

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

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

k043070

**B. Purpose for Submission:**

Clearance of New device

**C. Measurand:**

Quality Control Material (assayed) for Hemoglobin A1c (HbA1c)

**D. Type of Test:**

Not applicable

**E. Applicant:**

Canterbury Scientific Ltd

**F. Proprietary and Established Names:**

Liquid Stable HbA1c Control

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.1660; Quality Control Material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX; single (specified) analyte controls (assayed and unassayed)

4. Panel:

75; Chemistry

## **H. Intended Use:**

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The Liquid Stable HbA1c Control is intended for use as a quality control material to monitor the performance of laboratory testing procedures for HbA1c quantitation. The control is designed for use with ion exchange HPLC assays, Immunoassay based assays and Boronate Affinity based assays.

The use of quality control materials is indicated as an objective assessment of the precision and bias of methods and techniques in use and is an integral part of good laboratory practices. The two levels of controls allow performance monitoring within the clinical range.

The controls are for *in vitro* diagnostic use only and should not be used past the expiry date.

3. Special conditions for use statement(s):

For Prescription use only

The control is designed for use with ion exchange HPLC assays, Immunoassay based assays and Boronate Affinity based assays.

4. Special instrument requirements:

Bayer DCA 2000, Bio-Rad Variant II, Roche Hitachi 917 and Primus CLC 385

## **I. Device Description:**

The Liquid Stable HbA1c Control is a bi-level liquid HbA1c control. The control materials are made from human red cells and are provided ready-to-use. Value assignment and stability testing information is below.

Human source material was tested and found negative for HIV 1 and 2, HIV-1 antigen, HBV, HCV and Syphilis (TPHA and RPR) using FDA approved methods.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

Quantimetrix Corporation, GlycoHemosure HbA1c Control

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

k032791

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	Quality Control Material	Quality Control Material
Form	Liquid ready to use (2 levels)	Liquid ready to use (2 levels)
Matrix	Human hemoglobins, broad spectrum antibiotic, stabilizers	Human hemoglobins, preservatives, stabilizers

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Volume	0.5 mL – 1.0 mL	2.0 mL
Instrumentation	Ion Exchange HPLC, Immunoassay and Boronate Affinity	Immunoassay and Boronate Affinity

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

None referenced

**L. Test Principle:**

Not applicable. This submission is for clearance of control material.

**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):*

The Liquid Stable HbA1c Controls are prepared from normal non-diabetic adult human blood. A hemolysate is prepared from washed red cells. The abnormal HbA1c level control is prepared by in vitro glycation of non-diabetic hemolysate under controlled conditions.

Each lot is assayed by randomly selecting ten normal and abnormal liquid control samples. These samples are run in duplicate within one day on three different methodologies. The abnormal level expected range is derived from the mean of all the values  $\pm 11.0\%$ . The normal level expected range is derived from the mean of all the values  $\pm 5.0\%$ .

*Stability:*

Real time stabilities studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

Open vial stability is 30 days at 2 to 8°C.

Closed vial stability is 18 months at 2 to 8°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:

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.