3, total T4, TSH, and vitamin B12. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments.

This product may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.

In addition, level A-E of this product may be used as unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in the package insert. It is not intended to be used as an assayed quality control material for any other analyzer systems.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

This device may be used as an assayed quality control material only for the instrument system specified in the package insert.

I. Device Description:

The Audit MicroCV Immunoassay Linearity Set is a human and bovine serum albumin based, lyophilized, five level set of QC material, with each level containing 17 analytes and a preservative. Level A is near the lower limit of instruments and Level E is near the upper limit of instruments. Levels B-D are related by linear dilution of Level A and Level E.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Audit™ MicroCV™ General Chemistry Linearity Set

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

k042318

3. Comparison with predicate:

Similarities		
Item	Device: Audit MicroCV Immunoassay Linearity Set	Predicate: Audit MicroCV General Chemistry Linearity Set
Intended use	Linearity Material or Assayed QC Material (for analyzer specified in package insert only)	Linearity Material or Assayed QC Material (for analyzer specified in package insert only)
Number of Levels per set	5	5
Contents	5 x 5 ml	5 x 5 ml
Form	Lyophilized	Lyophilized
Preservative	Yes	Yes
Storage	2 to 8°C	2 to 8°C

Differences		
Item	Device: Audit MicroCV Immunoassay Linearity Set	Predicate: Audit MicroCV General Chemistry Linearity Set
Number of Analytes per Vial	17	30
Matrix	Human and bovine Serum Albumin based	Human Based Serum
Analytes	Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4, TSH, and Vitamin B12	Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate,

Differences		
Item	Device: Audit MicroCV Immunoassay Linearity Set	Predicate: Audit MicroCV General Chemistry Linearity Set
		Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid
Reconstituted Stability	5 days at 2 to 8°C	7 days at 2 to 8°C except for enzymes and bilirubin which are 48 hours

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

Not Applicable

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™ MicroCV™ Immunoassay Linearity Set is prepared such that the analyte concentrations are equidistant across levels A – E, with Level A containing the lowest concentrations and Level E the highest concentrations. A linearity study was performed for each analyte by measuring all five levels and calculating an R² value and comparing the measured value of each control level to the target value assigned to each level during the value assignment process (see Value Assignment below). The R² value and the measured vs. target values met the sponsor's acceptance criteria for each analyte.

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

Traceability

The base matrix consists of human serum albumin, bovine serum albumin, and preservatives. The analytes are derived from both human and non-human sources and were obtained from commercial vendors. The low and high level analytes were adjusted to within the desired target range of each assay. The remaining 3 points are dilutions of the low and high levels.

Shelf Life Stability

The sponsor's unopened bottle shelf life stability claim is two years from the date of manufacture. All analytes were placed on heat stress stability in closed bottles at 37°C and tested on day 0 and day 20. The sponsor supplied a Heat Stress Stability Prediction chart that allowed an analyte heat stressed for 17.5 days at 37°C to predict two year stability at 2-8°C. After 20 days at 37°C all analytes met the manufacturer's acceptance criteria for deviation from day 0. Real time stability studies are on going to support the accelerated studies.

Reconstituted Stability

The sponsor claims the reconstituted control is stable for 5 days when stored tightly capped at 2-8°C. All analytes were reconstituted on day 0 and stored in tightly capped bottles at 2-8°C for five days. All analytes were tested on day 0 and day 5 and met the manufacturer's acceptance criteria for deviation from day 0.

Value Assignment

Each analyte was measured multiple times and the mean value of each analyte was used to establish target values at each level. The target ranges were calculated as $\pm 20\%$ of the target value. These values are only applicable for the instrument specified for each analyte in the Instructions for Use.

- 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.