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

A. 510(k) Number:

k102617

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for CKMB, Myoglobin, and TnI analytes

D. Type of Test:

Not Applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit™ MicroCV™ Cardiac Markers Linearity Set

G. Regulatory Information:

1. Regulation section:

   21 CFR §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. Indications(s) for use:

   The Audit™ MicroCV™ Cardiac Markers Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains CKMB, Myoglobin, and Troponin I (TnI) analytes. The five levels demonstrate a linear relationship to each other for CKMB, Myoglobin, and TnI 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 analyzers specified in the package insert. The Audit™ MicroCV™ Cardiac Markers Linearity Set is "For In Vitro Diagnostic Use Only".

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Siemens Centaur XP Analyzer

I. Device Description:

The Audit™ MicroCV ™ Cardiac Markers Linearity Set Cardiac Markers Linearity Set MicroCV Cardiac Markers Linearity Set is a 5 level quality control solution set that contains CKMB, Myoglobin, and TnI analytes as the measurand. It is used to confirm the proper calibration, linear operating range and reportable range of CKMB, Myoglobin, and TnI 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.

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. 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. Because no test method can offer complete assurance that HIV, Hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test.

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:

Device Similarities and Differences		
Characteristic	Candidate Device Audit™ MicroCV™ Cardiac Markers Linearity Set (k102617)	Predicate Device Audit™ MicroCV™ General Chemistry Linearity Set (k042318)
Intended Use/Indications for use	The device is an assayed quality control material consisting of five levels human based serum. The five levels demonstrate a linear relationship to each other for analytes listed in the package insert.	Same
Product Use	Calibration verification quality control material	Same
Number of Analytes per vial	3	31
Number of levels per set	5	5
Contents	5 x 1 mL	5 x 5 mL
Matrix	Human Serum	Human Serum
Type of Analytes	CKMB, Myoglobin, Troponin I (TnI)	Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactase, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides, and Uric Acid.
Form	Lyophilized	Lyophilized
Storage	2 to 8° C for 18 months	2 to 8° C for 48 months
Open Bottle Stability	5 days at 2 to 8°C	7 days at 2 to 8° C

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

Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline – (CLSI EP6-A).

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Linearity was performed by measuring multiple replicates of each analyte on a Siemens Centaur XP analyzer. The mean concentration values of each level were plotted (concentration value vs. assigned level) and linear regression values were obtained.

CKMB: y=56.095x-55.705, R2 =0.9991
Myoglobin: y=188.89x-166.41, R2=.9998
Troponin: y=10.995x-11.297, R2= 0.9973

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

Traceability:

The assigned values of Cardiac Markers quality control material are traceable to an internal standard manufactured using highly purified material.

Stability:

All stability tests were performed with Siemens reagents on a Centaur XP instrument. Real-time studies are ongoing.

Accelerated Stability: Accelerated stability was performed to predict the product shelf life. Three vials of each level were stressed at 25° C for 48 days to predict 18 months stability when stored at 2-8° C. Vials were tested according to "destructive testing." The accelerated studies are supported by on-going real-time stability studies. The percent loss is calculated compared to Day Zero values and the product is considered stable when the loss reported is ≤ 10% loss. The results showed less than a ± 10% difference from the day zero results. The claimed shelf-life stability is 18 months when stored at 2-8° C.

Open Vial Stability: Open vial stability was performed to determine the viability of the product during the course of normal use. Four vials of each level were reconstituted, stored for five days at 2-8° C and tested using "destructive testing."

The percent loss is calculated compared to Day Zero values and the product is considered stable when the loss reported is ≤ 10% loss. The results showed less than a ± 10% difference from the day zero results. The claimed open vial stability is 5 days when stored at 2-8° C.

Value Assignment:

Value assignment was performed by one set of reagent for CKMB, Myoglobin and Troponin I analytes. Each analyte was measured seven times (seven separate vials) and the mean value of each was used to establish target concentration values at each level. The instrument (Centaur XP) was calibrated using Siemens calibrators and the calibration was verified by using Siemens control materials.

The results are as follows:

Levels	A		B		C		D		E	
Analyte Units Instrument	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
CKMB, ng/mL Siemens/ Centaur XP	2.19	1.86-2.52	56.64	48.14-65.14	110.12	93.60-126.64	165.93	141.04-190.82	228.02	193.82-262.22
MYO, ng/mL Siemens/ Centaur XP	20.87	17.74-24.00	210.31	178.76-241.86	406.99	345.94-468.04	585.27	497.48-673.06	777.84	661.16-894.52
TnI, ng/mL Siemens/ Centaur XP	0.70	0.60-0.81	9.99	8.49-11.49	21.08	17.92-24.24	32.00	27.20-36.80	44.67	37.97-51.37

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 package insert.

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.