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

A. 510(k) Number:

k100718

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for ammonia and ethanol

D. Type of Test:

Assayed and Unassayed Quality Control Materials

E. Applicant:

Aalto Scientific, Limited

F. Proprietary and Established Names:

Audit MicroCV Ammonia/Ethanol Linearity Set

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below

2. Indication(s) for use:

   The Audit MicroCV Ammonia/Ethanol Linearity Set is assayed quality control material consisting of five levels protein (bovine) based serum. Each level contains Ammonia and Ethanol analytes. The five levels demonstrate a linear

relationship to each other for Ammonia and Ethanol analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Ammonia and Ethanol. This product may be used as unassayed quality control material for Ammonia and Ethanol analytes. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit MicroCV Ammonia/Ethanol Linearity Set is "For In Vitro Diagnostic Use Only."

3. Special conditions for use statement(s):

   For in vitro diagnostic use

   For prescription use

4. Special instrument requirements:

   For use with Audit MicroCV Ammonia/Ethanol Linearity Set on the Hitachi 911 analyzer.

I. Device Description:

The Audit MicroCV Ammonia/Ethanol Linearity Set is a protein (bovine) based, aqueous calibration verification material containing five levels (Levels A through E) of ammonia and ethanol. The set is used to confirm proper calibration, linear operating range, and reportable range of the measured analytes. Level A contains ammonia and ethanol concentrations near the lower limit level and Level E contains ammonia and ethanol concentrations near the upper limit level of chemistry analyzers. Levels B-D are related by linear dilution of Level A and Level E.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Document^{R} Ammonia/Ethanol Calibration Verification Rest Set

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

   k944338

3. Comparison with predicate

	Candidate Device	Predicate (k944338)
Indications for Use	The Audit MicroCV Ammonia/Ethanol Linearity Set is assayed quality control material consisting of five levels protein (bovine) based serum. Each level contains Ammonia and Ethanol analytes. The five levels demonstrate a linear relationship to each other for Ammonia and Ethanol analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Ammonia and Ethanol. This product may be used as unassayed quality control material for Ammonia and Ethanol analytes. The product is intended for use with quantitative assays the indicated analyzer provided in the labeling. The Audit MicroCV Ammonia/Ethanol Linearity Set is "For In Vitro Diagnostic Use Only."	Same
Analytes	Ammonia and Ethanol	Same
Matrix	Aqueous	Same
Number of levels per set	5	Same
Fill volume	2.0 mL	4.0 mL
Target Ranges	Ammonia: 20 to 744 µM Ethanol: 1.6 to 704 mg/dL	Ammonia: 0 to 1000 µM Ethanol: 0 to 400 mg/dL
Storage and stability	2 days at 2 to 8°C (Opened vial) 2 years at 2 to 8°C (Closed vial)	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 MicroCV Ammonia/Ethanol Linearity Set is prepared such that a linear relationship exists among all five levels (Levels A through E). Level A has 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

The sponsor claims traceability of the ammonia and ethanol used in this linearity set to Pointe Scientific Ammonia Standard and Diagnostics Chemical Limited Ethanol Standard, respectively.

Value Assignment

Expected values for ammonia and ethanol were determined by repeat analyses on the Hitachi 911 chemistry analyzer with one set of Pointe Scientific Ammonia Standard and one set of Diagnostics Chemical Limited Ethanol Standard. Both analytes are cleared for use on the Hitachi 911 chemistry analyzer (Ammonia (k864706) and Ethanol (k993920)). Ammonia and Ethanol were measured 10 times and the mean values were used to assign target ammonia and ethanol concentrations values for each of the five linearity set levels. Expected 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.

Analyte	Units	Level A	Level B	Level C	Level D	Level E
Ammonia	µM	20-30	143-215	260-390	378-568	496-744
Ethanol	mg/dL	1.6-2.4	120-180	235-353	354-529	470-704

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the Audit MicroCV Ammonia/Ethanol 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 2 years is expected at the recommended storage temperature (2 to 8ºC). Real-time closed vial stability is ongoing. Real-time opened vial stability studies were also performed. Open vial stability of 2 days was demonstrated at the recommended storage temperature of 2 to 8ºC. Storage recommendations are provided in the labeling with additional warnings to prevent prolonged storage at room temperature and to not freeze linearity solutions.

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.