

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

A. 510(k) Number:

k103744

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for Hemoglobin A1c (HbA1c)

D. Type of Test:

Not applicable

E. Applicant:

Quantimetrix Corporation

F. Proprietary and Established Names:

Dropper A1c Diabetes Control

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR § 862.1660, Quality control material (assayed and unassayed).	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Quantimetrix Dropper A1c Diabetes Control is intended for the quality control of laboratory procedures used to quantitate HbA1c.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Beckman Coulter Synchron, Ortho-Clinical Vitros, Primus Corporation PDQ/Ultra, Roche Cobas Integra, Roche Diagnostics Hitachi, Siemens Healthcare Diagnostics DCA 2000/Vantage and Siemens Healthcare Diagnostics Dimension

I. Device Description:

The Dropper A1c Diabetes Control consists of two levels; one level represents Hb1A1c near the threshold level and one in the pathological range. The controls are supplied as a ready to use frozen liquid, requiring no reconstitution or dilution. They are prepared in a whole blood matrix fortified to target levels with reagent grade chemicals added to achieve the two levels. Preservatives have been added to inhibit microbial growth.

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
MAS Diabetes Control	k023307

Comparison with predicate:

Similarities and Differences		
Item	New Device	Predicate Device (k023307)
Indications for Use	Same	Assayed quality control material for monitoring Glycoslated Hemoglobin (A1c) assay procedures.
Analyte	Same	Hemoglobin A1c
Matrix	Same	Frozen liquid whole blood
Number of Levels	Same	Two
Composition	Reagent grade chemicals and constituents of human origin	Pure chemicals and constituents of human origin
Stability	Closed Vial: 3 years at -10 to -30°C 180 days at 2 to 8°C Open Vial: 180 days at 2 to 8°C 21 days at 18 to 25°C	Closed Vial: 2 years at -15 to -25°C 60 days at 2 to 8°C Open Vial: 21 days at 2 to 8°C

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

The Hemoglobin A1c material is traced to a National Glycohemoglobin Standardization Program (NGSP) Certified testing method performed on Siemens Dimension RxL and DCA 2000+ analyzers.

Value Assignment

The Dropper A1c Diabetes Control consists of two levels of Hemoglobin A1c (Hb1A1c); one level near the threshold level (Level 1) and one in the pathological range (Level 2). Value assignment is performed by running each level once per day on each analyzer for three days by two or more different operators (six or more tests per analyzer). All values for each analyzer are inputted and the range for each level is set at $\pm 20\%$ from the calculated mean value. The mean and ranges for Level 1 and 2 are provided for each analyzer in the table below.

Analyzer	Level 1		Level 2	
	Mean (%)	Expected Range (%)	Mean (%)	Expected Range (%)
Beckman Coulter Synchron	5.9	4.7 - 7.1	10.3	8.2 – 12.3
Ortho-Clinical Vitros	6.1	4.9 – 7.3	10.4	8.3 – 12.5
Primus Corporation PDQ/Ultra	8.3	6.6 – 9.9	17.7	14.1 – 21.2
Roche Cobas Integra	6.1	4.9 – 7.3	10.3	8.3 – 12.4
Roche Diagnostics Hitachi	5.2	4.1 – 6.2	15.3	12.3 – 18.4
Siemens Healthcare Diagnostics DCA 2000/Vantage	5.9	4.8 – 7.1	8.8	7.1 – 10.6
Siemens Healthcare Diagnostics Dimension	6.2	4.9 – 7.4	10.3	8.3 – 12.4

Analyzer	Level 1		Level 2	
	Mean (mmol/mol)	Expected Range (mmol/mol)	Mean (mmol/mol)	Expected Range (mmol/mol)
Beckman Coulter Synchron	41	28 - 54	89	66 - 111
Ortho-Clinical Vitros	43	30 - 56	90	67 - 113

Primus Corporation PDQ/Ultra	67	49 - 85	170	131 - 208
Roche Cobas Integra	43	30 - 56	89	67 - 112
Roche Diagnostics Hitachi	33	21 - 44	144	111 - 178
Siemens Healthcare Diagnostics DCA 2000/Vantage	41	29 - 54	73	54 - 92
Siemens Healthcare Diagnostics Dimension	44	30 - 57	89	67 - 112

Stability:

The closed vial stability was evaluated in accelerated and real-time stability studies. Unopened vials stored at 25°C (test material) or 37°C (test material) were tested against unopened vials stored at -10°C to -30°C (reference material) at predetermined time points during a 6 month interval. Based upon accelerated study data, the sponsor claims closed vial stability of 180 days at 2 to 8°C. Real-time stability study is on-going.

The open vial stability was evaluated in accelerated and real-time stability studies. Opened vials stored at 37°C (test material) were tested in duplicate against unopened vials stored at -10°C to -30°C (reference material) at predetermined time points during a 6 month interval. In a second real-time stability study, opened vials stored at 25°C (test material) were tested in duplicate against unopened vials stored at -10°C to -30°C (reference material) at five time points during a 1 month interval. Based upon accelerated and a real-time stability studies, the sponsor claims open vial stability of 180 days at 2 to 8°C or 21 days at 18 to 25°C.

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:

The expected values on each analyzer are presented in the 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.