LPP Lipoprotein Particle Profile™

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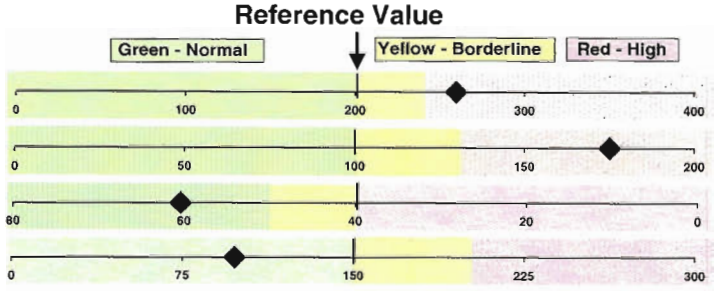
Primary Risk Assessment

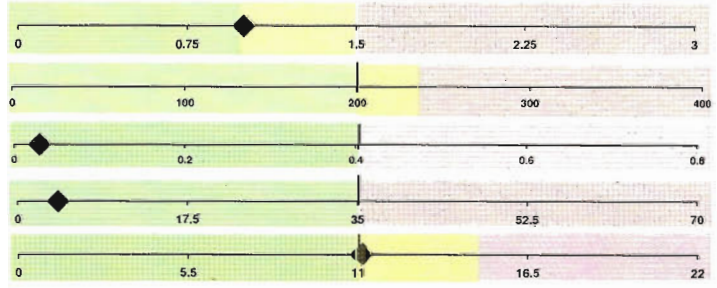
Direct Lipid Panel - Lipoprotein Particle Numbers in mg of Cholesterol Equivalents (CEQ) /dL

(may not be directly comparable to lipid values from other methods)



	Patient Results Values in (mg/dL)
Total Cholesterol - CEQ	260
LDL -CEQ [1]	175
HDL - CEQ [2]	60
Triglycerides	98

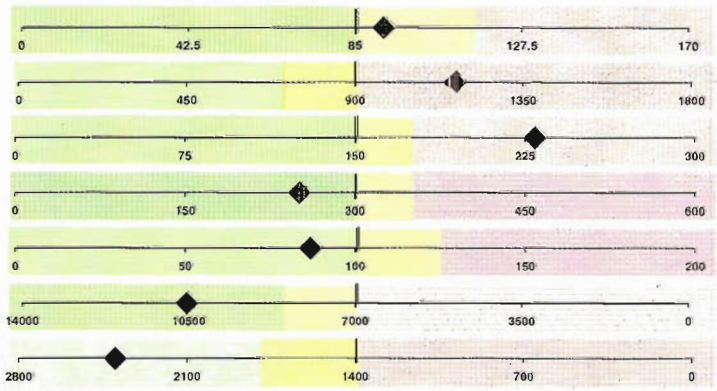
Risk Modification



Metabolic Syndrome Traits [4]	1.0
C-Reactive Protein-ss (mg/dL)	0.03
Insulin (µIU/mL)	4.2
Homocysteine (µmol/L)	11.1

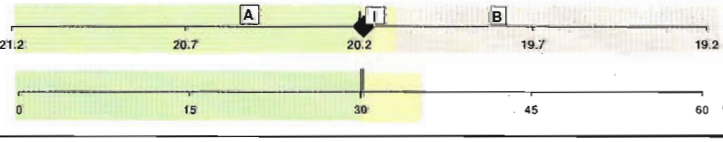
Therapeutic Approach Assessment

Lipoprotein Particle Numbers



	Values in (nmol/L)
VLDL	92
LDL Total [3]	1167
RLP (Remnant Lipoprotein)	230
Dense LDL III	251
Dense LDL IV	87
HDL Total [2]	10534
Buoyant HDL 2b [2]	2398

Additional Lipoprotein Risk Factors



LDL Phenotype / Size (nm)	Type I 20.19
Lp(a) (mg/dL) [5]	69.0

1. NCEP Goal for Low or Moderate Risk Patients is LDL < 130 mg/dL; for High Risk Patients is LDL < 100 mg/dL; for Very High Risk Patients is LDL < 70 mg/dL.
2. NCEP Goal for Males is HDL > 40 mg/dL (HDL particles > 7000 nmol/L) and HDL > 50 mg/dL (HDL particles > 8500 nmol/L) for Females.
   HDL2b Goal for Males is HDL2b> 1400 nmol/L and HDL2b > 1800 nmol/L for Females
3. LDL Particle Numbers Goals: Moderate Risk Patients <900 nmol/L; High Risk Patients < 700 nmol/L; Very High Risk Patients < 500 nmol/L
4. Metabolic Syndrome Diagnosis is Established with Three Traits. Add Metabolic Syndrome Traits above and Non-Lipid Traits:
   Abdominal Obesity > 40" M, 35" F; Elevated Blood Pressure >130/85 mm Hg; Fasting Glucose >100 mg/dL
5. Reference Value for Blacks is 50.0 mg/dL

SpectraCell Clinical Suggestions for Alert References

(1)	**Borderline High Total Cholesterol (200 < TC-CEQ <239):** Patient should be monitored closely with suggestions to improved diet and health regimen. Patients in this range with two or more risk factors or with pr[illegible]ing ischemic heart disease should be classified as "Hi[illegible]sk" and treated accordingly.
(2)	**High Total Cholesterol (TC-CEQ > 240):** Indicates hyperlipidemia requiring possible investigation or consideration as to causation, including secondary hyperlipidemia, other drugs therapies producing or aggravating hyperlipidemia, dietary factors, or genetic disorders. Diet and/or drug therapy should be considered in conjunction with patient's LDL and HDL values. TC values > 300 mg/dL suggest higher likelihood of genetic causation.
(3)	**Borderline to High LDL Cholesterol (100 < LDL-CEQ < 129):** Patients with no risk factors should be managed conservatively with possible suggestions of therapeutic lifestyle changes. Patients with 1 or more risk factors are recommended to initiate therapeutic lifestyle changes and/or drug therapy to lower LDL < 100 mg/dL. Very high risk patients with CHD or CHD equivalents are recommended to begin LDL-lowering drug therapy to lower LDL < 70 mg/dL.
(4)	**High LDL Cholesterol (130 < LDL-CEQ < 159):** With no risk factors, patients are recommended to initiate therapeutic lifestyle changes. Patients with 1 or more risk factors or who have attempted therapeutic lifestyle changes for 3 months without improvement are recommended to begin LDL-lowering drug therapy in conjunction with therapeutic lifestyle changes.
(5)	**Very High LDL Cholesterol (LDL-CEQ > 160):** According to NCEP guidelines, irrespective of risk factors or clinical history, patients are recommended to begin LDL-lowering drug therapy. Also consider genetic dyslipidemia disorders as causative factor. Diligent follow-up with lipoprotein profiles are suggested.
(6)	**Low HDL Cholesterol (Total HDL-CEQ <40):** Considered a risk factor according to NCEP clinical guidelines. Based on patient's LDL, therapeutic goal is LDL < 100 mg/dL. If patient's LDL > 100 mg/dL, therapeutic lifestyle changes are suggested. LDL lowering drug therapies are suggested as optional for patient with 100 < LDL < 130. Patient's with LDL > 130 mg/dL are suggested to be started on LDL lowering drug therapy. Suggested therapy is based on low HDL as a sole risk factor. Consider more aggressive therapy with 2 or more risk factors.
(7)	**Borderline to High Total Triglycerides (150 < TG < 199):** Recommended therapy by NCEP guidelines should be focused on diet, weight reduction and increased physical activity. Diligent follow-up recommended based on clinical presentation.
(8)	**High Triglycerides (200 < TG < 499):** According to NCEP guidelines, LDL becomes a target of therapy. Patients with 0-1 risk factors are recommended to target LDL cholesterol concentration of < 130 mg/dL. Patients with 2+ risk factors are recommended to target LDL cholesterol < 100 mg/dL. Patients with CHD or CHD equivalents are recommended to target LDL < 70 mg/dL. Initiation of therapeutic lifestyle changes and/or LDL-lowering drug, nicotinic acid or fibrate therapy should be considered in view of scale and target LDL adjustment.
(9)	**Very High Triglycerides (TG > 500):** Recommended to consider genetic disorder as causation in patients. Initial aim of therapy is recommended to prevent acute pancreatitis with low fat diet, weight reduction, increased physical activity, and a triglyceride lowering agent (nicotinic acid, fibrate or omega-3 fatty acids). Upon reduction of TG < 500 mg/dL, NCEP guidelines recommend initiation of secondary aim of LDL reduction through therapeutic lifestyle changes and/or LDL-lowering drug therapy.
(10)	**Metabolic Syndrome Diagnosis is Established with Three Traits.** Add Metabolic Syndrome Traits and Non-Lipid Traits: Abdominal Obesity, > 40" M, 35" F; Elevated Blood Pressure >130/85 mm Hg; Fasting Glucose >100 mg/dL. A Metabolic Syndrome Diagnosis raises the LDL treatment level to High Risk with an NCEP goal of LDL <100 mg/dL or particle numbers of <700 nmol/L. This goal can be achieved through diet and exercise and/or drug treatment. Metabolic Syndrome is associated with insulin resistance.
(11)	**High Lp-PLA2. (200 to 235 borderline, > 235 high):** Is associated with a two fold increased cardiovascular risk and vascular inflammation.
(12)	**C - Reactive Protein.** An inflammation risk factor that in combination with high Lp-PLA2 is a four fold increase in CVD risk.
(13)	**High Insulin. (Insulin > 35.0):** High fasting insulin is associated with increased cardiovascular risk and/or metabolic syndrome.
(14)	**Homocysteine.** A coagulation and inflammation risk factor that should be considered in addition to lipid risk factors.
(15)	**High VLDL Particle Number (VLDL > 115 nmol/L):** No reported clinical guidance by NCEP, however this correlates to triglyceride values of over 200 mg/dL, high RLP and possible metabolic syndrome.
(16)	**Borderline, High to Very High LDL Particle Number (LDL > 700, 900, 1100 nmol/L):** Patients with 2 or more risk factors are recommended to initiate therapeutic lifestyle changes and/or drug therapy to lower LDL < 900nmol/L. Patients with CHD or CHD equivalents are recommended to begin LDL-lowering drug therapy to LDL <700nmol/L. All patients with LDL particle numbers greater than 1100 nmol/l are recommended to be treated aggressively. The LDL particle number is the single most important value to assess cardiovascular risk.
(17)	**High Remnant Lipoprotein Particle Number (RLP >150 nmol/L):** RLP greater than 150 nmol/L indicates an above average RLP condition of this very atherogenic lipoprotein. This new NCEP risk factor has been shown to be highly correlated with CHD and should be monitored along with other risk factors during life style and/or drug treatment. Omega-3 fatty acids have been shown to reduce triglycerides and RLP.
(18)	**Borderline to High LDL III Particle Number (LDL III>300, 350 nmol/L):** Is above a safe level for this NCEP new risk factor. Patients with no risk factors should be managed conservatively with possible suggestions of therapeutic lifestyle changes. Patients with 2 or more risk factors are recommended to initiate therapeutic lifestyle changes and/or drug therapy to lower LDL < 700nmol/L. Patients with CHD or CHD equivalents are recommended to begin LDL-lowering drug therapy. All patients with LDL particle numbers greater than 1100 nmol/l are recommended to be treated aggressively. The LDL particle number is the single most important value to assess cardiovascular risk.
(19)	**Risk Factor for LDL IV (LDL IV> 100 nmol/L):** Is above a safe level for this new NCEP risk factor. Lp(a) is found typically between d=1.05 and d=1.08 and often is located in the range for LDL IV. Treatment for high LDL IV and Lp(a) are very similar, typically niacin and aggressive LDL treatment.
(20)	**Low HDL particle count <7000 nmol/L, 7000 - 8500 nmol/L is Borderline for Males and Low for Females:** Considered a risk factor according to NCEP clinical guidelines. Based on patient's LDL, therapeutic goal is LDL < 900 nmol/L. If patient's LDL > 900 nmol/L, therapeutic lifestyle changes are suggested. LDL lowering drug therapies are suggested as optional for patient with 900 nmol/L < LDL < 1100 nmol/L. Patient's with LDL > 1100 nmol/L are suggested to be started on LDL lowering drug therapy. Suggested therapy is based on low HDL as a sole risk factor. Consider more aggressive therapy with 2 or more risk factors.
(21)	**Risk Factor for HDL2b between 1400 and 1800 nmol/L is borderline for males and risk factor for females. Values less than 1400 is a risk factor for males:** Indicates that the HDL reverse transport system is not working well to remove excess cholesterol.
(22)	**Optimal HDL2b more than 1800 nmol/L for males and 2200 nmol/L for females:** Indicates that the HDL reverse transport is working effectively.
(23)	**Large LDL Type A (20.20 nm < LDL):** Seen as large/buoyant LDL, the least harmful LDL subfraction. Patient management should be directed towards recommended guidelines for total LDL management.
(24)	**Intermediate LDL Type I (20.10 < LDL <20.20 nm):** Patient management should be directed towards recommended guidelines for total LDL management, focusing on shifting patient overall LDL size/density to Type A.
(25)	**Small LDL Type B (LDL < 20.10 nm):** Small/dense Type B LDL. Patient management should be directed toward recommended guidelines for total LDL management, focusing on shifting patient overall LDL size/density to Type A. Many people with coronary heart disease have phenotype Type B and a high percentage of small LDL. Depending on other risk factors drug treatment and/or life style changes may be recommended. Use the LDL size as a guide as to the severity of the Type B designation. Check for Metabolic Syndrome.
(26)	**High Lp(a). (Lp(a) >30.0):** Lp(a) is highly associated with cardiovascular disease in studies. Lp(a) is an inherited trait and does not respond to diet, exercise or statin drugs. Treatment for high Lp(a) is typically niacin and aggressive LDL treatment. Lp(a) is a prothromobtic lipoprotein

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Report Date: 9/2/09 11:21 AM

Name:

Draw Date: August 27, 2009 DOB: November 19, 1956

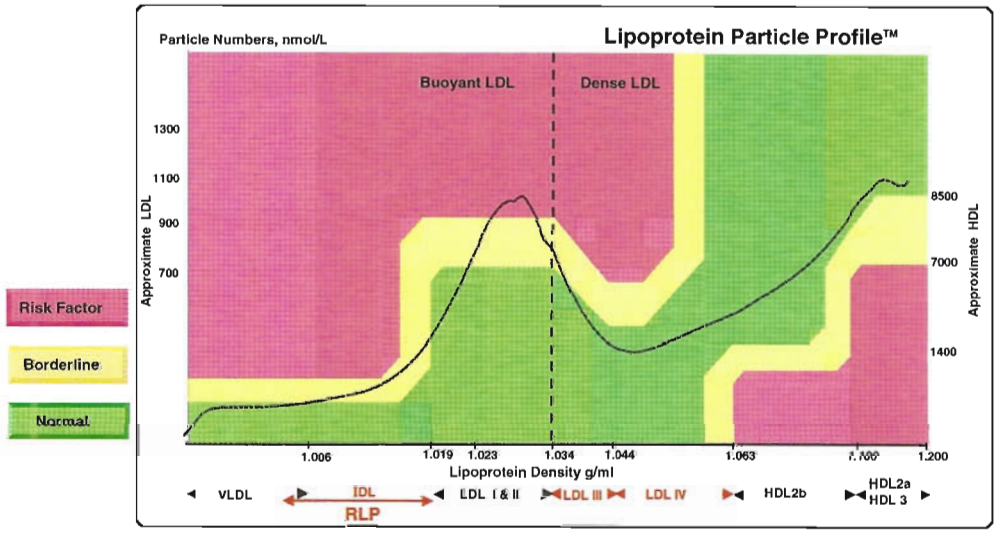
Primary Risk Assessment

Direct Lipid Panel - Lipoprotein Particle Numbers in mg of Cholesterol Equivalents (CEQ) /dL

(may not be directly comparable to lipid values from other methods)

	Value	NCEP Value	Alert (Notes Page 3)
Total Cholesterol - CEQ	260	<200	High (2)
LDL - CEQ	175	<130 [1]	Very High (5)
HDL - CEQ	60	>40 [2]	Health Factor
Triglycerides (mg/dL)	98	<150	

Results for serum Total Cholesterol, LDL and HDL as measured in mg/dL may be different than results for Total Cholesterol, LDL and HDL as measured in mg of cholesterol equivalents/dL. Cholesterol equivalent results depend on the particle number and the cholesterol saturation of the lipoprotein particles.



Risk Modification

	Value	Reference Value	Alert (Notes Page 3)
Metabolic Syndrome Traits	1.0	0 to 3 [4]	Possible (10)
C-Reactive Protein-ss (mg/dL)	0.03	<0.40	
Insulin (uIU/mL)	4.2	<35.0	
Homocysteine (umol/L)	11.1	<11.0	Borderline High (14)

Therapeutic Approach Assessment

Lipoprotein Particle Numbers (nmol/L)

	Value	Reference Value	Alert (Notes Page 3)
VLDL	92	<85	Borderline High (15)
LDL Total	1167	<900 [3]	Very High (16)
RLP (Remnant Lipoprotein)	230	<150	High (17)
Dense LDL III	251	<300	
Dense LDL IV	87	<100	
HDL Total	10534	>7000 [2]	Health Factor
Buoyant HDL 2b	2398	>1400 [2]	Health Factor (22)

Additional Lipoprotein Risk Factors

	Value	Reference Value	Alert / Phenotype
LDL Mean Size (nm) / Phenotype	20.19	>20.20	Intermediate LDL, Type I (24)
Lp(a) (mg/dL)	69.0	<30.0 [5]	High (26)

1. The NCEP Goal for Low or Moderate Risk Patients is LDL < 130 mg/dL; for High Risk Patients is LDL < 100 mg/dL; for Very High Risk Patients is LDL < 70 mg/dL.
2. The NCEP Goal for Males is HDL > 40 mg/dL (HDL particles > 7000 nmol/L) and HDL > 50 mg/dL (HDL particles > 8500 nmol/L) for Females. The HDL2b Goal for Males is HDL2b> 1400 nmol/L and HDL2b > 1800 nmol/L for Females
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5. Reference Value for Blacks is 50.0 mg/dL

LPP Lipoprotein Particle Profile™

ADVANCED TESTING FOR CARDIOVASCULAR RISK

Lipoprotein Particle Testing - Therapeutic Guidelines

Lipoprotein Abnormality	Lifestyle Changes (diet & exercise)	Statins	Niacin	Fibrates	Oral Estrogens	Resins	Absorption Inhibitors	Omega-3's EPA & DHA	Alcohol (moderate)
VLDL (Triglycerides)	♥	♥	♥♥	♥♥	✕	✕	♥	♥♥	■
RLP (IDL)	♥	♥	♥	♥	✕	✕	♥	♥♥ **	■
LDL I & II Buoyant	♥	♥♥	♥	♥	♥	♥	♥	♥ **	■
LDL III - Dense	♥	♥**	♥♥	♥	♥♥	♥	♥	■	■
LDL IV - or Lp(a)	■	■	♥♥	■	♥	■	■	■	■
HDL 2b - Buoyant	♥♥	♥	♥	♥	♥	■	■	■	♥
HDL 2a & 3	♥	♥	♥♥	♥	♥	■	■	■	♥

♥♥ Therapeutic ♥ Beneficial ■ Little or No Effect ✕ Negative Effect

*These guidelines provide some of the treatment options available to modify abnormal lipoprotein results determined by the LPP™ test.

**SpectraCell Laboratories observed response to treatment.

The National Cholesterol Education Program (NCEP) guidelines provide dosage information on the treatment options.

REFERENCES AVAILABLE ON REVERSE