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

A. 510(k) Number:

k101434

B. Purpose for Submission:

To obtain a substantial equivalence determination for this original application for the Audit™ MicroCV™ Procalcitonin Linearity Set.

C. Measurand:

Procalcitonin.

D. Type of Test:

Calibrators and Controls.

E. Applicant:

Aalto Scientific, Ltd.

F. Proprietary and Established Names:

Audit^{TM} Micro CV^{TM} Procalcitonin Linearity Set

Procalcitonin Linearity Set

G. Regulatory Information:

1. Regulation section:

   862.1660 Quality Control Material (assayed and unassayed)

2. Classification:

   Class I

3. Product code:

   MJX

4. Panel:

   83 - Microbiology

H. Intended Use:

1. Intended use(s):

   The Audit™ MicroCV™ Procalcitonin Linearity Set is assayed quality control material consisting of five levels of Procalcitonin analyte in bovine serum albumin. The five levels demonstrate a linear relationship to each other for the Procalcitonin analyte. 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 for Procalcitonin. This product may be used as an assayed quality control material for Procalcitonin analyte.

2. Indication(s) for use:

   The Audit™ MicroCV™ Procalcitonin Linearity Set is assayed quality control material consisting of five levels of Procalcitonin analyte in bovine serum albumin. The five levels demonstrate a linear relationship to each other for the Procalcitonin analyte. 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 for Procalcitonin. This product may be used as an assayed quality control material for Procalcitonin analyte.

3. Special conditions for use statement(s):

   Prescription use only.

4. Special instrument requirements:

   Mini - VIDAS BioMerieux

I. Device Description:

The Audit™ MicroCV™ Procalcitonin Linearity Set is a bovine serum albumin, freeze dried, five level set of QC material, with each level containing one analyte: Procalcitonin. It is used to confirm the proper calibration, linear operating range, and reportable range of Procalcitonin. 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Audit™ MicroCV™ General Chemistry Linearity Set

2. Predicate K number(s):

   k042318

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Linear, calibration verification quality control material	Same
Number of levels per vial	5	Same
Contents	5X 1 mL	Same
Matrix	Human based serum	Same
Sterile	Yes	Same
Form	Lyophilized	Lyophilized

Differences		
Item	Device	Predicate
Number of analytes per vial	1	30
Type of Analyte	Procalcitonin	General Chemistry
Matrix	Bovine Serum Albumin	Human-Based Serum
Preservatives	Sodium Azide	Sorbitol, Sodium Azide
Open vial stability	5 days at 2-8º C	7 days at 2 to 8º C except for enzymes and bilirubin, which are 48 hours

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

Not Applicable.

L. Test Principle:

Laboratories use a stable reference material to verify the accuracy and precision of testing methods and techniques. Audit® MicroCV™ Procalcitonin Linearity Set may

be used as one would use human serum to verify and validate the test method analytical measurement range.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Not applicable.

   b. *Linearity/assay reportable range:*

   Value Assignment was based on measurement of Procalcitonin 8 times (8 separate vials) and the mean value of Procalcitonin was used to establish target concentration values at each level. The target ranges were calculated as ± 20% of the target value. The mean concentration values of each level were plotted (concentration value vs. assigned level) and a linear regression values were obtained. If the five-point linear regression R^2 value is greater than 0.95 and if the plots are linear, then the product demonstrates linearity.

   Representative data from the Procalcitonin Linearity set is shown below for five lots:

Lot Numbers	091011	091012	091013	091014	091015
Levels	Level A	Level B	Level C	Level D	Level E
Mean Target Level (ng/mL)	0.60	35.57	73.49	123.26	162.63

Procalcitonin Linearity Set, Pilot 1, Lot 091011-091015

$y = 165.58x - 3.058$
$R^2 = 0.9966$
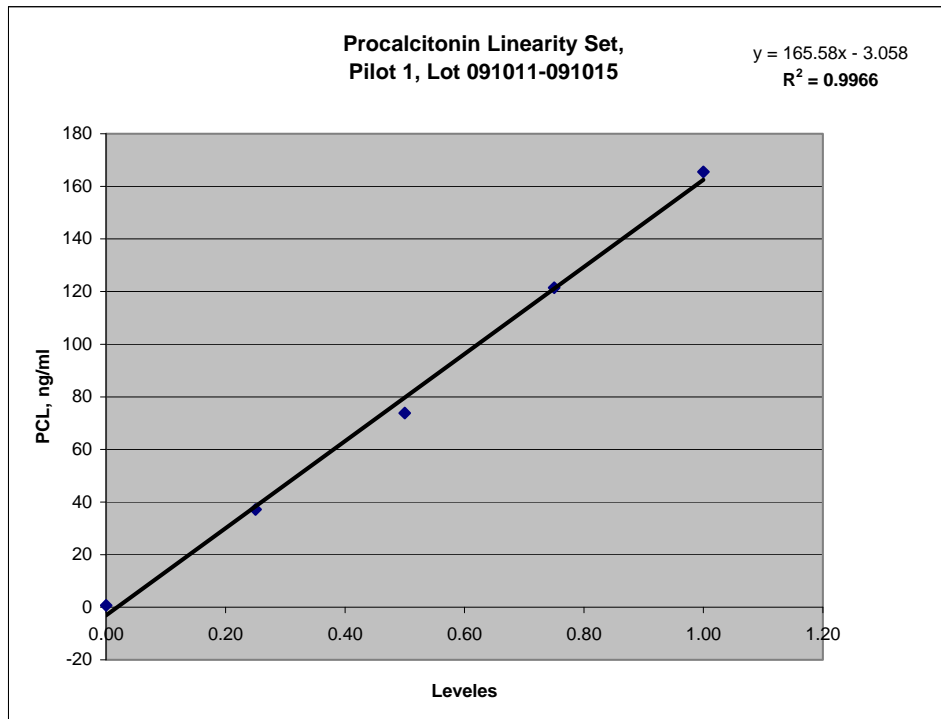
c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: Values assigned to the Audit^{TM} Micro CV^{TM} Procalcitonin Linearity Set can be traced to bioMerieux VIDAS Procalcitonin Reagent – 30450-01, Procalcitonin Calibrator – 30450-01, and Procalcitonin Control– 30450-01

The base matrix for building the low and high pools is bovine serum albumin. For the low pool (Level A), Procalcitonin is adjusted to be within 5% to 10% of the lowest limit of measurability for the Procalcitonin assay. For the high pool (Level E), Procalcitonin is adjusted to be within 5% to 10% of the highest limit of measurability for the Procalcitonin assay.

An accelerated "Heat Stress Stability Prediction" stability study was conducted to predict shelf life. Four vials of each level were stressed at 37º C for 10 days to predict one-year stability when stored at 2 – 8º C.

Two pilot lots, Pilot 1, Lot 091011-091015 and Pilot 2, Lot 81164-81168, were produced and tested. For both pilots, Procalcitonin in the stress stability study results were within ± 15% of the Day Zero value. This gives the Procalcitonin Linearity Control one-year shelf life stability.

Accelerated stability studies are supported by an on-going real-time stability studies.

Open vial stability was also performed to determine the viability of the product during the course of normal use. Four vials of each level (A through E) were opened and reconstituted with deionized water. Vials were then closed, stored for 5 days at 2-8 º C and tested following the same manner as the above stated destructive testing. The percent loss determined in comparison to Day Zero values was < 15% and the product is considered stable.

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:

   See section 1b above.

N. Proposed Labeling:

The labeling is sufficient and 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.