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

A. 510(k) Number:

k112742

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydrogenase (LD), Microalbumin, Microprotein, and Sodium.

D. Type of Test:

Not applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit® MicroLQ™ Spinal Fluid Control

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:

   Audit® MicroLQ™ Spinal Fluid Control is a quality control material intended for monitoring the precision of laboratory testing procedures.
   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 Audit® MicroLQ™ Spinal Fluid is for In Vitro Diagnostic use only.

3. Special conditions for use statement(s):

   The Audit® MicroLQ™ Spinal Fluid Control should not be used for calibration or standardization of the Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydrogenase (LD), Microalbumin, Microprotein, and Sodium.

4. Special instrument requirements:

   Performance was established on the Beckman Immage 800 and Roche P-Modular analyzers.

I. Device Description:

The Audit® MicroLQ™ Spinal Fluid Control is a human based, liquid set of QC material. Each level of the set contains Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydogenase (LD), Microalbumin, Microprotein, and Sodium analytes. It is used to confirm the proper calibration of Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydrogenase (LD), Microalbumin, Microprotein, and Sodium

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 K number(s):

   k101216

3. Comparison with predicate:

Similarities		
Item	New Device	Predicate
Characteristics	Audit® MicroLQ™ Spinal Fluid Control (k112742)	Audit™ MicroCV™ General Chemistry Linearity Set (k101216)
Intended Use	The Audit® MicroLQ™ Spinal Fluid Control is a quality control material intended for monitoring the precision of laboratory testing procedures.	Same
Analyzers	P-Modular and Beckman Immage 800	Beckman Immage 800
Format	Liquid	Same
Preservatives	Sodium azide	Same
Stability	2-8°C until expiration date	Same
Matrix	Human serum	Same

Differences		
Item	New Device	Predicate
Characteristics	Audit® MicroLQ™ Spinal Fluid Control (k112742)	Audit™ MicroCV™ General Chemistry Linearity Set (k101216)
Type of Analytes	Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydrogenase (LD), Microalbumin, Microprotein, and Sodium.	Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin.
Number of Analytes	10	7
Levels per set	2	5
Contents	6 x 3 ml	5 x 5 ml
Open vial stability	30 days at 2 to 8ºC	24 hours at 2 to 8ºC

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

None were 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
   All components of the The Audit® MicroLQ™ Spinal Fluid Control are obtained from a commercial vendor and inspected in-house.

   Stability
   Shelf life and open vial stability:
   Real-time testing at 2-8ºC was conducted and is still on-going. The stability study protocol and acceptance criteria have been reviewed and found to be acceptable. The current accelerated stability test results and ongoing real time stability studies support two year shelf life stability and 30 days open vial stability when stored at 2-8ºC.

   Value Assignment
   The control ranges as determined using Beckman Immage 800 analyzer for Immunoglobulin A, Immunoglobulin G, and Immunoglobulin M and Roche Modular-P analyzer for Chloride, Glucose, Lactate, Lactate Dehydrogenase, Microalbumin, Microprotein, and Sodium are provided in the assigned value sheet for each lot release. Values were assigned from replicate measurements as ± 15% CV around the mean. Representative values are shown in the table below.

   In the labeling the sponsor recommends that each end user laboratory establish its own means and acceptable ranges and use the assigned value sheet as guidance only.

Analyte	Reagent	Analyzer	Units	Level 1 Mean	Level 2 Mean
Chloride	Roche	P-Modular	mEq/L	124.8	76.8
Glucose	Roche	P-Modular	mg/dL	64	34
Lactate	Roche	P-Modular	mmol/L	2.4	36.0
LD	Roche	P-Modular	IU/L	22	50
Microalbumin,	Pointe	P-Modular	mg/dL	17.1	26.4
Microprotein	Pointe	P-Modular	mg/dL	30.9	80.6
Sodium	Roche	P-Modular	mEq/L	156.3	84.7
Immunoglobulin A	Beckman	Immage 800	mg/dL	1.20	2.85
Immunoglobulin G	Beckman	Immage 800	mg/dL	4.77	42.74
Immunoglobulin M	Beckman	Immage 800	mg/dL	0.800	1.689

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.