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

A. 510(k) Number:

k112143

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for T- Uptake

D. Type of Test:

Not Applicable.

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit® MicroCV™ T-Uptake Calibration/Verification Set

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR § 862.1660, Quality control material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Please see intended use below.

2. Indication(s) for use:

   Audit® MicroCV™ T-Uptake Calibration/Verification Set consists of five levels of human and bovine albumin based serum containing T-Uptake. The AuditR MicroCV™

T-Uptake Calibration/Verification Set is a quality control material intended for use in the quantitative verification of calibration and reportable range of the Roche T-uptake Assay when performed on the P-Modular Analyzer. 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™ T-Uptake Calibration/Verification is for In Vitro Diagnostic use only.

3. Special conditions for use statement(s):

   For prescription Use.

4. Special instrument requirements:

   Performance was established on P-Modular analyzer.

I. Device Description:

The Audit® MicroCV™ T-Uptake Calibration/Verification is a human and bovine albumin based liquid set of QC Material. Each of the five levels contains T-Uptake analyte. It is used to confirm the proper calibration, linear operating range, and reportable range of T-Uptake. Level A is near the lower limit level and Level E has concentrations near the upper limit of the P-Modular analyzer. Levels B, C, and D are prepared in a manner such that an equal distance exists between each consecutive level.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Audit® MicroCV™ M Immunoassay Linearity Set.

2. Predicate 510(k) number(s):
   k062668

3. Comparison with predicate:

Attribute	Audit® MicroCV™ T-Uptake Calibration/Verification Set **(Candidate Device - k112143)**	Audit® MicroCV™ Immunoassay Linearity Set **(Predicate - k062668)**
Indication for use / Intended for Use	The Audit® MicroCV™ T-Uptake Calibration/Verification Set is a quality control material intended for use in the quantitative verification of calibration and reportable range.	Same
Test System (Instrumentation / technology)	P-Modular analyzer / Enzymatic	Immunoassay

Analyte	T-Uptake	Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactine, Testosterone, Total PSA, Total T3, Total T4, TSH and Vitamin B12.
Open Bottle Stability	10 days at 2-8 ºC	5 days at 2-8 ºC
Shelf life	24 months at 2-8 ºC	12 months at 2-8 ºC

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

CLSI Guideline, 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

All components of the Audit® MicroCV™ T-Uptake Calibration/Verification 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® MicroCV™ T-Uptake Calibration/Verification Set were determined using an accelerated study to predict closed vial shelf life for each level. A closed vial shelf life of 24 months 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 10 days if stored tightly capped at 2 to 8 °C. Storage recommendations are provided in the labeling.

Value Assignment

Multiple replicates of the Audit® MicroCV™ T-Uptake Calibration/Verification Set are analyzed on the P- Modular analyzer during several days. Several replicates are tested and the target value of each level is the mean of the observed values. The target ranges are set at ± 10% of the target value.

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:

Level	Target	Expected Values / Range
Calibrator Level A	17.3	15.6-19.0
Calibrator Level B	20.5	18.5-22.6
Calibrator Level C	25.1	22.6-27.6
Calibrator Level D	33.2	29.9-36.5
Calibrator Level E	44.9	40.4-49.4

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.