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

A. 510(k) Number:

k152117

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for high sensitivity C-reactive protein (hsCRP)

D. Type of Test:

Not applicable.

E. Applicant:

Quantimetrix Corporation

F. Proprietary and Established Names:

Dropper® hsCRP High Sensitivity CRP Control

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 controls (assayed and unassayed)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use statement below.

2. Indication(s) for use:

   The Quantimetrix Dropper hsCRP High Sensitivity CRP Control is intended for the quality control of laboratory testing procedures of high sensitivity C-Reactive protein (CRP). It is intended for professional *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic and prescription use only.

4. Special instrument requirements:

   The controls are value assigned for use on hsCRP test systems (instruments and assays) listed in the proposed device labeling.

I. Device Description:

The Dropper® hsCRP Control is a ready-to-use liquid control that does not require reconstitution nor frozen storage. The product is supplied in three clinically significant levels filled to 1mL in plastic dropper bottles. The controls are formulated in a human serum derived matrix fortified with preservatives and stabilizers to maintain product integrity and inhibit microbial growth. Each control level is formulated with human CRP antigen to clinically significant targets that are ideal to monitor high sensitivity CRP test methods.

The three different levels are differentiated by the label and by a distinct color coded cap. Level 1 has a white cap, Level 2 has a blue cap and Level 3 has a red cap. The control base matrix derived from human serum spiked with CRP antigen. A single level kit configuration will be supplied a three 1mL bottles. A multi-level kit configuration will contain 1mL bottle of each of the three control levels.

The blood donor units comprising the serum are screened for HBs and HBc antigen, HCV, HIV1, and HIV2, and found to be nonreactive by US FDA accepted methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Liquicheck Cardiac Markers Plus Control LT

2. Predicate 510(k) number(s):

   k123663

3. Comparison with predicate:

Item	Dropper hsCRP High Sensitivity CRP Control, K152117 (Candidate Device)	Liquicheck Cardiac Markers Plus Control LT, K123663 (Predicate Device)
Intended use	The Quantimetrix Dropper® hsCRP Control is intended for use as a quality control of laboratory testing procedures of high sensitivity C-Reactive protein (CRP).	Same
Analyte	Single analyte, CRP (C-Reactive Protein)	Multi-analyte, Troponin, Creatine Kinase - Total (CK Total), CK-MB Isoenzyme, Digitoxin, C-Reactive Protein (CRP), Myoglobin, NT-proBNP.
Matrix	Human serum	Same

Item	Dropper hsCRP High Sensitivity CRP Control, K152117 (Candidate Device)	Liquicheck Cardiac Markers Plus Control LT, K123663 (Predicate Device)
Form	Ready-to-use liquid in a plastic dropper bottle.	Frozen liquid in a glass vial.
Fill Volume	1 mL	2.5 mL
Levels	3 level control	Same
Storage Conditions – Open Vial	90 days at 2-8°C 30 days at room temperature (18-25°C)	20 days at 2-8°C for most analytes (thawed and opened)
Storage Conditions – Unopened Vial (Shelf Life)	Refrigerated (2-8°C) until expiration date (36 months).	Frozen (minus 20°C to minus 70°C) until expiration date (36 months).

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

Standard/Guidance documents were not referenced in the submission.

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 - The CRP antigen that was used to formulate the Quantimetrix Dropper® hsCRP High Sensitivity Control was obtained from commercially available sources. The CRP was gravimetrically added to the serum based control matrix to achieve the desired target value for each of three control levels by using the Siemens Dimension® CardioPhase® High Sensitivity C-Reactive Protein (an assay standardized and traceable to the International Federation of Clinical Chemistry (IFCC) Reference for Plasma Proteins (CRM 470)).

Value Assignment - The value assignment testing is performed by submitting samples of a specific lot to be tested to multiple laboratories and Quantimetrix laboratory. Expected values are established from inter-laboratory and intra-laboratory data using instrument manufacturer's reagents. Data are derived from 10 to 20 replicate analyses and are specific to each lot of product. The device labeling lists mean and

expected range of the three control levels for several clinical chemistry analyzers and hsCRP methods. The sponsor suggests that each laboratory should establish its own ranges and specifications for the methods used to measure hsCRP, and that individual laboratory means should fall within the ranges listed in the device labeling. The protocol, data and acceptance criteria were found to be adequate.

Stability - Accelerated stability testing demonstrated that the opened control vials are stable for 90 days at 2-8°C, and for 30 days at room temperature (18-25°C). Based on an accelerated stability testing per the Kennon Method, the shelf life is claimed as 36 months when stored refrigerated at 2-8°C. Real time stability studies are ongoing and performed for every new lot production. The stability study protocol and acceptance criteria were reviewed and found to be adequate.

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 for the three level control solutions for a few cleared hsCRP test systems are listed as an example of one lot below:

Instruments / Method	Level 1 (mg/L)		Level 2 (mg/L)		Level 3 (mg/L)	
	Mean	Expected Range	Mean	Expected Range	Mean	Expected Range
Siemens Dimension®ExL / Dimension® *Cardio*Phase® High Sensitivity CRP / Immunoturbidimetric	0.99	0.79 - 1.19	5.00	4.45 - 5.55	9.75	8.77 - 10.73
Siemens BN™ II / N High Sensitivity CRP / Nephelometry	0.61	0.56 - 0.66	3.52	3.14 - 3.89	8.41	7.60 - 9.22
Abbott Architect® Systems / CRP Vario /Immunoturbidimetric	0.70	0.58 - 0.82	3.82	3.47 - 4.17	9.48	9.17 - 9.78
Roche Cobas® c311 / Tina-Quant® CRP (Latex) HS Test System / Particle Enhanced Immunoturbidimetric	0.79	0.64 - 0.93	4.26	3.79 - 4.72	11.05	10.72 - 11.37

The sponsor has included the above table in their proposed device labeling.

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.