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IVD

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B12397

Information for Use

Haemoglobin A1c Liquid Control Levels 1 and 2

European customers / Clients Européens / Europäische Kunden / Clientes europeos / Clienti europei / Europese klanten / Clientes europeus / Európai ügyfelek / Europeiska kunder / Avrupalı müşteriler / Европейски клиенти / Evropští zákazníci / Europæiske kunder / Europos klientai / Eurooppalaiset asiakkaat / Ευρωπαίοι πελάτες / 欧盟客户 / 欧州のお客様 / Европейские клиенты / العملاء الأوروبيين / Európski zákazníci

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 Gebrauchsweisungen 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.

es Las Instrucciones de uso están disponibles en múltiples lenguas en nuestra página web: www.canterburyscientific.com en la sección "Productos e instrucciones de uso". Puede solicitar un ejemplar impreso en el n. º de fax +64 3 3433342 o en el correo electrónico: info@canterburyscientific.com.

⚠ Este producto contiene materiales de origen humano o animal y debe ser manipulado como potencialmente infeccioso.

it Sul nostro sito Web sono disponibili le istruzioni per l'uso in varie lingue: www.canterburyscientific.com nella sezione "Products and Instructions for Use" (Prodotti e istruzioni per l'uso).
È possibile ricevere una versione cartacea inviando un fax al numero +64 3 3433342 o scrivendo un'e-mail all'indirizzo: info@canterburyscientific.com.

⚠ Questo prodotto contiene materiali di origine umana o animale e deve essere trattato come potenzialmente infettivo.

nl Op onze website is de gebruiksaanwijzing in meerdere talen beschikbaar: zie www.canterburyscientific.com onder het gedeelte "Producten en gebruiksaanwijzingen". Gedrukte versies kunnen worden aangevraagd via fax +64 3 3433342 of e-mail: info@canterburyscientific.com.

⚠ Dit product bevat materialen van menselijke en dierlijke oorsprong en moet worden behandeld als mogelijk infectieus.

pt No nosso site da internet, poderá encontrar Instruções de Utilização em várias línguas: www.canterburyscientific.com na secção "Produtos e Instruções de Utilização". Poderá obter uma versão em papel pelo fax +64 3 3433342 ou e_mail: info@canterburyscientific.com.

⚠ Este produto contém materiais de origem humana ou animal e deve ser considerado como potencialmente infeccioso.

hu A Használati utasítás több nyelven elérhető honlapunkon a www.canterburyscientific.com címen, a „Products and Instructions for Use" (Termékek és Használati utasítások) című részben.
A nyomtatott verzió fax (+64 3 3433342) vagy e-mail (info@canterburyscientific.com) útján szerezhető be.

⚠ Ez a termék emberi, illetve állati forrásból származó anyagokat tartalmaz, és potenciálisan fertőző anyagként kell kezelni.

sv Bruksanvisning på flera språk finns på vår hemsida: www.canterburyscientific.com under avsnittet "Produkter och bruksanvisningar". En pappersversion kan erhållas via fax +64 3 3433342 eller e--post: info@canterburyscientific.com.

⚠ Denna produkt innehåller material av humant eller djurursprung och ska behandlas som potentiellt smittsam.

tu Birçok dilde Kullanım Talimatları Web sitemizde mevcuttur: "Products and Instructions for Use" (Ürünler ve Kullanım Talimatları) bölümü altında www.canterburyscientific.com adresinde. Basılı sürüm faks +64 3 3433342 veya e-posta ile sağlanabilir: info@canterburyscientific.com.

⚠ Bu ürün insan veya hayvan kaynaklı materyaller içermektedir ve potansiyel olarak bulaşıcı olduğu düşünülerek işlem yapılmalıdır.

bg Инструкциите за употреба на различни езици можете да намерите на нашия уебсайт: www.canterburyscientific.com в раздел "Products and Instructions for Use" ("Продукти и инструкции за употреба"). Можете да се сдобиете с техния хартиен вариант чрез факс +64 3 3433342 или на имейл: info@canterburyscientific.com.

⚠ Този продукт съдържа материали от човешки или животински произход и следва да се третира като потенциално заразен.

cz Návod k použití v několika jazycích je k dispozici na našich webových stránkách: www.canterburyscientific.com v části „Výrobky a návod k použití". Tištěnou verzi lze získat faxem +64 3 3433342 nebo e--mailem: info@canterburyscientific.com.

⚠ Tento výrobek obsahuje lidské nebo zvířecí zdrojové materiály a musí tedy být považován jako potenciálně infekční.

da Brugsanvisninger 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 infektiøst.

lt Naudojimo instrukcijas keliomis kalbomis galima rasti mūsų interneto svetainėje www.canterburyscientific.com, skyriuje „Produktai ir naudojimo instrukcijos". Popierinę versiją galima gauti faksu +64 3 3433342 arba el. paštu info@canterburyscientific.com.

⚠ Šio produkto sudėtyje yra žmogaus ir gyvūnų kilmės medžiagų, todėl jį reikia laikyti potencialiai infekciniu.

fi Sivustoltamme löytyy käyttöohjeet useilla eri kielillä: www.canterburyscientific.com, osa "Tuotteet ja käyttöohjeet". Voit hankkia tulostetun version faksaamalla 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.

el Οδηγίες χρήσης σε διάφορες γλώσσες είναι διαθέσιμες στον δικτυακό τόπο μας: www.canterburyscientific.com στην ενότητα «Προϊόντα και οδηγίες χρήσης». Έντυπη μορφή μπορεί να ληφθεί μέσω φαξ +64 3 3433342 ή e--mail: info@canterburyscientific.com.

⚠ Αυτό το προϊόν περιέχει υλικά ανθρώπινης ή ζωικής προέλευσης και πρέπει να αντιμετωπίζεται ως δυνητικά μολυσματικό.

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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

⚠ 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。

ja 他言語版の「ご使用上の注意」を当社ウェブサイト（www.canterburyscientific.com）の「Products and Instructions for Use」セクションで入手できます。印刷版はファックス（+64 3 3433342）又は電子メール（info@canterburyscientific.com）で入手できます。

⚠ 本製品にはヒト又は動物由来の原料が含まれているため、感染症の可能性があるものとしてお取り扱いください。

ru Инструкции по эксплуатации на разных языках имеются на нашем интернет-сайте: www.canterburyscientific.com в разделе Products and Instructions for Use (Продукция и инструкции по эксплуатации). Бумажную версию можно получить по факсу: +64 3 3433342 или электронной почте: info@canterburyscientific.com.

⚠ Данный препарат содержит материалы человеческого или животного происхождения и должен рассматриваться как потенциально инфицированный.

ar تتوفر 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.

hr Upute za uporabu na raznim jezicima dostupne su na našoj web stranici: www.canterburyscientific.com pod odjeljkom „Proizvodi i upute za upotrebu". Papirnata se verzija može dobiti telefaksom na broj +64 3 3433342 ili e-poštom: info@canterburyscientific.com.

⚠ Ovaj proizvod sadrži ljudski ili životinjski izvor materijala i treba biti tretiran kao potencijalno zarazan.

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 čísle +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 Instrucţiuni de utilizare în mai multe limbi sunt disponibile pe site-ul nostru: www.canterburyscientific.com la secţiunea "Products and Instructions for Use" (Produse şi instrucţiuni de utilizare). Se poate obţine o versiune tipărită prin trimiterea unui fax la numărul +64 3 3433342 sau a unui e-mail la adresa: info@canterburyscientific.com.

⚠ Acest produs conţine materiale sursă umane sau animale şi trebuie tratat ca fiind un produs potenţial infecţios.

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 B12397

Description:

- 12 vials of extendSURE™ Haemoglobin A1c liquid control Level 1 of 1.0 mL fill.
- 12 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 manufacturer'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
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 Vigyázat! Olvassa el a kísérő dokumentumokat. Försiktighet, konsultera medföljande dokument Dikkat, birlikte gelen dokümana bakın Внимание, консултирайте се с придружаващите документи Upozornění: Seznamte se s doprovodnými dokumenty Vigtigt, se vedlagte dokumenter Dėmesio! Žr. pridėtus 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 تنبيه، راجع المستندات المرفقة Upozornenie, pozrite sprievodnú dokumentáciu	Biological Risks Risques biologiques Biogefährlich Riesgos biológicos Rischi biologici Biologische risico's Riscos biológicos Biológiai veszély! Biologiska risker Biyolojik Riskler Биологични рискове Biologická rizika Biologisk fare Biologiniai pavojai Biologiset vaarat Βιολογικοί κίνδυνοι 生物危害风险 生物学的リスク Биологическая опасность المخاطر البيولوجية Biologické riziká	Temperature limitation Température limite Zulässiger Temperaturenbereich Limitación de temperatura Limitazione della temperatura Temperatuurgrens Limites de temperatura Hőmérséklet-korlátozás Temperaturgräns Sıcaklık sınırı Ограничение на температурата Teplotní rozmezí Temperaturbegrænsning Temperatūros ribos Lämpötilarajoitus Περιορισμός θερμοκρασίας 温度限制 温度制限 Температурные ограничения حدود درجات الحرارة Teplotné obmedzenie	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 Talimatlarına Bakın Консултирайте се с инструкциите за употреба Viz Návod k použití Se brugsanvisningen 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	Control Contrôle Kontrolle Control Controllo Controle Controlo Kontroll Kontroll Kontrol Контролен материал Kontrola Kontrol Kontrolė Kontrolli Έλεγχος 质控品 コントロール Контроль سائل التحكم Kontrola	Batch Code (Lot) Code de lot (Lot) Chargencode (Chargenbezeichnung) Código de lote (Lote) Codice batch (lotto) Batchcode (partij) Código de Lote (Lote) Sarzskód (sarzs) Batchkod (lot) Küme Kodu (Grup) Код на серия (партида) 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 التشغيلة (اللوط) Kód šarže
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