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

A. 510(k) Number:

k070223

B. Purpose for Submission:

Notification of intent to manufacture and market a new device

C. Measurand:

Quality control material for apolipoprotein AI, apolipoprotein B, cholesterol, HDL cholesterol, LDL cholesterol, and triglyceride

D. Type of Test:

Quality control materials

E. Applicant:

Aalto Scientific LTD

F. Proprietary and Established Names:

Proprietary - Audit™ MicroCV™ Lipids Linearity Set
Established Name – Quality Control Material

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660 Quality control material (assayed and unassayed)

2. Classification:

   Class I

3. Product code:

   JJY

4. Panel:

75

H. Intended Use:

1. Intended use(s):

   See Indications for Use Below

2. Indication(s) for use:

   The Audit™ MicroCV™ Lipids Linearity Set (Low) consists of five levels. Each level contains the following analytes: Apolipoprotein A1, Apolipoprotein B, Cholesterol, HDL Cholesterol, LDL Cholesterol and Triglyceride and 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 provides a chart that lists the target value and the corresponding ranges by analyte and by instrument.

I. Device Description:

The Audit™ MicroCV™ Lipids Linearity Set (Low) is a human based, lyophilized, five level set of QC material, with each level containing 6 analytes. It is used to confirm the proper calibration, linear operating range, and reportable range of Lipids methods for the analytes listed. 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 product was tested by FDA approved methods and found to be negative for antibodies to HIV and HCV and non-reactive to HBsAg.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Audit™ MicroCV™ General Chemistry Set

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

   k042318

3. Comparison with predicate:

Characteristics	Audit™ MicroCV™ Lipids Linearity Set (Low) (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (k042318)
Intended Use	Audit™ MicroCV™ Lipids Linearity Set (Low) is assayed quality control material consisting of Delipidized Human Serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes and may be used for proficiency testing in inter-laboratory surveys. In addition, this product may also be used 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.	Audit™ MicroCV™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes and may be used for proficiency testing in inter-laboratory surveys. In addition, this product may also be used 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.
Number of Analytes per vial	6	30
Number of levels per set	5	5
Contents	5 x 2 mLs	5 x 5 mLs
Matrix	Delipidized Human Serum	Human Based Serum
Type of Analytes	Lipids	General Chemistry
Form	Lyophilized	Lyophilized
Stabilizers	Sucrose	None

Preservatives	Sorbitol	Sorbitol
Storage	2 to 8º C Until expiration date	2 to 8º C Until expiration date
Reconstituted Stability	24 hours at 2 to 8º C	24 hours at 2 to 8º C

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

CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach

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 base matrix is delipidized human serum albumin and bovine serum albumin. This is the starting matrix for building the Low and High Pools. Extracts of cholesterol and triglycerides, serum extracts of HDL cholesterol complex (Apolipoprotein A, Cholesterol) and of LDL cholesterol complex (Apolipoprotein B, Cholesterol, Triglycerides) are added to the high level (Level E). For the Low Pool (Level A), all analytes are adjusted to be within 5% to 10% of the lowest limit of measurability for their corresponding assay. For the High Pool (Level E), all analytes are adjusted to be within 5% to 10% of the highest limit of measurability for their corresponding assay.

   Value Assignment: The sponsor states that each analyte is to be analyzed a total of 30 times and the mean of the measurements is used as the target concentration. Once a target concentration is established for Levels A – E, these concentrations are plotted on the y-axis vs levels 1 – 5 on the x-axis. If the r^2 regression line is ≥ 0.95 the relationship between the levels is accepted as linear.

Opened Bottle Stability: The sponsor recommends that the reconstituted product be stored at 2-8^{0}C and used within 24 hours of reconstitution. Stability at 2-8^{0}C was demonstrated by real time studies. All analytes satisfied the sponsor's acceptance criteria of ± 15% deviation from analyte concentration at day 0.

Closed Bottle Stability (Shelf Life): The sponsor's shelf life stability claim is two years from date of manufacture. . All analytes were heat stressed at 37^{0}C for 20 days to predict two year stability when stored at 2-8^{0}C. The percent loss is determined in comparison to Day Zero values and the product is considered stable when the loss reported is $\leq$ 15% loss or gain. All analytes satisfied the sponsor's acceptance criteria at 20 days of testing verifying the closed bottle stability claim. Real time studies are ongoing.

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:

A table is provided in the labeling that lists the target value and the corresponding ranges by analyte and by instrument.

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.