

Cholestech LDX®

Multi-Analyte Control

L1 L2



Exp: 2010-11-03

LOT 0034

L1 (Red Cap)

Tapa roja/Roter Verschluss/Tappo rosso
Bouchon rouge/Tampa vermelha/Rød hætte
Rött lock/Róikínno nápa/Červený uzáver
Rød hætte

LOT 00340566

Constituent/ Componente/Bestandteil/ Costituente/Constituant/ Constituente/Bestanddel/ Bestándsdel/Συστατικό/ Zložka/Bestanddel	Expected Range/ Intervalo esperado/Erwarteter Bereich/ Intervallo atteso/Plage attendue/ Intervallo esperado/Forventet område/ Förväntat intervall/Αναμενόμενο εύρος τιμών/ Očakávaný rozsah/Forventet område
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L2 (Black Cap)

Tapa negra/Schwarzer Verschluss
Tappo nero/Bouchon noir/Tampa negra Sort
hætte/Svart lock/Μαύρο nápa
Čierny uzáver/Svart hætte

LOT 00340567

Constituent/ Componente/Bestandteil/ Costituente/Constituant/ Constituente/Bestanddel/ Bestándsdel/Συστατικό/ Zložka/Bestanddel	Expected Range/ Intervalo esperado/Erwarteter Bereich/ Intervallo atteso/Plage attendue/ Intervallo esperado/Forventet område/ Förväntat intervall/Αναμενόμενο εύρος τιμών/ Očakávaný rozsah/Forventet område
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For all Lipid Cassettes
Para todos los casetes de lípidos/Für alle Lipidkassetten/Per tutte le cassette per lipidi/Pour toutes les cassettes Lipides/Para todas as cassetes de lípidos/Til alle lipidkassetter/Für alle lipidkassetter/Για όλες τις κασέτες λιπιδίων/Pre všetky lipidové kazety/For alle lipidkassetter

Total Cholesterol	137-193 mg/dL	3.54-4.99 mmol/L	205-288 mg/dL	5.30-7.45 mmol/L
HDL Cholesterol	29-46 mg/dL	0.75-1.18 mmol/L	50-78 mg/dL	1.28-2.02 mmol/L
Triglycerides	96-142 mg/dL	1.09-1.60 mmol/L	194-286 mg/dL	2.19-3.23 mmol/L
Glucose	97-143 mg/dL	5.38-7.93 mmol/L	219-323 mg/dL	12.16-17.91 mmol/L

For ALT Cassettes
Para los casetes de ALT/Für alle ALT-Kassetten/Per le cassette per ALT/Pour les cassettes ALT/Para cassetes de ALT/Til ALT kassetter/Für ALT-kassetter/Για τις κασέτες ALT/Pre kazety ALT/For ALT-kassetter

ALT	39-71 U/L	91-165 U/L
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For ALT/AST Cassettes
Para los casetes de ALT/AST/Für alle ALT/AST-Kassetten/Per le cassette per ALT/AST/Pour les cassettes ALT/AST/Para cassetes de ALT/AST/Til ALT/AST kassetter/Für ALT/AST-kassetter/Για τις κασέτες ALT/AST/Pre kazety ALT/AST/For ALT/AST-kassetter

ALT	39-71 U/L	91-165 U/L
AST	29-54 U/L	64-117 U/L

Sample Setting/Ajuste de la muestra/Probeneinstellung/Impostazione del campione/Réglage de l'échantillon/Definição da amostra/Prøveindstilling/Inställning för provet/Πόθμση δείγματος/Nastavenie vzorky/Prøveinnstilling
Set the sample type to SAMPLE in the Cholestech LDX configuration menu.

Ajuste el tipo de muestra a MUESTRA = «Sangre entera» en el menú de configuración del sistema Cholestech LDX.
Den Probenotyp im Konfigurationsmenü des Cholestech LDX auf PROBE = „Vollblut“ einstellen.
Impostare il tipo di campione su CAMPIONE = “Sangue intero” nel menu di configurazione Cholestech LDX.
Réglez le type d'échantillon sur ÉCHANTILLON = « Sang total » dans le menu de configuration de Cholestech LDX.
Defina o tipo de amostra para AMOSTRA = “Whole B.” (Sangue total) no menu de configuração do Cholestech LDX.
Inställ prøvetypen på PRØVE = “Whole B.” (Fullblod) i Cholestech LDX konfigurationsmenyen.
Ställ in provtyp som PROV = “Whole B.” (Helblod) på Cholestech LDX inställningsmeny.
Ρυθμίστε τον τύπο δείγματος στο ΔΕΙΓΜΑ = “Whole B.” (Ολοκ αίμα) στο μενού διαμόρφωσης του Cholestech LDX.
V konfigurácii ponúke zariadenia Cholestech LDX nastavte typ vzorky na SAMPLE = “Whole B.” (VZORKA = „celá krv B.“)
Inställ prøvetypen som PRØVE = “Whole B.” (fullblod) på konfigurationsmenyen for Cholestech LDX.

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CECIP

AR-MED Ltd
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Egham TW20 9BD
United Kingdom

<p>IVD</p> <ul style="list-style-type: none"> For In Vitro Diagnostic Use Para uso diagnóstico in vitro In-Vitro-Diagnostik Exclusivamente per uso diagnóstico in vitro Destiné à un usage pur de diagnostic in vitro Para utilização em diagnóstico in vitro Til in vitro diagnostisk brug För diagnostisk användning in vitro For in vitro diagnostisk system In vitro diagnostické zdravotnícké pomôcky Til in vitro diagnostisk bruk 	<p>REF</p> <ul style="list-style-type: none"> Catalog Number Número de catálogo Katalognummer Número di catalogo Número de catálogo Katalognummer Αριθμός καταλόγου Katalognummer Katalognummer 	<p>L1 L2</p> <ul style="list-style-type: none"> Level 1 and Level 2 Nível 1 y nivel 2 Konzentration 1 und Konzentration 2 Nivello 1 e Livello 2 Niveaus 1 et niveaus 2 Nivå 1 e nivå 2 Nivå 1 och nivå 2 Emnivoú 1 kai 2 Level 1 a Level 2 Nivå 1 og nivå 2 	<p>ⓘ</p> <ul style="list-style-type: none"> Consult instructions for use Consulte las instrucciones de uso Gebrauchsanweisung beachten Consultare le istruzioni per l'uso Consulter le mode d'emploi Consultar as instruções de utilização Se brugsanvisningen Konsultera bruksanvisningen Συμβουλευθείτε τις οδηγίες χρήσης Obznaníte sa s návodom na použitie Se brúksanvisningen 	<p>⚠</p> <ul style="list-style-type: none"> Temperature Limitation Límite de temperatura Temperaturbereich Limite di temperatura Limite de temperatura Limites de temperatura Temperaturbegrensning Temperaturbegrensning Περιορισμός θερμοκρασίας Temperaturrestriktion Temperaturbegrensning 	<p>⚠</p> <ul style="list-style-type: none"> Biological Risks Riesgos biológicos Risques biologiques Rischi biologici Riscos biológicos Risques biologiques Βιολογικά κίνδυνος Βιολογικά κίνδυνος Βιολογικά κίνδυνος Βιολογικό κίνδυνο Βιολογικό κίνδυνο
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<p>LOT</p> <ul style="list-style-type: none"> Lot Number Número de lote Charge number Codice del lotto Número de lot Número de lote Lotnummer Partinummer Αριθμός παρτίδας Códo Sæte Lotnummer 	<p>Multi-Analyte Control</p> <ul style="list-style-type: none"> Multi-Analyte Control Controlo multi-analito Multi-Analytekontrolle Controlo multi-analítico Controlo multi-analyses Controlo de multi-analito Multi-analytiskontrol Multi-analytiskontrol Μulti-analytiskontrol Multi-analytiskontrol 	<p>Professional Use Only</p> <ul style="list-style-type: none"> Professional Use Only Para uso profesional solamente Nur zum Gebrauch durch Fachleute vorgesehen Exclusivamente per uso professionale Réservé à un usage professionnel Apenas para utilização por profissionais Kun beregnet til faglig brug Endast för professionell användning Παράθεση αποκλειστικά για χρήση από επαγγελματίες Len tre profesionálne použitie Kun til professionel brug 	<p>ⓘ</p> <ul style="list-style-type: none"> Manufacturer Fabricante Hersteller Fabricante Fabricant Fabricant Fremstillet af Tillverkad av Κατασκευαστής Výrobca Produsent 	<p>CECIP</p> <ul style="list-style-type: none"> Authorized Representative in the European Community Representante autorizado en la Comunidad Europea Bevollmächtigter in der EG Mandatatar autorizato per la Comunità Europea Mandatatar dans la Communauté européenne Mandatataro na Comunitàte Europejska Representant det Europaiske Fællesskab Autorizovaný zástupce v Evropské společenství Καταστάσεις αντιπροσώπων για την Ευρωπαϊκή Κοινότητα Εξουσιοδοτημένοι εκπαιδευτές για την Ευρωπαϊκή Κοινότητα Autorizované zástupce v rámci Evropského společenstva Representant i Europe 	<p>⚠</p> <ul style="list-style-type: none"> Use By Fecha de caducidad Verfallsdatum Utilizzare entro Utiliser avant le Utilize até Holdbar til Använd före Hyppigastu käytön Prost do Brúke innan
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Cholestech LDX®

Multi-Analyte Control

L1 L2 IVD CE

REF 12-712 (1 Vial Set)
12-713 (3 Vial Set)

Professional Use Only

Intended Use
Assayed quality control material for use with the Cholestech LDX System.

Summary and Explanation
Cholestech LDX Level 1 and Level 2 Controls are designed to be used only for monitoring the performance of test procedures on the Cholestech LDX System.

Principles of the Procedure
The controls must be run to evaluate the performance of the test procedures at both the low and high levels of each analyte.

The results obtained for the controls are to be compared with the assigned values given on the assay sheet, accompanying the package insert, to determine if the procedure is within control limits.

Reagents
The controls are prepared from human and animal constituents in an aqueous preservative medium containing antimicrobial agents.

Precautions
1. For *in vitro* diagnostic use.
2. All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.

3. This product should not be discarded in general waste but should be discarded with infectious medical waste.
4. This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product supplied invalidates any diagnostic use of the product.

Instructions for Use
1. Remove one vial of each of Cholestech LDX Level 1 and Level 2 Controls from the refrigerator. (Note date opened on vial labels.)
2. Warm vials to room temperature for 10 minutes (18–30°C, 64–86°F).
3. Test one level of control material and then the other level in the following manner:

- Refer to the Cholestech LDX Control Material Assay Sheet accompanying this product for information regarding the appropriate setting for sample type in the Cholestech LDX Configuration Menu. If you need to change the sample setting, see the Cholestech LDX System User Manual section "Setting the Configuration Menu."
- Mix each vial by gently inverting 7–8 times.
- Unscrew the vial cap. Use the 35µl MiniPet™ Pipette and tips provided in the Cholestech LDX Starter Pack to dispense the control material onto a test cassette. Use a new tip for each control level. Discard tip with infectious medical waste.
- After use, wipe the top of the vial with a standard, absorbent laboratory wipe and replace the cap.
- REMEMBER, if necessary, reset the sample type to the sample type you are using.

Materials provided: Control Level 1 and Control Level 2.
Materials not provided: 35µl MiniPet (P/N 11-846), Pipette Tips (P/N 11-010), Cassettes

Procedure
When the vials are at room temperature, the control material can be used. For testing instructions, refer to the package insert for the test cassette you are using. The controls are to be tested in the same manner a patient's sample would be tested. Frequency of testing controls: refer to the package insert for the test cassette you are using.

Storage and Stability
Cholestech LDX Controls are to be stored upright and refrigerated at 2–8°C (36–46°F). Stored under this condition, unopened vials can be expected to give stable results until the expiration date listed on the box. Opened vials are stable for 30 days refrigerated at 2–8°C (36–46°F). Minimize exposure to strong light.
DO NOT FREEZE.

Indications of Product Deterioration
Inability to obtain expected values may indicate product deterioration. Do not use a vial of control if there is evidence of a crack in the vial or microbial growth (cloudiness or odor). If the recovered values are not within the expected ranges:

1. Check expiration date on control vial. Discard outdated product.

- Review control product package insert and the operating procedure for the Cholestech LDX Analyzer and test cassettes, then run a test on a new vial of control.
- If the values are still outside of the expected ranges, call Cholestech Technical Service at 1.800.733.0404 (US only) or 510.732.7200 (Outside US).

Limitations of Procedures

- When pipetting control material remove the pipette tip from the sample well before releasing the plunger or control material may be removed from the sample well causing erroneous results.
- Check the control assay sheet for the correct sample setting for running controls.
- Verify that the lot number on the control vial and the assay sheet are the same. Each control lot has different control ranges.
- Erroneous control results may occur if the control material is not stored according to the storage instructions or if controls are used past the closed or open vial expiration date.
- Discard any vial if there is evidence of product deterioration such as cloudiness or odor.
- This control material is not to be used as a standard or for instrument calibration.
- For more information, refer to the "Limitations" section of the package insert for the test cassette being used or the "Precautions and Warnings" section of the Cholestech LDX System User Manual.

Expected Results
Refer to the assay sheet for expected results. Be sure that the lot number on the vial of control corresponds to the lot number on the assay sheet.
The value and expected range for each analyte are derived from data using several Cholestech LDX Analyzers and cassette lots. The expected range established applies only to this lot of control. If a laboratory prefers to set its own ranges, see the Cholestech LDX System Procedure Manual section "Quality Control" for instructions.
Technical assistance may be obtained by contacting Cholestech Technical Service at 1.800.733.0404 (US only) or 510.732.7200 (Outside US).
U.S. Patents 5,614,414 and 5,770,451

For instructions in European languages contact your local distributor. For the name of your distributor email ctec_support@cholestech.com or call Cholestech Customer Service, 510.732.7200.

Para instrucciones en idiomas europeos, póngase en contacto con su distribuidor local. Si no sabe cuál es el nombre de su distribuidor, envíe un correo electrónico a ctec_support@cholestech.com o llame al Servicio de Atención al Cliente de Cholestech al 510.732.7200.

Anleitungen in europäischen Sprachen erhalten Sie von Ihrem örtlichen Händler. Den Namen des örtlichen Händlers erhalten Sie, wenn Sie per E-Mail (ctec_support@cholestech.com) nachfragen oder sich telefonisch an den Kundendienst von Cholestech unter der Rufnummer 510.732.7200 wenden.

Per ottenere le istruzioni tradotte nelle lingue europee, rivolgersi al distributore di zona. Per ottenere il nome del distributore di zona, inviare un messaggio di posta elettronica a ctec_support@cholestech.com o chiamare il servizio clienti Cholestech al numero 510.732.7200.

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Hvis der ønskes anvisninger på europæiske sprog, kontaktes den lokale forhandler. Navnet på forhandleren fås ved at sende en e-mail til ctec_support@cholestech.com eller ringe til Cholestech kundservice på telefon 510.732.7200. Kontakt din lokale återförsäljare för anvisningar på europeiska språk. Fråga efter närmaste återförsäljare per e-post till ctec_support@cholestech.com eller ring Cholestech kundservice, 510.732.7200.

Για οδηγίες σε Ευρωπαϊκές γλώσσες, επικοινωνήστε με τον τοπικό σας διανομέα. Για το όνομα του διανομέα σας, αποσταθείτε email στη διεύθυνση ctec_support@cholestech.com ή επικοινωνήστε με την υπηρεσία εξυπηρέτησης πελατών της Cholestech στο τηλέφωνο 510.732.7200.

Polkyny v európskych jazykoch získate od miestneho distribútora. Ak chcete získať meno distribútora, napíšte e-mailovú správu na adresu ctec_support@cholestech.com alebo zavolať na oddelenie služieb pre zákazníkov spoločnosti Cholestech na číslo 510.732.7200.

Kontakt din lokale forhandler hvis du vil ha instruksjoner på et europeisk språk. Navnet på forhandleren får du ved å sende en e-post til ctec_support@cholestech.com eller kontakte kundservice hos Cholestech på telefon 510.732.7200.