Laboratory Name:	
Laboratory Address:	
Date of this packet:	
Insert Revision:	26196en Rev. A 2010/12

Alere Cholestech LDX® Laboratory Procedure

Lipid Profile•GLU	**TC•HDL•GLU**	**TC•GLU**
Lipid Profile	**TC•HDL**	**TC**

This procedure is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. **Any modifications to this document are the sole responsibility of the Facility.**

1. 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 Alere Cholestech LDX® Analyzer.

2. Summary and Explanation

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

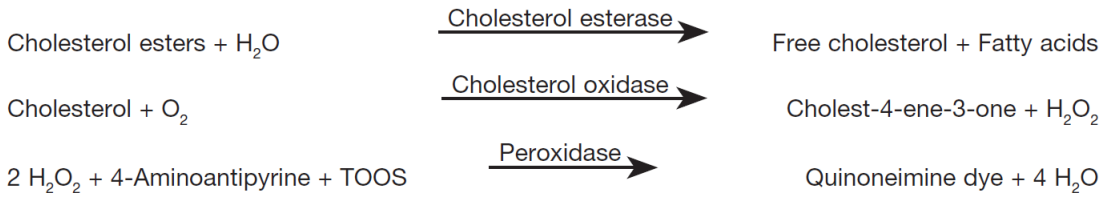
homeostatic mechanism is able to keep glucose levels within such a narrow range, values outside this range generally indicate a disease state. Insulin is the principal hormone regulating glucose levels, and any defect in the production or action of insulin can lead to one of the several forms of diabetes 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 Alere 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.

3. Test Principle

The Alere 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 an Alere Cholestech LDX® cassette.

The cassette is then placed into the Alere 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- and very 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 Alere 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.



The Alere 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.

$$\text{Triglycerides} + H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{Free fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerol kinase} + Mg^{2+}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow[\text{Oxidase}]{\text{Glycerol phosphate}} \text{Dihydroxyacetone phosphate} + H_2O_2$$

$$2\ H_2O_2 + \text{4-Aminoantipyrine} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4\ H_2O$$

The Alere 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.

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose oxidase}} \text{o-D-gluconolactone} + H_2O_2$$

$$2\ H_2O_2 + \text{4-Aminoantipyrine} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4\ H_2O$$

A brown (magnetic) stripe on each cassette contains the calibration information required for the Alere Cholestech LDX® Analyzer to convert the reflectance reading (% R) to the total cholesterol, HDL cholesterol, triglycerides and glucose concentrations.

4. Reagents

A. Materials Provided

<table>
<tr><th>Component</th><th>Content</th><th>Quantity</th></tr>
<tr><td>Test Cassettes</td><td>Each cassette contains a minimum of:
<table><tr><th></th><th>TC</th><th>HDL</th><th>TRG</th><th>GLU</th></tr><tr><td>Dextran sulfate (50,000 M.W.), µg</td><td>–</td><td>17.2</td><td>–</td><td>–</td></tr><tr><td>Magnesium acetate, µg</td><td>–</td><td>153</td><td>–</td><td>–</td></tr><tr><td>Cholesterol esterase, U (Pseudomonas species)</td><td>0.287</td><td>0.287</td><td>–</td><td>–</td></tr><tr><td>Lipase, U (Bacterial source)</td><td>–</td><td>–</td><td>53.9</td><td>–</td></tr><tr><td>Cholesterol oxidase, U (Pseudomonas species)</td><td>0.049</td><td>0.049</td><td>–</td><td>–</td></tr><tr><td>Peroxidase (horseradish), U</td><td>0.266</td><td>0.266</td><td>0.133</td><td>0.133</td></tr><tr><td>4-Aminoantipyrine, µg</td><td>5.39</td><td>2.52</td><td>2.73</td><td>5.11</td></tr><tr><td>N-Ethyl-N-sulfohydroxypropyl m-toluidine, sodium salt, µg</td><td>77.0</td><td>16.2</td><td>16.1</td><td>32.3</td></tr><tr><td>Glycerol kinase, U (Cellulomonas species)</td><td>–</td><td>–</td><td>0.399</td><td>–</td></tr><tr><td>Glucose oxidase, U (Cellulomonas species)</td><td>–</td><td>–</td><td>–</td><td>0.539</td></tr><tr><td>Adenosine triphosphate, µg (Bacterial source)</td><td>–</td><td>–</td><td>18.8</td><td>–</td></tr><tr><td>Glycerol phosphate oxidase, U (Aerococcus viridans)</td><td>–</td><td>–</td><td>0.238</td><td>–</td></tr><tr><td>Magnesium chloride, µg</td><td>–</td><td>–</td><td>1.37</td><td>–</td></tr></table>Nonreactive ingredients: buffers and stabilizers</td><td>10</td></tr>
<tr><td>Package insert</td><td></td><td>1</td></tr>
</table>

B. Materials Required But Not Provided

- Alere Cholestech LDX® System
- Alcohol swabs and gauze for cleaning puncture site
- Lancets for capillary blood collection
- Alere Cholestech LDX® 40 µL Lithium Heparin Capillary Tubes
- Alere Cholestech LDX® Capillary Plungers
- Gloves
- Biohazard waste containers
- Quality control material
- MiniPet™ Pipette and tips or micropipetter that will deliver 40 µL for use with venipuncture samples and quality control material
- Vacuum collection tubes, needles, tube holders and sample tubes if the sample is to be collected by venipuncture

5. Warnings and Precautions

For professional *in vitro* diagnostic use only.

All blood samples, 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 biohazardous waste container after use.

6. Storage and Handling

A. Storage

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.

NOTE: Once the 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.

B. 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.

7. Specimen Collection and Handling

Sample Type	The Alere Cholestech LDX® System is CLIA waived for fingerstick or venous whole blood unprocessed samples only. If you run serum or plasma on the Alere Cholestech LDX® System you will have to comply with the regulations for moderate complexity. See the Alere Cholestech LDX® System User Manual for a summary of these regulations.
Sample Requirement	Sample Volume: 40 µL of whole blood.
Fingerstick whole blood	• When testing triglycerides or glucose, the subject should fast for 9–12 hours before the sample is collected. • Collect the sample from a fingerstick into a Alere Cholestech LDX® 40 µL Capillary Tube. (See the Fingerstick Procedure below). • Place the blood into the cassette within 8 minutes after collection. • Blood from the fingerstick should flow freely. Too much squeezing of the finger may cause inaccurate 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 inaccurate results.** Use a pipette and tip to place blood into the cassette.
Specimen Storage	• Whole blood should be used within 30 minutes. • Samples should be at room temperature for testing. • Mix all samples by gently inverting at least 7 times before testing. • Glucose levels decrease 5 to 10 mg/dL (0.28 to 0.55 mmol/L) per hour in whole blood at room temperature.

8. Test Procedure

A. Calibration

No calibration is performed by the user. Test information is encoded on the brown stripe of the cassette. The brown magnetic stripe is read by the Alere Cholestech LDX® Analyzer each time a cassette is run.

An Optics Check should be run on the analyzer each day that patient samples are tested. See the Alere Cholestech LDX® User Manual for instructions.

NOTE: A warm hand and good blood flow from the puncture site are essential in order to collect a good capillary sample.

WARNING: Squeezing the finger excessively may cause inaccurate test results.

B. Fingerstick Procedure

1. The patient should sit quietly for five minutes before the blood sample is collected.
2. Put a capillary plunger into the end of a Alere Cholestech LDX® 40 µL Capillary Tube with the red mark. Set aside.
3. Choose a spot that is on the side of **one of the center fingers** of either hand. The fingers and hands should be warm to the touch. To warm the hand, you can:
   a. Wash the patient's hand with warm water, or…
   b. Apply a warm (not hot) compress to the hand for several minutes, or…
   c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.

4. Clean the site with an alcohol swab. Dry thoroughly with a gauze pad **before pricking the finger**.
5. Firmly prick the selected site with a lancet.
6. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood as it may contain tissue fluid.
7. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. **Do not milk the finger.** The puncture should provide a free-flowing drop of blood.
8. Hold the capillary tube horizontally or at a slightly descending angle by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action to the black mark. **Do not collect air bubbles.** If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
9. Fill the capillary tube within 10 seconds.
10. Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops.

C. Using the MiniPet™ Pipette

Use this procedure to apply a venous blood sample, or control, calibration verification or proficiency testing materials to the cassette. Any pipette that can deliver 40 µL may be used.

1. Firmly attach the pipette tip to the end of the 40 µL MiniPet™ Pipette. Use a new tip for each sample.
2. To fill the pipette, push the plunger down as far as you can. Place the pipette tip midway into the sample and **slowly** release the plunger. Confirm that no air bubbles are in the pipette tip.
3. Place the pipette tip into the cassette sample well. Dispense the sample into the cassette sample well by pressing the plunger down. Move the pipette tip out of the sample well before releasing the plunger again.
4. Remove the pipette tip and throw it away in a biohazard waste container.

NOTE: If the plunger is released before the pipette tip is out of the sample well, it will remove the sample just dispensed.

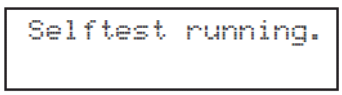
NOTE: Keep the cassette horizontal at all times after applying the sample.

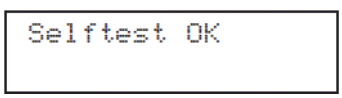
D. Running a Test

1. If the cassettes have been refrigerated, allow them to come to room temperature (at least 10 minutes) before opening.
2. Make sure the analyzer is plugged in and has warmed up.
3. Remove the cassette from its pouch. Hold the cassette by the short sides **only**. Do not touch the black bar or the magnetic stripe. Place the cassette on a flat surface.

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

4. Press **RUN**. The analyzer will do a selftest, and the screen will display:

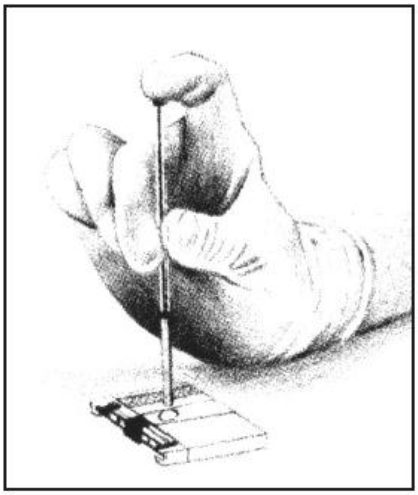




5. The cassette drawer will open, and the screen will display:

```
Load cassette
and press RUN.
```

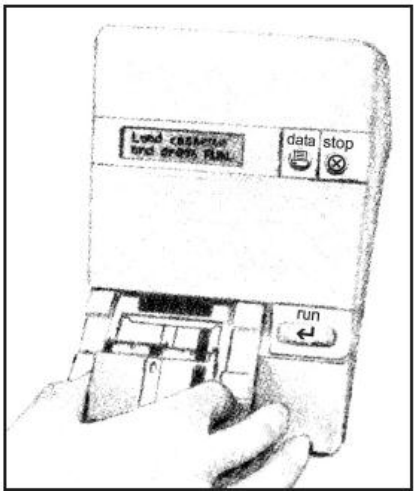
6. Place the sample into the cassette well. Use an Alere Cholestech LDX® Capillary Tube for fingerstick samples. Use a 40 µL pipette for venous blood samples and quality control, calibration verification, and proficiency testing materials.



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

7. Keep the cassette flat after the sample has been applied. **WARNING: Allowing the sample to sit in the cassette will cause inaccurate results. Immediately place the cassette into the drawer of the analyzer.** The black reaction bar must face toward the analyzer. The brown magnetic stripe must be on the right.
8. **DO NOT PUSH IN THE DRAWER**. Press **RUN**. The drawer will close. During the test, the screen will display:

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



9. Put everything that touched the blood samples or control, calibration verification, or proficiency testing material into a biohazardous waste container.
10. When the test is complete, the analyzer will beep, and the screen will display:

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

11. Press DATA to view additional results.
12. When the results are outside the measuring range of the test, the screen will display:

```
[Test Name]>###
```

or

```
[Test Name]<###
```

13. If there is a problem with the test, a message will appear on the screen. See the Troubleshooting section of the Alere Cholestech LDX® System User Manual if this happens.

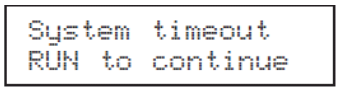
    Please call Alere™ Product Support to report any problems or if you have questions about the operation of the Alere Cholestech LDX® System.
14. When the drawer opens, remove the cassette, and put it in a biohazardous waste container. Leave the analyzer drawer empty when not in use.
15. Record the results on the appropriate form.
16. To run another cassette, press **RUN**. The screen will display:

```
Load cassette
and press RUN.
```

17. Repeat step 3, and steps 6 through 15.

NOTE: If you do not want to run another test and the drawer is open, press STOP to close the drawer.

18. Otherwise, after four minutes a beep will sound and the screen will display:



19. If necessary, press the **DATA** button to view the results from the last cassette used.

NOTE: Pressing the RUN button will erase the previous result.

9. Results

Test results will be displayed on the screen when the test is complete. Calculated results are displayed 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

10. Quality Control

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

A. Choice of Materials

Liquid Level 1 and Level 2 controls that work well with the Alere Cholestech LDX® System are available. If you use other controls, you will need to establish ranges for the Alere Cholestech LDX® System.

B. 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 the procedure.

C. External Quality Control

External control material should be used to demonstrate that the reagents and the assay procedure perform properly. Good Laboratory Practice principles suggest that controls should be run whenever the laboratory director has any question about test system integrity, reagent storage conditions, or the reliability of any test result.

If the controls do not perform as expected, repeat the test or contact Alere™ Product Service before testing patient samples.

Controls should be tested:

- With each new lot of cassettes;
- With every new shipment of cassettes, even if the lot has been received previously;

- When reagents may have been stored or handled in a way that can degrade their performance;
- As otherwise required by your laboratory's standard quality control procedures;
- As otherwise required by federal, state and local guidelines.

Record the results in a Quality Control Log.

The quality control results should be in range before testing patient samples. See the Alere Cholestech LDX® System User Manual if they are not. Please call Alere™ Product Support to report any problems or if you have any questions about quality control.

11. 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 Alere Cholestech LDX® System has not been tested on samples from newborns.
- Blood glucose

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

Substance Concentration (mg/dL)

Ascorbic Acid	1	Hemoglobin	125
Bilirubin	5	Lactose	100
Creatinine	30	Lovastatin (Mevacor)	4
Cysteine	10	Nicotinic Acid (Niacin)	10
Fructose	30	Urea	500
Gemfibrozil (Lopid)	15	Uric Acid	15
Glutathione	1		

- Hematocrits between 30% and 49% 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]

12. Expected Values

A. 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 presents NCEP's updated clinical guidelines for cholesterol testing and management and describes the following classifications for cholesterol and triglyceride testing:

Analyte	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.

B. 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]

C. 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]

D. Glucose

The American Diabetes Association has identified categories of increased risk for diabetes based upon glucose[14]:

- Fasting plasma glucose (FPG) 100 -125 mg/dL (5.6 -6.9 mmol/L); impaired fasting glucose
- 2-hr plasma glucose in the 75-g oral glucose tolerance test (OGTT) 140 -199 mg/dL (7.8 - 11.0 mmol/L); impaired glucose tolerance

For these tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

The American Diabetes Association has criteria for the diagnosis of diabetes mellitus based upon glucose[14]:

- FPG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hr.
- 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

In the absence of unequivocal hyperglycemia, diagnosis should be confirmed by repeat testing. When screening for diabetes, any abnormal glucose result should be referred to a physician for further follow-up.

13. Performance Characteristics

A. Precision

	Within-Run Precision Whole Blood (heparin)		**Day-to-Day Precision** Commercial Control Material	
	Level 1	Level 2	Level 1	Level 2
Total Cholesterol, n =	10	10	20	20
$\bar{X}$ (mg/dL) =	184	299	161	244
SD (mg/dL) =	4.6	7.3	4.3	8.6
CV (%) =	2.5	2.4	2.7	3.5
HDL Cholesterol, n =	10	10	20	20
$\bar{X}$ (mg/dL) =	29	46	29	46
SD (mg/dL) =	1.0	2.2	1.3	2.9
CV (%) =	3.4	4.8	4.5	6.3
Triglycerides, n =	10	10	20	20
$\bar{X}$ (mg/dL) =	256	362	121	276
SD (mg/dL) =	4.0	13.1	2.8	8.7
CV (%) =	1.6	3.6	2.3	3.2
LDL Cholesterol, n =	10	10	20	20
$\bar{X}$ (mg/dL) =	87	197	108	143
SD (mg/dL) =	4.3	7.5	4.6	8.4
CV (%) =	4.9	3.8	4.3	5.9
Glucose, n =	10	10	20	20
$\bar{X}$ (mg/dL) =	103	127	103	311
SD (mg/dL) =	6.4	5.7	3.6	15.4
CV (%) =	6.2	4.5	3.5	5.0

B. 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 cholesterol5 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 estimated LDL was compared to that calculated from the above validated total cholesterol, HDL cholesterol and triglycerides 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 = Alere 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%

14. References

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Test Procedure Review Sheet

Laboratory Name:	
Laboratory Address:	
Date of this packet:	
Insert Revision:	26196en Rev. A 2010/12

Supervisor	Date Reviewed	Supervisor	Date Reviewed