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

A. 510(k) Number:

k101427

B. Purpose for Submission:

New Device

C. Measurand:

High Sensitivity C-Reactive Protein (hs-CRP) linearity set

D. Type of Test:

Not Applicable

E. Applicant:

Aalto Scientific, Ltd

F. Proprietary and Established Names:

Audit™ MicroCV™ hs -CRP Linearity Set

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material

2. Classification:

Class I, Reserved

3. Product code:

JJX- Single (Specified) Analyte Control (Assayed and Unassyed)

4. Panel

Clinical Chemistry 75

H. Intended Use:

1. Intended use(s):

   See indication for use below.

2. Indication(s) for use:

   The Audit™ MicroCV™ hs-CRP Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains High Sensitivity C-Reactive Protein (hs -CRP) analyte. The five levels demonstrate a linear relationship to each other for High Sensitivity C-Reactive Protein (hs -CRP) analyte. It is intended to simulate human patient serum samples for purpose of monitoring and detecting systematic analytical deviations of laboratory testing procedures for High Sensitivity C-Reactive Protein (hs -CRP). This product may be used as quality control material for High Sensitivity C-Reactive Protein (hs -CRP) analyte. 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 the indicated analyzer provided in the labeling. The Audit™ MicroCV™ hs-CRP Linearity Set is "For In Vitro Diagnostic Use Only"

3. Special conditions for use statement(s):

   AUDIT® MicroCV™ hs-CRP Linearity Set is not to be used for calibration or standardization of the hs-CRP assay.

4. Special instrument requirements:

   The performance was established on the Hitachi 911 analyzer.

I. Device Description:

The Audit™ MicroCV™ hs-CRP Linearity Set is an in vitro diagnostic device consisting of five levels of liquid linearity materials containing hs-CRP and additives in human serum. There are 5 vials labeled A, B, C, D, and E, and contain 2 mL for each level.

Material of human origin used in the manufacture of this test set has been tested using FDA approved methods and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device

Audit™ MicroCV™ General Chemistry Linearity Set

2. Predicate K number

k042318

3. Comparison with predicate

Similarities and differences between new and predicate devices

Characteristics	Audit™ MicroCV™ hs-CRP Linearity Set (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (k042318)
Intended Use	Same	Linear, calibration verification quality control material
Number of Analytes per vial	1	30
Number of levels per set	5	5
Contents	5 x 2 mLs	5 x 5 mLs
Matrix	Human Based Serum	Human Based Serum
Type of Analytes	Clinical Chemistry	General Chemistry
Form	Liquid	Lyophilized
Preservatives	Sodium Azide	Sorbitol Sodium Azide
Storage	2 to 8º C for 24 months	2 to 8º C for 24 months
Open Vial Stability	10 days at 2-8 C	7 days at 2 to 8º C except for enzymes and bilirubin, which are 48 hours
Sterile	No	No

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

None were 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:

Not Applicable

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

Traceability and Value assignment

Component is obtained from an approved vendor and inspected by the sponsor upon arrival.

Value assignment is performed on one Hitachi 911 instrument with one lot of reagent for hs-CRP analyte. hs-CRP was measured 5 times (5 separate vials) and the mean value of hs-CRP 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 are plotted (concentration value vs. assigned level) and a linear regression values obtained and evaluated.

Stability studies:
Open-Vial Stability:

Five vials of levels A, B, C, D and E are opened and exposed to the environment for 30 minutes then closed and repeated for a total of 3 cycles. Vials are then closed and stored for 10 days at 2 – 8º C. The percent loss is determined in comparison to Day Zero values.

The protocol, data and acceptance criteria were found to be adequate.

The data supported the package insert claims that the analyte is stable after opening the vial when stored at 2 – 8º C for 10 days.

Accelerated Stability:

Five vials of levels A ,B.C.D and E were stressed at 37º C for 20 days to predict two-year stability when stored at 2 – 8º C. Performance data was collected through "destructive testing" by Quality Control according to specifications. The protocol, data and acceptance criteria were found to be adequate. Accelerated stability studies are supported by an on-going real-time stability study.

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Homocysteine Linearity Set was evaluated on the Hitachi 911 analyzer with Pointe hs-CRP reagents.

The shelf life claim is 24 months. This is based on the accelerated stability results and on-going real-time stability studies.

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:

   Target values:

Homocysteine	Mean mg/dL	Range mg/dL
Level A	0.12	0.10-0.14
Level B	0.35	0.28-0.42
Level C	0.55	0.44-0.66
Level D	0.77	0..62-0.92
Level E	0.97	0.78-1.16

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.