

Cholestech LDX®

Multi-Analyte Control

L1 L2



Exp: 2009-08-12

LOT 8317

L1 (Red Cap)

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

LOT 83170566

**Expected Range/
Intervalo esperado/Erwarteter Bereich/
Intervallo atteso/Plage attendue/
Intervalo esperado/Forventet område/
Förväntat intervall/Αναμενόμενο εύρος τιμών/
Očakávaný rozsah/Forventet område**

L2 (Black Cap)

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

LOT 83170567

**Expected Range/
Intervalo esperado/Erwarteter Bereich/
Intervallo atteso/Plage attendue/
Intervalo esperado/Forventet område/
Förväntat intervall/Αναμενόμενο εύρος τιμών/
Očakávaný rozsah/Forventet område**

**Constituent/
Componente/Bestandteil/
Costituente/Constituant/
Constituente/Bestanddel/
Beständsdel/Συστατικό/
Zložka/Bestanddel**

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/För alla lipidkassetter/Για όλες τις κασέτες λιπιδίων/Pre všetky lipidové kazety/For alle lipidkassetter

Total Cholesterol	136-192 mg/dL	3.53-4.96 mmol/L	217-305 mg/dL	5.62-7.90 mmol/L
HDL Cholesterol	28-44 mg/dL	0.73-1.14 mmol/L	51-81 mg/dL	1.33-2.08 mmol/L
Triglycerides	100-148 mg/dL	1.13-1.67 mmol/L	213-314 mg/dL	2.40-3.54 mmol/L
Glucose	103-152 mg/dL	5.74-8.46 mmol/L	236-348 mg/dL	13.11-19.32 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/För ALT-kassetter/Για τις κασέτες ALT/Pre kazety ALT/For ALT-kassetter

ALT 36-66 U/L 108-197 U/L

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/För ALT/AST-kassetter/Για τις κασέτες ALT/AST/Pre kazety ALT/AST/For ALT/AST-kassetter

ALT 36-66 U/L 108-197 U/L
AST 30-55 U/L 63-115 U/L

**Sample Setting/Ajuste de la muestra/Probeneinstellung/Impostazione del campione/Réglage de l'échantillon/
Definición da amostra/Prøveindstilling/Inställning för provet/Πύθμιση δείγματος/Nastavenie vzorky/Prøveinstilling**
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.

Ställ in provtyp som PROV = "Whole B." (Helblod) på Cholestech LDX inställningsmeny.

Publiser typen som PROV = "Whole B." (Ολικό αίμα) στο μενού διαμόρφωσης του Cholestech LDX.

V konfiguracnej ponuke zariadenia Cholestech LDX nastavte typ vzorky na SAMPLE = „celá krv B.“

Inställ provtypen som PROBE = "Whole B." (fullblod) på konfigurationsmenyen for Cholestech LDX.



CE/REP
AR-MED Ltd
Runnymede Malthouse
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-Diagnostikum Exclusivamente per uso diagnóstico in vitro Destiné à un usage pour le diagnostic in vitro Para utilização em diagnóstico in vitro Til in vitro diagnostisk brug För diagnostisk användning in vitro Το in vitro διαγνωστικό 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 Numéro de catalogue Numero de catálogo Katalognummer Katalognummer Αριθμός καταλόγου Kataloģovs Ēģis 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 Επίπεδο 1 και 2 Level 1 i Level 2 Nivå 1 og nivå 2 	<p>Biological Risks</p> <ul style="list-style-type: none"> Consult instructions for use Consulte las instrucciones de uso Gebrauchsanweisung beachten Consultare le istruzioni per l'uso Consulte le mode d'emploi Consultar as instruções de utilização Se brugsanvisningen Konsultera bruksanvisningen Εμφωλουτήστε τις οδηγίες χρήσης Obzornajte sa s návodom na použitie Se bruksanvisningen 	<p>Temperature Limitation</p> <ul style="list-style-type: none"> Limite de temperatura Temperaturbereich Limite di temperatura Niveau 1 et niveau 2 Limites de température Temperaturbegrensning Temperaturbegrensning Περιορισμός θερμοκρασίας Temperaturlimitation Temperaturbegrensning 	<p>Biological Risks</p> <ul style="list-style-type: none"> Riesgos biológicos Biologische Risiken Rischi biologici Risques biologiques Riscos biológicos Risikos biologisk Biologiska risker Βιολογικοί κίνδυνοι Biologické riziká Biologisk risiko
<p>LOT</p> <ul style="list-style-type: none"> Lot Number Número de lote Chargeenummer Code de lotto Numero de lote Numero de lote Lotnummer 	<p>Multi-Analyte Control</p> <ul style="list-style-type: none"> Multi-Analyte Control Control multianalito Multi-Analytkontrolle Controllo multi-analita Contrôle multi-analyses Controlo de multi-análisis Multianalytiskontroll Multianalytiskontroll Μultianalytiskontroll Μultianalytiskontroll Multianalytiskontroll Multianalytiskontroll 	<p>Professional Use Only</p> <ul style="list-style-type: none"> Professional Use Only Para uso profesional solamente Nur zum Gebrauch durch Fachleute vorgesehen Exclusivement per uso professionale Reservé à un usage professionnel Apens para utilização por profissionais Kun bereget til faglig brug Endast för professionell användning Μόνο για επαγγελματική χρήση μόνο Len pre profesionálne použitie Kun til profesjonell bruk 	<p>CE/REP</p> <ul style="list-style-type: none"> Authorized Representative in the European Community Representante autorizado en la Comunidad Europea Besoligtiget i det EG Mandatario autorizzato per la Comunità Europea Mandatário dans la Communauté européenne Mandatário na Comunidade Europeia Repräsentant i det Europeiske Fællesskab Autorizovaný zástupce v rámci Evropské společnosti 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"> Fecha de caducidad Verfallsdatum Utilizzare entro Utiliser avant le Utilizar até Holdbar til Använd före Αναμενόμενη διάρκεια Použit do Brukes innen 	

Cholestech LDX®

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

- 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.

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.

LDX Analyzer and test cassette, then run cassette on a new lot or 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@cholestechn.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@cholestechn.com o llame al Servicio de Atención al Cliente de Cholestech al 510.732.7200.

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