

Information for Use

Haemoglobin A1c Liquid Control Levels 1 and 2



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en Instructions For Use in multiple languages are available on our website: www.canterburyscientific.com under the "Products and Instructions for Use" section. A paper version can be obtained by fax +64 3 3433342 or e-mail: info@canterburyscientific.com.



This product contains human or animal source materials and should be treated as potentially infectious.

fr Le mode d'emploi est disponible en plusieurs langues sur notre site internet : www.canterburyscientific.com dans la rubrique « Products and Instructions for Use [Produits et mode d'emploi] ». Un exemplaire papier peut être obtenu en envoyant une demande par fax au +64 3 3433342 ou par e-mail à l'adresse : info@canterburyscientific.com.



Ce produit contient des substances d'origine animale ou humaine et doit, par conséquent, être considéré comme un produit potentiellement infectieux.

de Gebrauchsanweisungen in mehreren Sprachen stehen auf unserer Website zur Verfügung: www.canterburyscientific.com im Bereich „Produkte und Gebrauchsanweisungen“. Ein gedruckte Version kann per Fax über +64 3 3433342 oder per E-Mail angefordert werden: info@canterburyscientific.com.




Dieses Produkt enthält Ausgangsstoffe menschlichen und tierischen Ursprungs und muss als potenziell infektiös gehandhabt werden.

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da	Bruksanvisninger er tilgængelige på flere sprog på vores website: www.canterburyscientific.com i sektionen "Products and Instructions for Use". En trykt udgave kan fås via fax ved henvendelse på tlf. +64 3 3433342 eller e-mail: info@canterburyscientific.com .  Dette produkt indeholder humane eller animalske kildematerialer og skal behandles som potentielt infektøst.
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fi	Sivustoltamme löytyy käyttöohjeet useilla eri kielillä: www.canterburyscientific.com , osa "Tuotteet ja käyttöohjeet". Voit hankkia tulostetun version faksamalla numeroon +64 3 3433342 tai lähettämällä sähköpostia osoitteeseen: info@canterburyscientific.com .  Tämä tuote sisältää ihmis- tai eläinperäisiä lähdemateriaaleja ja sitä on käsiteltävä mahdollisen tartuntavaaran aiheuttavana tuotteena.
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cs	在本公司网站上提供多种语言版本的《产品使用说明书》，网址 www.canterburyscientific.com ；在网站首页的“Products and Instructions for Use”（产品与使用说明书）部分，可找到这些文档。纸质印刷版本可发传真至+64 3 3433342或发送电子邮件至 info@canterburyscientific.com 索取。  本产品含有人或动物来源的材料，应作为潜在传染性材料对待。
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ar	توفر إرشادات الاستخدام بعدة لغات على موقعنا على ويب: www.canterburyscientific.com قسم "المنتجات وإرشادات الاستخدام". يمكن الحصول على نسخة ورقية بالفاكس على رقم +64 3 3433342 أو بالبريد الإلكتروني: info@canterburyscientific.com .  يحتوي هذا المنتج على مواد ذات مصدر بشري أو حيواني ويجب التعامل معها على أنها من المحتمل أن تكون معدية.
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sk	Pokyny na použitie v rôznych jazykoch sú dostupné na našej webovej stránke: www.canterburyscientific.com v časti „Produkty a pokyny na použitie“. Papierovú verziu je možné získať faxom na číslo +64 3 3433342 alebo e-mailom: info@canterburyscientific.com .  Tento produkt obsahuje materiály ľudského alebo zvieracieho pôvodu a malo by sa s ním zaobchádzať ako s potenciálne infekčným materiálom.
ro	Instrucțiuni de utilizare în mai multe limbi sunt disponibile pe site-ul nostru: www.canterburyscientific.com la secțiunea "Products and Instructions for Use" (Produse și instrucțiuni de utilizare). Se poate obține o versiune tipărită prin trimiterea unui fax la numărul +64 3 3433342 sau a unui e-mail la adresa: info@canterburyscientific.com .  Acest produs conține materiale sursă umane sau animale și trebuie tratat ca fiind un produs potențial infecțios.

Description and Intended Use

The extendSURE™ Haemoglobin A1c liquid controls **CONTROL** are prepared from human blood and contain normal haemoglobin, preservatives and stabilizers. The controls are formulated to give enhanced stability.

The Level 2 control is produced by a process of controlled *in vitro* glycation of non-diabetic blood.

The controls are designed for use as quality control materials to monitor the accuracy and precision of laboratory testing procedures for HbA1c quantitation for the following assay types: ion exchange HPLC, immunoassay and enzymatic procedures.  For specific application in a particular assay refer to the analyser's operating manual. The control is not to be used as a calibrator. Good laboratory practice dictates that a quality control program be established in all laboratories. This program consists of the routine assay of these controls by trained laboratory personnel and evaluation of the documented results against laboratory acceptable limits. If results are outside these limits re-run the control and investigate method parameters, environmental factors and techniques. If after re-running the control the result(s) continues to remain outside the acceptable limits, contact the manufacturer of the control for further control interpretation assistance.

Further good laboratory practice dictates that control samples and results be quarantined from patient samples and results.

Clinical Application of Haemoglobin A1c Measurement

The measurement of HbA1c is especially useful in the diabetic patient. Blood glucose levels fluctuate widely and instantaneous blood glucose testing does not reflect the averaged situation. The formation of HbA1c occurs slowly (about 0.05%/day) and continuously during the 120-day lifetime of the red cell. The measurement of HbA1c is useful to physicians as a long-term integral of blood glucose concentration and thus as a measure of the degree of control or self-management by the diabetic patient. However, each laboratory should determine a reference interval that corresponds to the characteristics of the population being tested. Each percentage point increase in HbA1c level corresponds to an increase in average blood glucose level of about 30 mg/dL or 1.7 mmol/L. As a general rule HbA1c levels above 10% represent poor diabetic control, whereas values between 6.5% and 7.5% are indicative of good control.

Kit Contents

REF B12396

Description:

- 2 vials of extendSURE™ Haemoglobin A1c liquid control Level 1 of 1.0 mL fill.
- 2 vials of extendSURE™ Haemoglobin A1c liquid control Level 2 of 1.0 mL fill.
- 1 Information Sheet.
- 2 Lot Specific Value Assignment Cards

Precautions/Warnings

WARNING



Potentially Biohazardous Material

Human red cells were used as a source material in the manufacture of the controls. Each unit was obtained from blood donors and tested by FDA accepted methods and found non reactive for Hepatitis B surface antigen, Anti-HCV, Anti-HIV 1 & 2 and Syphilis. No test method can offer complete assurance that the control containing human sourced materials will be absent of these and other infectious agents. Good laboratory practice dictates that all human source material should be considered potentially infectious and be handled with the same precautions used with patient specimens.




CAUTION

- Please **READ** through this **INFORMATION SHEET** before using the control materials.
- **FOR IN VITRO DIAGNOSTIC **IVD** USE.**
- **SAFETY CLOTHING** (glasses, gloves and laboratory coat) are **RECOMMENDED** when using these controls.
- **Discarded or spilt controls should be treated and disposed of as directed by your laboratory safety guidelines or by local ordinance.**
- **This PRODUCT CONTAINS a small amount of POTASSIUM CYANIDE. DO NOT INGEST.**
- **DO NOT USE CONTROLS BEYOND USE BY DATE and only use one control lot at a time.**
- **If there is evidence of MICROBIAL CONTAMINATION or BROWN DISCOLORATION or PRECIPITATION in the controls, discard the vial.**

Storage and Handling

Unopened

The extendSURE™ Haemoglobin A1c liquid unopened control vials should be stored in an upright position at 2-8°C. Controls can be used until the last day of the use by month  shown on the bottle and is stable for 30 months from the date of manufacture.

Opened

The extendSURE™ Haemoglobin A1c liquid opened control vials should be stored in an upright position at 2-8°C. Once the controls are opened; they can be used for 30 days when stored tightly capped. The controls should not be frozen and thawed.

Control Procedure

The extendSURE™ Haemoglobin A1c liquid controls are ready for use and should be treated in the same manner as unknown patient specimens and run in accordance with the manufacture's instructions accompanying the respective instrument/method. The controls exhibit column elution profiles comparable to patient whole blood haemolysates.

Value Assignment, Traceability Statement and Assay Values

The Control Mean **MEAN** and Range **RANGE** values for Haemoglobin A1c on the AU and DxC chemistry systems are detailed on the enclosed extendSURE™ Lot Specific Value Assignment Card

LOT SPECIFIC VALUE ASSIGNMENT CARD in Units **UNITS** of % (NGSP Aligned **NGSP ALIGNED**) and mmol/mol (IFCC Aligned **IFCC ALIGNED**) as well as in units of g/dL and mmol/L. Also detailed to each card is a value for Total Haemoglobin in units of g/dL and mmol/L.

Values for Level 1 **Level 1** Control are printed on one side of each card with values for Level 2 **Level 2** Control printed on the other side.

These assay values were derived from replicate analyses and are traceable and specific to the Manufacture's

Instrument/Haemoglobin A1c Reagent Assay

MANUFACTURER'S INSTRUMENT/HAEMOGLOBIN A1c REAGENT ASSAY using instruments and reagents lots available at the time of assay and are specific to this lot of Haemoglobin A1c liquid controls.

Since the assay values are dependent upon assay procedures as well as several other factors and because other assay systems may produce different values it is recommended that each laboratory should establish its own control limits from day-to-day use of the test. Any result that falls outside the limits established by your laboratory should be investigated.

In vitro Diagnostic Directive (IVDD, 98/79/EC and ISO 15223-1:2016) Symbols

				CONTROL	LOT
<p>Caution, consult accompanying documents Attention, consulter les documents joints Achtung, Begleitdokumente beachten Precaución, consulte la documentación adjunta Attenzione, consultare i documenti allegati Let op, raadpleeg de begeleidende documenten Cuidado: consultar os documentos anexos Vigyázatz! Olvassa el a kísérelő dokumentumokat. Försiktighet, konsultera medföljande dokument Dikkat, bilirkte gelen dokümana bakın Внимание, консультируйте се с придружаващите документи Upróznění: Seznamte se s doprovodnými dokumenty Vigtigt, se vedlagte dokumenter Demesiol Žr. pridetus dokumentus Huomio, katso oheisasiakirjat Προσοχή, συμβουλευθείτε τα συνοδευτικά έγγραφα 注意, 参阅随附说明文档 警告、付属の文書を参照 Предостережение, сверьтесь с сопроводительными документами تنبیه، راجع المستندات المرفقة Upróznenie, pozrite sprievodnú dokumentáciu</p>	<p>Biological Risks Risques biologiques Biogefährlich Riesgos biológicos Rischi biologici Biologische risico's Riscos biológicos Biológiai veszély! Biologiska risker Bijoloji Riskler Бιολογични рискове Biologická rizika Biologisk fare Biologiniai pavojai Biologiset vaarat Βιολογικοί κίνδυνοι 生物危害风险 生物学的リスク Биолоγическая опасность المخاطر البيولوجية Biologické riziká</p>	<p>Temperature limitation Température limite Zulässiger Temperaturbereich Limitación de temperatura Limitazione della temperatura Temperatuurgrens Limites de temperatura Hőmérséklet-korlátok Temperatürgrens Sıcaklık sınırı Ограничение на температурата Templotní rozmezí Temperaturbegrensning Temperatūros ribos Lämpötilarajoitus Περιορισμός θερμοκρασίας حدود درجات الحرارة Templotné obmedzenie</p>	<p>Consult Instructions for Use Consulter la notice d'emploi Gebrauchsanweisung beachten Consulte las instrucciones de uso Consultare le istruzioni per l'uso Raadpleeg de gebruiksaanwijzing Consultar as Instruções de utilização Olvassa el a Használati utasítást. Läs bruksanvisningen Kullanma Talimatlarını Bakın Консултирайте се с инструкциите за употреба Viz Návod k použití Se bruksanvisningen Žr. naudojimo instrukcijas Katso käyttöohje Συμβουλευθείτε τις οδηγίες χρήσης 参阅使用说明书 使用説明書を参照 Сверьтесь с инструкцией по эксплуатации راجع إرشادات الاستخدام Pozrite pokyny na použitie</p>	<p>Control Contrôle Kontrolle Controllo Control Kontroll Kontrol Kontrol Контроль Kontrola Kontrolle Kontrolli Έλεγχος 质控品 コントロール Контроль Kontrola سائل التحكم</p>	<p>Batch Code (Lot) Code de lot (Lot) Chargencode (Chargenbezeichnung) Código de lote (Lote) Codice batch (lotto) Batchcode (partij) Código de Lote (Lote) Sarzs kód (sarzs) Batchkod (lot) Küme Kodu (Grup) Код на серия (партия) Kód dávky (šarže) Batchkode (lot) Partijos kodas (serija) Eräkoodi (erä) Κωδικός παρτίδας (Παρτίδα) 批号 (批次编号) ロットコード Код серии (партия) كود التشغيل (اللو) Kód šarže</p>
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