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

A. 510(k) Number:
k101226

B. Purpose for Submission:
New Device

C. Measurand:
Controls for C-Reactive Protein, conventional, and Rheumatoid Factor

D. Type of Test:
Not applicable

E. Applicant:
Aalto Scientific, Ltd.

F. Proprietary and Established Names:
Audit™ MicroCV™ RF/CRP 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:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The Audit™ MicroCV™ RF/CRP Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. The five levels demonstrate a linear relationship to each other for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. This product may also be used as unassayed quality control material for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. 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 product is intended for use with quantitative assays on manual, automatic, and semi-automatic analyzers. The Audit™ MicroCV™ RF/CRP Linearity Set is "For In Vitro Diagnostic Use Only".
2. Indication(s) for use:
   Same as intended use
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   This device may be used as an assayed quality control material only for the instrument specified in the package insert.

I. Device Description:

The 5 level quality control solution set contains C-reactive protein and Rheumatoid Factor as the measurands. Level A is near the lower limit 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. The set includes 5x1 mL ready to use vials, one each of levels A, B, C, D and E.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   LiniCAL™ Calibration RF/CRP Verifiers For Beckman Coulter Synchron CX® Systems
2. Predicate 510(k) number(s):
   k023661
3. Comparison with predicate:

Similarities		
Item	New Audit™ Device	Predicate LiniCAL™ Device
Intended Use	The Audit™ MicroCV™ RF/CRP Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. The five levels demonstrate a linear relationship to each other for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. This product may be used as unassayed quality control material for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. 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 product is intended for use with quantitative assays on manual, automatic, and semi-automatic analyzers. The Audit™ MicroCV™ RF/CRP Linearity Set is "For In Vitro Diagnostic Use Only".	LiniCAL Calibration Verifier RF/CRP is intended for use in the clinical laboratory to objectively verify calibration and assess linearity regarding RF and CRP. Five targeted assayed materials are provided to allow monitoring the manufacturer's reportable range.
Number of analytes per vial	2	same
Number of levels per set	5	same
Content	5x1 mL	same

Similarities		
Item	New Audit™ Device	Predicate LiniCAL™ Device
Matrix	Human Serum	same
Type of Analytes	C-Reactive Protein (CRP) Rheumatoid Factor (RF)	C-Reactive Protein Rheumatoid Factor
Form	Liquid	same

Differences				
Item	Device		Predicate	
Expected values	RF (IU/mL	CRP (mg/dL)	RF(IU/mL)	CRP (mg/dL)
Level A	0	0	33.5	0.55
Level B	375	75	238	3.88
Level C	750	150	418	7.98
Level D	1125	225	562	12.3
Level E	1500	300	765	17.5
Shelf Life	2 to 8ºC for 19 months		2 to 8ºC for 48 months	
Open Vial Stability	5 days at 2 to 8ºC		14 days at 2 to 8ºC	

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

Not applicaple

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:
     RF is obtained from RF Positive Plasma and is traceable to WHO (World Health Organization) Human, International Reference Preparation 1970.
     CRP is obtained from recombinant human C-reactive protein and is traceable to reference material CRM 470.
     Stability**:**
     Open Vial Stability:
     5 vials of each level were left open for 30 minutes, then closed and stored at 2-8°C. This cycle is repeated 5 times (one cycle each day). Vials are tested at the end of the 5 days. The results showed 0.0% - 15% difference from the day zero results. The claimed open vial stability is 5 days when stored tightly capped at 2-8°C.
     Shelf Life Stability:
     An "accelerated" stability study was used to predict shelf life. Five vials of

each level were stressed at 37°C for 20 days. The percent loss is determined in comparison to Day Zero values. The results showed 0.0% - 12.06% difference from the day zero results. The shelf life is based on the accelerated stability studies and on the on-going real-time stability studies. The claimed shelf life is 19 months at 2-8°C.

Value assignment:

The reference materials that were used for value assignment are the calibration and control sets provided by the manufacturers of the reagents – Beckman for RF and Pointe Scientific for CRP. Hitachi 911 and Array analyzers were used for CRP and RF respectively. The analyzers were calibrated and the control was used with the value assignment run. Value assignment for each level was based on 10 results for each level. Target values were calculated. Expected vs. observed values were graphed and a linear regression value was obtained to determine the linearity of the five levels. The linear range is defined by the highest and lowest measured concentrations where the response is linear. The dilution scheme is as follows:

Level A = 100% Low Pool (no analyte)
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

The results are summarized below:

	CRP in mg/dL			RF in IU/mL		
	Expected	observed	% difference	expected	observed	% difference
Level A	0	0.04	0.0	0	0	0.0
Level B	75	70	6.7	375	411	9.6
Level C	150	150	0.0	750	771	2.8
Level D	225	233	3.6	1125	1174	4.4
Level E	300	309	3.0	1500	1576	5.1

Linear regression values:

Analyte	Slope	Intercept	Correlation
CRP	1.040	-3.80	0.99
RF	1.044	3.40	0.99

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.