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

A. 510(k) Number:
k082714

B. Purpose for Submission:
New Device

C. Measurand:
Calibrator/Control Materials for Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Methotrexate, Phenobarbitol, Phenytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin test systems.

D. Type of Test:
Control material

E. Applicant:
Aalto Scientific, Ltd.

F. Proprietary and Established Names:
Audit MicroCV Therapeutic Drug (TDM) Linearity Set

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR§ 862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   The Audit™ MicroCV™ Therapeutic Drug (TDM) Linearity Set consists of five levels in Human and Bovine serum albumin matrix. Each level contains the following analytes: Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Methotrexate, Phenobarbital, Phenytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid and Vancomycin. 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 professional use only.

4. Special instrument requirements:
   The labeling lists instruments on which the device is meant to be used:

I. Device Description:

The Audit MicroCV Therapeutic Drug (TDM) Linearity Set is a human based, lyophilized, five level set of QC material, with each level containing 14 analytes. It is used to confirm the proper calibration, linear operating range, and reportable range of Therapeutic Drug (TDM) methods for the analytes listed in the Indications for Use. 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.

Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg.

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:

Characteristics	Audit™ MicroCV™ Therapeutic Drug (TDM) Linearity Set (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Similarities		
Intended Use	See above	Similar
Number of levels per set	5	5
Contents	5 x 5 mL	5 x 5 mL
Storage	2 to 8º C Until expiration date	2 to 8º C Until expiration date
Form	Lyophilized	Lyophilized
Stabilizers	None	None

Differences		
Type of Analytes	Therapeutic Drug	General Chemistry
Matrix	Human and animal based serum albumin	Human Based Serum
Number of Analytes per vial	14	30
Preservatives	Sodium azide	Sorbitol Sodium azide
Reconstituted Stability	5 days at 2 to 8º C	7 days at 2 to 8º C except for enzymes and bilirubin, which are 48 hours

K. Standard/Guidance Document Referenced (if applicable):
None 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:
   Materials used in the production of this device are ACS or USP grade pharmaceuticals which are authenticated from the vendor's certificate of analysis. The product is tested throughout the manufacturing process with primary analytical standards traceable to USP standard references. Materials are obtained from approved vendors and put through an internal quality control process.

   Stability:
   The stability protocols and acceptance criteria for this product were reviewed and found to be acceptable. The product has an open-vial stability of 5 days when stored at 2-8 $^{\circ}$C. An accelerated stability study determined a shelf life stability of 2 years when stored at 2-8 $^{\circ}$C, and real-time studies are ongoing.

   Value Assignment:
   Quality control protocols for value assignments were reviewed and found to be acceptable. Level A (low pool) all analytes are adjusted to be within 5-10% of the lowest limit of measurability for their corresponding analyte. For Level E (high pool), all analytes are adjusted to be within 5% to 10% of the highest limit of measurability for their corresponding analyte. Levels are then

diluted to the following:

Level A = 100% Low Pool
Level B = 75% Low Pool, 25% High Pool
Level C = 50% Low Pool, 50% High Pool
Level D = 25% Low Pool, 75% High Pool
Level E = 100% High Pool

    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.