


Package Insert Sheet

REF	HB517	extendSURE™ Lyophilized HbA1c Linearity Controls 5 vials of linearity control (0.25mL) Warning! Potentially Biohazardous Material. 1 Vial of reconstitution fluid (2mL) – contains 0.09% sodium azide.	 CANTERBURY scientific Canterbury Scientific Ltd. 14 Pope Street, Christchurch, New Zealand Ph +64 3 343 3345 Fax +64 3 343 3342 info@canterburyscientific.com www.canterburyscientific.com
LOT	5005		
EXP	2010-03		
Store	2° - 8°C		

INTENDED USE The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls are intended to verify the linearity of HbA1c assays across the clinically important range (4 to 18%, NGSP aligned) using protocols setup within individual clinical laboratories.

SUMMARY AND PRINCIPLE HbA1c measurement is established as an indication of glycaemic control in diabetes. Good laboratory practice requires clinical laboratories to verify the linearity of an assay within the reportable range. This kit contains 5 levels of HbA1c material to enable such verification.

REAGENT 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.

LIMITATIONS extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls should not be used past the expiry date. If there is evidence of microbial contamination or brown discoloration in the control, the vial should be discarded. The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls are not intended for use as a calibration or quality control material.

KIT CONTENTS

1	Vial of Level 1 Control	(0.25 mL)
1	Vial of Level 2 Control	(0.25 mL)
1	Vial of Level 3 Control	(0.25 mL)
1	Vial of Level 4 Control	(0.25 mL)
1	Vial of Level 5 Control	(0.25 mL)
1	Vial of Reconstitution Fluid	(2.0 mL)
1	Package Insert	

WARNING AND PRECAUTIONS

For In Vitro Diagnostic Use

WARNING: THIS PRODUCT CONTAINS A CHEMICAL KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

WARNING! POTENTIALLY BIOHAZARDOUS MATERIAL

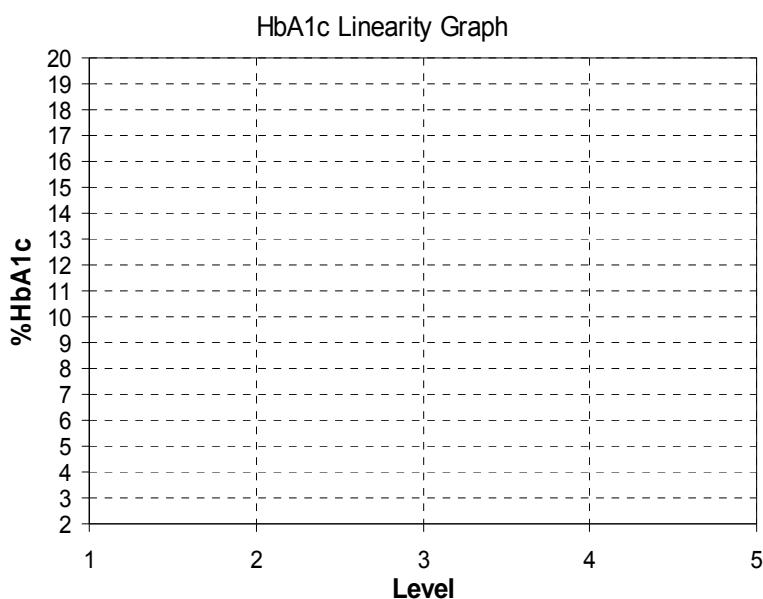
Human sourced materials were used in the manufacturing of this product. Each donor unit was tested using a **CE** (Conformité Européene) and Therapeutic Goods Administration (Australia) approved method for hepatitis B surface antigen (HbsAg), antibodies to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), and syphilis and found to be negative.

CAUTION: Because no test method can offer complete assurance that HIV, Hepatitis B or C viruses, or other infectious agents are absent, these products should be handled as potentially infectious. Hence handle the extendSURE™ Lyophilized HbA1c Linearity control set with the same precautions used with patient specimens.

STORAGE AND STABILITY The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls will be stable until the last day of the expiration date shown on the vial when stored unopened at 2° - 8°C. Once the control is opened; it can be used for 7 days when stored tightly capped at 2° - 8°C. The control should not be stored uncapped.

PROCEDURE Remove the cap from each vial and add 0.25mL (250µL) of reconstitution fluid (0.09% sodium azide). Replace the caps mix gently by swirling. Allow to stand for 15 minutes with intermittent swirling. Visually check that all the material has dissolved prior to use. The controls should be used in the same manner as patient samples on your glycated hemoglobin analysis method.

The product should be used in accordance with the linearity verification procedures recommended by the instrument manufacturer. The HbA1c levels are evenly spaced. Plot results against the corresponding level number using a graph such as below. Each laboratory is responsible for establishing its own criteria for acceptable performance limits to verify linearity. (See, Clinical Laboratory Standards Institute (formerly NCCLS), *Evaluation of the Linearity of Quantitative Measurement Procedures: Statistical Approach; Approved Guideline*. EP6-A. Wayne, PA. Vol 23, No. 16, First Edition, 04/01/2003)



The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls have been tested as suitable for use on the following instruments.

Method Type	Company	Instrument/Comment
Ion Exchange HPLC	BioRad Corporation	Variant Classic
	Tosoh	G7
Immuno Assay	Siemens Healthcare Diagnostics	DCA2000. Only control levels 1-4 are suitable for this instrument
	Olympus	AU Series
	Roche	Hitachi 917
Boronate Affinity	Primus	Only control levels 1-4 are suitable for these instruments

LOT NUMBER: 5005

EXPIRATION DATE: 2010-03