

**DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k071648

B. Purpose for Submission:

New Device

C. Measurand:

HbA1c

D. Type of Test:

Quality control materials for HbA1c

E. Applicant:

Canterbury Scientific Ltd.

F. Proprietary and Established Names:

extendSURE Lyophilized HbA1c Linearity Controls

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 analyte controls
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
The extendSURE lyophilized hemoglobin A1c linearity controls are intended to verify the linearity of HbA1c assays across the patient reportable range (4 to 18% NGSP aligned) using protocols established in individual laboratories.
2. Indication(s) for use:
See Intended use section above
3. Special conditions for use statement(s):
For In Vitro Diagnostic Use

4. Special instrument requirements:

Bio-Rad Variant, Olympus AU series, Roche Hitachi 917, Primus and Siemens DCA2000

I. Device Description:

The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls are a lyophilized preparation from human blood and contains preservatives and stabilizers. The reconstitution fluid contains a 0.09% solution of sodium azide in type 1 water. In the labeling the sponsor states that each donor unit was tested for hepatitis B surface antigen, antibodies to hepatitis C and antibodies to HIV-1 and HIV-2, and syphilis and found to be negative.

J. Substantial Equivalence Information:

1. Predicate device name(s): Lyphochek Hemoglobin A1c Linearity Set

2. Predicate 510(k) number(s): k003030

3. Comparison with predicate:

Both devices are whole blood-based products with the same intended use. The differences are the reconstituted volume, 0.25 mL for this device and 0.50 mL for the predicate device and the number of vials of materials provided, 5 vials for this device and 4 vials for the predicate.

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

CLSI EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*
Not Applicable

b. *Linearity/assay reportable range:*
See traceability below.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The values for the low and high level controls, which are approximately 4% and 18 % (NGSP) respectively, are assigned by replicate analysis of each control on the marketed instrument using marketed calibrators in assaying the marketed Hemoglobin A1c device. The marketed device is NGSP certified and the values obtained for this device are thus NGSP aligned.

The high and low level hemolysates are adjusted to the same total hemoglobin concentration and the intermediate levels are produced by these two hemolysates in equally spaced proportional ratios.

The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls are stable for 36 months from the date of manufacture when stored unopened at 2° - 8°C. The opened control is stable for 7 days when stored tightly capped at 2° - 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.