



- 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.

	mg/dL to mmol/L	mmol/L to mg/dL
	<i>divide mg/dL by</i>	<i>multiply mmol/L by</i>
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)	<i>Low</i>	<i>High</i>
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)	>2.59 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.

<b>Substance Concentration (mg/dL)</b>			
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	Genisic Acid	0.5
Lactose	100	Methyl dopamine	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.<sup>9,10</sup>
- There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.<sup>11</sup>

## 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.<sup>1</sup> The ATP III report presented the NCEP's updated clinical guidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing:

	<i>mg/dL</i>	<i>(mmol/L)</i>	<i>Classification</i>
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.<sup>1</sup> 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.<sup>12,13</sup> A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests a high risk of CHD.<sup>12</sup>

### 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.<sup>1</sup>

### Glucose

The American Diabetes Association has modified the criteria for fasting plasma glucose (FPG) and the diagnosis of diabetes mellitus.<sup>14</sup>

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

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

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

<b>HDL Cholesterol:</b>	Whole Blood (heparin)	
<i>Within-Run Precision</i>	<i>Level 1</i>	<i>Level 2</i>
n =	10	10
<i>X</i> (mg/dL) =	29	46
SD (mg/dL) =	1.0	2.2
CV (%) =	3.4	4.8

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

<b>Triglycerides:</b>	Whole Blood (heparin)	
<i>Within-Run Precision</i>	<i>Level 1</i>	<i>Level 2</i>
n =	10	10
<i>X</i> (mg/dL) =	256	362
SD (mg/dL) =	4.0	13.1
CV (%) =	1.6	3.6

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

<b>LDL Cholesterol:</b>	Whole Blood (heparin)	
<i>Within-Run Precision</i>	<i>Level 1</i>	<i>Level 2</i>
n =	10	10
<i>X</i> (mg/dL) =	87	197
SD (mg/dL) =	4.3	7.5
CV (%) =	4.9	3.8

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

<b>Glucose:</b>	Whole Blood (heparin)	
<i>Within-Run Precision</i>	<i>Level 1</i>	<i>Level 2</i>
n =	10	10
<i>X</i> (mg/dL) =	103	127
SD (mg/dL) =	6.4	5.7
CV (%) =	6.2	4.5

<b>Day-to-Day Precision</b>	Commercial Control Material	
<i>Level 1</i>	<i>Level 2</i>	
n =	20	20
<i>X</i> (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<sup>®</sup> 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)

	No. of	Slope	Correlation	Bias at	
<b>Analyte</b>	<b>Pairs</b>	<b>y-intercept</b>	<b>Coefficient</b>	<b>Coefficient</b>	<b>Bias at</b>
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%

## REFERENCES

- ↑ Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 2001;285:2486-97.
- ↑ Bachorik PS, Ross JW, for the National Cholesterol Education Program Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendations for measurement of low-density lipoprotein cholesterol: executive summary. *Clin Chem* 1995;41:1414-20.
- ↑ Tietz NW, ed. *Fundamentals of Clinical Chemistry*. Philadelphia, Pa.: WB Saunders Co., 1987.
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- ↑ Roeschlau P, Bernt E, Gruber W. Enzymatische bestimmung des gesamt-cholesterins im serum. *Z Klin Chem Klin Biochem* 1974;12:226.
- ↑ Fossati P, Prencipe L. Serum triglycerides determined colorimetrically with an enzyme that produces hydrogen peroxide. *Clin Chem* 1982;28:2077-80.
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- ↑ Blumenfeld TA, Hertelendy WG, Ford SH. Simultaneously obtained skin-puncture serum, skin-puncture plasma, and venous serum compared, and effects of warming the skin before puncture. *Clin Chem* 1977;23:1705-10.
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- ↑ Kinosian B, Glick H, Garland G. Cholesterol and coronary heart disease: predicting risks by levels and ratios. *Ann Intern Med* 1994;121:641-7.
- ↑ Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 2004; Vol 27, Supplement 1: S5-10.

<b>IVD</b>	<b>REF</b>	<span>⚠</span>
<ul style="list-style-type: none"><li><i>In Vitro</i> diagnostic medical device</li> <li>Dispositivo médico para diagnóstico <i>in vitro</i></li> <li><i>In-vitro</i>-Diagnostikum</li> <li>Dispositivo medico-diagnostico <i>in vitro</i></li> <li>Dispositif médical de diagnostic <i>in vitro</i></li> <li>Dispositivo médico para diagnóstico <i>in vitro</i></li> <li>Medicinsk udstyr til <i>in vitro</i>-diagnostik</li> <li>Medicinteknisk produkt avsedd för <i>in vitro</i>-diagnostik</li> <li><i>In Vitro</i> diagnostisk medisinsk utstyr</li> <li>ιατροτεχνολογικό βοηθήμα που χρησιμοποιείται για διάγνωση <i>in vitro</i></li></ul>	<ul style="list-style-type: none"><li>Catalog Number</li> <li>Número de catálogo</li> <li>Katalognummer</li> <li>Numero di catalogo</li> <li>Dispositivo de catalogue</li> <li>Número de catálogo</li> <li>Katalognummer</li> <li>Katalognummer</li> <li>Κατάλογnummer</li> <li>Αριθμός καταλόγου</li></ul>	<ul style="list-style-type: none"><li>Caution, consult accompanying documents</li> <li>Precaución, consulte los documentos adjuntos</li> <li>Achtung, lesen Sie die beigelegten Dokumente</li> <li>Attenzione: consultare la documentazione allegata</li> <li>Attention, consulter les documents joints</li> <li>Αιτιολογία, consultiar os documentos adjuntos</li> <li>Forsiktig, læs medfølgende dokumenter</li> <li>Försiktighetsåtgärd: konsultera medföljande dokument</li> <li>Forsiktig, se medfølgende dokumentasjon</li> <li>Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα</li></ul>

<span>⊗</span>	<span>⊗</span>
<ul style="list-style-type: none"><li>Do not reuse</li> <li>No reutilizar</li> <li>Nicht wiederverwenden</li> <li>Non riutilizzare</li> <li>Ne pas réutiliser</li> <li>Não reutilizar</li> <li>Kun til engangsbrug</li> <li>Engångsbruk</li> <li>Til engangsbruk</li> <li>Μην επαναχρησιμοποιείτε</li></ul>	<ul style="list-style-type: none"><li>Do not use if package is damaged or open</li> <li>No utilizar si el envase está abierto o dañado</li> <li>Nicht verwenden, wenn Verpackung geöffnet oder beschädigt ist</li> <li>Non utilizzare se la confezione è aperta o danneggiata</li> <li>Ne pas utiliser si l'emballage est ouvert ou endommagé</li> <li>Não utilizar se a embalagem se apresentar aberta ou danificada</li> <li>Må ikke anendes, hvis pakken er beskadiget eller åbnet</li> <li>Får inte användas om förpackningen skadats eller öppnats</li> <li>Må ikke brukes hvis innpakningen er skadet eller åpen</li> <li>Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά ή έχει ανοιχτεί</li></ul>

<span>⏴</span>	<span>⏵</span>	<span>🏭</span>	<b>LOT</b>
<ul style="list-style-type: none"><li>Use By</li> <li>Fecha de caducidad</li> <li>Verfallsdatum</li> <li>Utilizzare entro</li> <li>Utiliser avant le</li> <li>Utilizãt at</li> <li>Holdbar til</li> <li>Använd före</li> <li>Bruk innen</li> <li>Ημερομηνία λήξης</li></ul>	<ul style="list-style-type: none"><li>Temperature Limitation</li> <li>Límite de temperatura</li> <li>Temperaturbereich</li> <li>Limiti di temperatura</li> <li>Limite de température</li> <li>Limites de temperatura</li> <li>Temperaturbegrænsning</li> <li>Temperaturbegrænsning</li> <li>Τεριορισμός θερμοκρασίας</li></ul>	<ul style="list-style-type: none"><li>Manufacturer</li> <li>Fabricante</li> <li>Hersteller</li> <li>Fabbricante</li> <li>Fabricant</li> <li>Fabricante</li> <li>Fremstillet af</li> <li>Produzent</li> <li>Κατασκευαστής</li></ul>	<ul style="list-style-type: none"><li>Lot Number</li> <li>Número de lote</li> <li>Cargennummer</li> <li>Code del lotto</li> <li>Número de lote</li> <li>Número de lote</li> <li>Lotnummer</li> <li>Partinummer</li> <li>Partinummer</li> <li>Αριθμός παρτίδας</li></ul>

<b>EC REP</b>	<span>ℹ</span>	<b>Professional Use Only</b>
<ul style="list-style-type: none"><li>Authorized representative in European Community</li> <li>Representante autorizado en la Comunidad Europea</li> <li>Bevollmächtigter in der Europäischen Gemeinschaft</li> <li>Rappresentante autorizzato per la Comunità Europea</li> <li>Mandatäre dans la Communauté européenne</li> <li>Mandatário na Comunidade Europeia</li> <li>Representant i det Europeiske Fællesskab</li> <li>Auktoriserad representant i Europeiska gemenskapen</li> <li>Autorisert representant i Det europeiske felleskap</li> <li>Εξουσιοδοτημένος αντιπρόσωπος για την Ευρωπαϊκή Κοινότητα</li></ul>	<ul style="list-style-type: none"><li>Consult instructions for use</li> <li>Consulte las instrucciones de uso</li> <li>Gebrauchsanweisung beachten</li> <li>Consultare le istruzioni per l'uso</li> <li>Consulte le mode d'emploi</li> <li>Consultar as instruções de utilização</li> <li>Se brugsanvisningen</li> <li>Konsultera bruksanvisningen</li> <li>Se bruksanvisningen</li> <li>Συμβουλευτείτε τις οδηγίες χρήσης</li></ul>	<ul style="list-style-type: none"><li>Professional Use Only</li> <li>Para uso profesional solamente</li> <li>Nur zum Gebrauch durch Fachleute vorgesehen</li> <li>Exclusivamente per uso professionale</li> <li>Réservé à un usage professionnel</li> <li>Apenas para utilização por profissionais</li> <li>Kun beregnet til faglig brug</li> <li>Endast för professionell användning</li> <li>Kun til yrkesmessig bruk</li> <li>Για επαγγελματική χρήση μόνον</li></ul>

<span>🇪🇺</span>	<span>⏴</span> (9–30°C) <span>⏵</span>	<span>⚠</span>
<ul style="list-style-type: none"><li>CRMLN Certified</li> <li>Certificación CRMLN</li> <li>CRMLN-zertifiziert</li> <li>Certificazione CRMLN</li> <li>Homologué par le CRMLN</li> <li>Certificado pela CRMLN</li> <li>CRMLN-certificeret</li> <li>CRMLN-certifierad</li> <li>CRMLN-sertifisert</li> <li>Πιστοποιημένο κατά CRMLN</li></ul>	<ul style="list-style-type: none"><li>Room Temperature expiration date: date at room temperature plus 30 days</li> <li>Fecha de caducidad a temperatura ambiente: a los 30 días de ponerse el producto a dicha temperatura</li> <li>Verfallsdatum bei Raumtemperatur: Anfangsdatum der Lagerung bei Raumtemperatur plus 30 Tage</li> <li>Data di scadenza a temperatura ambiente: data a temperatura ambiente più 30 giorni</li> <li>Date de péremption à température ambiante<span> </span>: date à température ambiante plus 30 jours</li> <li>Prazo de validade à temperatura ambiente: 30 dias após a data de colocação à temperatura ambiente</li> <li>Utløbsdato ved stuetemperatur: dato ved stuetemperatur plus 30 dage</li> <li>Utløgsdatum vid rumtemperatur: datum för rumstemperatur plus 30 dagar</li> <li>Utløpsdato ved romtemperatur: romtemperatur-dato pluss 30 dager</li> <li>Ημερομηνία λήξης σε θερμοκρασία δωματίου: ημερομηνία σε θερμοκρασία δωματίου συν 30 ημέρες</li></ul>	<ul style="list-style-type: none"><li>Contains sufficient for &lt;n&gt; tests</li> <li>Contient du matériel en quantité suffisante pour &lt;n&gt; tests</li> <li>Enthält genügend für &lt;n&gt; Tests</li> <li>Contenido suficiente para &lt;n&gt; análisis</li> <li>Cantidad suficiente para &lt;n&gt; pruebas</li> <li>Conteúdo suficiente para &lt;n&gt; testes</li> <li>Indeholder nok til &lt;n&gt; test</li> <li>Tillräckligt innehåll för &lt;n&gt; tester</li> <li>Innholdet er nok til &lt;n&gt; tester</li> <li>Περιεχόμενο επαρκές για &lt;n&gt; εξετάσεις</li></ul>