

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

A. 510(k) Number:

k111964

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Phosphorous, Urea Nitrogen, Uric Acid (in Set 1);
Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium,
Microprotein, Microalbumin (in Set 2).

D. Type of Test:

Not applicable

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit MicroCV™ Urine/Fluids Chemistry Linearity Set

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660, Quality Control Material

2. Classification:

Class I, reserved

3. Product code:

JJY, multi-analyte controls, all kinds

4. Panel:

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is assayed quality control material consisting of two sets of five levels of aqueous buffer. Each level of Set 1 contains the following analytes: Phosphorous, Urea Nitrogen, Uric Acid. Each level of Set 2 contains the following analytes: Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin. These five levels of each set demonstrate a linear relationship to each other for their respective analytes, reagents and instruments.

The product is intended for use with quantitative assays on the indicated analyzer specified in the labeling. 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™ MicroCV™ Urine/Fluids Chemistry Linearity Set is “For In Vitro Diagnostic Use Only”.

3. Special conditions for use statement(s):

For prescription use only.

The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set should not be used for calibration or standardization of the assays for Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin, Phosphorous, Urea Nitrogen, Uric Acid.

4. Special instrument requirements:

Performance was established on the Roche P-Modular analyzer.

I. Device Description:

The Audit™ MicroCV™ Urine/Fluids Chemistry Linearity Set is a two-set ten-vial lyophilized quality control material with Set 1 containing Phosphorous, Urea Nitrogen, Uric Acid and Set 2 containing Amylase, Calcium, Glucose, Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin. Each set has five levels (Levels A through E, each level packaged into a 2-ml vial). Level A contains the indicated analytes at concentrations near the lower limit level. Level E contains the indicated analytes at 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):

The Audit™ MicroCV™ General Chemistry Linearity Set

2. Predicate K number(s):

k042318

3. Comparison with predicate:

Similarities		
Item	Candidate device	Predicate device (k042318)
Indications for Use	Same	Device is assayed quality control materials intended to detect systematic analytical deviations of laboratory testing procedures.
Number of levels per set	Same	5
Form	Same	Lyophilized

Differences			
Item	Device		Predicate
Number of Analytes per vial	Set 1	Set 2	30
	3	10	
Matrix	Aqueous buffer		Human based Serum
Kit Contents	10 x 2 mL		5 x 5 ml
Storage	2 – 8 °C for 12 months		2 – 8 °C for 1 year
Open Bottle Stability	3 days for Set 1, 10 days for Set 2 at 2 – 8 °C		1 day at 2 – 8 °C
Analytes	Phosphorous, Urea Nitrogen, Uric Acid (Set 1); Amylase, Calcium, Glucose,		Acid Phosphatase, Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin

	Chloride, Creatinine, Magnesium, Potassium, Sodium, Microprotein, Microalbumin (Set 2).	(Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, LDH, LDL Cholesterol, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid
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K. Standard/Guidance Document Referenced (if applicable):

CLSI 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:*

Not applicable

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

Traceability and value assignment

All components used for the Audit™ Micro CV™ Urine/Fluids Chemistry Linearity Set are obtained from commercial vendors and are inspected in-house .

For each analyte, value assignment for Level A through Level E is performed on one instrument (Roche P-Modular) by one set of reagent. Each analyte was measured 15 times (15 separate vials) and the mean value of each analyte was used to establish target concentration values listed on the insert at each level. The target ranges listed on the package insert were calculated as ± 15% of the observed value. The results on Roche P-modular are shown in the table below:

Assay/ Reagent	Units	A		B		C		D		E	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
BUN	mg/dL	34.8	29.5-40.0	859.9	730.9-988.8	1663.4	1413.9-1912.9	2448.5	2081.2-2815.8	3218.5	2735.7-3701.3
Phosphorus	mg/dL	10.7	9.1-12.4	60.4	51.3-69.4	109.0	92.7-125.4	153.7	130.7-176.8	200.1	170.1-230.1
Uric Acid	mg/dL	4.41	3.70-8.07	31.86	27.10-36.64	54.03	45.90-62.14	74.06	63.00-85.17	94.55	80.40-108.73
Amylase	mg/dL	10	9-12	366	311-421	714	607-821	1057	899-1216	1378	1171-1585
Calcium	mg/dL	2.15	1.83-2.47	12.22	10.39-14.05	22.35	19.00-25.71	32.28	27.44-37.12	41.56	35.33-47.79
Creatinine	mg/dL	8.23	7.00-9.47	153.38	130.38-176.39	297.11	252.54-341.68	439.86	373.88-505.84	575.12	488.85-661.39
Glucose	mg/dL	8	7-9	169	144-194	329	279-378	492	418-565	648	551-745
Magnesium	mg/dL	2.65	2.25-3.05	7.64	6.49-8.78	12.47	10.60-14.34	17.55	14.92-20.18	22.34	18.89-25.69
Sodium	mEq/L	27.6	23.5-31.7	72.4	61.6-83.3	119.2	101.4-137.1	166.8	141.8-191.8	211.9	180.1-243.7
Potassium	mEq/L	2.23	1.89-2.56	25.50	21.68-29.33	48.72	41.41-56.03	70.27	59.73-80.81	87.98	74.78-101.17
Chloride	mEq/L	19.6	16.6-22.5	67.5	57.4-77.7	114.0	131.1-96.9	163.2	138.7-187.7	210.9	179.3-242.6
Microprotein	mg/dL	8.9	7.6-10.3	85.1	72.3-97.8	129.8	110.3-149.3	153.0	130.1-176.0	214.5	182.3-246.6
Microalbumin	mg/dL	5.3	4.5-6.1	9.7	8.2-11.1	13.7	11.7-15.8	18.5	21.2-15.7	24.5	20.9-28.2

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Accelerated stability was performed to predict the shelf-life and open-vial of the linearity sets. Real-time stability is ongoing to support the stability of the linearity sets. The sponsor states that the shelf-life of the linearity sets are 12 months when stored at 2-8° C. The open-vial stability after reconstitution is 3 days for Set1 and 10 days for Set 2, respectively, at 2-8° C.

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.