Cholestech **LDX**®

TC
Total Cholesterol Test Cassette
(REF 10-986)

TC•GLU
Total Cholesterol and Glucose Panel Test Cassette
(REF 10-988)

TC•HDL
Total Cholesterol and HDL Panel Test Cassette
(REF 10-987)

TC•HDL•GLU
Total Cholesterol, HDL Cholesterol and Glucose Panel Test Cassette
(REF 10-990)

LIPID PROFILE
Total Cholesterol, HDL Cholesterol and Triglycerides Panel Test Cassette
(REF 10-989)

LIPID PROFILE•GLU
Total Cholesterol, HDL Cholesterol, Triglycerides and Glucose Panel Test Cassette
(REF 10-991)

***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.

CE

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Refer to the CD in the analyzer package for instructions in English. The instructions are available from your local distributor.

Le CD contenu dans l'emballage de l'analyseur inclut les directives d'utilisation en français. Le mode d'emploi est disponible auprès du distributeur local.

Anweisungen auf Deutsch befinden sich auf der CD in der Verpackung des Analysegeräts. Die Anleitung ist von Ihrem Händler erhältlich.

Fare riferimento al CD nella confezione dell'analizzatore per istruzioni in italiano. Le istruzioni sono disponibili presso il distributore di zona.

Consulte el CD incluido en el envase del analizador para obtener instrucciones en español. También puede pedir las instrucciones a su distribuidor local.

Consulte o CD no pacote do analisador para instruções em Português. As instruções estão disponíveis junto do seu distribuidor local.

Der henvises til den vedlagte CD i analysatorpakken for instruktioner på dansk. Instruktionerne fås hos den lokale forhandler.

Se CD:n i analysatorförpackningen beträffande instruktioner på svenska. Instruktionerna finns att få hos din lokala återförsäljare.

For instruksjoner på norsk, henvis til CD'en vedlagt i analysatorpakken. Instruksjonene fås hos din nærmeste forhandler.

Ανατρέξτε στο CD στη συσκευασία του αναλυτή για οδηγίες στα Ελληνικά. Οι οδηγίες είναι διαθέσιμες από τον τοπικό διανομέα σας.

INTENDED USE

For the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are 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. NCEP recommends that for routine patient evaluation and follow-up, LDL cholesterol should be estimated from measurement of total and HDL cholesterol and triglycerides using the Friedewald formula.[2] 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.[3] 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, triglycerides and glucose can be measured simultaneously from a single drop of blood using the Cholestech LDX System's rapid, accurate technology. Estimated LDL cholesterol and non-HDL cholesterol and a TC/HDL ratio are calculated using the measured values with software version V3.0 and higher.

SUMMARY AND EXPLANATION

The Cholestech LDX System combines enzymatic methodology[4] and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides 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 both the total cholesterol and triglyceride reaction pads. 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.[5] 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,[6] and Roeschlau.[7] 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.

Cholesterol esters + H_2O —(Cholesterol esterase)→ Free cholesterol + Fatty acids

Cholesterol + O_2 —(Cholesterol oxidase)→ Cholest-4-ene-3-one + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + TOOS —(Peroxidase)→ Quinoneimine dye + 4 H_2O

The Cholestech LDX Analyzer measures triglycerides by an enzymatic method based on the hydrolysis of triglycerides by lipase to glycerol and free fatty acids. Glycerol, in a reaction catalyzed by glycerol kinase, is converted to glycerol-3-phosphate. In a third reaction, glycerol-3-phosphate is oxidized by glycerol phosphate oxidase to dihydroxyacetone phosphate and hydrogen peroxide.[8] The color reaction utilizing horseradish peroxidase is the same as for the total cholesterol and HDL cholesterol.

Triglycerides + H_2O —(Lipase)→ Glycerol + Free fatty acids

Glycerol + ATP —(Glycerol kinase + Mg^{2+})→ Glycerol-3-phosphate + ADP

Glycerol-3-phosphate + O_2 —(Glycerol phosphate Oxidase)→ Dihydroxyacetone phosphate + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + TOOS —(Peroxidase)→ Quinoneimine dye + 4 H_2O

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, HDL cholesterol and triglycerides. The resultant color in all the reactions is measured by reflectance photometry.

Glucose + O_2 —(Glucose oxidase)→ o-D-gluconolactone + H_2O_2

2 H_2O_2 + 4-Aminoantipyrine + TOOS —(Peroxidase)→ Quinoneimine dye + 4 H_2O

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, HDL cholesterol, triglycerides and glucose concentrations.

CASSETTES

Each cassette contains a minimum of:

	TC	HDL	TRG	GLU
Dextran sulfate, µg (50,000 MW)	–	8.9	–	–
Magnesium acetate, µg	–	79.5	–	–
Cholesterol esterase, U (Pseudomonas species)	0.34	0.34	–	–
Lipase (Bacterial source)	–	–	80	–
Cholesterol oxidase, U (Pseudomonas species)	0.058	0.058	–	–
Peroxidase (horseradish), U	0.32	0.32	0.16	0.16
4-Aminoantipyrine, µg	6.4	3.0	3.3	6.08
N-Ethyl-N-sulfohydroxypropyl-m-toluidine, sodium salt, µg	92.0	19.3	19.2	38.6
Glycerol kinase, U (Cellulomonas species)	–	–	0.48	–
Glucose oxidase, U (Cellulomonas species)	–	–	–	0.64
Adenosine triphosphate, µg (Bacterial source)	–	–	22.4	–
Glycerol phosphate oxidase, U (Aerococcus viridans)	–	–	0.29	–
Magnesium chloride, µg	–	–	0.76	–

Nonreactive ingredients: Buffers and stabilizers

Cassette Storage and Stability

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

Place cassettes in the refrigerator after receipt. Cassettes may be used until the date printed on the pouch when stored in a refrigerator (36–46°F / 2–8°C).

The cassettes may be stored for up to 30 days at room temperature (48–86°F / 9–30°C). The new expiration date is the date the cassettes are placed at room temperature plus 30 days. Write the new expiration date on the side of the cassette box in the space provided.

The new expiration date is the date the cassettes are placed at room temperature + 30 days.

- Once cassettes have been stored at room temperature, they should not be returned to the refrigerator.
- Do not use a cassette that has been stored at room temperature for more than 30 days.
- Do not use a cassette beyond the printed expiration date.
- Do not reuse cassettes.

Cassette Handling

Cassettes should sit at room temperature for 10 minutes before opening the 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 µL of whole blood.
- When testing triglycerides or glucose, the subject should fast for 9-12 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 8 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 run on the Analyzer each day that patient samples are tested. See the Cholestech LDX System User Manual for instructions.

TEST PROCEDURE

Materials Provided:

Test 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 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

1. Let cassette sit at room temperature for 10 minutes.
2. Remove the cassette from its pouch. Hold the cassette by the short side **only**. Do not touch the black bar or the brown magnetic stripe. Put the cassette on a flat surface.

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

3. Press **RUN.** If the analyzer has been idle for more than 4 minutes, in a few seconds the screen will display:

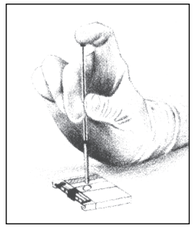
```
selftest
running.
```

```
selftest OK
```

4. The cassette drawer will open. The screen will display:

```
Load cassette
and press RUN
```

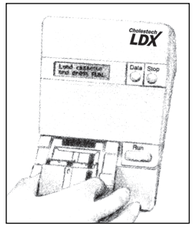
5. Place the sample into the cassette well. Use a Cholestech LDX Capillary Tube for fingerstick samples. Use the MiniPet Pipette for controls or venous blood samples.



NOTE: Fingerstick samples must be applied within eight (8) minutes or the blood may clot.

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

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



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

```
[Test Name]=###
warnings
```

10. Press **DATA** to show more results.
11. When the results are outside the measuring range, the screen will display:

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

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

```
Load cassette
and press RUN
```

16. Repeat the test procedure.
17. Otherwise, after 4 minutes a beep will sound and the screen will display:

```
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

External quality control should be run routinely to show that your system is giving accurate results. Cholestech recommends the following quality control procedures for the 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 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).

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 1.800.733.0404 or 1.510.732.7200 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 divide mg/dL by	mmol/L to mg/dL multiply mmol/L by
TC	38.664	38.664
HDL	38.664	38.664
TRG	88.54	88.54
LDL	38.664	38.664
GLU	18.018	18.018

LIMITATIONS

Analyte	Measuring Range	For results outside the measuring range, the LDX displays:	
	mg/dL (mmol/L)	*Low*	*High*
TC	100-500 (2.59-12.9)	<100 mg/dL (<2.59 mmol/L)	>500 mg/dL (>12.9 mmol/L)
HDL	15-100 (0.39-2.59)	<15 mg/dL (<0.39 mmol/L)	>100 mg/dL (>2.59 mmol/L)
TRG	45-650 (0.51-7.34)	<45 mg/dL (<0.51 mmol/L)	>650 mg/dL (>7.34 mmol/L)
GLU	50-500 (2.78-27.8)	<50 mg/dL (<2.78 mmol/L)	>500 mg/dL (>27.8 mmol/L)

Additional Limitations That Display N/A:

- If the measured value of TRG is >650 mg/dL (>7.34 mmol/L), the LDX displays "N/A" for HDL.
- If the measured value of TRG is >400 mg/dL (>4.51 mmol/L), the LDX displays "N/A" for the LDL estimate.
- If the measured value of TC, HDL or TRG is outside the measuring range, the LDX displays "N/A" for the LDL estimate. [Software version 2.02 calculates LDL estimates with measured TRG values as low as 30 mg/dL (0.34 mmol/L).]

- 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, triglyceride 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.
- Blood glucose results performed at altitudes above 5000 feet have not been validated.

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	Dipyrone	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.
- Blood collection tubes with glycerol should not be used for the triglyceride test.
- Hand creams and soaps with glycerol may cause falsely high triglyceride results.
- The triglyceride test measures triglycerides and free glycerol. Free glycerol usually is less than 20 mg/dL.[9,10]
- There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.[11]

EXPECTED VALUES

Cholesterol and Triglycerides

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 cholesterol and trigylceride testing:

	mg/dL	(mmol/L)	Classification
LDL cholesterol			
	<100	(<2.59)	Optimal
	100–129	(2.59–3.34)	Near optimal/above optimal
	130–159	(3.36–4.11)	Borderline high
	160–189	(4.14–4.89)	High
	≥190	(≥4.91)	Very high
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
Triglycerides			
	<150	(<1.69)	Normal
	150–199	(1.69–2.25)	Borderline high
	200–499	(2.26–5.64)	High
	≥500	(≥5.65)	Very 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.[12,13] A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of CHD.[12]

non-HDL

ATP III identifies non-HDL cholesterol (total cholesterol minus HDL cholesterol) as a secondary target of therapy in persons with high triglycerides (≥200 mg/dL). The goal for non-HDL cholesterol in persons with high serum triglycerides can be set at 30 mg/dL higher than that for LDL cholesterol on the premise that a VLDL cholesterol level ≤30 mg/dL is normal.[1]

Glucose

The American Diabetes Association has modified the criteria for fasting plasma glucose (FPG) and the diagnosis of diabetes mellitus.[14]

FPG <100 mg/dL	Normal fasting glucose
FPG 100–125 mg/dL	Impaired 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

Precision

Total Cholesterol:

Within-Run Precision	Whole Blood (heparin) Level 1	Level 2
n =	10	10
X̄ (mg/dL) =	184	299
SD (mg/dL) =	4.6	7.3
CV (%) =	2.5	2.4

Day-to-Day Precision	Commercial Control Material Level 1	Level 2
n =	20	20
X̄ (mg/dL) =	161	244
SD (mg/dL) =	4.3	8.6
CV (%) =	2.7	3.5

HDL Cholesterol:

Within-Run Precision	Whole Blood (heparin) Level 1	Level 2
n =	10	10
X̄ (mg/dL) =	29	46
SD (mg/dL) =	1.0	2.2
CV (%) =	3.4	4.8

Day-to-Day Precision	Commercial Control Material Level 1	Level 2
n =	20	20
X̄ (mg/dL) =	29	46
SD (mg/dL) =	1.3	2.9
CV (%) =	4.5	6.3

Triglycerides:

Within-Run Precision	Whole Blood (heparin) Level 1	Level 2
n =	10	10
X̄ (mg/dL) =	256	362
SD (mg/dL) =	4.0	13.1
CV (%) =	1.6	3.6

Day-to-Day Precision	Commercial Control Material Level 1	Level 2
n =	20	20
X̄ (mg/dL) =	121	276
SD (mg/dL) =	2.8	8.7
CV (%) =	2.3	3.2

LDL Cholesterol:

Within-Run Precision	Whole Blood (heparin) Level 1	Level 2
n =	10	10
X̄ (mg/dL) =	87	197
SD (mg/dL) =	4.3	7.5
CV (%) =	4.9	3.8

Day-to-Day Precision	Commercial Control Material Level 1	Level 2
n =	20	20
X̄ (mg/dL) =	108	143
SD (mg/dL) =	4.6	8.4
CV (%) =	4.3	5.9

Glucose:

Within-Run Precision	Whole Blood (heparin) Level 1	Level 2
n =	10	10
X̄ (mg/dL) =	103	127
SD (mg/dL) =	6.4	5.7
CV (%) =	6.2	4.5

Day-to-Day Precision	Commercial Control Material Level 1	Level 2
n =	20	20
X̄ (mg/dL) =	103	311
SD (mg/dL) =	3.6	15.4
CV (%) =	3.5	5.0

ACCURACY (METHOD COMPARISON)

The 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 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 cholesterol[5] and has documented agreement with the CDC Reference Method.

The cassette triglyceride test was compared with a validated method, utilizing hydrolysis with lipase. The comparison method has documented agreement with a CDC Reference Method.

The cassette glucose was compared with a hexokinase reference method.

The cassette estimated LDL cholesterol was compared to that calculated from the above validated total cholesterol, HDL cholesterol and triglyceride methods.

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

TC	120–300
HDL	26–85
TRG	40–500
GLU	25–575

Results

X = Reference Method (serum)
Y = Cholestech LDX Analyzer (venous whole blood)

Analyte	No. of Pairs	Slope	y-intercept	Correlation Coefficient	Bias at	
Total cholesterol	40	0.98	2.41	0.97	200	–1%
HDL cholesterol	40	0.97	0.23	0.95	35	–2%
Triglycerides	40	1.0	0.13	0.99	250	0%
Glucose	40	0.99	1.01	0.98	150	0%

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IVD

- *In Vitro* diagnostic medical device
- Dispositivo médico para diagnóstico *in vitro*
- *In-vitro*-Diagnostikum
- Dispositivo medico-diagnostico *in vitro*
- Dispositif médical de diagnostic *in vitro*
- Dispositivo médico para diagnóstico *in vitro*
- Medicinsk udstyr til *in vitro*-diagnostik
- Medicinteknisk produkt avsedd för *in vitro*-diagnostik
- *In Vitro* diagnostisk medisinsk utstyr
- Ιατροτεχνολογικό βοήθημα που χρησιμοποιείται για διάγνωση *in vitro*

REF

- Catalog Number
- Número de catálogo
- Katalognummer
- Numero di catalogo
- Numéro de catalogue
- Número de catálogo
- Katalognummer
- Katalognummer
- Αριθμός καταλόγου

- Caution, consult accompanying documents
- Precaución, consulte los documentos adjuntos
- Achtung, lesen Sie die beigelegten Dokumente
- Attenzione: consultare la documentazione allegata
- Attention, consulter les documents joints
- Atenção, consultar os documentos inclusos
- Forsigtig, læs medfølgende dokumenter
- Försiktighetsåtgärd: konsultera medföljande dokument
- Forsiktig, se medfølgende dokumentasjon
- Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα

- Do not reuse
- No reutilizar
- Nicht wiederverwenden
- Non riutilizzare
- Ne pas réutiliser
- Não reutilizar
- Kun til engangsbrug
- Engångsbruk
- Til engangsbruk
- Μην επαναχρησιμοποιείτε

- Do not use if package is damaged or open
- No utilizar si el envase está abierto o dañado
- Nicht verwenden, wenn Verpackung geöffnet oder beschädigt ist
- Non utilizzare se la confezione è aperta o danneggiata
- Ne pas utiliser si l'emballage est ouvert ou endommagé
- Não utilizar se a embalagem se apresentar aberta ou danificada
- Må ikke anvendes, hvis pakken er beskadiget eller åbnet
- Får inte användas om förpackningen skadats eller öppnats
- Må ikke brukes hvis innpakningen er skadet eller åpen
- Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά ή έχει ανοιχτεί

- Use By
- Fecha de caducidad
- Verfallsdatum
- Utilizzare entro
- Utiliser avant le
- Utilizar até
- Holdbar til
- Använd före
- Brukes innen
- Ημερομηνία λήξης

- Temperature Limitation
- Límite de temperatura
- Temperaturbereich
- Limiti di temperatura
- Limite de température
- Límites de temperatura
- Temperaturbegrænsning
- Temperaturbegränsning
- Temperaturbegrensning
- Περιορισμός θερμοκρασίας

- Manufacturer
- Fabricante
- Hersteller
- Fabbricante
- Fabricant
- Fabricante
- Fremstillet af
- Tillverkad av
- Produsert av
- Κατασκευαστής

LOT

- Lot Number
- Número de lote
- Chargennummer
- Codice del lotto
- Numéro de lot
- Número de lote
- Lotnummer
- Partinummer
- Partinummer
- Αριθμός παρτίδας

EC REP

- Authorized representative in European Community
- Representante autorizado en la Comunidad Europea
- Bevollmächtigter in der Europäischen Gemeinschaft
- Rappresentante autorizzato per la Comunità Europea
- Mandataire dans la Communauté européenne
- Mandatário na Comunidade Europeia
- Repræsentant i det Europæiske Fællesskab
- Auktoriserad representant i Europeiska gemenskapen
- Autorisert representant i Det europeiske felleskap
- Εξουσιοδοτημένος αντιπρόσωπος για την Ευρωπαϊκή Κοινότητα

- 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
- Se bruksanvisningen
- Συμβουλευτείτε τις οδηγίες χρήσης

Professional Use Only

- Professional Use Only
- Para uso profesional solamente
- Nur zum Gebrauch durch Fachleute vorgesehen
- Esclusivamente per uso professionale
- Réservé à un usage professionnel
- Apenas para utilização por profissionais
- Kun beregnet til faglig brug
- Endast för professionell användning
- Kun til yrkesmessig bruk
- Για επαγγελματική χρήση μόνον

- CRMLN Certified
- Certificación CRMLN
- CRMLN-zertifiziert
- Certificazione CRMLN
- Homologué par le CRMLN
- Certificado pela CRMLN
- CRMLN-certificeret
- CRMLN-certifierad
- CRMLN-sertifisert
- Πιστοποιημένο κατά CRMLN

(9–30°C)

- Room Temperature expiration date: date at room temperature plus 30 days
- Fecha de caducidad a temperatura ambiente: a los 30 días de ponerse el producto a dicha temperatura
- Verfallsdatum bei Raumtemperatur: Anfangsdatum der Lagerung bei Raumtemperatur plus 30 Tage
- Data di scadenza a temperatura ambiente: data a temperatura ambiente più 30 giorni
- Date de péremption à température ambiante : date à température ambiante plus 30 jours
- Prazo de validade à temperatura ambiente: 30 dias após a data de colocação à temperatura ambientes
- Udløbsdato ved stuetemperatur: dato ved stuetemperatur plus 30 dage
- Utgångsdatum vid rumstemperatur: datum för rumstemperatur plus 30 dagar
- Utløpsdato ved romtemperatur: romtemperatur-dato pluss 30 dager
- Ημερομηνία λήξης σε θερμοκρασία δωματίου: ημερομηνία σε θερμοκρασία δωματίου συν 30 ημέρες

Σ

- Contains sufficient for <n> tests
- Contient du matériel en quantité suffisante pour <n> tests
- Enthält genügend für <n> Tests
- Contenuto sufficiente per <n> analisi
- Cantidad suficiente para <n> pruebas
- Conteúdo suficiente para <n> testes
- Indeholder nok til <n> test
- Tillräckligt innehåll för <n> tester
- Inneholder er nok til <n> tester
- Περιεχόμενο επαρκές για <n> εξετάσεις