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

A. 510(k) Number:

k101216

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for Alpha-1-Antitrypsin, Complement C3, Complement C4, Immuoglobulin G, Immunoglobulin A, Immunoglobulin M, Transferrin

D. Type of Test:

Not applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit™ MicroCV™ Protein Linearity Set

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Audit™ MicroCV™ Protein Linearity is assayed quality control material consisting

of five levels protein (human) based serum. Each level contains Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin analytes. The five levels demonstrate a linear relationship to each other for Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M, and Transferrin analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M, and Transferrin. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit MicroCV Protein Linearity Set is "For In Vitro Diagnostic Use Only."

3. Special conditions for use statement(s):

The Audit™ MicroCV™ Protein Linearity Set should not be used for calibration or standardization of the Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M or Transferrin assays.

4. Special instrument requirements:

Performance was established on the Beckman Immage analyzer.

I. Device Description:

The Audit™ MicroCV™ Protein Linearity Set is a protein (human) serum based, aqueous quality control material containing five levels (Levels A through E) of Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin. The set is used to confirm proper calibration, linear operating range, and reportable range of the measured analytes. Level A contains Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin concentrations near the lower limit level. Level E contains Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin concentrations near the upper limit level of chemistry analyzers. Levels B-D are related by linear dilution of Level A and Level E.

All human source materials used to produce this product have been tested for HbsAg, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA cleared/approved tests.

J. Substantial Equivalence Information:

1. Predicate device name(s)

Audit™ MicroCV™ General Chemistry Linearity Set

2. Predicate 510k number(s)

k042318

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate
Intended/Indications for Use	The Audit™ MicroCV™ Protein Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples to detect systematic analytical deviations of laboratory testing procedures.	Same
Number of Analytes per vial	7	30
Number of levels per set	5	Same
Matrix	Human based Serum	Same
Form	Liquid	Lyophilized
Stabilizers	None listed	None listed
Preservatives	Sodium Azide	Sorbitol Sodium Azide
Storage	2 to 8˚C until expiration date	Same
Open bottle Stability	24 hours at 2-8˚C	Same

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

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

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™ Micro CV™ Protein Linearity Set is prepared such that a linear relationship exists among all five levels (Levels A through E). Level A has a concentration near the lower limit level and Level E has concentrations near the upper limit level of instruments. Levels B-D are related by linear dilution of Level A and Level E using dilution schemes based on guidelines provided by NCCLS EP6-A.

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

Traceability

All components of the Audit™ Micro CV™ Protein Linearity Set are obtained from a commercial vendor and inspected in-house.

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the Audit Micro CV Protein Linearity Set were determined using an accelerated study to predict closed vial shelf life for each level of the linearity set. A closed vial shelf life of 1 year is expected at the recommended storage temperature (2 to 8˚C). Real- time closed vial stability is ongoing. Real-time opened vial stability studies were also performed. The sponsor states the open vial stability is 24 hours (1 day) if stored tightly capped at 2 to 8 ˚C. Storage recommendations are provided in the labeling.

Value Assignment

Expected values for the analytes in this submission were determined by repeat analyses on the Beckman Immage analyzer. All seven analytes are cleared for use on the Beckman Immage analyzer (Alpha-1-Antitrypsin (k964766), Complement C3 (k964842), Complement C4 (k964842), IgG, IgA, IgM (k993547) and Transferrin (k963427). All seven analytes were measured 5 times and the mean values were used to assign the target concentration values for each of the five linearity set levels. The target ranges were calculated as ± 10% of the target value. The mean concentration values of each level were plotted (concentration value vs. assigned level) and a linear regression value obtained. If the five-point linear regression R^2 value was greater that 0.95 and if the plots are linear, the product passed the linearity test. Values may change depending on lot, instrumentation, methodology and assay temperature. Lot-specific expected value ranges are provided in the package insert. Expected value ranges for each level of the linearity set are summarized in the table below.

Beckman Immage Analyzer

Analyte	Units	A	B	C	D	E
Alpha-1-Antitrypsin	mg/dL	24-36	86-130	157-235	222-332	293-439
Complement C3	mg/dL	23-35	147-221	288-432	387-581	514-772
Complement C4	mg/dL	4-6	26-39	47-71	70-104	86-128
Immunoglobulin G	mg/dL	54-82	604-906	1115-1673	1606-2410	2062-3094
Immunoglobulin A	mg/dL	15-23	130-196	244-366	350-524	457-685
Immunoglobulin M	mg/dL	22-32	127-191	230-344	341-511	427-641
Transferrin	mg/dL	30-46	190-286	356-534	553-829	809-1213

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 the labeling for each specific lot.

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.