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

A. 510(k) Number:
k042318

B. Purpose for Submission:
New Device

C. Analytes:
Thirty clinical chemistry analytes identified in sections H and J below

D. Type of Test:
Not Applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names

Audit™ MicroCV™ General Chemistry Linearity Set

G. Regulatory Information:

1. Regulation Section:
   21 CFR § 862.1660 Quality control material (assayed and unassayed)
2. Classification:
   Class I, reserved
3. Product Code:
   JJY
4. Panel:
   75 Clinical Chemistry

H. Intended Use:

1. Intended Use / Indication(s) for Use:

   The Audit™ Micro*CV*™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate, Lipase,

Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. 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, levels B - 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.

2. Special Conditions for Use Statement:
   None
3. 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 base matrix consists of bovine serum and delipidized human serum. A low pool (level A) and a high pool (level E) are prepared by spiking in the analytes to the base matrix. The other levels are prepared as follows, so that the concentrations are equally spaced.

Level B	3 parts Level A plus 1 part Level E
Level C	1 part Level A plus 1 part Level E
Level D	1 part Level A plus 3 parts Level E

The formulation also includes stabilizers and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Maine Standards Co. Validate
   Cliniqa Corporation LiniCAL / Enzyme
   Cliniqa Corporation LiniCAL / General Chemistry
2. Predicate K number(s):
   k023410
   k040535
   k033162
3. Comparison with predicates:

Similarities			
Item	**Device**	**Validate**	**LiniCAL Enzyme/General Chemistry**
Intended Use	**Same**	**Linearity Material**	**Linearity Material**

Differences			
Item	**Device**	**Validate**	**LiniCAL Enzyme/General Chemistry**
Intended Use	**Linearity Material or Assayed QC Material (for analyzer specified in package insert only)**	**Linearity Material Only**	**Linearity Material Only**
Analyzer(s)	**Multiple Analyzers**	**Multiple Analyzers**	**Beckman Coulter Synchron**
Analytes	**Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid**	**Alkaline Phosphatase, ALT, Amylase, AST, CK, GGT, LD, Lipase, Total Bilirubin**	**Alkaline Phosphatase, ALT, Amylase, AST, Cholinesterase, CK, LD, Lipase, GGT, Pancreatic Amylase, Albumin, BUN, Calcium, Creatinine, Lactate, Magnesium, Phosphorous, Total Protein, Triglyceride, Glucose, Iron, Sodium, Potassium, Chloride**
Storage	**2 to 8° C**	**-10 to -20° C**	**2 to 8° C (enzymes -10 to -20° C)**

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

NCCLS EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material

In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions

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™ General Chemistry 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.

c. Traceability, Stability, Expected Values (controls, calibrators, or method):

Traceability: The base matrix is a mixture of human and bovine serum. NaCl, LiCl, Lactic Acid, BUN (Urea), $CaCl_2$, Creatinine, Dextose, $MgCl_2$, $NaHPO_4$, Uric Acid, KCl, Iron, Na Acetate, Conjugated Bilirubin, and Bilirubin are used as analyte adjustors. All are ACS or Reagent Grade Commercially available chemicals. LD, AST, ALT, CK, GGT, Amylase, Lipase, Alkaline Phosphatase, and Acid Phosphatase are plant or animal derived material from commercial vendors, who supply a certificate of authenticity. Triglyceride concentrations are adjusted using an in-house preparation of egg extract of triglyceride. Albumin, Cholesterol, HDL Cholesterol and LDL Cholesterol are endogenous substances whose concentrations are adjusted by varying the volume of the base matrix.

Opened Bottle Stability: The sponsor recommends that the reconstituted product be stored at 2-8^{o} C and used within 24 hours of reconstitution. Stability at 2-8^{o} C was demonstrated by real-time studies. All analytes satisfied the sponsor's acceptance criteria of $\leq \pm$ 10% deviation from analyte concentration at day 0.

Closed Bottle (Shelf Life) Stability: The sponsor's closed bottle stability claim is one year from the date of manufacture. All analytes were heat-stressed at 37^{o} C and measured at day 0, day 10, and day 20 to estimate storage stability at 2-8^{o} C. The sponsor supplied a Heat Stress Stability Prediction chart in which an analyte stressed for 8.7 days at 37^{o} C can be used to predict one year of storage at 2-8^{o} C. An acceptance criterion was $\leq \pm$ 10% deviation from analyte concentration at day 0. All analytes satisfied the sponsor's acceptance criterion at 10 days of stressing, verifying the closed bottle stability claim. Real-time stability studies are ongoing.

Value Assignment: The sponsor states that each analyte is to be analyzed a total of thirty (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 value of the regression line is ≥ 0.975, the relationship between the levels is accepted as linear.

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 Cutoff:

Not applicable.

5. Expected Values/Reference Range:

Not Applicable.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.