

Cholestech GDX™

A1C Controls

LOT

REF 12-322

IVD CE

L1

L2

Expected Range A1C (%) (DCCT) / Intervalo esperado de A1C (%) (DCCT)
Erwarteter Wertebereich in A1C (%) (DCCT) / Intervalo atteso HbA1c (%) (DCCT)
Plage attendue pour A1C (%) (DCCT) / Intervalo de Valores Esperados A1C (%) (DCCT)
Forventet område A1C (%) (DCCT) / Förväntat intervall A1C (%) (DCCT) / Odotettu vaihteluväli A1C (%) (DCCT)
A1C için Beklenen Aralık (%) (DCCT) / Αναμενόμενο εύρος τιμών A1C (%) (DCCT)

CLIAwaived™

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Refer to the CD in the analyzer package for instructions in English. The instructions are available from your local distributor.

Consulte el CD incluido en el envase del analizador para obtener instrucciones en español. También puede pedir las instrucciones a su distribuidor local.

Anweisungen auf Deutsch befinden sich auf der CD in der Verpackung des Analysegeräts. Die Anleitung ist von Ihrem Händler erhältlich.

Fare riferimento al CD nella confezione dell'analizzatore per istruzioni in italiano. Le istruzioni sono disponibili presso il distributore di zona.

Le CD contenu dans l'emballage de l'analyseur inclut les directives d'utilisation en français. Le mode d'emploi est disponible auprès du distributeur local.

Consulte o CD no pacote do analisador para instruções em Português. As instruções estão disponíveis junto do seu distribuidor local.

Der henvises til den vedlagte CD i analysatorpakken for instruktioner på dansk. Instruktionerne fås hos den lokale forhandler.

Se CD:n i analysatorförpackningen beträffande instruktioner på svenska. Anvisningarna kan erhållas från en lokal distributör.

Lue suomenkieliset ohjeet analysaattorin pakkauksessa olevalta CD:ltä. Ohjeet ovat saatavissa paikalliselta jälleenmyyjältä.

Türkçe talimat için analizör paketindeki CD'ye bakınız. Talimat yerel dağıtıcınızdan elde edilebilir.

Ανατρέξτε στο CD στη συσκευασία του αναλυτή για οδηγίες στα Ελληνικά. Οι οδηγίες είναι διαθέσιμες από τον τοπικό διανομέα σας.

Use of Quality Controls

Cholestech GDX A1C Controls are designed for use with the Cholestech GDX System. The controls may be used in the laboratory and at point-of-care to monitor the performance of the Cholestech GDX System. Two levels of control are provided to allow performance to be measured.

Summary and Explanation

The measurement of hemoglobin A1C is recommended for monitoring the long-term care of people with diabetes.^{1,2} The concentration of A1C within red blood cells reflects the average level of blood sugar (glucose) over the previous 2–3 months. The higher the blood sugar level, the higher the A1C.

Principles of the Procedure

Cholestech GDX A1C Controls should be treated in the same way as patient samples and tested according to the package insert supplied with Cholestech GDX A1C Test Cartridges and the user manual supplied with the Cholestech GDX System.

Control Material

Cholestech GDX A1C Controls are prepared from human blood that has been freeze dried.

Storage and Stability

Store unopened at 2–8°C (36–46°F). The expiration date is on the outside of the pack. After the controls are prepared, they are stable for 5 days at 2–8°C or for 3 months at -20°C. Controls samples are stable if thawed and re-frozen on up to 4 occasions.

Cholestech GDX A1C Controls

Product Description

Cholestech GDX A1C Controls, including the following:

- This package insert
- 3 bottles (white cap) Level 1 Control, 0.5 mL
- 3 bottles (black cap) Level 2 Control, 0.5 mL
- 1 dropper bottle Diluent, 3.4 mL

Required items, available from Cholestech

Product Description

Cholestech GDX System, including 10 µL MiniPet™ Pipette
Cholestech GDX A1C Test Cartridges
Pipette tips (or equivalent)

Precautions

- For *In Vitro* Diagnostic Use.
- Cholestech GDX A1C Controls are made from human blood. The individual donors have been tested and found to be non-reactive for a range of infectious diseases, including HBsAg, HCV, and HIV, by Food and Drug Administration USA (FDA) approved tests. No testing method can claim that all infectious agents are absent, so they should be handled as though they are capable of transmitting an infectious disease.
- Disposable gloves should be worn when using the controls and performing the test.
- When you have finished the test, all test materials should be disposed of as potentially infectious waste.



Warning

- These controls must be used only with the Cholestech GDx System and A1C Test Cartridges. Results obtained using other methods cannot be guaranteed to fall within the stated range.
- Do not use Cholestech GDx A1C Controls beyond the stated expiration date.

Quality Control

Cholestech GDx A1C Controls allow you to check that the Cholestech GDx System is working correctly. The controls must be used:

- With each new shipment of test cartridges (even if cartridges are from the same lot previously received).
- With each new lot of test cartridges.

Use the controls according to the quality standards set by your organization or laboratory.

Procedure

1. To add a control sample to the red-capped sample tube of the Cholestech GDx A1C Test Cartridge use the MiniPet Pipette.
2. Remove the cap and stopper from the Cholestech GDx A1C Control bottle. Remove the cap from the Diluent dropper bottle.
3. Add 10 drops of diluent to the control bottle.
4. Replace the stopper on the control bottle firmly. Mix the contents of the bottle gently, using a swirling action. DO NOT shake.

Note: Make sure that the caps are returned to the bottles they came from, and are not mixed up (Level 1 white cap; Level 2 black cap).

5. Allow the bottle to stand for 20 minutes before use, until the control material is completely dissolved.
6. Before using the control, gently swirl the bottle several times to ensure complete mixing. If the control solution contains visible pieces of solid material, then it should be left for a further 10 minutes. After this time, if the material has still not dissolved, then the control should be thrown away.
7. Follow the testing procedure described in the Cholestech GDx A1C Test Cartridge package insert. Also refer to the Cholestech GDx Analyzer User Manual.

Results

Refer to the assay section for expected results. Be sure that the lot number on the vial of controls corresponds to the lot number in the assay section.

If any other result is obtained, repeat the test with a new A1C test cartridge from the same lot. If the result continues to fall outside the printed range, check the Cholestech GDx Analyzer, using a Cholestech GDx Optics Check Cartridge.

If problems continue, contact Cholestech Technical Service.

Technical Assistance









For technical help and troubleshooting, please refer to the Cholestech GDx Analyzer User Manual and Cholestech GDx A1C Test Cartridge package insert. If technical help is required, please contact: Cholestech Technical Service Tel 1.510.732.7200 or your local distributor.

Limitations


Cholestech GDx A1C Controls are designed for use with the Cholestech GDx System and A1C Test Cartridges. Their accuracy with other similar tests cannot be guaranteed.

References

1. American Diabetes Association. *Diabetes Care* 2002; 25(Suppl.1):S33 – S49.
2. Goldstein DE et al. *Diabetes Care* 1995; 18:896 – 909.

A1C Controls	REF		LOT
<ul style="list-style-type: none">• Multi-Analyte Control• Control multianalito• Katalognummer• Controllo multianalita• Contrôle multi-analytes• Controllo de multi-analito• Multianalytkontrol• Multianalytkontroll• Multi-kontrola analitov• Multianalit Kontrol• Μάρτυρας πολλαπλών αναλυτών	<ul style="list-style-type: none">• Catalog Number• Número de catálogo• Katalognummer• Numero di catalogo• Numéro de catalogue• Número de catálogo• Katalognummer• Katalognummer• Luettelonumero• Katalog Numarası• Αριθμός καταλόγου	<ul style="list-style-type: none">• Use By• Fecha de caducidad• Verfallsdatum• Utilizzatore entro• Utiliser avant le• Utilizar até• Holdbar til• Använd före• Viimeinen käyttöajankohta• Son Kullanma Tarihi• Ημερομηνία λήξης	<ul style="list-style-type: none">• Lot Number• Número de lote• Chargennummer• Codice del lotto• Número de lot• Número de lote• Lotnummer• Partinummer• Eränumero• Lot Numarası• Αριθμός παρτίδας
 <ul style="list-style-type: none">• Consult instructions for use• Consulte las instrucciones de uso• Gebrauchsanweisung beachten• Consulutare le istruzioni per l'uso• Consulter le mode d'emploi• Consultar as instruções de utilização• Se brugsanvisningen• Konsultera bruksanvisningen• Lue käyttöohjeet• Kullutusohjeet• Συμβουλευτείτε τις οδηγίες χρήσης	 <ul style="list-style-type: none">• Biological Risks• Riesgos biológicos• Biologische Risiken• Rischi biologici• Risques biologiques• Riscos biológicos• Biologiske risici• Biologiska risker• Fertilitaarisvaara• Βιολογικοί κίνδυνοι• Βιολογικοί κίνδυνοι	 <ul style="list-style-type: none">• Temperature Limitation• Limite de temperatura• Temperaturbereich• Limiti di temperatura• Limiti di temperatura• Limites de température• Limites de temperatura• Temperaturbegrenzung• Temperaturbegrensning• Lämpötilarajoitus• Sicaklık Sınırları• Περιορισμός θερμοκρασίας	 <ul style="list-style-type: none">• CE Mark• Marcado CE• CE-Zeichen• Marchio CE• Norme CE• Marca CE• CE-mærke• CE-märkning• CE Mark• CE-merkki• Σήμανση CE  <ul style="list-style-type: none">• Manufacturer• Fabricante• Hersteller• Fabbricante• Fabricant• Fabricante• Fremstillet af• Tillverkad av• Valmistaja• CE-merkki• Üretici• Κατασκευαστής
 <ul style="list-style-type: none">• For In Vitro Diagnostic Use• Para uso diagnóstico in vitro• In-vitro-Diagnostikum• Esclusivamente per uso diagnostico in vitro• Destiné à un usage pour le diagnostique in vitro• Para utilização em diagnóstico in vitro• Til in vitro diagnostisk brug• För diagnostisk användning in vitro• In vitro -diagnostiikka varten• In Vitro Tanısal Kullanım İçin• Για in vitro διαγνωστική χρήση	 <ul style="list-style-type: none">• Level 1 and Level 2• Nivel 1 y nivel 2• Konzentration 1 und Konzentration 2• Livello 1 e Livello 2• Niveau 1 et niveau 2• Nivel 1 e Nivel 2• Niveau 1 og niveau 2• Nivå 1 och nivå 2• Taso 1 ja taso 2• Düzey 1 ve Düzey 2• Επιπέδου 1 και 2		

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