510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k082717

B. Purpose for Submission:
New Device

C. Measurand:
Control Materials for Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA-125, CA 15-3, Free Prostate specific antigen (free PSA), and total prostate specific antigen (total PSA) test systems.

D. Type of Test:
Quality control material – linearity verifiers for 6 serum tumor markers

E. Applicant:
Aalto Scientific, Ltd.

F. Proprietary and Established Names:
Audit™ MicroCV™ Tumor Markers Linearity Set

G. Regulatory Information:

1. Regulation section:
   21 CFR§ 862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class I, reserved
3. Product code:
   JJY, Multi-analyte controls, all kinds (assayed)
4. Panel:
   Immunology (82)

H. Intended Use:

1. Intended use(s):
   See indications for use below.
2. Indication(s) for use:
   The Audit™ MicroCV™ Tumor Markers Linearity Set consists of five levels in Human based serum. Each level contains the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA-125, CA 15-3, Prostate specific antigen-free (free PSA), total PSA. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments. This product may be used for proficiency testing in interlaboratory surveys.
3. Special conditions for use statement(s):
   Prescription use only.
4. Special instrument requirements:
   Quality control material for the analyzer systems specified in the package insert.

I. Device Description:
The Audit™ MicroCV™ Tumor Markers Linearity Set is a human serum based, lyophilized, five level set of QC material, with each level containing 6 analytes. It is used to confirm the linear operating range of Tumor Marker methods for the analytes listed.

Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Audit MicroCV General Chemistry Linearity Set
2. Predicate 510(k) number(s):
   k042318
3. Comparison with predicate:

Characteristics	Audit™ MicroCV™ Tumor Markers Linearity Set (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	The Audit™ MicroCV™ Tumor Markers Linearity Set consists of five levels in Human based serum. Each level contains the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA-125, CA 15-3, Prostate specific antigen-free (free PSA), total PSA. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments. This product may be used for proficiency testing in interlaboratory surveys.	Audit™ MicroCV™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes and may be used for proficiency testing in interlaboratory surveys. In addition, this product may also be used to perform CLIA directed calibration verification for these same analytes with similar reagents on similar instrumentation in accordance with current CLIA-88 guidelines and regulations.
Number of Analytes per vial	6	30
Number of levels per set	5	5
Contents	5 x 1 mL	5 x 5 mL
Matrix	Human based serum	Human Based Serum
Type of Analytes	Cancer Markers	General Chemistry
Form	Lyophilized	Lyophilized
Stabilizers	None	None

Preservatives	Sodium Azide	Sorbitol Sodium Azide
Storage	2 to 8º C Until expiration date	2 to 8º C Until expiration date
Reconstituted Stability	7 days at 2 to 8º C	7 days at 2 to 8º C except for enzymes and bilirubin, which are 48 hours

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

None referenced.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

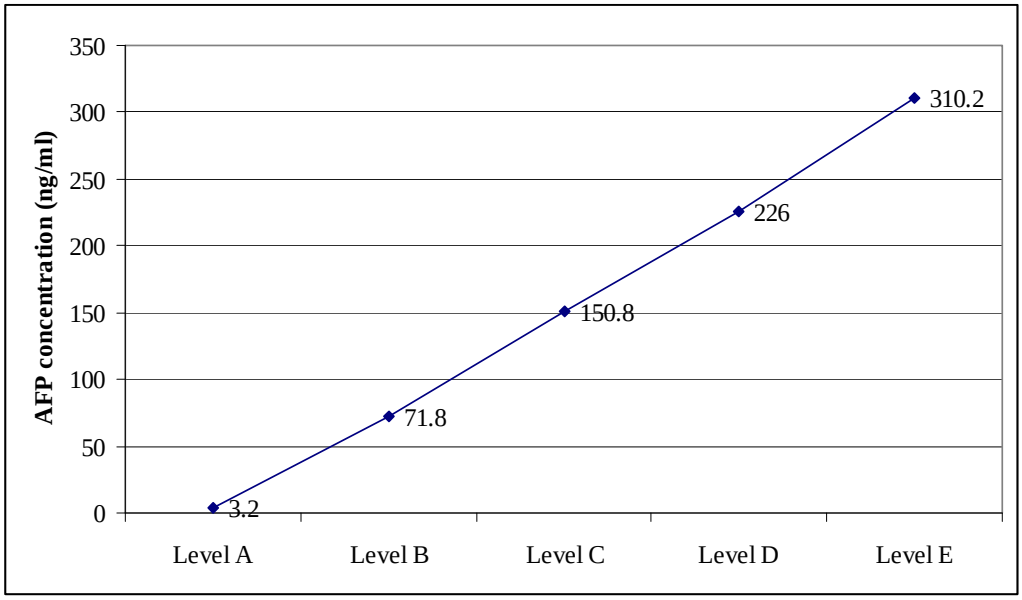
1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable

b. Linearity/assay reportable range:

Linearity was determined using CLSI EP6-A. An example linearity graph is as follows:



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

Traceability:

Materials are obtained from approved vendors and put through an internal quality control process.

Stability:

The stability protocols and acceptance criteria for this product were reviewed and found to be acceptable. The product has an open-vial stability of 7 days when stored at 2-8 ^{o}C. An accelerated stability study determined a shelf life stability of 2 years when stored at 2-8 ^{o}C, and real-time studies are ongoing.

Value Assignment:

Level A (low pool) all analytes are adjusted to be within 5-10% of the lowest limit of measurability for their corresponding assay. For Level E (high pool), all analytes are adjusted to be within 5% to 10% of the highest limit of measurability for their corresponding assay. Levels are then diluted to the following:

Level A = 100% Low Pool
Level B = 75% Low Pool, 25% High Pool
Level C = 50% Low Pool, 50% High Pool
Level D = 25% Low Pool, 75% High Pool
Level E = 100% High Pool

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:
   Not Applicable

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.