


Information for Use

extendsSURE™ HbA1c Liquid Controls


Attention: The following updates have been made to this version of the IFU

1. CE mark is followed by the Notified Body number, 2797.
2. Amended the device name to be consistent with the labels.
3. Amended language boxes on front pages to remove reference to containing animal sources.
4. Updated Intended Use to add Beckman Coulter chemistry systems.
5. Amended Description and Intended Use section to add:
 - a. Actions to take in the event of a serious incident in EU.
 - b. Reference to summary of safety and performance report
6. Removed references to CSL fax number.
7. Amended the Unopened section to say that controls can be used until the use by  shown on the bottle.
8. Removed “ready for use” statement from the section Control Procedure.
9. Amended title of symbols table to reference In Vitro Diagnostic Regulation (EU) 2017/746.
10. Amended text font.
11. Removal of reference to Traceability Statement under Control Procedure and addition of Performance Characteristics section with detailed information on Traceability and Batch-to-Batch Variation. Addition of References section to list references cited under the Performance Characteristics section.
12. Updated EC REP address.
13. Two letter language codes amended for Chinese (zh), Czech (cs) and Turkish (tr).
14. Added Kazakh language.
15. Added CH-REP symbol, corresponding translations and CH-REP details.



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

en Instructions For Use in multiple languages are available on our website: www.canterburyscientific.com under the “Technical Resources” section. A paper version can be obtained by e-mail: info@canterburyscientific.com.

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


fr Les instructions d'utilisation sont disponibles en plusieurs langues sur notre site web, www.canterburyscientific.com, dans la rubrique «Technical Resources [Ressources techniques] ». Vous pouvez obtenir un exemplaire papier par e-mail, à l'adresse : info@canterburyscientific.com.

 Ce produit contient des substances humaines et doit, par conséquent, être traité comme un produit potentiellement infectieux.


de Bedienungsanleitungen in verschiedenen Sprachen sind auf unserer Webseite erhältlich: www.canterburyscientific.com im Abschnitt „Technical Resources“ (technische Ressourcen). Ein Papierexemplar erhalten Sie auf Anfrage per E-Mail: info@canterburyscientific.com.

 Dieses Produkt enthält aus menschlichen Quellen gewonnene Materialien, die als potenziell infektiös gehandhabt werden sollten.

es Las Instrucciones de uso están disponibles en varios idiomas en nuestro sitio web: www.canterburyscientific.com en la sección “Recursos técnicos”. Puede solicitar un ejemplar impreso a través del correo electrónico:- info@canterburyscientific.com.

 Este producto contiene materiales de origen humano y debe tratarse como potencialmente infeccioso.


it Le istruzioni per l'uso in più lingue sono disponibili sul nostro sito Web: www.canterburyscientific.com, nella sezione "Risorse tecniche". La versione cartacea può essere ottenuta tramite e-mail: info@canterburyscientific.com.

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

nl Gebruiksaanwijzingen in meerdere talen zijn beschikbaar op onze website: www.canterburyscientific.com onder de rubriek 'Technical Resources'. Een papieren versie is verkrijgbaar via e-mail: info@canterburyscientific.com.

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


pt Estão disponíveis no nosso site Instruções de Utilização em várias línguas: www.canterburyscientific.com na secção "Recursos Técnicos". Uma versão em papel pode ser obtida por e-mail: info@canterburyscientific.com.

 Este produto contém materiais de origem humana e deve ser tratado como potencialmente infeccioso.


hu Használati utasítás több nyelven rendelkezésre áll webhelyünkön, a www.canterburyscientific.com címen, a „Műszaki erőforrások” részben. A papíralapú változat e-mailben igényelhető az alábbi címről: info@canterburyscientific.com.

 Ez a termék emberi eredetű anyagokat tartalmaz, és potenciálisan fertőzőként kezelendő.


sv På vår webbplats finns bruksanvisningar på flera språk: www.canterburyscientific.com i avsnittet "Tekniska hjälpmedel". En pappersversion kan erhållas per e-post: info@canterburyscientific.com.

 Denna produkt innehåller humant källmaterial och den bör behandlas som potentiellt smittsam.


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 Bu ürün insan kaynaklı materyaller içermektedir ve potansiyel olarak bulaşıcı olduğu düşünülecek şekilde işlem yapılmalıdır.


bg Инструкциите за употреба на различни езици можете да намерите на нашия уебсайт: www.canterburyscientific.com, под раздел „Технически ресурси”. Версия на хартиен носител може да бъде получена по -имейл: info@canterburyscientific.com.

 Този продукт съдържа материали от човешки произход и следва да се третира като потенциално заръзен.


cs Návod k použití v několika jazycích je k dispozici na našich webových stránkách: www.canterburyscientific.com v části "Technical Resources" (Technické zdroje) → Instructions for use (Návody k použití). Papírovou verzi lze získat e-mailem: info@canterburyscientific.com.

 Tento výrobek obsahuje biologické materiály z lidského organismu a musí tedy být považován za potenciálně infekční.


da Brugsanvisning på flere sprog er tilgængelig på vores hjemmeside: www.canterburyscientific.com under afsnittet "Tekniske ressourcer". En papirversion kan fås via e-mail: info@canterburyscientific.com.

 Dette produkt indeholder humane kildematerialer og skal behandles som potentielt infektøst.

lt Naudojimo instrukcijas keliomis kalbomis galima rasti mūsų interneto svetainėje www.canterburyscientific.com skyriuje Techniniai ištekliai. Popierinę versiją galima gauti el. paštu: info@canterburyscientific.com.

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


fi Sivustoltamme löytyy käyttöohjeet useilla eri kielillä: katso sivulta www.canterburyscientific.com kohta Technical Resources (Tekniset resurssit). Paperiversio on saatavilla sähkö-postitse: info@canterburyscientific.com.

 Tämä tuote sisältää ihmisperäisiä 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 «Τεχνικοί πόροι». Εντυπη μορφή μπορεί να ληφθεί μέσω e-mail: info@canterburyscientific.com.

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


ru Инструкции по применению на разных языках доступны на нашем сайте: www.canterburyscientific.com в разделе «Технические ресурсы». Бумажную версию можно получить, отправив запрос на -адрес info@canterburyscientific.com.

 Этот продукт содержит человеческие биоматериалы и требует осторожного обращения как потенциально инфекционно опасный.

hr Használati utasítás több nyelven rendelkezésre áll webhelyünkön, a www.canterburyscientific.com címen, a „Műszaki erőforrások” részben. A papíralapú változat e-mailben igényelhető az alábbi címről: info@canterburyscientific.com.

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sk Pokyny na použitie v rôznych jazykoch sú dostupné na našej webovej lokalite: www.canterburyscientific.com v časti Technické zdroje. Papierovú verziu je možné získat e-mailom na adrese: info@canterburyscientific.com.

 Tento produkt obsahuje materiály ľudského pôvodu a malo by sa s ním zaobchádzať ako s potenciálne infekčným materiálom.

ro Instrucțiunile de utilizare în mai multe limbi sunt disponibile pe site-ul nostru web: www.canterburyscientific.com la secțiunea „Resurse tehnice”. O versiune imprimată poate fi obținută prin e-mail: info@canterburyscientific.com.


 Acest produs conține materiale de origine umană și trebuie tratat ca fiind un produs potențial infecțios.

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
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
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
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 Sản phẩm này chứa nguyên liệu có nguồn gốc từ con người và nên được xử lý như sản phẩm có thể lây nhiễm.

kk Бірнеше тілде колдану жөнүндөгү нускалыктар биздин веб-сайтта кол жетімді: www.canterburyscientific.com сайтында «Өнімдер мен пайдалану нускаулары» бөлімінде. Қағаз нускасын +64 3 3433342 факсы немесе электрондық пошта арқылы алуға болады: info@canterburyscientific.com.

 Бұл өнімде адам немесе жануарлар көздерінен алынған материалдар бар және оны жұқпалы болуы мүмкін деп қарау керек.

Description and Intended Use

The extendSURE™ HbA1c 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 extendSURE™ HbA1c Liquid Controls is used for performing quality control of HbA1c Assay on the Beckman Coulter DxC, DxC AU and AU chemistry systems.  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.

For users and/or patients established in the EU, any serious incident that has occurred in relation to the device shall be reported to Canterbury Scientific Limited and the competent authority of the Member State in which the user and/or the patient is established.

The summary of safety and performance report is available on request from Canterbury Scientific Limited or EUDAMED URL <https://ec.europa.eu/tools/eudamed> where it is linked to the Basic UDI-DI.

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™ HbA1c Liquid Control Level 1 of 1.0 mL fill.
- 12 vials of extendSURE™ HbA1c Liquid Control Level 2 of 1.0 mL fill.
- 1 Information Sheet.
- 3 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

The product must be stored protected from light, preferably in the original box.

Unopened

The extendSURE™ HbA1c Liquid Control unopened vials should be stored in an upright position at 2-8°C. Controls can be used until the use by  shown on the bottle and is stable for 30 months from the date of manufacture.

Opened

The extendSURE™ HbA1c Liquid Control opened 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™ HbA1c Liquid Controls 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 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.

Performance Characteristics

Traceability and Batch-to-Batch Variation

The International Federation of Clinical Chemistry (IFCC) Aligned values assigned to the extendSURE™ HbA1c Liquid Controls on the enclosed extendSURE™ Lot Specific Value Assignment Card are traceable to the IFCC reference method via IFCC HbA1c reference material (HBA-IFCC-CAL).

Analyte	Reference Material / Method	Units	Instrument Type	Level	Target Mean ¹	Performance Range ²
HbA1c	IFCC (HBA-IFCC-CAL)	mmol/mol	AU Systems	1	36 - 48	All lots prior to Lot 4090: ±7 All lots from Lot 4090: ±6
				2	64 - 108	All lots prior to Lot 4090: ±15 All lots from Lot 4090: ±14
			DxC AU Systems ³	1	36 - 48	All lots from Lot 4197: ±7
				2	64 - 108	All lots from Lot 4197: ±14
			DxC Systems	1	36 - 48	All lots prior to Lot 4090: ±7 All lots from Lot 4090: ±7
				2	64 - 108	All lots prior to Lot 4090: ±17 All lots from Lot 4090: ±16
	NGSP (HBA-IFCC-CAL)	%HbA1c	AU Systems	1	5.5-6.5	All lots prior to Lot 4090: ±1.0 All lots from Lot 4090: ±1.0
				2	8.0-12.0	All lots prior to Lot 4090: ±1.8 All lots from Lot 4090: ±1.7
			DxC AU Systems ³	1	5.5-6.5	All lots from Lot 4197: ±1.0
				2	8.0-12.0	All lots from Lot 4197: ±1.7
			DxC Systems	1	5.5-6.5	All lots prior to Lot 4090: ±1.1 All lots from Lot 4090: ±1.0
				2	8.0-12.0	All lots prior to Lot 4090: ±2.0 All lots from Lot 4090: ±1.8

¹During manufacture of the extendSURE™ HbA1c Liquid Controls, Canterbury Scientific targets mean mmol/mol and % HbA1c values in the indicated ranges for Level 1 and Level 2 controls. Lot Specific Values Assigned fall within this target range.

²During value assignment of the extendSURE™ HbA1c Liquid Controls, for the first validation lot (Lot # 4062), the performance range was set at ±20% of the mean %HbA1c value assigned for both Level 1 and Level 2 for this lot. For the subsequent second and third validation lots (Lots 4064 & 4066), the performance range was established as the performance range for lot N-1 and subsequently maintained at ±20% of the %HbA1c value assigned to both Level 1 and Level 2 controls for the first validation lot (Lot 4062). As the performance range of lot 4066 was greater than six times the overall standard deviation of lot 4090 (the first subsequent lot), the performance range was revised to ±17% of the %HbA1c value assigned for both Level 1 and Level 2 controls of lot 4090. Subsequently the performance range for all subsequent lots after lot 4090 have been set at the performance range for lot N-1 and it has been maintained at ±17% of the %HbA1c value assigned for both Level 1 and Level 2 controls of lot 4090. Performance range is determined during product development and is monitored with each lot based upon warning flags, documented changes in technology and professional judgement, and historical ranges are maintained. Lot Specific Value Assignment Cards indicate the values that correspond with assigned performance range.

³Value assignment on the DxC 700 AU was introduced from Lot 4197. As this was a new system at the time, mean and performance range of the previous lot of systems that have the closest characteristics to the DxC 700 AU were selected. In this case, means and performance ranges from the AU system were assigned from (and inclusive of) Lot 4197 for all levels, with the exception of IFCC Level 1 for which the wider range of 17% of the mean value was used, as permissible under internal value assignment process controls.

The relationship between results from the NGSP (National Glycohemoglobin Standardization Program) network (DCCT aligned) and the IFCC network has been evaluated and the following Master Equation has been developed for interconversion of results from IFCC (mmol/mol) to NGSP (%) units and subsequently used to provide NGSP Aligned values on the enclosed extendSURE™ Lot Specific Value Assignment Card.

Master Equation














$$\text{NGSP} = (0.0915 \times \text{IFCC (mmol/mol)}) + 2.15$$

The definition of the relationship between the two networks links IFCC traceable results to clinically meaningful HbA1c results from the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS). The Master Equation also provides these DCCT results with traceability to a higher order reference method.

Value assignment of the extendSURE® HbA1c Liquid Controls is performed against HbA1c calibrators for which value assignment is performed at facilities that maintain NGSP certification for traceability to the DCCT reference method through comparison with European Reference Laboratory ESRL # 13 on the following Beckman Coulter instruments: AU480, AU680, AU5800, DxC700AU.

References: 1, 2, 3, 4, 5, 6, 7, 8

In Vitro Diagnostic Regulation (EU) 2017/746 and ISO 15223-1:2016 Symbols

 <p>Caution, consult accompanying documents Attention, consulter les documents joints Achtung, Begleitdokumente beachten Precacución, consulte la documentación adjunta Attenzione, consultare i documenti allegati Let op, raadpleeg de begeleidende documenten Cuidado: consultar os documentos anexos Vigyázat! Olvassa el a kisérdokumentumokat. Försiktighet, konsultera medföljande dokument Dikkat, birlíkthe gelen dokümana bakın Внимание, консультируйте се с придружаващите документи Urozornění: Seznamte se s doprovodnými dokumenty Viktigt, se vedlagte dokumenter Démessio! Zr. pridružen dokumentus Huomio, katso ohjeasiakirjat Προσοχή, συμβουλευθείτε τα συνοδευτικά έγγραφα Предостережение, сверьтесь с сопроводительными документами Urozornenie, konzultirajte priložene dokumente Urozornenie, pozrite sprievodnú dokumentáciu Atentie, consultați documentele anexate المعرفة المستندات راجع: تنبيه 注意、参阅随附说明文档 警告、付属の文書を参照 Thận trọng, tham khảo các tài liệu đi kèm Назар аударыңыз, ислепсе құжаттармен танысыңыз</p>	 <p>Biological Risks Risques biologiques Biegefähiglich 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 Биологическая опасность Biološki rizici Biologické riziká Riscuri biologice المخاطر البيولوجية 生物危害风险 生物学的リスク Rủi ro Sinh học Биологиялық қауіптер</p>	 <p>Temperature limitation Température limite Zulässiger Temperaturbereich Limitación de temperatura Limitazione della temperatura Temperaturgrens Limites de temperatura Hörmérséklet-korlátozás Temperaturgräns Sıcaklık sınırı Ограничение на температурата Teplotní rozmezí Temperaturbegrensning Temperatūros ribos Lämpötilarajotus Περιορισμός θερμοκρασίας Температурные ограничения Temperaturno ograničenje Pozrite obmedzenie Limitare de temperatură حدود درجات الحرارة 温度限制 温度制限 Giới hạn nhiệt độ Температура шери</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 Talimatlarına Bakın Консултирайте се с инструкциите за употреба Viz Návod k použití Se brugsanvisningen Zr. naudojimo instrukcijas Kätsu käyttöohje Συμβουλευθείτε τις οδηγίες χρήσης Сверьтесь с инструкцией по эксплуатации Konzultirajte upute za uporabu Pozrite pokyny na použitie Consultati instructiunile de utilizare الاستخدام إرشادات راجع 参閱使用说明书 使用説明書を参照 Tham khảo Hướng dẫn Sử dụng Пайдалану жөнiндегi нұсқаулықпен танысыңыз</p>	 <p>Control Contrôle Kontrolle Control Controllo Controlle Controlo Kontroll Kontrol Kontrolen материал Kontrola Kontrol Kontrolé Kontrolli Έλεγχος Kontrola Kontrola Control</p>	 <p>Batch Code (Lot) Code de lot (Lot) Chargencode (Chargenbezeichnung) Código de lote (Lote) Codice batch (lotto) Batchcode (partij) Código de Lote (Lote) Batchkod (lot) Kúme Kodu (Grup) Код на серия (партида) Kód dávky (šarže) Batchkode (lot) Partijos kodas (serija) Eräkoodi (erä) Κωδικός партиδας (Παρτιδα) Κόδ σειρι (partia) Serijski broj (Lot) Kód šarže Cod lot (Lot) كود التشغيل (الوط) 批号 (批次编号) ロットコード Mã lô sản xuất (Số lô) Партия коды (лот)</p>
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