

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k112705

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-antitrypsin (AAT), Albumin, Complement C4 (C4), complement C3 (C3), Alpha-2-macroglobulin, Alpha-1-acid glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-microglobulin

D. Type of Test:

Quality control material

E. Applicant:

Aalto Scientific Ltd.

F. Proprietary and Established Names:

Audit® MicroLQ™ Serum Protein Control

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1660, Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product code:
JJY, Multi-analyte controls, all kinds (assayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
Audit® MicroLQ™ Serum Protein Control is an assayed, ready-to-use liquid, bi-level human serum-based control for use with assays designed to quantitate: Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin. It is intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin assays. 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 Beckman Immage 800.

The Audit® MicroLQ™ Serum Protein Control is for In Vitro Diagnostic use only.

2. Indication(s) for use:
Same as Intended Use
3. Special conditions for use statement(s):
None
4. Special instrument requirements:
Performance was established on the Beckman Immage 800 analyzer.

I. Device Description:

The Audit® MicroLQ™ Serum Protein Control is a human serum-based protein control mixture. The base matrix is human serum. This is the starting matrix for building the two sets of controls: Low (Level 1) and High (Level 2) Controls. Both sets of controls contain the following analytes: Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin. The Level 1 set contains lower levels of each analyte (except for beta-2-microglobulin) and the Level 2 set contains higher levels of each analyte.

The product is kitted as bi-level control with three 2-mL vials for each level, for a total of 6 vials.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):
Audit® MicroCV™ Protein Linearity Set, k101216
2. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Assayed QC material	Same
Analytes	Includes Alpha-1-antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin M, Immunoglobulin A, Transferrin	Same
Matrix	Human serum-based	Same
Storage	2-8°C	Same
Form	Liquid	Same

Differences		
Item	Device	Predicate
Analytes	Includes Immunoglobulin E, Prealbumin, Antithrombin III, Albumin, Alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Haptoglobin, and Beta-2-Microglobulin	These analytes are not included
Type of Control	Bi-level control	Linearity set (5 levels)

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

The analytes used in this control material are human derived materials obtained from commercial vendors and QC tested in-house.

Value assignment

Each analyte value assignment for Level 1 and Level 2 was performed on the Beckman Immage 800 analyzer. All 16 analytes have been cleared for use with the Beckman Immage analyzer. Each analyte was measured 15 times (over a three-day period) and the mean value of each analyte was used to establish target concentration values at each level. The target ranges were calculated as $\pm 15\%$ of the target value. Expected value ranges for Level 1 and Level 2 of each analyte are shown in the table below. There is no Level 1 value for Beta-2-Microglobulin.

Assay/Reagent	Units	Level 1		Level 2	
		Mean	Range	Mean	Range
Immunoglobulin E	IU/mL	231	196-265	573	487-659
Immunoglobulin M	mg/dL	106	90-122	328	279-377
Immunoglobulin G	mg/dL	744	633-856	2081	1769-2394
Immunoglobulin A	mg/dL	267	227-307	644	547-740
Prealbumin	mg/dL	24.5	20.8-28.2	60.0	51.0-69.0
Antithrombin III	mg/dL	20.2	17.2-23.2	52.0	44.2-59.8
Alpha-1-Antitrypsin	mg/dL	97.5	82.9-112.2	250	212-287
Albumin	mg/dL	2377	2021-2734	6617	5625-7610
Complement C4	mg/dL	19.9	16.9-22.9	55.3	47.0-63.6
Complement C3	mg/dL	66.7	56.7-76.7	197	167-227
alpha-2-Macroglobulin	mg/dL	89.2	75.8-102.6	274	233-315
Alpha-1-Acid Glycoprotein	mg/dL	53.5	45.5-61.5	160	136-184
Ceruloplasmin	mg/dL	25.2	21.4-29.0	68.2	58.0-78.5
Transferrin	mg/dL	176	149-203	506	430-582
Haptoglobin	mg/dL	103	87-117	284	241-327
Beta-2-Microglobulin	mg/L	N/A	N/A	0.955	0.812-1.099

Stability

A stability/shelf-life claim of 3 years at 2-8°C was determined based on an accelerated stability study on two lots of material. All vials that were used for stressed stability studies were first stressed in the incubator for 30 days, after which time the vials were opened, left at room temperature for 15 minutes, closed and left for 30 minutes at 2-8°C. The percent loss was determined in comparison to Day Zero values and the product is considered stable when the loss reported is \leq 15% loss. Confirmatory real-time stability tests are ongoing.

There is no specific claim in the product labeling for on-board vial stability. After opening, the contents should be used according to the instrument manufacturer's instructions and immediately returned to 2-8°C. The control material should not be left in the instrument and should be recapped and returned to the refrigerator after each use.

- d. *Detection limit:*
Not applicable
- e. *Analytical specificity:*
Not applicable

