

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

**A. 510(k) Number:**

k100715

**B. Purpose for Submission:**

New device

**C. Measurand:**

Homocysteine Linearity set

**D. Type of Test:**

Not Applicable

**E. Applicant:**

Aalto Scientific, Ltd

**F. Proprietary and Established Names:**

Audit™ MicroCV™ Homocysteine 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:

JJX- Single (Specified) Analyte Control

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™ Homocysteine Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains Homocysteine analyte. The five levels demonstrate a linear relationship to each other for Homocysteine analyte. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Homocysteine. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit™ MicroCV™ Homocysteine Linearity Set should not be used for calibration or standardization of the Homocysteine assay. The Audit™ MicroCV™ Homocysteine Linearity Set is “For In Vitro Diagnostic Use Only”.

3. Special conditions for use statement(s):

The Audit™ MicroCV™ Homocysteine Linearity Set should not be used for calibration or standardization of the Homocysteine assay.

3. Special instrument requirements:

The performance was established on the Siemens Centaur XP analyzer.

## **I. Device Description:**

The Audit™ MicroCV™ Homocysteine 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 1 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

Liquichek Homocysteine Control

2. Predicate K number

k984071

3. Comparison with predicate

*Similarities and differences between new and predicate devices*

	Audit™ MicroCV™ Homocysteine Linearity Set k100715	Bio-Rad Laboratories Liquichek Homocysteine Control k984071
Indications for Use	It is assayed quality control materials intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Homocysteine.	Same
Number of Analytes per vial	1	Same
Number of levels per set	5	2
Contents	5x1 mL	6 x 1 mL
Matrix	Human Serum	Same
Type of Analytes	Homocysteine	Same
Form	Liquid	Same
Storage	2 to 8° C for 24 months	-10 to -70° C for 36 months

**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 in house.

Value Assignment was performed on one Centaur instrument with one lot of Homocysteine reagent. Value assignment for each level was based on five results. Target values were calculated from mean values of the five results for each level. The target ranges were calculated as  $\pm 10\%$  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 and evaluated.

Stability studies:

Open-Vial Stability:

The protocol, data and acceptance criteria were reviewed and found to be adequate. The data supported the package insert claims that the analyte is stable after opening the vial when stored at 2 – 8° C for 10 days.

Accelerated Stability:

The protocol, data and acceptance criteria were reviewed and found to be adequate. Accelerated stability studies are supported by an on-going real-time stability study. 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:

	Units	Instrument	A	B	C	D	E
Homocysteine	umol/L	CentaurXP/Siemens	3.06- 4.60	14.82- 22.22	28.33- 42.49	41.66- 62.50	49.12- 73.68

**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.