



Exp: 2009-12-04



9063

L1 (Red Cap)

Tapa roja/Roter Verschluss/Tappo rosso
Bouchon rouge/Tampa vermelha/Rød hætte
Rött lock/Kόκκινο πώμα/Červený uzáver
Rød hette



90630566

L2 (Black Cap)

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



90630567

Constituent/ Komponente/Bestandteil/ Costituente/Constituant/ Constituante/Bestanddel/ Bestāndsdel/Συστατικό/ Zložka/Bestanddel	Expected Range/ Intervalo esperado/Erwarteter Bereich/ Intervallo atteso/Plage attendue/ Intervalo esperado/Forventet område/ Förväntat intervall/Αναμενόμενο εύρος τιμών/ Očakávaný rozsah/Forventet område	Expected Range/ Intervalo esperado/Erwarteter Bereich/ Intervallo atteso/Plage attendue/ Intervalo 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 cassettes de lípidos Til alle lipidkassetter/För alla lipidkassetter/Για όλες τις κασέτες λιπιδίων/Pre všetky lipidové kazety/For alle lipidkassetter

Total Cholesterol	136-191 mg/dL	3.52-4.94 mmol/L	210-296 mg/dL	5.43-7.66 mmol/L
HDL Cholesterol	25-40 mg/dL	0.65-1.03 mmol/L	51-80 mg/dL	1.32-2.07 mmol/L
Triglycerides	103-152 mg/dL	1.16-1.72 mmol/L	213-313 mg/dL	2.41-3.54 mmol/L
Glucose	100-147 mg/dL	5.55-8.16 mmol/L	223-329 mg/dL	12.38-18.26 mmol/L

For ALT Cassettes

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

ALT	36-66 U/L	138-252 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 cassettes de ALT/AST/
Til ALT/AST kassetter/För ALT/AST-kassetter/Για τις κασέτες ALT/AST/Pre kazety ALT/AST/For ALT/AST-kassetter

ALT	36-66 U/L	138-252 U/L
AST	27-50 U/L	75-137 U/L

**Sample Setting/Ajuste de la muestra/Probeneinstellung/Impostazione del campione/Réglage de l'échantillon/
Definição da amostra/Proveinstilling/Inställning för provet/Pύθμιση δείγματος/Nastavenie vzorky/Proveinstilling**

Set the sample type to SAMPLE = "Whole B." 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.
Indstil prøvetypen på PRØVE = "Whole B." (Fuldblod) i Cholestech LDX konfigurationsmenuen.

Ställ in provtyp som PROV = "Whole B." (Helblod) på Cholestech LDX inställningsmeny.
Ρυθμίστε τον τύπο δείγματος στο ΔΕΙΓΜΑ = "Whole B." (Ολικό αίμα) στο μενού διαμόρφωσης του Cholestech LDX.
V konfiguracnej ponuke zariadenia Cholestech LDX nastavte typ vzorky na SAMPLE = „Whole B.“ (VZORKA = „celá krv B.“)
Indstill prøvetypen som PRØVE = "Whole B." (fullblod) på konfigurasjonsmenyen for Cholestech LDX.



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<p>IVD</p> <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 diagnostico in vitro Para utilização em diagnóstico in vitro Til in vitro diagnostisk brug For diagnostisk anvandning in vitro Για in vitro διαγνωστική χρήση In vitro diagnostická zdravotnická pomůcka Til in vitro diagnostisk bruk 	<p>REF</p> <ul style="list-style-type: none"> Catalog Number Número de catálogo Katalognummer Numero di catalogo Número de catalogo Katalognummer Katalognummer Αριθμός καταλόγου Katalognové číslo 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 Livello 1 e Livello 2 Niveau 1 et Niveau 2 Nível 1 e Nível 2 Niveau 1 og niveau 2 Nivå 1 och nivå 2 Επιπέδου 1 και 2 Level 1 a Level 2 Nivå 1 og nivå 2 	<p>i</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 Συμβουλευτείτε τις οδηγίες χρήσης Obzornite sa s nāvodom na pouzitie Se bruksanvisningen 	<p>Temperature Limitation</p> <ul style="list-style-type: none"> Temperature Limitation Limite de temperatura Temperaturbereich Limiti di temperatura Limite de temperatura Limites de temperatura Temperaturbegrensning Temperaturbegrensning Περιορισμός θερμοκρασίας Teplotné obmedzenia Temperaturbegrensning 	<p>Biological Risks</p> <ul style="list-style-type: none"> Biological Risks Riesgos biológicos Biologische Risiken Rischi biologici Risques biologiques Riscos biológicos Biologiske risici Biologiska risker Βιολογικοί κίνδυνοι Biologické riziká Biologisk risiko
<p>LOT</p> <ul style="list-style-type: none"> Lot Number Número de lote Charge/nummer Codice del lotto Número de lote Número de lote Lotnummer Partnummer Αριθμός παρτίδας Číslo šarže Lotnummer 	<p>Multi-Analyte Control</p> <ul style="list-style-type: none"> Multi-Analyte Control Control multianalito Multi-Analytkontrolle Controllo multianalita Contrôle multi-analyses Controlo de multi-análito Multianalytikkontrol Multianalytkontroll Μultianalytisk kontrol Μultianalytiske kontrolné vzorky Multianalyttkontroll 	<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 Reservé à un usage professionnel Apenas para utilização por profissionais Kun beregnet til faglig brug Endast för professionell användning Για επαγγελματική χρήση μόνο Len pre profesionálne použitie Kun til profesjonell bruk 	<p>Manufacturer</p> <ul style="list-style-type: none"> Manufacturer Fabricante Hersteller Fabbricante Fabricant Fabricante Fremstillet af Tilvekkad av Κατασκευαστής Vytroba Produsent 	<p>ECIREP</p> <ul style="list-style-type: none"> Authorized Representative in the European Community Representante autorizado en la Comunidad Europea Bevollmächtigter in der EG Mandatario autorizzato per la Comunità Europea Mandatnaire dans la Communauté européenne Mandatário na Comunidade Europeia Repräsentant i det Europæiske Fællesskab Auktoriserad representant i Europeiska gemenskapen Εξουσιοδοτημένος αντιπρόσωπος για την Ευρωπαϊκή Κοινότητα Autorizovaný zástupce v rámci Európskeho spoločenstva Representant i Europa 	<p>Use By</p> <ul style="list-style-type: none"> Use By Fecha de caducidad Verfallsdatum Utilizzare entro Utiliser avant le Utilizar até Holdbar til Använd före Ημερομηνία λήξης Použit do Brukes innen

Cholestech LDX[®]

Multi-Analyte Control



Professional Use Only

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

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

- For *in vitro* diagnostic use.
- 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.
- This product should not be discarded in general waste but should be discarded with infectious medical waste.
- 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

- Remove one vial of each of Cholestech LDX Level 1 and Level 2 Controls from the refrigerator. (Note date opened on vial labels.)
- Warm vials to room temperature for 10 minutes (18–30°C, 64–86°F).
- 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:

- Check expiration date on control vial. Discard outdated products.

- Review control product package insert and the operating procedure for the Cholestech LDX Analyzer and test cassette, 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@cholesteck.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@cholesteck.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@cholesteck.com) nachfragen oder sich telefonisch an den Kundendienst von Cholestech unter der Rufnummer 510.732.7200 wenden.

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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@cholesteck.com eller ringe til Cholestech kundeservice på telefon 510.732.7200.

Kontakta din lokala återförsäljare för anvisningar på europeiska språk. Fråga efter närmaste återförsäljare per e-post till ctec_support@cholesteck.com eller ring Cholestech kundeservice, 510.732.7200.

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

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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@cholesteck.com eller kontakte kundeservice hos Cholestech på telefon 510.732.7200.

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