

Cholestech LDX[®] Cholesterol Analyzer Test

Distributed by

CLIAwaived[™] Inc.



The Cholestech LDX[®] Cholesterol Analyzer Test combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides, and glucose. Samples used for testing can be whole blood from a finger stick (collected in a lithium heparin-coated capillary tube) or venipuncture. The sample is applied to a Cholestech LDX cassette. *(For professional in vitro diagnostic use only.)*

BENEFITS:

- Easy to use; fast & reliable results
- Results in 5 minutes
- Single-use disposable cassettes
- Room temperature storage for 30 days
- FDA-Cleared / CLIA Waived



*Note: The High Sensitivity C-Reactive Protein Tests are Moderately Complex and are not CLIA Waived.

Ordering Information:	
Product Description	Catalog #
Cholestech LDX Analyzer System (1 system)	CTH-10-959
Cholestech Total Cholesterol Cassette (10 cassettes)	CTH-10-986
Cholestech TC HDL Tests (10 cassettes)	CTH-10-987
Cholestech TC GLU Tests (10 cassettes)	CTH-10-988
Cholestech TC HDL GLU Tests (10 cassettes)	CTH-10-990
Cholestech Lipid Profile GLU (10 cassettes)	CTH-10-991
Cholestech Lipid Profile Tests (10 cassettes)	CTH-10-989
Cholestech Thermal Label Printer (1 printer)	CTH-11-781
Cholestech Thermal Printer Labels (1 roll)	CTH-11-785
Cholestech LDX ALT/AST Tests (10 cassettes)	CTH-12-788
High Sensitivity C-Reactive Protein Tests* (10 tests) *Moderately Complex	CTH-12-807
Cholestech ROM Upgrade Kit (1 kit)	CTH-13-184

CPT Code Reimbursement Information

Reimbursement Information:		
CPT Code #		National Limit Amount
Lipid Profile, waived procedure (Total Cholesterol, HDL Cholesterol and Triglycerides)		
Option A:	80061QW (Lipid Panel, waived procedure)	\$18.72
Option B:	82465QW (Total Cholesterol, waived method)	\$6.08
	83718QW (HDL Cholesterol, waived method)	\$11.44
	84478QW (Triglycerides, waived method)	\$8.04
Lipid Profile and Glucose, waived procedure (Total Cholesterol, HDL Cholesterol, Triglycerides and Glucose)		
Option A:	80061QW (Lipid Panel, waived procedure)	\$18.72
	82947QW (Glucose, quantitative, waived procedure)	\$5.48
Option B:	82465QW (Total Cholesterol, waived method)	\$6.08
	83718QW (HDL Cholesterol, waived method)	\$11.44
	84478QW (Triglycerides, waived method)	\$8.04
	82947QW (Glucose, quantitative waived procedure)	\$5.48
Total Cholesterol, HDL Cholesterol and Triglycerides		
	82465QW (Total Cholesterol, waived method)	\$6.64
	83718QW (HDL Cholesterol, waived method)	\$11.44
	82947QW (Glucose, quantitative, waived procedure)	\$5.48
Total Cholesterol, HDL Cholesterol		
	82465QW (Total Cholesterol, waived method)	\$6.08
	83718QW (HDL Cholesterol, waived method)	\$11.44
Total Cholesterol and Glucose		
	82465QW (Total Cholesterol, waived method)	\$6.08
	82947QW (Glucose, quantitative, waived procedure)	\$5.48
Total Cholesterol		
	82465QW (Total Cholesterol, waived method)	\$6.08
Glucose		
	82947QW (Glucose, quantitative)	\$5.48
	82950QW (Glucose Post Dose, includes glucose)	\$6.64
	82951QW (Glucose Tolerance Test (3 tests))	\$17.99
	82952QW (Glucose Tolerance Test - each additional test beyond 3 tests)	\$3.50

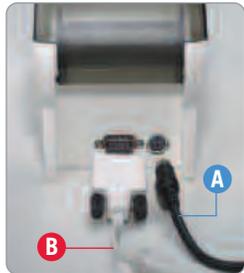
DISCLAIMER – The CPT information contained in this document is provided as representative examples of reimbursement in this category. It is intended to assist providers in accurately obtaining reimbursement for health care services. It is not intended to increase or maximize reimbursement by any payor. Providers should consult their payor organizations with regard to local reimbursement policies. The information provided in this document is for information purposes only and represents no statement, promise or guarantee by CLIAwaived™ Inc. All CPT codes are supplied for information purposes only and represent no statement, promise or guarantee by CLIAwaived™ Inc. that these codes will be appropriate or that reimbursement will be made. CPT codes and descriptions are copyrights of the American Medical Associations. CPT does not include fee schedules, relative values or related ratings. The source for this information is the Center for Medicare and Medicaid Services. The content provided by the Center for Medicare and Medicaid Services is updated frequently. It is the responsibility of the service provider to confirm the appropriate coding required by their local Medicare carriers, fiscal intermediaries and commercial payors. All product information and prices are subject to change without notice at any time. Please call our office before ordering to verify current prices.

Cholestech LDX[®] Cholesterol Analyzer Test Setup Instructions

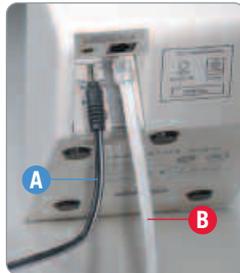
Setup

Take the time to examine and familiarize yourself with the contents of the Cholestech LDX System.

1 Connecting the Cholestech LDX to the Printer



Plug the printer power supply **A** into the printer and the wall or power strip. Connect the end of the printer cable **B**, labeled "To Printer," to the printer.



Plug the power supply **A** into the Cholestech LDX and the wall or power strip. Insert the end of the white printer cable **B**, labeled "To Cholestech LDX," into the Analyzer.

2 Configuration Menu



Before starting to test, press and hold **STOP** to enter the Configuration Menu and select options for language, units, sample type, printer, risk assessment, date, and time.

The **DATA** button allows you to select choices for each of the menu items in the Configuration Menu. The **RUN** button enters your choices and advances you to the next menu item.

3 Optics Check

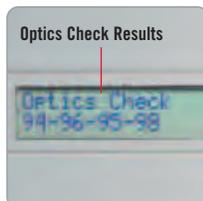
Run the Optics Check Cassette

Press the **RUN** button. The drawer will open. Place the Optics Check Cassette into the cassette drawer. Press the **RUN** button again to close the drawer.



Record Results

Check to see that the four numbers are within the acceptable range printed on the Optics Check Cassette. Record the results on the Optics Check Log. If the numbers are outside the range, the Analyzer will be temporarily disabled until another optics check is run that falls within range.



The Optics Check Cassette is used to check the optical system of the Analyzer. Run the Optics Check Cassette: once each day before patient samples are tested and after the Cholestech LDX has been moved or serviced.

4 Running Controls

Cholestech Level 1 and 2 Controls

Controls must be run following manufacturer's recommendations. Controls must be at room temperature before testing. Verify that the lot number on the control vial and the assay sheet are the same. Mix each vial by gently inverting 7–8 times immediately before use. Store controls in the refrigerator when not in use.



Testing QC Material

Use the MiniPet™ Pipette and tips to measure and dispense the control sample into the cassette. Place the cassette in the drawer *immediately* and press **RUN**. Record results on the Quality Control Log. Results must be within established ranges before patient samples can be tested.



Cholestech LDX® Cholesterol Analyzer Test Procedure Instructions

Test Procedure

1 Open the Drawer



Press the **RUN** button on the Analyzer. The cassette drawer will open, and the screen will display: **LOAD CASSETTE AND PRESS RUN.**

2 Perform a Fingerstick



After cleaning the selected site with alcohol and drying it thoroughly, firmly prick the site with a lancet. Gently squeeze the finger to obtain a large drop of blood. **Wipe off the first large drop of blood.**

3 Collect the Sample



Squeeze the finger gently again until a large drop of blood forms. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. Fill the capillary tube within 10 seconds. Do not allow any bubbles to enter the capillary tube.

4 Dispense the Sample



Place the end of the capillary tube into the sample well and dispense the sample by pushing down on the plunger. Keep the cassette level after the sample has been applied.

5 Insert the Cassette



Immediately place the cassette into the Analyzer drawer with the black reaction bar toward the Analyzer and the brown magnetic stripe on the right.

6 6 Begin the Test



Press **RUN**. The drawer will close. When the test is finished, the Analyzer will beep and the drawer will open. **Put everything that touched the blood sample into a biohazardous waste container.**

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Press **RUN**. The drawer will close. When the test is finished, the Analyzer will beep and the drawer will open. **Put everything that touched the blood sample into a biohazardous waste container.**

7 View the Results



Press the **DATA** button on the Analyzer once or twice (depending on the test cassette) to view remaining results.

8 Print the Results



The results will print when the test is finished.

This reference guide provides a brief summary of the testing procedure. For more information, see the test cassette product inserts, the Cholestech LDX System User Manual, or the Cholestech LDX System Training Video.