

Cholestech
LDX[®]

TC·HDL·GLU

Total Cholesterol, HDL 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. 10-990

Indications For Use:

For the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio is calculated by the Cholestech LDX.

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.¹ 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.¹ 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.

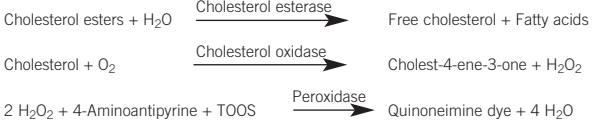
Glucose is the major energy source for the human body and is necessary for the growth, development and maintenance of virtually all cells in the tissues and organs.² Blood glucose levels are maintained within a relatively narrow range by a combination of interacting factors that decrease the glucose 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, HDL cholesterol and glucose can be measured simultaneously from a single drop of blood using the Cholestech LDX System’s rapid, accurate technology. A TC/HDL ratio is calculated using the measured values.

Test Principle

The Cholestech LDX System combines enzymatic methodology³ and solid-phase technology to measure total cholesterol, HDL 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 the low-density lipoproteins (LDL and VLDL) are precipitated with dextran sulfate (50,000 MW) and magnesium acetate precipitating reagent.⁴ The filtrate, containing both glucose and HDL cholesterol, is transferred to both the glucose and HDL cholesterol reaction pads. The Cholestech LDX Analyzer measures total cholesterol and HDL cholesterol by an enzymatic method based on the method formulation of Allain et al.⁵ and Roeschlau.⁶ Cholesterol esterase hydrolyzes the cholesterol esters in the filtrate or 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 and HDL cholesterol concentrations of the sample.



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. Calculated results are shown after the **DATA** button is pressed.

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
HDL	38.664	38.664
GLU	18.018	18.018

LIMITATIONS

- The measuring range for total cholesterol is 100–500 mg/dL. Results outside this range will appear as <100 mg/dL or >500 mg/dL.
- The measuring range for HDL cholesterol is 15–100 mg/dL. Results outside this range will appear as <15 mg/dL or >100 mg/dL.
- The measuring range for glucose is 50–500 mg/dL. Results outside this range will appear as <50 mg/dL or >500 mg/dL.
- The glucose test is specific for D-glucose. Other sugars that may be present in the blood do not react in the glucose test (i.e., fructose, lactose).
- Samples with total cholesterol, HDL cholesterol or glucose values outside the measuring range should be sent to a laboratory for testing.
- Performance of the Cholestech LDX System has not been tested on samples from newborns.
- Glucose tests done at altitudes above 5,000 feet may give low results.

Some substances may cause false results with enzymatic tests. The substances listed below were tested for all analytes. Less than 10% interference was seen at the levels shown.

Substance Concentration (mg/dL)		
Hemoglobin	125	Gemfibrozil 15
L-Dopa	0.8	Bilirubin 5
Ascorbic Acid	1	Probucol 32.5
Urea	500	Nicotinic Acid 10
Fructose	30	Clofibrate 80
Uric Acid	15	Lovastatin 4
Creatinine	30	Dipyron 10
Glutathione	1	Methotrexate 450
Cimetidine	7.5	Nitrofurantoin 2
Oxytetracycline	4	Gentisic Acid 0.5
Lactose	100	Methyldopamine 0.5
Cysteine	2.5	

- Hematocrits between 30% and 52% do not affect results.
- There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.⁷

EXPECTED VALUES

Cholesterol:

The National Heart, Lung and Blood Institute issued the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) in May 2001.¹ The ATP III report presented the NCEP's updated clinical guidelines for cholesterol testing and management and described the following classifications for total and HDL cholesterol testing:

	<u>mg/dL</u>	<u>(mmol/L)</u>	<u>Classification</u>
Total cholesterol	<200	(<5.18)	Desirable
	200–239	(5.18–6.19)	Borderline high
	240	(6.22)	High
HDL cholesterol	<40	(<1.03)	Low
	60	(1.55)	High

The ATP III identified HDL cholesterol levels below 40 mg/dL (1.03 mmol/L) as associated with increased risk of coronary heart disease (CHD) in men and women.¹ A high HDL cholesterol level greater than or equal to 60 mg/dL (1.55 mmol/L) is protective and decreases CHD risk.

TC/HDL Ratio:

The ATP III report does not comment on use of the ratio of total to HDL cholesterol. Various authors have suggested that the TC/HDL ratio is the strongest lipid risk factor and can be a useful summary of CHD risk.^{8,9} A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of CHD.⁸

Glucose:

The American Diabetes Association has modified the criteria for fasting plasma glucose (FPG) and the diagnosis of diabetes mellitus.¹⁰

FPG <110 mg/dL	Normal fasting glucose
FPG 110 and <126 mg/dL	Intermediate fasting glucose
FPG 126 mg/dL	Provisional diagnosis of diabetes confirmed by one of the three methods below

The revised criteria for diagnosis of diabetes:

- Symptoms of diabetes plus casual plasma glucose concentration 200 mg/dL (11.1 mmol/L). Casual is defined as any time of day without regard to time since last meal. (The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.)
- FPG 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours.
- 2 hr. post glucose load 200 mg/dL during an oral glucose tolerance test. The test should be performed as described by WHO (World Health Organization) using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

Any of the above abnormal glucose levels must be confirmed, on a subsequent day, by any one of the three methods listed above. When screening for diabetes, any abnormal glucose result should be referred to a physician for further follow-up.

Performance Characteristics

Total Cholesterol:	Whole Blood (heparin)	
	<u>Level 1</u>	<u>Level 2</u>
<u>Within-Run Precision</u>		
n =	10	10
\bar{X} (mg/dL) =	184	299
SD (mg/dL) =	4.6	7.3
CV (%) =	2.5	2.4

	Commercial Control Material	
	<u>Level 1</u>	<u>Level 2</u>
<u>Day-to-Day Precision</u>		
n =	20	20
\bar{X} (mg/dL) =	161	244
SD (mg/dL) =	4.3	8.6
CV (%) =	2.7	3.5

HDL Cholesterol:

	Whole Blood (heparin)	
	<u>Level 1</u>	<u>Level 2</u>
<u>Within-Run Precision</u>		
n =	10	10
\bar{X} (mg/dL) =	29	46
SD (mg/dL) =	1.0	2.2
CV (%) =	3.4	4.8

	Commercial Control Material	
	<u>Level 1</u>	<u>Level 2</u>
<u>Day-to-Day Precision</u>		
n =	20	20
\bar{X} (mg/dL) =	29	46
SD (mg/dL) =	1.3	2.9
CV (%) =	4.5	6.3

Glucose:

	Whole Blood (heparin)	
	<u>Level 1</u>	<u>Level 2</u>
<u>Within-Run Precision</u>		
n =	10	10
\bar{X} (mg/dL) =	103	127
SD (mg/dL) =	6.4	5.7
CV (%) =	6.2	4.5

	Commercial Control Material	
	<u>Level 1</u>	<u>Level 2</u>
<u>Day-to-Day Precision</u>		
n =	20	20
\bar{X} (mg/dL) =	103	311
SD (mg/dL) =	3.6	15.4
CV (%) =	3.5	5.0

Accuracy (Method Comparison):

The TC-HDL-GLU cassette total cholesterol was compared with a validated method traceable to the CDC-modified Abell-Kendall reference method traceable to National Institute of Standards and Technology (NIST) standards.

The TC-HDL-GLU cassette HDL cholesterol was compared with a validated method, utilizing dextran sulfate/magnesium chloride precipitation and enzymatic cholesterol determination. The HDL cholesterol comparison method is based on the selected method for HDL cholesterol⁴ and has documented agreement with the CDC Reference Method.

The TC-HDL-GLU cassette glucose was compared with a hexokinase reference method.

The range of values tested (mg/dL) was as follows:

TC	120–300
HDL	26–85
GLU	25–575

Results:








X = Reference Method (serum)

Y = Cholestech LDX Analyzer (venous whole blood)

	No. of		Correlation		
<u>Analyte</u>	<u>Pairs</u>	<u>Slope</u>	<u>y-intercept</u>	<u>Coefficient</u>	<u>Bias at</u>
Total cholesterol	40	0.98	2.41	0.97	200 –1%
HDL cholesterol	40	0.97	0.23	0.95	35 –2%
Glucose	40	0.99	1.01	0.98	150 0%

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- Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997; 20:1183–97.

	<i>In vitro</i> diagnostic medical device
	Catalog number
	Attention. See instructions for use
	Single use
	Do not use if package is damaged or open
	Lot number
	Use by:

CHOLESTECH 

3347 Investment Blvd.
Hayward, CA 94545 U.S.A.
Tel 800 733.0404
Fax 510 732.7227
www.cholestech.com

Authorized Representative
AR-MED Ltd
Runnymede Malthouse
Egham TW20 9BD
United Kingdom

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