

***Cholestech***  
***LDX***<sup>®</sup>

## TC-GLU

### Total Cholesterol and Glucose Panel Test Cassette

***CLIA-WAIVED***—These tests are waived under CLIA '88 regulations. If a laboratory modifies the test system instructions, then the test is considered highly complex and subject to all CLIA requirements.

**IVD** For professional *in vitro* diagnostic use.

### Catalog No. 10-988

#### Indications For Use:

For the quantitative determination of total cholesterol and glucose in whole blood.

#### Introduction

Cholesterol is a major cause of coronary heart disease (CHD), and large clinical trials show that lipid-lowering therapy substantially reduces risk for CHD.<sup>1</sup> The National Institutes of Health periodically issues clinical guidelines for cholesterol testing and management as part of the National Cholesterol Education Program (NCEP). The most recent update, the third report of NCEP’s Adult Treatment Panel (ATP III), recommended that a fasting lipoprotein profile should be obtained at least every five years in all adults aged 20 years and older.<sup>1</sup> This lipid profile consists of total, HDL, and LDL cholesterol and triglycerides. When the testing opportunity is nonfasting, total and HDL cholesterol can provide meaningful information on CHD risk. While the major focus of ATP III is on lowering LDL cholesterol, HDL cholesterol and triglycerides are identified as significant risk factors. Low HDL cholesterol values increase CHD risk whereas high HDL values protect against CHD. Elevated triglycerides are also a strong independent risk factor for CHD most often observed in individuals with metabolic syndrome. The ATP III established therapeutic goals for LDL and HDL cholesterol and triglycerides depending upon individual CHD risk factors. Follow-up measurement of these lipid parameters is necessary to ensure that individuals achieve treatment goals.

Glucose is the major energy source for the human body and is necessary for the growth, development and maintenance of virtually all cells in the tissues and organs.<sup>2</sup> Blood glucose levels are maintained within a relatively narrow range by a combination of interacting factors that decrease the glucose level when it gets too high and increase it when it drops too low. Because this delicate homeostatic mechanism is able to keep glucose levels within such a narrow range, values outside this range generally indicate a disease state. Insulin is the principal hormone regulating glucose levels, and any defect in the production or action of insulin can lead to one of the several forms of diabetes mellitus. Persons with diabetes mellitus may develop a number of serious complications, and some studies have shown that careful control of blood glucose levels may reduce the incidence or delay the onset of these complications.

Total cholesterol and glucose can be measured from a single drop of blood using the Cholestech LDX System’s rapid, accurate technology.

#### Test Principle

The Cholestech LDX System combines enzymatic methodology<sup>3</sup> and solid-phase technology to measure total cholesterol and glucose. Samples used for testing can be whole blood from a fingerstick (collected in a lithium heparin-coated capillary tube) or venipuncture. The sample is applied to a Cholestech LDX cassette. The cassette is then placed into the Cholestech LDX Analyzer where a unique system on the cassette separates the plasma from the blood cells. A portion of the plasma flows to the right side of the cassette and is transferred to the total cholesterol reaction pad. Simultaneously, plasma flows to the left side of the cassette where it is transferred to the glucose reaction pad. The Cholestech LDX

Analyzer measures total cholesterol by an enzymatic method based on the method formulation of Allain et al,<sup>4</sup> and Roeschlau.<sup>5</sup> Cholesterol esterase hydrolyzes the cholesterol esters in the plasma to free cholesterol and the corresponding fatty acid. Cholesterol oxidase, in the presence of oxygen, oxidizes free cholesterol to cholest-4-ene-3-one and hydrogen peroxide. In a reaction catalyzed by horseradish peroxidase, the peroxide reacts with 4-Aminoantipyrine and N-Ethyl-N-sulfohydroxypropyl-m-toluidine, sodium salt (TOOS) to form a purple-colored quinoneimine dye proportional to the total cholesterol concentration of the sample.

Cholesterol esters + H<sub>2</sub>O Cholesterol esterase → Free cholesterol + Fatty acids

Cholesterol + O<sub>2</sub> Cholesterol oxidase → Cholest-4-ene-3-one + H<sub>2</sub>O<sub>2</sub>

2 H<sub>2</sub>O<sub>2</sub> + 4-Aminoantipyrine + TOOS Peroxidase → Quinoneimine dye + 4 H<sub>2</sub>O

The Cholestech LDX Analyzer measures glucose by an enzymatic method that uses glucose oxidase to catalyze the oxidation of glucose to gluconolactone and hydrogen peroxide. The color reaction utilizing horseradish peroxidase is the same as that for total cholesterol. The resultant color in all the reactions is measured by reflectance photometry.

Glucose + O<sub>2</sub> Glucose oxidase → o-D-gluconolactone + H<sub>2</sub>O<sub>2</sub>

2 H<sub>2</sub>O<sub>2</sub> + 4-Aminoantipyrine + TOOS Peroxidase → Quinoneimine dye + 4 H<sub>2</sub>O

A brown (magnetic) stripe on each cassette contains the calibration information required for the Cholestech LDX Analyzer to convert the reflectance reading (% R) to the total cholesterol and glucose concentrations in mg/dL.

### TC-GLU

#### Total Cholesterol and Glucose Panel Cassette

Each TC-GLU cassette contains a minimum of:

	<b>TC</b>	<b>GLU</b>
Cholesterol esterase, U (Pseudomonas species)	0.34	–
Cholesterol oxidase, U (Pseudomonas species)	0.058	–
Peroxidase (horseradish), U	0.32	0.16
4-Aminoantipyrine, µg	6.4	6.08
N-Ethyl-N-sulfohydroxypropyl-m-toluidine, sodium salt, µg	92.0	38.6
Glucose oxidase, U (Cellulomonas species)	–	0.64

Nonreactive ingredients: Buffers and stabilizers

#### Cassette Storage and Stability

Cassettes **must** be stored in the sealed foil pouches.

Cassettes may be used until the date printed on the pouch when stored in a refrigerator (36–46°F / 2–8°C). Or the cassettes may be stored for up to 30 days at room temperature (less than 86°F / 30°C). Once cassettes have been stored at room temperature, they should not be returned to the refrigerator.

- Do not use a cassette beyond the printed expiration date.
- Do not use a cassette that has been stored at room temperature for more than 30 days.
- Do not reuse cassettes.

#### Cassette Handling

Cassettes should sit at room temperature for 10 minutes before opening pouch. Use the cassette as soon as the pouch is opened.

#### Sample Type

**Please Note:**

The Cholestech LDX System is CLIA-waived for fingerstick or venous whole blood unprocessed samples only. If you run serum or plasma on the Cholestech LDX, you will be classified as moderately complex and will have to comply with the regulations for moderate complexity. See the Cholestech LDX System User Manual for a summary of these regulations.

#### Sample Handling

- Sample Volume: 35–50 µL of whole blood.
- The subject should fast for 12 hours before the sample is collected.

#### Fingerstick whole blood:

- Collect the sample from a fingerstick into a Cholestech LDX Capillary Tube. (See the Fingerstick Procedure in the Cholestech LDX System User Manual.)
- Place the blood into the cassette within 5 minutes of collection.
- Blood from the fingerstick should flow freely. Too much squeezing of the finger may cause poor results.

#### Venous whole blood:

- Collect blood into a green-top tube (heparin anticoagulant).

**NOTE: Do not use a tube with any other additives because it may cause poor results.**

- Use a MiniPet™ Pipette and tip to place blood into the cassette.
- Whole blood should be used within 30 minutes.
- Samples should be at room temperature for testing.
- Mix all samples by inverting gently 7–8 times before testing.
- Glucose levels decrease 5 to 10 mg/dL per hour in whole blood at room temperature.

**PRECAUTION: All blood samples and containers, capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazard waste container after use.**

#### Calibration

No calibration is done by the user. Test information is on the brown stripe of the cassette. The brown stripe is read by the Cholestech LDX each time a cassette is run.

An optics check should be done on the Analyzer each day. See the Cholestech LDX System User Manual for instructions.

## TEST PROCEDURE

### Materials Provided:

**TC-GLU cassettes**

Additional Materials Required:

- Cholestech LDX Analyzer and power supply
- Alcohol swabs and gauze for cleaning puncture site
- Lancets for capillary blood collection
- Cholestech LDX Capillary Tubes (with lithium heparin anticoagulant)
- Cholestech LDX Capillary Plungers
- Gloves
- Biohazard waste containers
- Quality control material
- MiniPet Pipette and tips or micropipetter that will deliver 35–50 µL for use with venipuncture samples and quality control material
- Vacuum collection tubes, needles and tube holders if sample is to be collected by venipuncture

#### Running a Test

- Let cassette sit at room temperature for 10 minutes.
- Remove the cassette from its pouch. Do not touch the black bar or the brown stripe. Put the cassette on a flat surface.

**NOTE: Gloves should be worn when working with blood samples.**

- Press **RUN**. In a few seconds the screen will read:

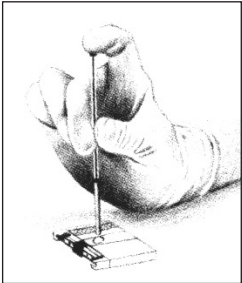
Selftest running.

Selftest OK

- The cassette drawer will open. The screen will read:

Load cassette and press RUN

- Place the sample into the cassette well. Use a Cholestech LDX Capillary Tube for fingerstick samples. Use the MiniPet Pipette for controls or venous blood samples.



**NOTE: Fingerstick samples must be applied within five (5) minutes or the blood will clot.**

- Keep the cassette flat after the sample has been applied. Place the cassette into the drawer of the Analyzer at once. The black bar must face the Analyzer. The brown stripe must be on the right.
- Press **RUN**. The drawer will close. During the test the screen will read:

[Test Name(s)]  
Test Running\*\*\*

- Put everything that touched the blood sample or control in a biohazard waste container.
- When the test is complete, the Analyzer will beep. The screen will read:

[Test Name(s)]=###  
warnings

- When the results are outside the measuring range, the screen will read:

[Test Name]>###or  
[Test Name]<###

- If there is a problem with the test, a message will appear on the screen. See the Cholestech LDX System User Manual if this happens.
- When the drawer opens, remove the cassette. Put it in a biohazard waste container. Leave the Analyzer drawer empty when not in use.
- Record the results.
- To run another cassette, press **RUN**. The screen will read:

Load cassette and press RUN

- Repeat the test procedure.
- Otherwise, after 4 minutes a beep will sound and the screen will read:

System timeout  
RUN to continue

If the **RUN** button is not pushed within 15 seconds, the drawer will close. Then the screen will go blank.

## QUALITY CONTROL

Quality control should be run routinely to show that your system is giving accurate results. We recommend the following quality control procedures for the Cholestech LDX System.

#### Choice of Materials

A high and a low control for each analyte is preferred. Cholestech-recommended controls work well with the Cholestech LDX System. If you use other controls, you will need to set ranges for the Cholestech LDX System.

#### Handling

- Follow the instructions that come with your controls.
- Check the expiration date before use. Do not use if expired.
- See “Running a Test” for procedure.

#### External Quality Control

External controls must also be used to demonstrate that the reagents and the assay procedure perform properly.

Liquid Lipid/Glucose Level 1 and Level 2 Controls are available from Cholestech. Controls must be tested:

- With each new shipment of cassettes (even if cassettes are from the same lot previously received).
- With each new lot of cassettes.
- As otherwise required by your laboratory’s standard quality control procedures.
- If you are not running the Cholestech LDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service before testing patient samples.

**The quality control results must be in range before testing patient samples. See the Cholestech LDX System User Manual if they are not. Please call Cholestech Technical Service at 800-733-0404 if you have any questions about quality control.**

## RESULTS

Test results will show on the screen when the test is complete.

To convert:

	mg/dL to mmol/L	mmol/L to mg/dL
	<u>divide mg/dL by</u>	<u>multiply mmol/L by</u>
TC	38.664	38.664
GLU	18.018	18.018

