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Boston Heart Diagnostics

Luke G. Nelligan D.O.

January 22, 2016

A History of Scientific Research and Discoveries

Dr. Asztalos

Dr. Schaefer

Boston Heart develops proprietary Boston Heart Fatty Acid Balance™ test, and the NEW Diagnostic Report

Clinical trials: lowering LDL-C alone leaves substantial “residual” risk

Drs. Asztalos and Schaefer: α-1 HDL has significant inverse association with coronary artery stenosis

1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2013 2014

Dr. Asztalos: characterizes HDL subclasses

Drs. Asztalos and Schaefer: patients with established CVD have significantly different HDL subpopulation profiles than controls

Boston Heart forms and develops exclusive offerings:

- Boston Heart HDL Map®
- Boston Heart Cholesterol Balance®
- Boston Heart Navigator®

Boston Heart develops its Lifestyle Program, proprietary Boston Heart Prediabetes Assessment™ and gains exclusive rights to conduct the Boston Heart Statin Induced Myopathy (SLCO1B1) Genotype test in the U.S.

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Agenda

CLINICAL UPDATE

Addressing Challenges in CVD Risk Reduction

BOSTON HEART DIAGNOSTICS

Testing Beyond the Primary Drivers of Atherosclerosis

PATIENT CASE STUDIES

Diagnostic Testing Leads to CVD Risk Assessment and Patient Management

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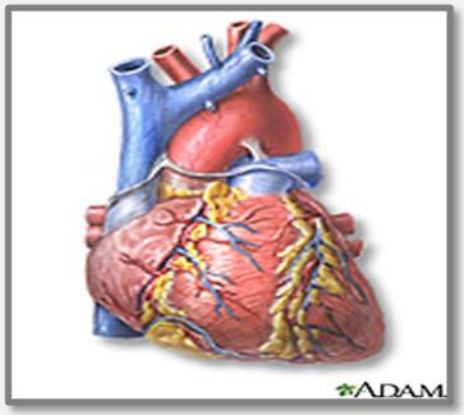
The Challenge

Improvement in CVD Risk Reduction Is Needed Despite Advances

- Cardiovascular disease (CVD) is the leading cause of death in U.S., despite guideline-driven care[1]
- Recent decline in CVD death rate, but CVD still accounts for 33% of all deaths[2]
- Total CVD healthcare costs in 2011 were $320.1 billion, projected to be $918 billion by 2030[2]
- 50% of people who have had a heart attack have normal LDL cholesterol[3]



1.Mozaffarian D, Benjamin EJ, Go AS et al. *Circulation. 2015;131:e129.*
2.Mozaffarian D, Benjamin EJ, Go AS et al. *Circulation. 2015;131:e4-5,e282.*
3.Sachdeva et al. *Am Heart J. 2009;157:111-117.e2*
http://www.nlm.nih.gov/medlineplus/images/heart.jpg

Addressing Challenges in CVD Risk Reduction

Guidelines Evolving

Slowly With A Narrow Focus

NCEP ATP I 1988[1]
- Exclusive focus on LDL-C reduction
- Strong

NCEP ATP II 1993[2]
- Risk assessmen

NCEP ATP III 2001[3]
- Lower LDL-C

NCEP ATP III 2004[4]
- LDL-C optional goal of <70 mg/dL in very hi

Low- to moderate-dose statin monotherapy

Moderate- to high-dose statin

Moderate- to high-dose statin

High-dose statin, increased use of combination therapy

- Statins, fibrates not first-line

t guides therapy
- LDL-C goal

threshold for therapy initiation in

(i.e., C plus multiple risk factors, especially

mg/dL)
- Statins included in

reduction to <100

drugs, fibrates for

mg/dL in patients with CHD

1. Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. *Arch Intern Med. 1988;148:36-69.*
2. Summary of the second report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). *JAMA. 1993;269:3015-3023.*
3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *JAMA. 2001;285(19):2486-2497.*
4. Grundy SM et al. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. *Circulation. 2004;110:227-239.*

ACC/AHA Cholesterol Guidelines 2013

Overview

Lifestyle Modification is foundation of ASCVD risk reduction.

RCTs have no evidence to support specific LDL-C and non-HDL-C targets.

Appropriate intensity of statin should be used to reduce ASCVD risk.

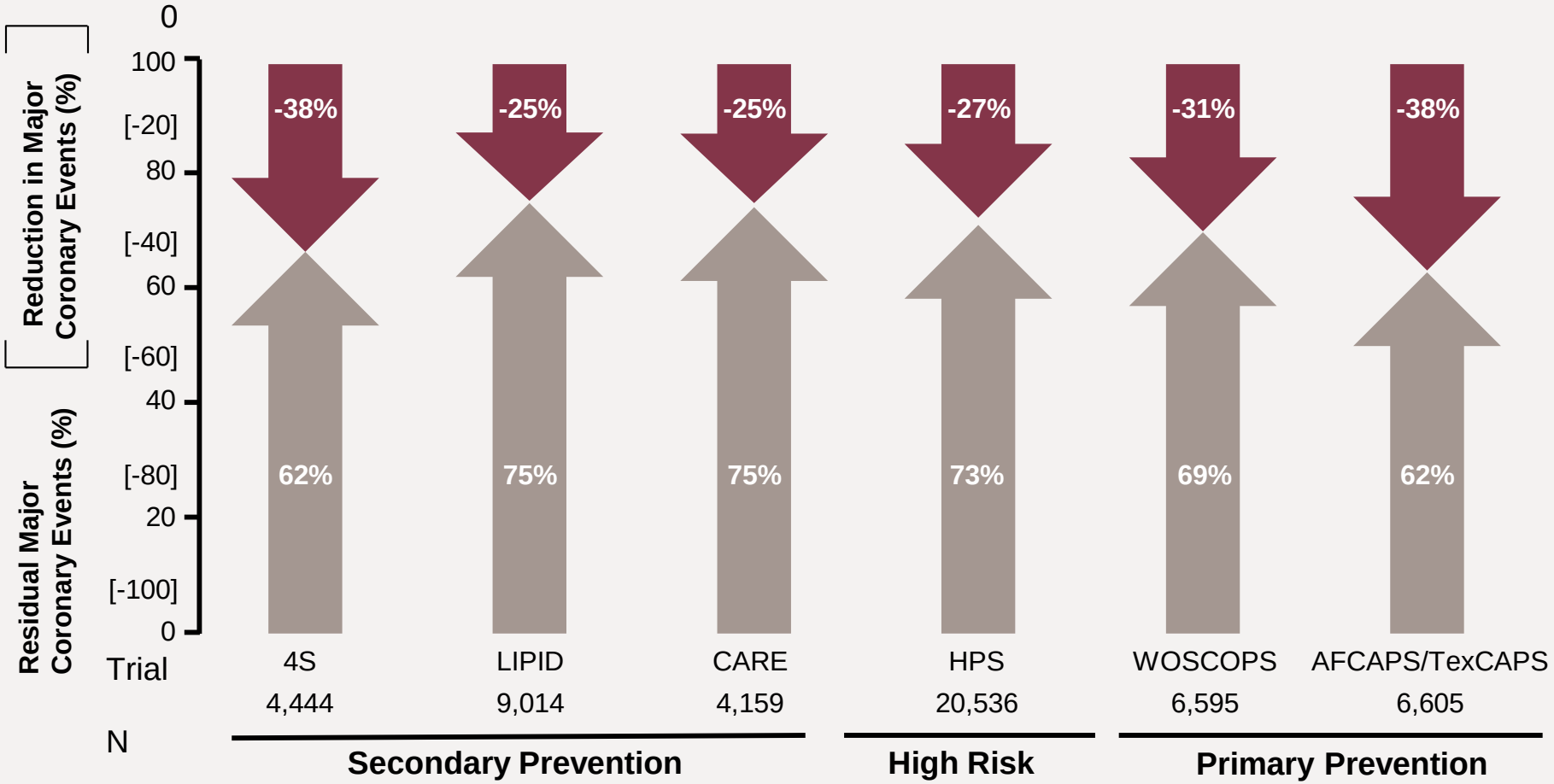
Higher risk individuals are more likely to benefit from therapy.

Use of CV Risk Calculator recommended to assess 10 year ASCVD risk.

Non statin therapies do not provide acceptable risk reduction compared to potential risk.

Treatment decisions in selected individuals who are not included in the four major statin benefit groups may be informed by other factors as recommended by the Risk Assessment

Majority of Residual Risk for Cardiovascular Events Remains Despite LDL-C Lowering Therapy



Adapted from Libby P. The forgotten majority: unfinished business in cardiovascular risk reduction. *J Am Coll Cardiol*. 2005;46(7):1225-1228.

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Using Traditional Cholesterol Testing to Identify and Treat CVD Risk is Not Enough

- Clinical trials have identified additional tests—not found on a routine lipid panel—that identify CVD risk[1-3]
- Advanced CVD risk markers are needed to identify underlying disorders that contribute to the 70-75% residual risk

Traditional testing is only the tip of the iceberg

Better diagnostic methods needed to identify residual CVD risk

1. Asztalos et al. *Arterioscler Thromb Vasc Biol. 2004;24(11):2181-2187.*
2. Asztalos et al. *Arterioscler Thromb Vasc Biol. 2005;25(10):2185-2191.*
3. Lamon-Fava et al. *Arterioscler Thromb Vasc Biol. 2008;28(3):575-579*

CVD Risk and Prediction of Events Over Time

Over 10 years CVD Risk
- Increased age
- Hypertension
- Diabetes
- Smoking

Over Six months CVD Risk
- hsCRP > 3.0 mg/L
- $LpPLA_2$ > 235 ng/mL
- MPO > 633 pmol/L
- Fibrinogen

Recent Myocardial Damage
- Elevated Troponin T or Troponin I
- Elevated Creatine kinase-MB

Reducing Individual Risk, One Heart at a Time

Exclusive tests and Lifestyle Program only available at Boston Heart

Boston Heart HDL Map®

Boston Heart HDL Map™ Tests[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk	HDL Particles	Optimal Male HDL Map	Patient's HDL Map
α-1			9.1			
Range	>20	14-20	<14 mg/dL			
α-2		45.3				
Range	>55	45-55	<45 mg/dL			
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Range	<15	15-18	>18 mg/dL			
Preß-1		14.6				
Range	<10	10-15	>15 mg/dL			

Boston Heart Prediabetes Assessment™

Boston Heart Prediabetes Assessment™

Low | Borderline | High Risk

0% 10% 20% 100%

Interpretation: HIGH (56.7%) or (8.0) times normal risk of developing diabetes within 10 years. Recommend diet and exercise program, and consider metformin.

Boston Heart Cholesterol Balance®

Boston Heart Cholesterol Balance™ Test[1]

Normalized Value (µmol x 100/mmol of Total Cholesterol)

		Optimal	Borderline	High
Production Markers				
Lathosterol	76	0	90	160
Desmosterol	76	0	70	90
Absorption Markers				
Beta-Sitosterol	225	0	100	180
Campesterol	357	0	150	260

OPTIMAL

HIGH

Cholesterol Balance Score		Over Absorber		Over Producer
Production/Absorption	0.3	0.2	0.5	1.1

Boston Heart Statin Induced Myopathy (SLCO1B1) Genotype

Genetic Tests by Genotyping [1,4]

Statin Induced Myopathy (SLCO1B1) Date of Service: 03/19/2013

T/C

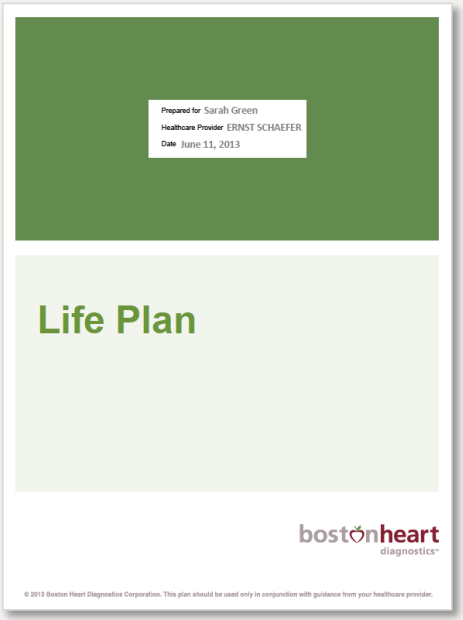
Interpretation: · (T/C) genotype – decreased statin metabolizer
· Increased risk of statin induced myopathy

Boston Heart Fatty Acid Balance™

Boston Heart Fatty Acid Balance™ Test[1]

	Optimal	Borderline	High Risk
Saturated FA Index			34.5
Range	<30.0	30.0-32.0	>32.0 %
Trans FA Index	0.27		
Range	<0.80	0.80–1.10	>1.10 %
	Optimal	Borderline	Low
Monounsaturated FA Index	30.8		
Range	>22.0	19.0–22.0	<19.0 %
Unsaturated/Saturated Ratio Index			1.88
Range	>2.25	2.00–2.25	<2.00
Omega-3 FA Index			1.81
Range	>4.50	1.85–4.50	<1.85 %
EPA		28.7	
Range	>50.0	10.0–50.0	<10.0 µg/mL
DHA		56.5	
Range	>100.0	45.0–100.0	<45.0 µg/mL
ALA		19.3	
Range	>30.0	12.0–30.0	12.0 µg/mL
	Low	Mid	High
Omega-6 FA Index	31.6		
Range	<41.0	41.0–46.0	>46.0 %
Linoleic Acid (LA)		1003.7	
Range	<825.0	825–1040	>1040 µg/mL
Arachidonic Acid (AA)			344.4
Range	<220	220–290	>290 µg/mL
AA/EPA Ratio Index	12.0		
Range	<13.0	13.0–25.0	>25.0
Omega-6/Omega-3 Ratio Index	14.22		
Range	<15.0	15.0–24.0	>24.0

Boston Heart Lifestyle Program



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Boston Heart Comprehensive Menu

Boston Heart offers comprehensive CVD risk testing, including **but not limited to**:

Lipids	Inflammation	Genetics	Metabolics
• Boston Heart HDL Map • Boston Heart Cholesterol Balance • ApoA-1 • ApoB • Direct LDL-C • HDL-C • sdLDL-C • Lp(a) • Total Cholesterol • Triglycerides • VLDL-C	• MPO • hs-CRP • Fibrinogen • $LpPLA_2$	• Boston Heart Statin Induced Myopathy (SLCO1B1) Genotype Test • Clopidogrel -- CYP2C19 • ApoE • Prothrombin (Factor II) • Factor V Leiden • MTHFR	• Boston Heart Prediabetes Assessment • Boston Heart Fatty Acid Balance • Adiponectin • Glucose • GSP • HbA1C • Insulin • Insulin Resistance
Sex Hormones, Thyroid, Liver, Kidney, Muscle			

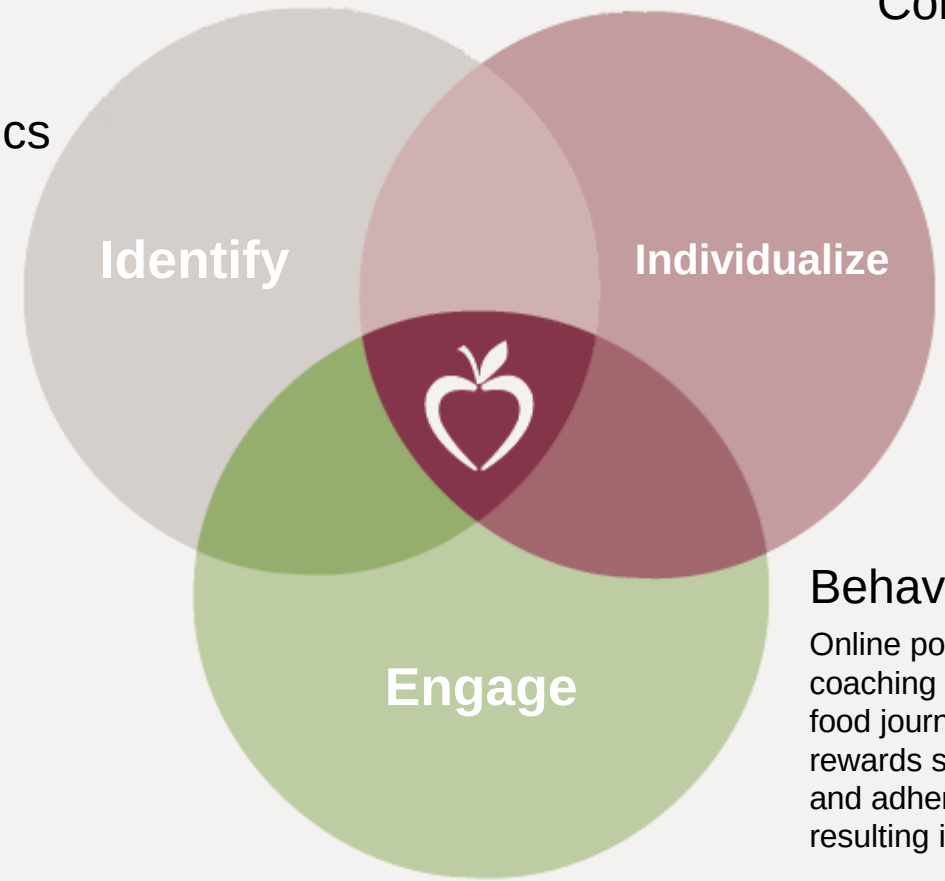
Integrating Next Generation CVD Diagnostic Solutions into Your Practice

Offering a Differentiated Cardiovascular Condition Management Approach

Boston Heart's integrated programs leverage diagnostic results with high clinical utility to address lifestyle factors that impact risk and patient adherence

Best-In-Class Diagnostics

A comprehensive yet focused panel of blood-based diagnostics to identify and stratify at-risk patients



Comprehensive Treatment & Communication Plans

Integrated diagnostics drive optimized therapeutic regimens and easy-to-understand, personalized therapy and nutrition plans for patients that raise health literacy and drive action

Behavior Modification

Online portal with education and coaching from registered dietitians, food journaling and incentive and rewards systems to drive compliance and adherence to treatment plans resulting in improved health outcomes

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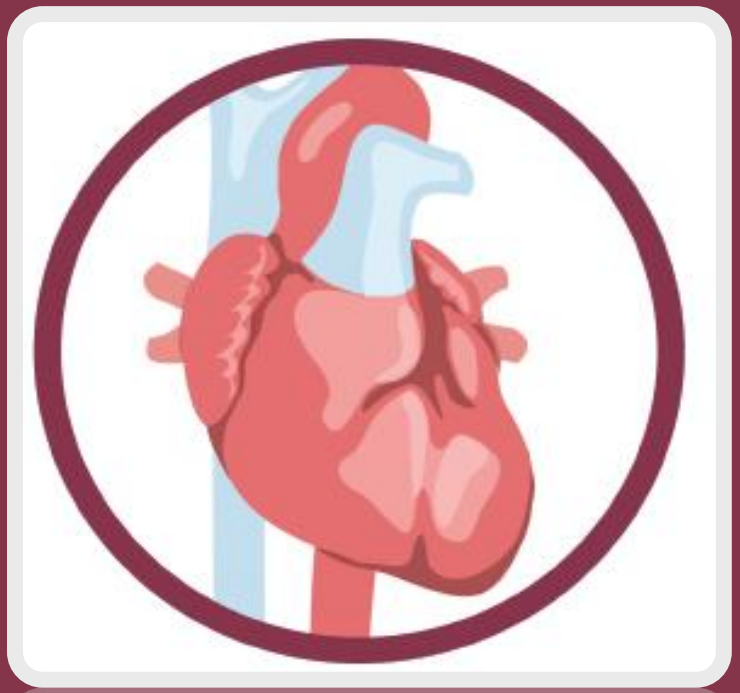
Four Parts of Heart Disease Testing at Boston Heart

What is your patient's risk for heart disease?



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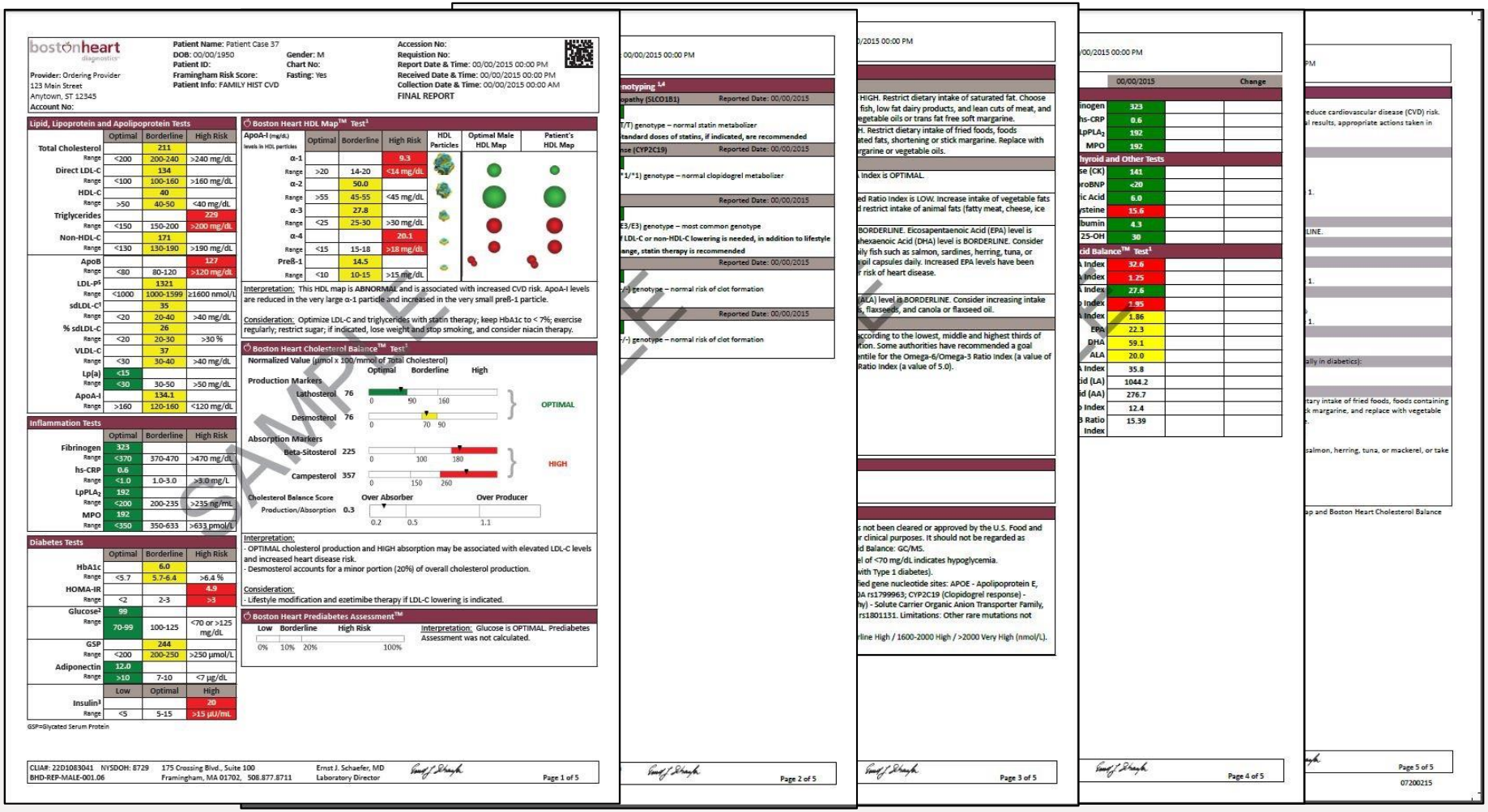
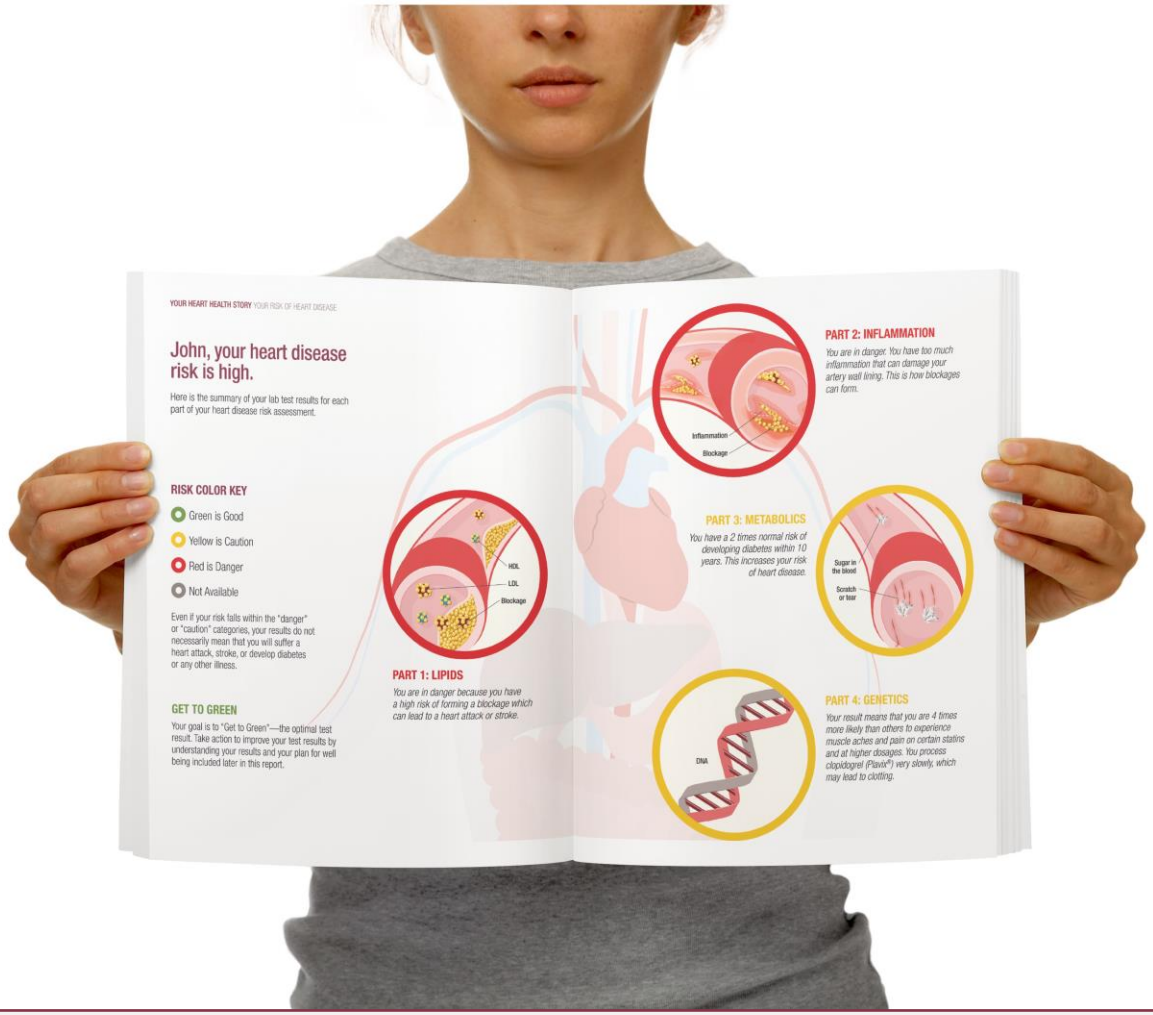
Boston Heart Laboratory Report

Heart, John (PID: 99999)



Diagnostic Report for the Patient



John Heart's Clinical Information

Heart, John (PID: 99999)

65 year old white male, 5'10", 179 lbs

Medical hx:

- Headaches, gastro-esophageal reflux disease, smoker, low back muscle spasms w/pain

Medications:

- Antacid, omega 3/fish oil

Social hx:

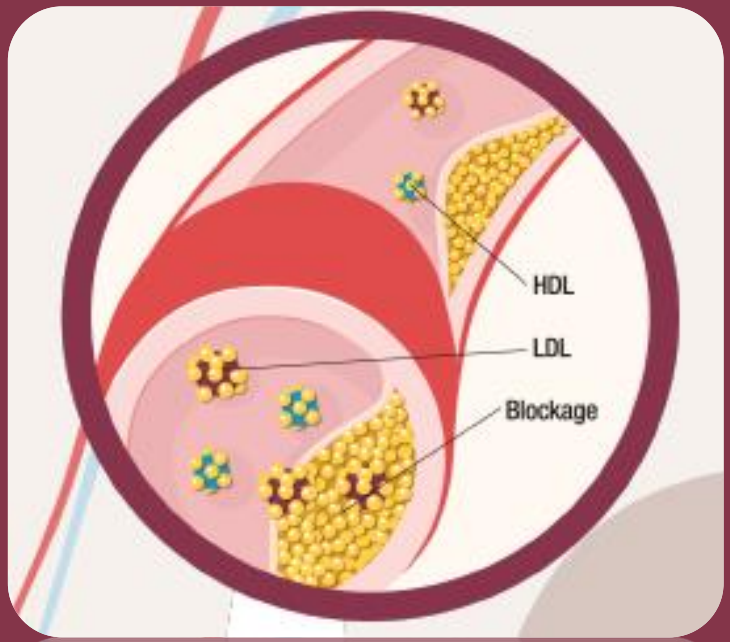
- Smokes < 1pack per day (E-cigs), rare liquor use, works as a distance truck driver

Family hx: None available

Image courtesy of imagerymajestic at FreeDigitalPhotos.net

Part 1: Lipids

Are your patients at risk of forming blockages?



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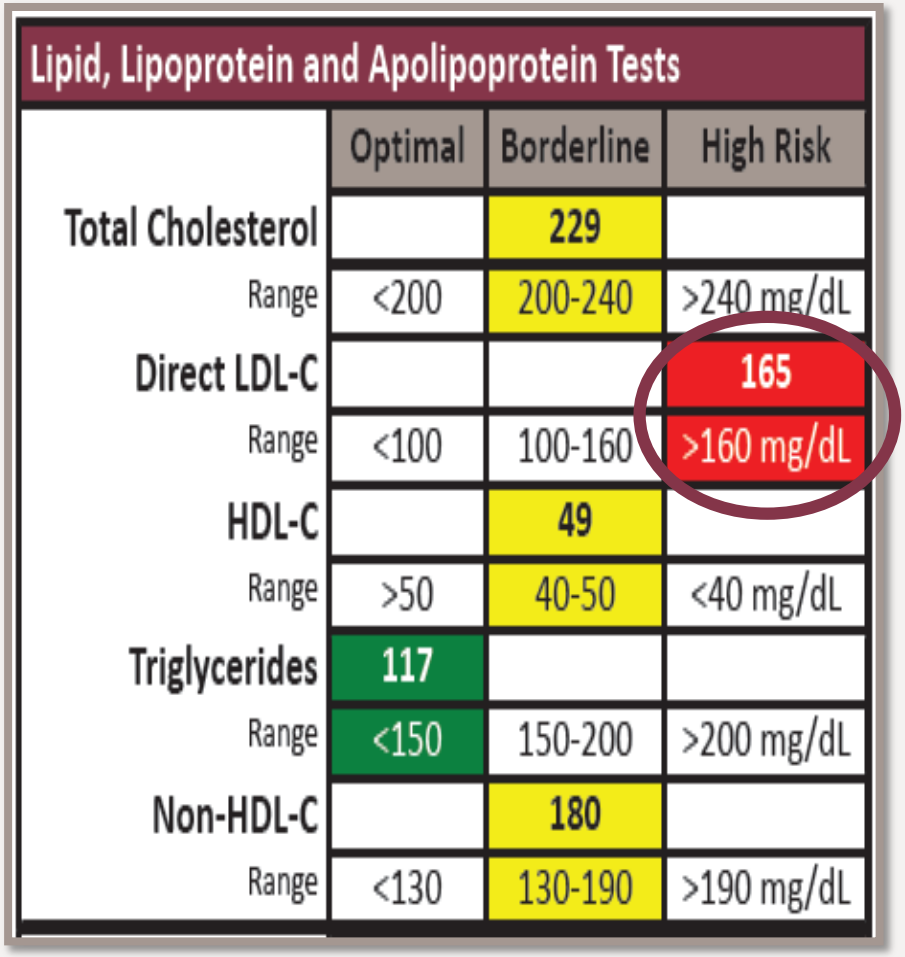
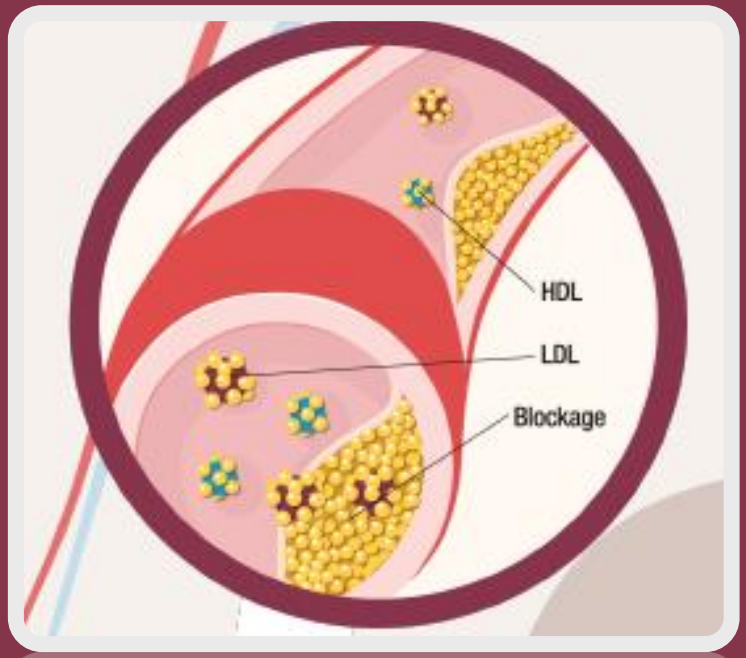
The Routine Lipid Panel

- When is treatment absolutely necessary?
- Does John need treatment with only 1 high and 3 borderline risk markers without a history of heart disease?



Lipid, Lipoprotein and Apolipoprotein Tests			
	Optimal	Borderline	High Risk
Total Cholesterol		229	
Range	<200	200-240	>240 mg/dL
Direct LDL-C			165
Range	<100	100-160	>160 mg/dL
HDL-C		49	
Range	>50	40-50	<40 mg/dL
Triglycerides	117		
Range	<150	150-200	>200 mg/dL
Non-HDL-C		180	
Range	<130	130-190	>190 mg/dL

Boston Heart HDL Map®



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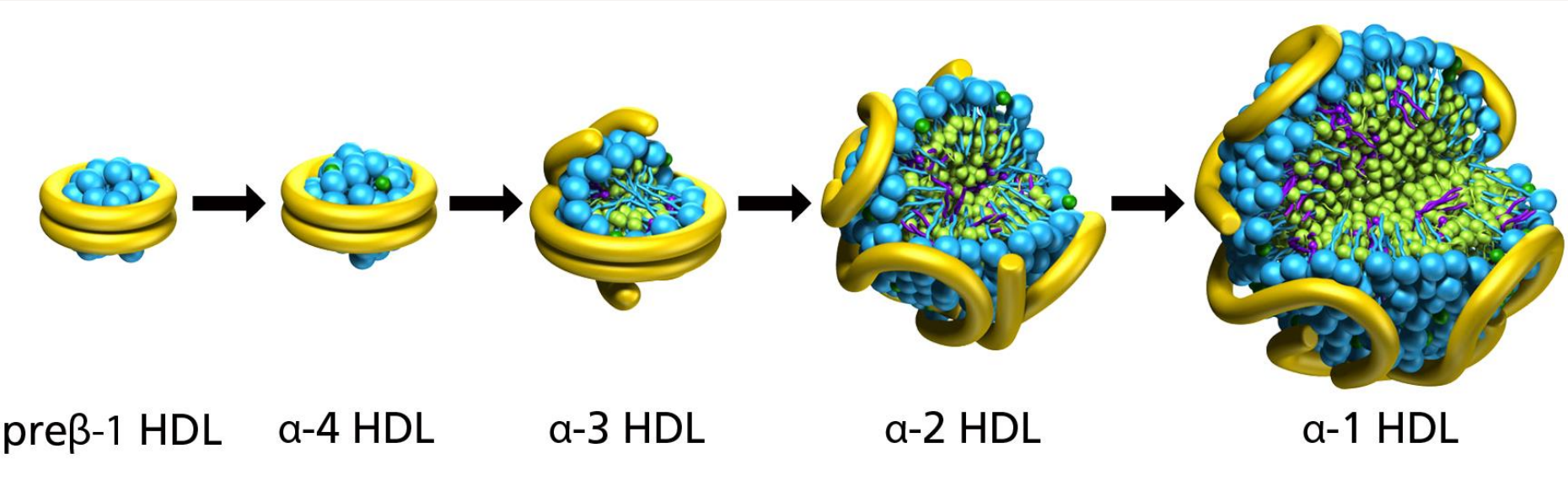
Boston Heart HDL Map

Definition

- Only test available that quantifies the amount of apoA-1 protein in each of the 5 HDL subclasses.



Boston Heart HDL Map

Definition

- Provides information to accurately identify patients at increased CVD risk.

Boston Heart HDL Map™ Tests[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk	HDL Particles	Optimal Male HDL Map	Patient's HDL Map
α-1			9.1			
Range	>20	14-20	<14 mg/dL			
α-2		45.3				
Range	>55	45-55	<45 mg/dL			
α-3			31.7			
Range	<25	25-30	>30 mg/dL			
α-4		16.2				
Range	<15	15-18	>18 mg/dL			
Preß-1		14.6				
Range	<10	10-15	>15 mg/dL			

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Boston Heart HDL Map

Clinical Significance

HDL subpopulations are better predictors of CVD risk than HDL-C[1]

Reference	Measure	Change	Endpoint	Associated Decrease in CVD/CHD Risk
Brown[1]	HDL-C	1% □increase	CVD	1%
	LDL-C	1% □decrease	CVD	1%
Asztalos[2]	**α-1 HDL particle**	**1 mg/dL increase**	**CHD**	**26%**
	HDL-C	1 mg/dL increase	CHD	2%

Low α-1 level is a significant predictor of recurrent CVD events[2].

1. Brown et al. *Curr Opin Lipidol*. 2006;17:631-636.
2. Asztalos et al. *Arterioscler Thromb Vasc Biol.* 2004;24(11):2181-2187.

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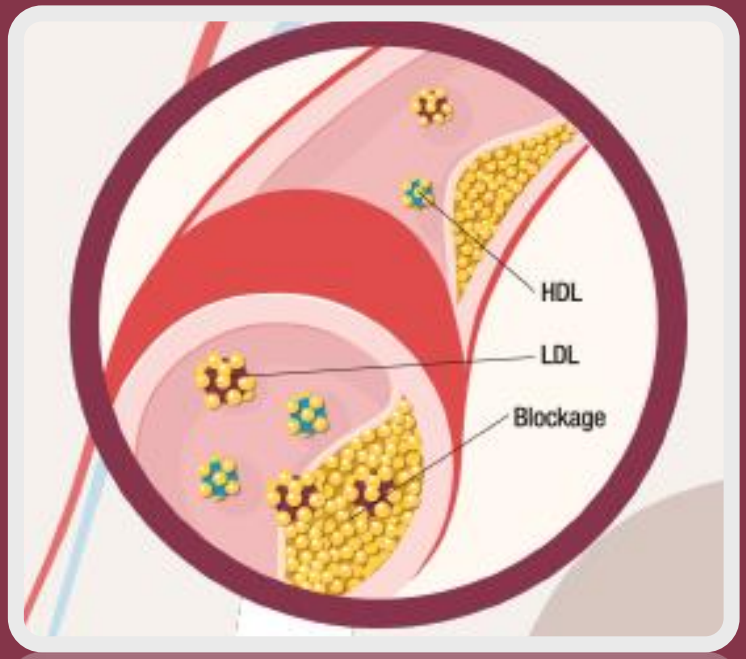
Impact of Treatments on Formation of HDL Subpopulations and Metabolism[1-5]

HDL Parameter	Niacin	Statins	Fibrates
HDL-C	↑ 20%-40%	↑ 2%-10%	↑4%-10%
apoA-I concentration	↑	—	—
α-1 particles	↑ up to 115%	↑12%-36%	Slight ↓
Preβ-1 particles	↓ up to 30%	↓ up to 40%	—
Metabolism	↑ ApoA-I production ↑ ABCA1 expression in liver	↓ CETP activity No Δ apoA-I kinetics	↑ gene expression of apoA-I, apo-II & LPL ↑apoA-I FCR

1.Lamon-Fava S et al. *Arterioscler Thromb Vasc Biol*.2008: 28;1672-1678.
2. Asztalos BF et al. *Arterioscler Thromb Vasc Biol*.2003:23;847-852.
3. Lamon-Fava S et al. *J Lipid Res* 2007;48:1746-53.
4. Asztalos B et al. *Atheroscler* 2002;164:361-9.
5. Asztalos BF et al *Am J Cardiol* 2007; 99: 681-685.
6. Watts G et al. *Diabetes Care* 2003;52:803-11.
7. Asztalos B et al. *Metabolism* 2008;57:77-83

Boston Heart Cholesterol Balance® Test



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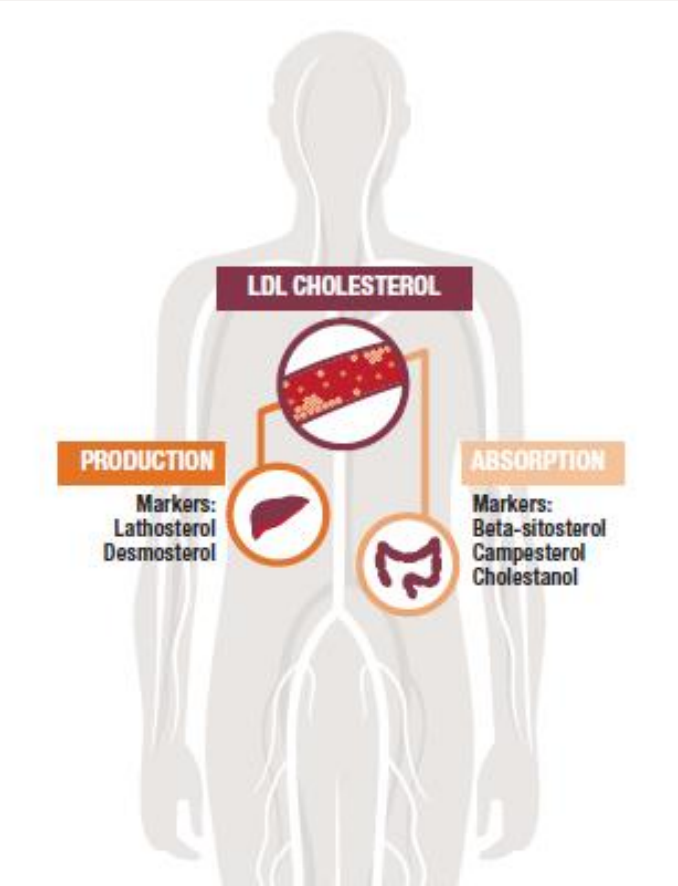
Plasma Cholesterol Levels

Reflects Production Absorption & Clearance[1]

Cholesterol is the Most Abundant Sterol in Plasma

Body cells and liver produce 75% of cholesterol in blood



Dietary intake contributes 25% of cholesterol in blood

1. Schaefer EJ. ed. *High Density Lipoproteins, Dyslipidemia, and Coronary Heart Disease*. New York, NY: Springer. 2010 :3.

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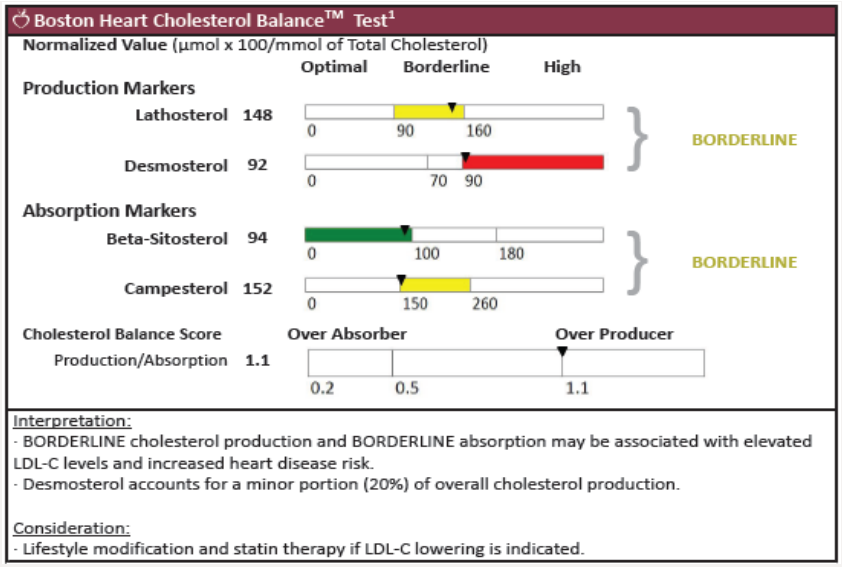
Boston Heart Cholesterol Balance

Clinical Significance

- Plasma lathosterol & desmosterol levels are markers of cholesterol production
- High lathosterol indicates cholesterol overproduction
  - Associated with higher LDL-C and increased CVD risk
- Elevated levels of plasma desmosterol associated with increased cholesterol production or decreased conversion of desmosterol to cholesterol.
- High campesterol and beta-sitosterol indicate cholesterol overabsorption
  - Associated with higher LDL-C and increased CVD risk



Ratio of normalized production markers to normalized absorption markers

Van Himbergen TM et al. *Arterioscler Thromb Vasc Biol* 2010;30:113-120.

Assmann G et al . *Nutrition, Metabolism & Cardiovascular Disease* 2006;16:13-21.

Miettinen TA et al. *Br Med J* 1998; 316:1127-30.

Matthan NB et al . *J Lipid Res* 2009;50:1927-1935.

Schaefer EJ (Ed.). 2010. *High Density Lipoproteins, Dyslipidemia, and Coronary Heartrt Disease*. New York:Springer, (p. 1-3)

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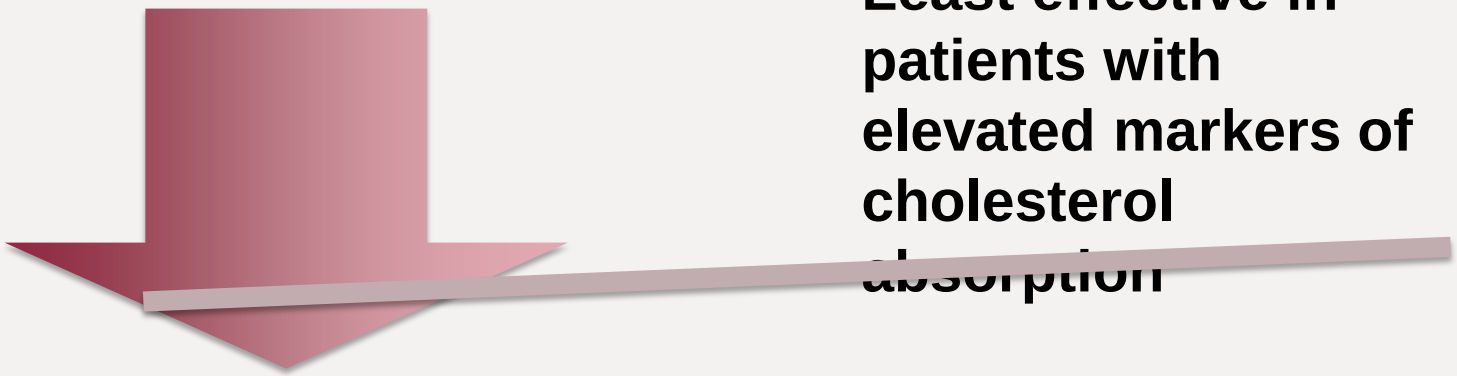
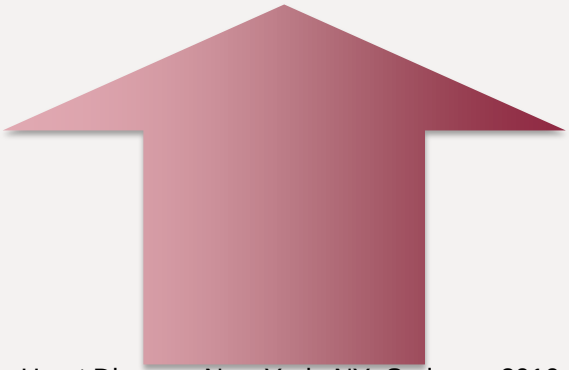
Boston Heart Cholesterol Balance

Maximal Effectiveness of Statin Therapy[1]



Beta-sitosterol & Campesterol
Least effective in patients with elevated markers of cholesterol absorption

Lathosterol & Demosterol
Most effective in patients with elevated markers of cholesterol production



1. Schaefer EJ, ed. High Density Lipoproteins, Dyslipidemia, and Coronary Heart Disease. New York, NY: Springer; 2010.

Beyond the Routine Lipid Panel…

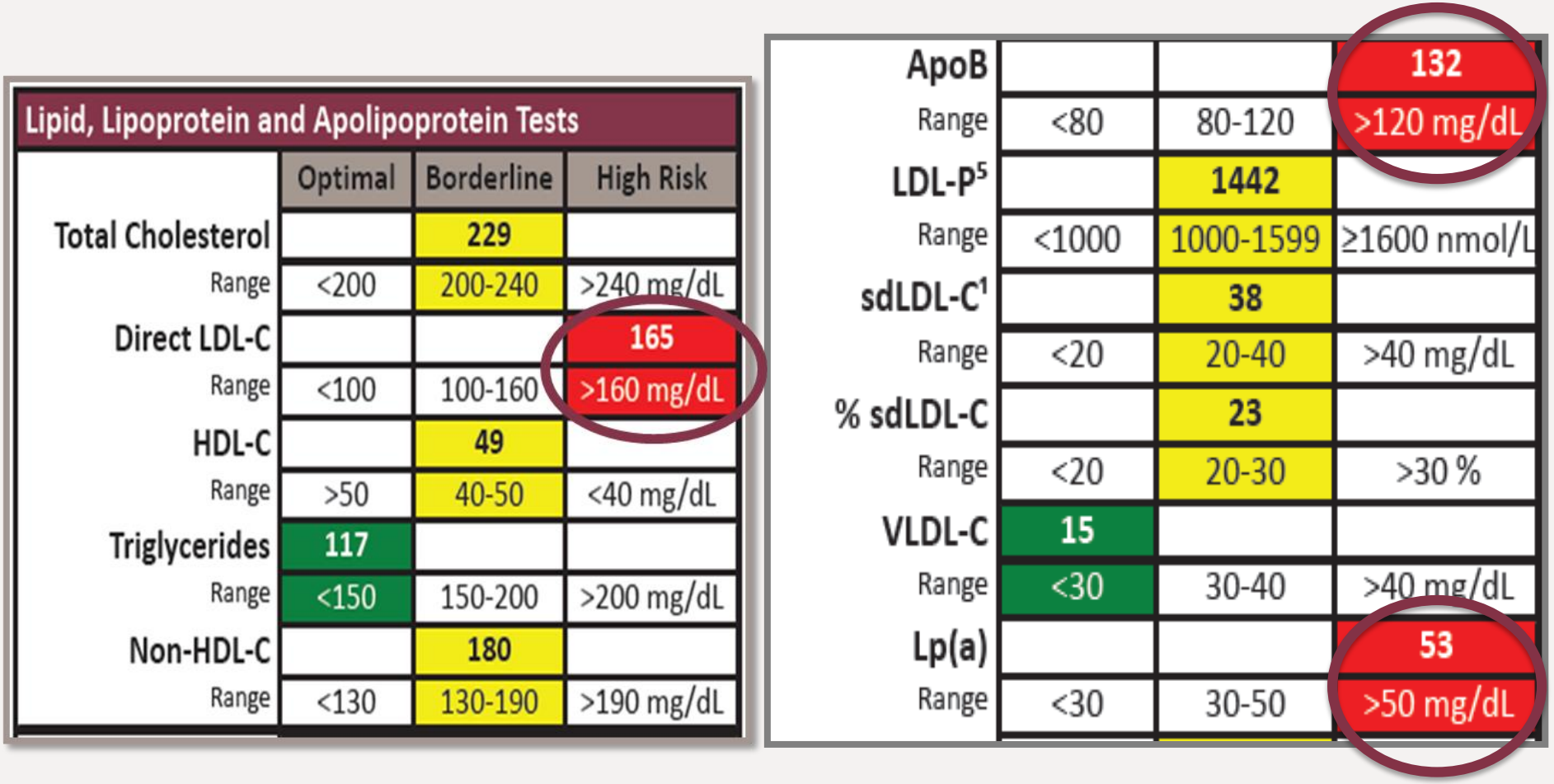
Tests Related to LDL-C

- Use Boston Heart tests with the routine lipid panel to assess risk of developing CVD
- Provides more information about John's level of risk to develop cardiovascular disease

John Heart's Results

ApoB			**132**
Range	<80	80-120	>120 mg/dL
LDL-P[3]		**1442**	
Range	<1000	1000-1599	≥1600 nmol/L
sdLDL-C[1]		**38**	
Range	<20	20-40	>40 mg/dL
% sdLDL-C		**23**	
Range	<20	20-30	>30 %
VLDL-C	**15**		
Range	<30	30-40	>40 mg/dL
Lp(a)			**53**
Range	<30	30-50	>50 mg/dL
ApoA-I		**141.6**	
Range	>160	120-160	<120 mg/dL

Using All LDL Related Lipid Tests



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Non-HDL-C		180	
Range	<130	130-190	>190 mg/dL
ApoB			132
Range	<80	80-120	>120 mg/dL
LDL-P[5]		1442	
Range	<1000	1000-1599	≥1600 nmol/L
sdLDL-C[1]		38	
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% sdLDL-C		23	
Range	<20	20-30	>30 %
VLDL-C	15		
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Lp(a)			53
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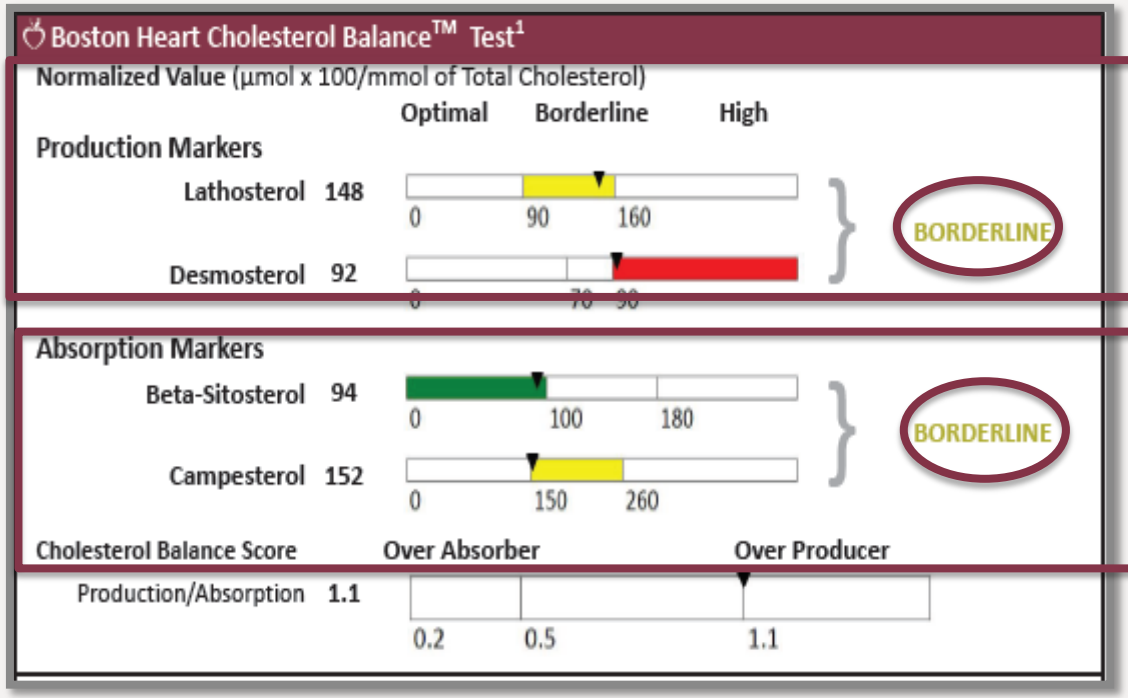
Boston Heart Cholesterol Balance

Helps Identify Source of High LDL-C



Production Markers

- Measure of cholesterol production by the liver
- Lathosterol & Desmosterol

Absorption Markers

- Measure of cholesterol absorbed from food
- Beta-sitosterol & Campesterol

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Beyond the Routine Lipid Panel…

Tests Related to HDL-C

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ApoA-I		141.6	
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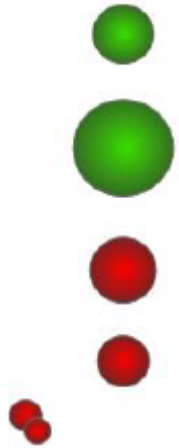
Boston Heart HDL Map

Boston Heart HDL Map™ Test[1]

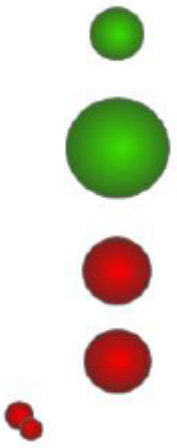
ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk
α-1		**15.9**	
Range	>20	14-20	<14 mg/dL
α-2	**58.9**		
Range	>55	45-55	<45 mg/dL
α-3		**26.0**	
Range	<25	25-30	>30 mg/dL
α-4			**24.7**
Range	<15	15-18	>18 mg/dL
Preß-1	**7.6**		
Range	<10	10-15	>15 mg/dL

HDL Particles

Optimal Male HDL Map



Patient's HDL Map



Interpretation: This HDL map is in the **BORDERLINE** CVD risk category based on ApoA-I levels in the very large α-1 particle.

Consideration: Optimize LDL-C and triglycerides; keep HbA1c to < 7%; exercise regularly; restrict sugar; if indicated, lose weight and stop smoking.

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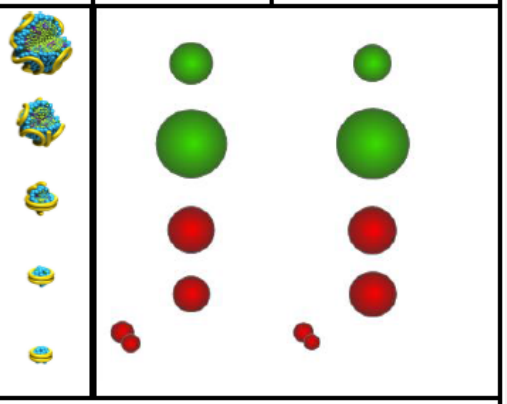
Using All HDL Related Lipid Tests

Lipid, Lipoprotein and Apolipoprotein Tests	Optimal	Borderline	High Risk
HDL-C		**49**	
Range	>50	40-50	<40 mg/dL
ApoA-I		**141.6**	
Range	>160	120-160	<120 mg/dL

Boston Heart HDL Map™ Test[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk
α-1		**15.9**	
Range	>20	14-20	<14 mg/dL
α-2	**58.9**		
Range	>55	45-55	<45 mg/dL
α-3		**26.0**	
Range	<25	25-30	>30 mg/dL
α-4			**24.7**
Range	<15	15-18	>18 mg/dL
Preß-1	**7.6**		
Range	<10	10-15	>15 mg/dL

HDL Particles | Optimal Male HDL Map | Patient's HDL Map



Interpretation: This HDL map is in the **BORDERLINE** CVD risk category based on ApoA-I levels in the very large α-1 particle.

Consideration: Optimize LDL-C and triglycerides; keep HbA1c to < 7%; exercise regularly; restrict sugar; if indicated, lose weight and stop smoking.

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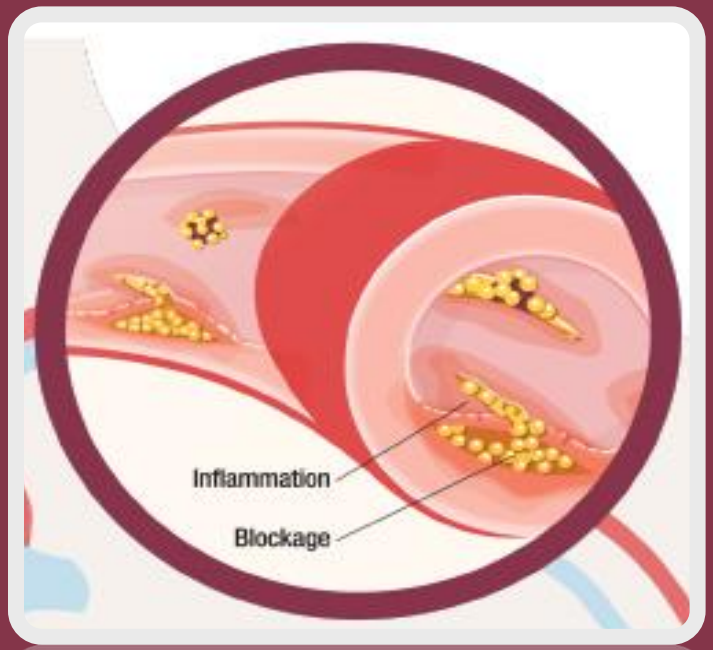
Part II: Inflammation

Do your patients have inflammation that can damage their arteries?



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Inflammation Testing

Near Term Risk of Having a Cardiovascular Event

- hs-CRP
  - Marker of inflammation
- $LpPLA_2$
  - Marker of blockage forming, cracking or shifting
- MPO
  - Marker of blockage forming or breaking

Inflammation Tests	Optimal	Borderline	High Risk
hs-CRP	0.7		
Range	<1.0	1.0-3.0	>3.0 mg/L
$LpPLA_2$	196		
Range	<200	200-235	>235 ng/mL
MPO		589	
Range	<350	350-633	>633 pmol/L
Interpretation: BORDERLINE MPO. Consider CVD status evaluation.			

Fibrinogen – a marker of early inflammation was NOT ordered.

High values of three biomarkers are an indicator for near term risk of CVD

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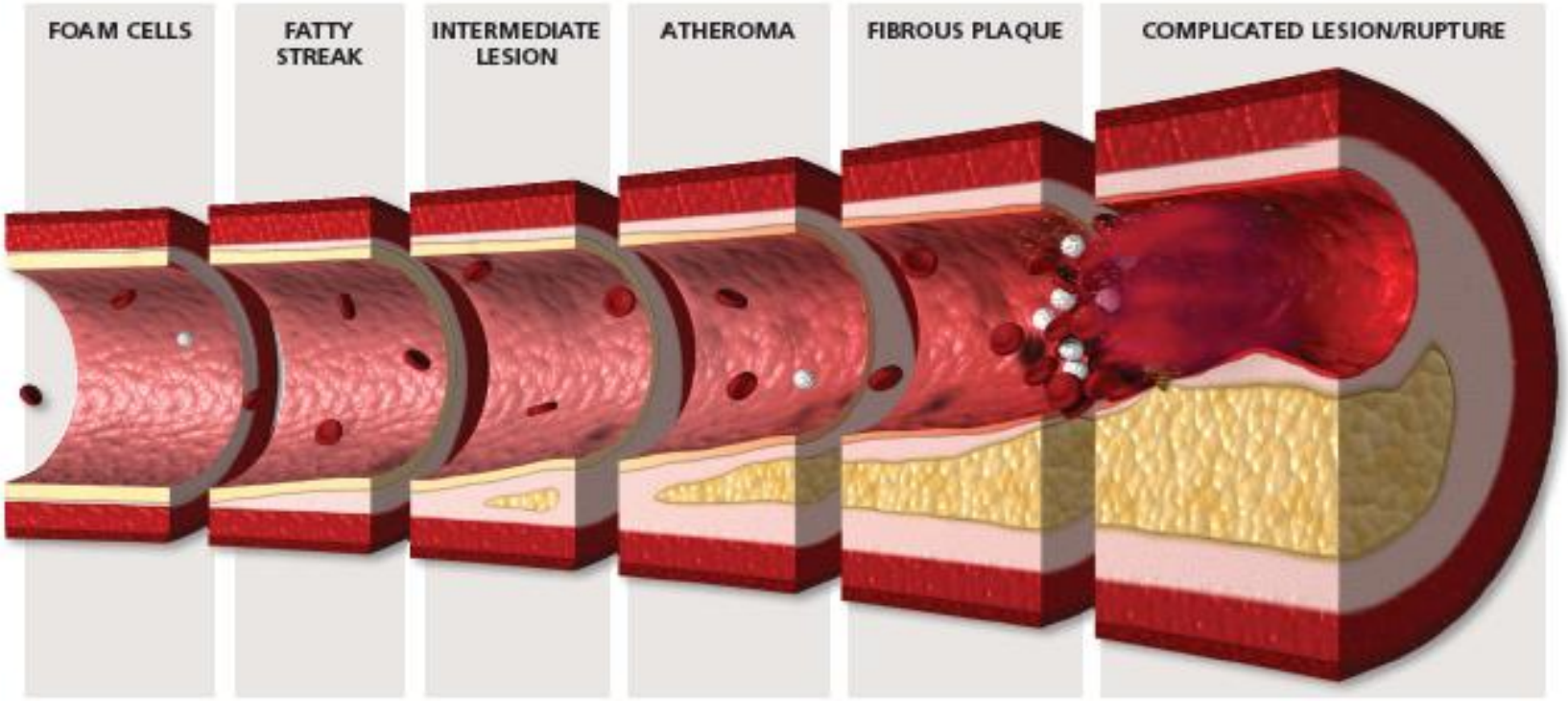
Coronary Atherosclerosis Timeline

MPO value >633 pmol/L increases 30 and 180 day MACE* event risk approximately threefold in patients presenting with chest pain[2]



*MACE = major adverse cardiovascular event (death, MI, bypass, PTCA) in patients who are CK negative with normal troponin.

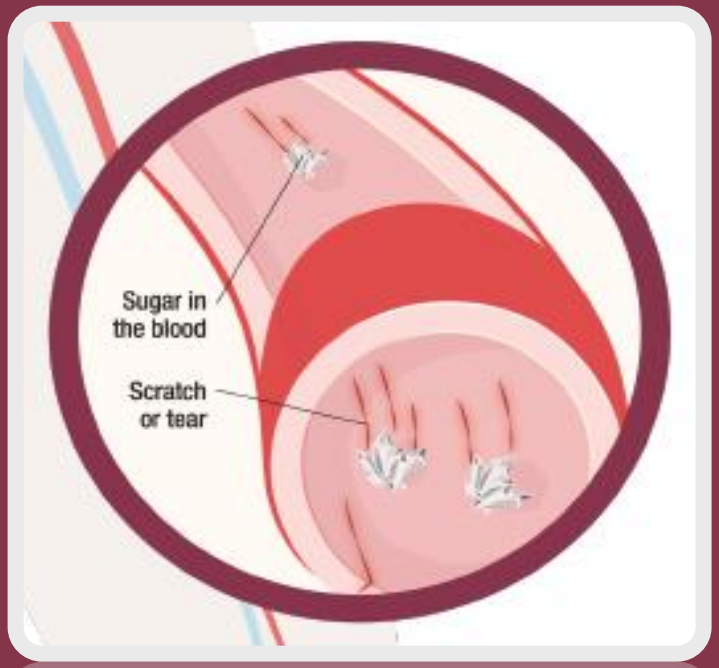
Inflammation Tests

Inflammation Tests	Optimal	Borderline	High Risk
hs-CRP	0.7		
Range	<1.0	1.0-3.0	>3.0 mg/L
$LpPLA_2$	196		
Range	<200	200-235	>235 ng/mL
MPO		589	
Range	<350	350-633	>633 pmol/L
Interpretation: BORDERLINE MPO. Consider CVD status evaluation.			

Fibrinogen – a marker of early inflammation was NOT ordered.

Part III: Metabolics

Is diabetes increasing your patients' risk of heart disease?



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Metabolic Tests

Diabetes Tests			
	Optimal	Borderline	High Risk
HbA1c		**5.8**	
Range	<5.7	5.7-6.4	>6.4 %
HOMA-IR			**70.4**
Range	<2	2-3	>3
Glucose[2]		**122**	
Range	70-99	100-125	<70 or >125 mg/dL
GSP		**231**	
Range	<200	200-250	>250 µmol/L
Adiponectin			**6.1**
Range	>10	7-10	<7 µg/dL
	Low	Optimal	High
Insulin[3]			**232**
Range	<5	5-15	>15 µU/mL

Metabolic Tests and John's Risk for Diabetes

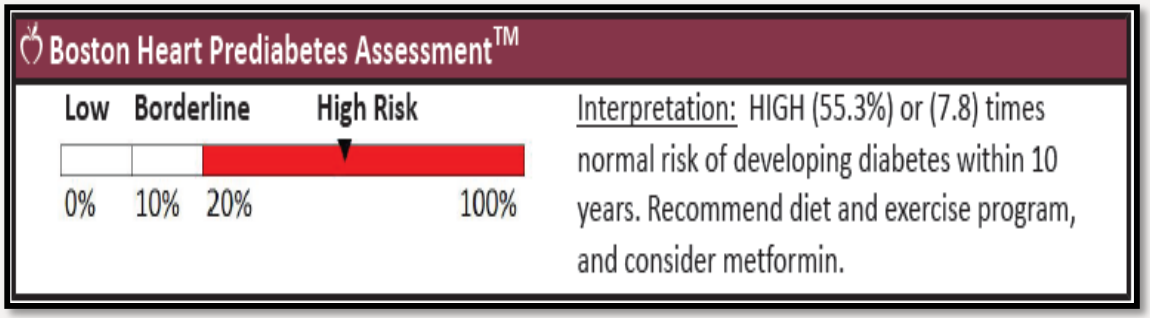
- Do you think John may be at risk to develop diabetes?

Diabetes Tests			
	Optimal	Borderline	High Risk
HbA1c		**5.8**	
Range	<5.7	5.7-6.4	>6.4 %
HOMA-IR			**70.4**
Range	<2	2-3	>3
Glucose[2]		**122**	
Range	70-99	100-125	<70 or >125 mg/dL
GSP		**231**	
Range	<200	200-250	>250 µmol/L
Adiponectin			**6.1**
Range	>10	7-10	<7 µg/dL
	Low	Optimal	High
Insulin[3]			**232**
Range	<5	5-15	>15 µU/mL

Boston Heart Prediabetes Assessment™

Clinical Significance

- Identifies patients at low, borderline and high risk of developing diabetes over 10 years
- Predicts the risk of developing diabetes in subjects with prediabetes with higher accuracy than other methods.



Schaefer EJ, et al. A new model for the prediction of diabetes: mellitus: results from the Framingham Offspring Study (manuscript in ubmission).
Kolberg JA, et al. Diabetes Care. 2009; 32(7):1207-1212.
Lyssenko V, et al. Diab Vasc Dis Res. 2012;9:59-67.
Noble D, et al. BMJ. 2011;343:d7163.

Boston Heart Prediabetes Assessment

Clinical Significance

http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/

Part IV: Genetics

Do your patients' genetic profiles help guide individualized treatment plans?

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Boston Heart Statin Induced Myopathy (SLCO1B1) Genotype Test

Clinical Significance

- 60% of patients who stopped taking a statin cite muscle pain as the primary reason for discontinuation[1]
- True risk of statin induced myopathy is ~10%[2]
  - Causes a significant amount of noncompliance
- Only about 1 out of 4 people carry either one or two copies of the SLCO1B1 variant

1. Wei MY et. al. J Clin Lipidol. 7(5):472-483.
2. Voora D, et. al. J Am Coll Cardiol. 2009;54:1609-1616.

Boston Heart Statin Induced Myopathy (SLCO1B1) Genotype Test

Clinical Significance and Treatment Considerations

SLCO1B1 Genotype	Clinical Significance	Treatment Considerations
T/T (valine/valine)	Normal metabolizer	Standard dose of statins*
T/C (valine/alanine)	Decreased metabolizer Less LDL-C lowering response increases risk of statin induced myopathy and are at an up to 4.5-fold increased risk of developing myopathy on statin therapy	Moderate to low doses of water soluble statins*.
C/C (alanine/alanine)	Markedly decreased metabolizer Statins get less LDL-C lowering and are at an up to 17-fold increased risk of developing myopathy on statin therapy	Low doses of water soluble statins*

***If indicated, are recommended**

Link E, et al. N Engl J Med. 2008;359(8):789–99.
Niemi M, Pasanen MK, Neuvonen PJ. Pharmacol Rev. 2011;63:157-181.
The SEARCH Collaborative Group. N Eng J Med. 2008;359:789-799.
Voora D, Shah SH, Spasojevic I, et al. J Am Coll Cardiol. 2009;54:1609-1616.

Genetic Tests

Definitions

Statin Induced Myopathy Gene – muscle aches and pains due to statins

Aids in treatment decisions related to dosage of clopidogrel (PLAVIX).

Apolipoprotein E Gene: Are lifestyle changes, medications and/or supplements better for you?

Blood clot protein genes

Genetic Tests by Genotyping [1,4]	
Statin Induced Myopathy (SLCO1B1)	Date of Service: 07/28/2014
T/C	
Interpretation:	· (T/C) genotype – decreased statin metabolizer · Increased risk of statin induced myopathy · Moderate to low doses of water soluble statins (in order of solubility: pravastatin, pitavastatin, rosuvastatin or fluvastatin), if indicated, are recommended
Clopidogrel Response (CYP2C19)	Date of Service: 07/28/2014
*1/*1	
Interpretation:	· (*1/*1) genotype – normal clopidogrel metabolizer
ApoE	Date of Service: 07/28/2014
E3/E3	
Interpretation:	· (E3/E3) genotype – most common genotype · If LDL-C or non-HDL-C lowering is needed, in addition to lifestyle change, statin therapy is recommended
Factor II	Date of Service: 07/28/2014
-/-	
Interpretation:	· (-/-) genotype – normal risk of clot formation
Factor V Leiden	Date of Service: 07/28/2014
-/-	
Interpretation:	· (-/-) genotype – normal risk of clot formation

Genetic Tests

Treatment Options

Is John's statin causing muscle pain?

Normal clopidogrel metabolizer?

Does John's form of gene respond better to medication or lifestyle?

Is John likely to form dangerous blood clots?

Genetic Tests by Genotyping [1,4]

Statin Induced Myopathy (SLCO1B1) — Date of Service: 06/17/2014

T/C

Interpretation:
- (T/C) genotype – decreased statin metabolizer
- Increased risk of statin induced myopathy
- **Moderate to low doses of water soluble statins (in order of solubility: pravastatin, pitavastatin, rosuvastatin or fluvastatin), if indicated, are recommended**

Clopidogrel Response (CYP2C19) — Date of Service: 06/17/2014

***1/*1**

Interpretation:
- (*1/*1) genotype – normal clopidogrel metabolizer

ApoE — Date of Service: 06/17/2014

E3/E3

Interpretation:
- (E3/E3) genotype – most common genotype
- **If LDL-C or non-HDL-C lowering is needed, in addition to lifestyle change, statin therapy is recommended**

Factor II — Date of Service: 06/17/2014

-/-

Interpretation:
- (-/-) genotype – normal risk of clot formation

Factor V Leiden — Date of Service: 06/17/2014

-/-

Interpretation:
- (-/-) genotype – normal risk of clot formation

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Testing Beyond Primary Drivers of Atherosclerosis: Fatty Acids

Impact of Fatty Acids to the Cell Membrane (Phospholipids)

The *Good*.

Double bonds in the good fatty acids improve the fluidity of the membrane allowing for better LDL receptor recycling

The *Bad*.

Saturated and trans fats cause lack of membrane fluidity and lack of LDL receptor recycling

The *Balanced*.

Enhances fluidity and function of the phospholipid membrane (each phospholipid has two fatty acids attached)

P Kuo, M Weinfeld, M A Rudd, et al. Plasma membrane enrichment with cis-unsaturated fatty acids enhances LDL metabolism in U937 monocytes. *Arterioscler Thromb Vasc Biol.* 1990;10:111-118

Boston Heart Fatty Acid Balance™

Definition

Measures the major key fatty acids for the purposes of CV risk assessment & disease management.

Boston Heart Fatty Acid Balance™ Test[1]				
	Optimal	Borderline	High	
Saturated FA Index		30.7		Saturated FA Index is BORDERLINE. Consider restricting dietary intake of saturated fat by choosing poultry without skin, fish, low fat dairy products, lean cuts of meat, and replacing butter with vegetable oils or trans fat free soft margarine.
Range	<30.0	30.0-32.0	>32.0 %	
Trans FA Index	0.45			Trans FA Index is OPTIMAL.
Range	<0.80	0.80–1.10	>1.10 %	
	Optimal	Borderline	Low	
Monounsaturated FA Index		19.7		Monounsaturated FA Index is BORDERLINE. Consider increasing intake of almonds, avocado or vegetable oils such as canola or olive oil.
Range	>22.0	19.0–22.0	<19.0 %	
Unsaturated/Saturated Ratio Index		2.21		Unsaturated/Saturated Ratio Index is BORDERLINE. Consider increasing intake of vegetable fats (nuts, seeds, oils) and restricting intake of animal fats (fatty meat, cheese, ice cream, butter).
Range	>2.25	2.00–2.25	<2.00	
Omega-3 FA Index		2.19		Omega-3 FA Index is BORDERLINE. Eicosapentaenoic Acid (EPA) level is BORDERLINE. Docosahexaenoic Acid (DHA) level is BORDERLINE. Consider increasing intake of oily fish such as salmon, sardines, herring, tuna, or mackerel, or take fish oil capsules daily. Increased EPA levels have been associated with lower risk of heart disease.
Range	>4.50	1.85–4.50	<1.85 %	
EPA		14.8		
Range	>50.0	10.0–50.0	<10.0 µg/mL	
DHA		67.9		
Range	>100.0	45.0–100.0	<45.0 µg/mL	
ALA		21.5		Alpha Linolenic Acid (ALA) level is BORDERLINE. Consider increasing intake of walnuts, chia seeds, flaxseeds, and canola or flaxseed oil.
Range	>30.0	12.0–30.0	<12.0 µg/mL	
	Low	Mid	High	
Omega-6 FA Index		45.9		Values are reported according to the lowest, middle and highest thirds of our reference population. Some authorities have recommended a goal below the 10th percentile for the Omega-6/Omega-3 Ratio Index (a value of 9.0) and the AA/EPA Ratio Index (a value of 5.0).
Range	<41.0	41.0–46.0	>46.0 %	
Linoleic Acid (LA)			1353.6	
Range	<825.0	825.0–1040.0	>1040.0 µg/mL	
Arachidonic Acid (AA)		242.4		
Range	<220.0	220.0–290.0	>290.0 µg/mL	
AA/EPA Ratio Index		16.4		
Range	<13.0	13.0–25.0	>25.0	
Omega-6/Omega-3 Ratio Index		16.66		
Range	<15.0	15.0–24.0	>24.0	

Itakura H, et al. J Atheroscler Thromb. 2011;18(2):99-107.
Mozaffarian D, et al. N Engl J Med. 2006;354:1601-13.
Fernandez ML , West KL. J Nutr. 2005;135(9):2075-2078.

Clinical Significance of Fatty Acids

Fatty Acid	Clinical Significance
Saturated	Raise levels of LDL-C and increase heart disease risk
Trans	Markedly increase risk of heart disease by increasing LDL-C and decreasing HDL-C
Monounsaturated	Beneficial fat that lowers heart disease risk
Unsaturated - saturated ratio index	Increase polyunsaturated fatty acid intake lowers LDL-C and decreases heart disease risk
Omega-6	Plasma values >40% increase risk of heart disease
Omega-3	When given in specific doses can decrease TG levels in people with elevated plasma levels of TG. Decrease heart disease morbidity and mortality

Schaefer EJ. *Am J Clin Nutr* 2002;75:191-212.
Lichtenstein AH et al. *N Engl J Med*.1999;340:1933-40.
Mozaffarian D, et al. *N Engl J Med* 2006;354:1601-1613.
Fernandez ML ,et al. J Nutr 2005;135:2075-2078.

Lee JH et al. *Mayo Clinic Proc*. 2008;83:324-332
Estruch R et al.*N Engl J Med*. 2013;368:1279-90
Ooi E. et al. *Journal of Lipid Research.*2012;53:1958-67

Boston Heart Lifestyle Program

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Boston Heart Lifestyle Program

Boston Heart offers a scientifically designed and personalized Lifestyle Program integrating test results, choice nutrition, exercise and support with Registered Dietitians to help patients achieve long-term heart-health.

An Integrated Approach to Patient Wellness

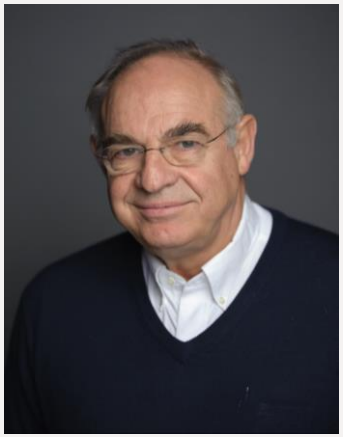
all starts with the **scientifically designed Life Plan** which is created using a pr
gorithm that combines test results, medical history and personal preferences to
ersonalized nutrition plan.

atients then have access to the **support of Registered Dietitian coaches** who
understand how to integrate the Life Plan into everyday life. They will help set g
spire patients to follow through with healthier habits that can reduce the risk of h
sease.

nally, patients have **access to easy-to-use, online resources**, such as a food
xercise journal used to track progress, nutrition and exercise articles and 24/7 se
ccess to test results, Diagnostic Reports and Life Plans

bostonheart diagnostics®

Based on Science Designed by Experts



Ernst Schaefer, MD
Co-founder and Medical Director of Boston Heart and a leader in developing new ways to address CVD risk

Michael Dansinger, MD
Medical Director at Boston Heart, Director of the Diabetes Reversal Program at Tufts, and nutrition doctor for NBC's *The Biggest Loser*

Joi Gleason, RD
Lead Dietitian at Boston Heart, research nutritionist at the Lipid Metabolism Lab at the Human Nutrition Research Center on Aging

The insights from this scientific research inform our nutritional guidance

Case Study

bostonheart diagnostics®

Patient Overview
Barbara: 50 Years Old with High LDL-C

- **Height** 5′3″, **weight** 153 lbs, **BMI** 27.1 kg/m^2
- **Medical history**: consistently high LDL-C
- **Current medications**: Niacin and Omega-3
- No family history of premature CVD and diabetes; non-smoker; does not want to take a statin; had lost 10 lbs prior to her first Boston Heart test

First Boston Heart Results
April 2013

EXPANDED RISK ASSESSMENT

Lipid, Lipoprotein and Apolipoprotein Tests	Optimal	Borderline	High Risk
Total Cholesterol		234	
Range	<200	200-240	>240 mg/dL
Direct LDL-C			167
Range	<100	100-160	>160 mg/dL
HDL-C			40
Range	>60	50-60	<50 mg/dL
Triglycerides		150	
Range	<150	150-200	>200 mg/dL
Non-HDL-C			194
Range	<130	130-190	[illegible]
ApoB			133
Range	<80	80-120	>120 mg/dL
LDL-P[5]			2055
Range	<1000	1000-1299	≥1300 nmol/L
sdLDL-C[1]		31	
Range	<20	20-40	>40 mg/dL
% sdLDL-C	19		
Range	<20	20-30	>30 %
VLDL-C	27		
Range	<30	30-40	>40 mg/dL
Lp(a)			97
Range	<20	20-30	>30 mg/dL
ApoA-I			129.8
Range	>180	140-180	<140 mg/dL

Boston Heart testing confirms Barbara's:

- LDL-C is high
- HDL-C is low
- Triglycerides are borderline
- ApoA-I is low
- Lp(a) is high – a risk marker for CVD

Losing 10 lbs was not enough to improve her cholesterol levels.

Unwilling to take a statin so she started plant sterols, red yeast rice, niacin, CoQ-10 and Omega-3

bostonheart diagnostics®

Abnormal HDL Map with Very Low α-1 HDL Particles

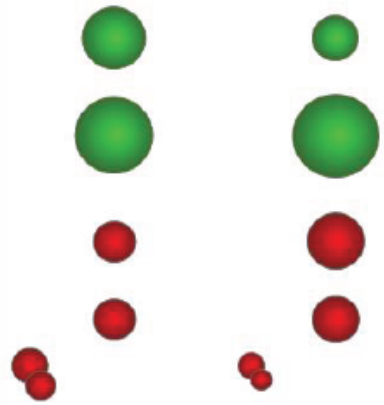
Barbara Green

Boston Heart HDL Map™ Test[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk
α-1			**16.1**
Range	>30	20-30	<20 mg/dL
α-2	**55.0**		
Range	>45	34-45	<34 mg/dL
α-3		**24.8**	
Range	<13.5	13.5-30	>30 mg/dL
α-4		**16.9**	
Range	<13.5	13.5-25	>25 mg/dL
Preß-1	**9.6**		
Range	<17	17-25	>25 mg/dL

HDL Particles

Optimal Female HDL Map



Patient's HDL Map

Interpretation: This HDL map is **ABNORMAL** and is associated with increased CVD risk. ApoA-I levels are reduced in the very large α-1 particle.

Consideration: Optimize LDL-C and triglycerides; keep HbA1c to < 7%; exercise regularly; restrict sugar; if indicated, lose weight and stop smoking, and consider niacin therapy.

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Second Boston Heart Results July 2013

Barbara Green

Barbara was doing her own diet and exercise, but she only showed some improvement.

Lipid, Lipoprotein and Apolipoprotein Tests

	Optimal	Borderline	High Risk
Total Cholesterol	198		
Range	<200	200-240	>240 mg/dL
Direct LDL-C		136	
Range	<100	100-160	>160 mg/dL
HDL-C			43
Range	>60	50-60	<50 mg/dL
Triglycerides	88		
Range	<150	150-200	>200 mg/dL
Non-HDL-C		155	
Range	<130	130-190	>190 mg/dL
LDL-P[5]			1528
Range	<1000	1000-1299	≥1300 nmol/L
sdLDL-C[1]		21	
Range	<20	20-40	>40 mg/dL
% sdLDL-C	15		
Range	<20	20-30	>30 %
VLDL-C	19		
Range	<30	30-40	>40 mg/dL
Lp(a)			88
Range	<20	20-30	>30 mg/dL
ApoA-I			136.1
Range	>180	140-180	<140 mg/dL

Inflammation Tests

	Optimal	Borderline	High Risk
hs-CRP	0.4		
Range	<1.0	1.0-2.0	>2.0 mg/L
$LpPLA_2$	152		
Range	<200	200-235	>235 ng/mL

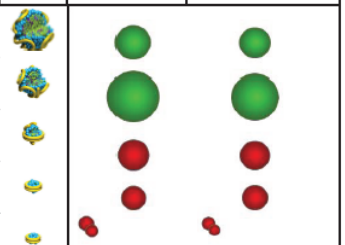
Diabetes Tests

	Optimal	Borderline	High Risk
HbA1c	5.4		
Range	<5.7	5.7-6.4	>6.4 %
	Low	Optimal	High
Insulin[3]		5	
Range	<5	5-15	>15 µU/mL

Boston Heart HDL Map™ Tests[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk
α-1		24.1	
Range	>30	20-30	<20 mg/dL
α-2		55.1	
Range	>65	55-65	<55 mg/dL
α-3	22.1		
Range	<25	25-30	>30 mg/dL
α-4		16.6	
Range	<15	15-18	>18 mg/dL
Preß-1	7.9		
Range	<10	10-15	>15 mg/dL

HDL Particles | Optimal Female HDL Map | Patient's HDL Map

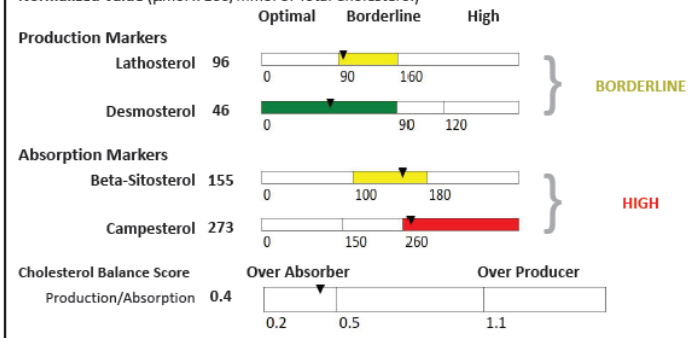


Interpretation: This HDL map is in the **BORDERLINE** CVD risk category based on ApoA-I levels in the very large α-1 particle.

Consideration: Optimize LDL-C and triglycerides; keep HbA1c to < 7%; exercise regularly; restrict sugar; if indicated, lose weight and stop smoking.

Boston Heart Cholesterol Balance™ Tests[1]

Normalized Value (µmol x 100/mmol of Total Cholesterol)



Interpretation:
· BORDERLINE cholesterol production and HIGH absorption may be associated with elevated LDL-C levels and increased heart disease risk.
· Desmosterol accounts for a minor portion (20%) of overall cholesterol production.

Consideration:
· Lifestyle modification, statin and ezetimibe therapy if LDL-C lowering is indicated.

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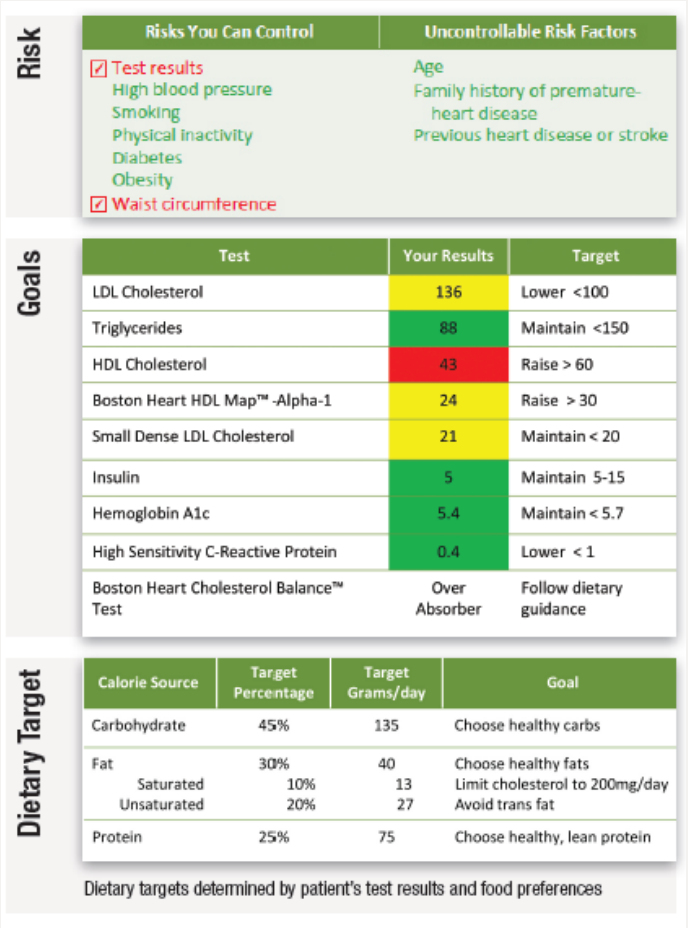
Lifestyle Program August 2013

- Joined the Boston Heart Lifestyle Program

- Between August-November 2013:
  - Completed 2 coaching sessions
  - Used online food and exercise journal consistently



Risk

Risks You Can Control	Uncontrollable Risk Factors
☑ Test results	Age
High blood pressure	Family history of premature-heart disease
Smoking	Previous heart disease or stroke
Physical inactivity	
Diabetes	
Obesity	
☑ Waist circumference	

Goals

Test	Your Results	Target
LDL Cholesterol	136	Lower <100
Triglycerides	88	Maintain <150
HDL Cholesterol	43	Raise > 60
Boston Heart HDL Map™ -Alpha-1	24	Raise > 30
Small Dense LDL Cholesterol	21	Maintain < 20
Insulin	5	Maintain 5-15
Hemoglobin A1c	5.4	Maintain < 5.7
High Sensitivity C-Reactive Protein	0.4	Lower < 1
Boston Heart Cholesterol Balance™ Test	Over Absorber	Follow dietary guidance

Dietary Target

Calorie Source	Target Percentage	Target Grams/day	Goal
Carbohydrate	45%	135	Choose healthy carbs
Fat	30%	40	Choose healthy fats
Saturated	10%	13	Limit cholesterol to 200mg/day
Unsaturated	20%	27	Avoid trans fat
Protein	25%	75	Choose healthy, lean protein

Dietary targets determined by patient's test results and food preferences

Post-Lifestyle Boston Heart Results November 2013

Barbara Green

Barbara's weight reduced from 153lbs to 131lbs since her first set of results in April.

After joining the Lifestyle Program, her HDL-C increased 20 points and her α-1 was in the optimal range with a low risk of CVD.

Lipid, Lipoprotein and Apolipoprotein Tests

	Optimal	Borderline	High Risk
Total Cholesterol	156		
Range	<200	200-240	>240 mg/dL
Direct LDL-C	87		
Range	<100	100-160	>160 mg/dL
HDL-C	61		
Range	>60	50-60	<50 mg/dL
Triglycerides	65		
Range	<150	150-200	>200 mg/dL
Non-HDL-C	95		
Range	<130	130-190	>190 mg/dL
ApoB	69		
Range	<80	80-120	>120 mg/dL
LDL-P[5]	972		
Range	<1000	1000-1299	≥1300 nmol/L
sdLDL-C[1]	14		
Range	<20	20-40	>40 mg/dL
% sdLDL-C	16		
Range	<20	20-30	>30 %
VLDL-C	8		
Range	<30	30-40	>40 mg/dL
Lp(a)			104
Range	<20	20-30	>30 mg/dL
ApoA-I		157.3	
Range	>180	140-180	<140 mg/dL

Inflammation Tests

	Optimal	Borderline	High Risk
hs-CRP	<0.2		
Range	<1.0	1.0-2.0	>2.0 mg/L
$LpPLA_2$	171		
Range	<200	200-235	>235 ng/mL

Diabetes Tests

	Optimal	Borderline	High Risk
HbA1c	5.2		
Range	<5.7	5.7-6.4	>6.4 %
	Low	Optimal	High
Insulin[3]	4		
Range	<5	5-15	>15 µU/mL

Boston Heart HDL Map™ Tests[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk	HDL Particles	Optimal Female HDL Map	Patient's HDL Map
α-1	47.5					
Range	>30	20-30	<20 mg/dL			
α-2		57.1				
Range	>65	55-65	<55 mg/dL			
α-3	19.6					
Range	<25	25-30	>30 mg/dL			
α-4	13.4					
Range	<15	15-18	>18 mg/dL			
Preß-1	8.4					
Range	<10	10-15	>15 mg/dL			

Interpretation: This HDL map is **OPTIMAL** and is associated with a low risk of CVD.

Consideration:

Boston Heart Cholesterol Balance™ Tests[1]

Normalized Value (µmol x 100/mmol of Total Cholesterol)

		Optimal	Borderline	High	
Production Markers					
Lathosterol	71	0	90	160	OPTIMAL
Desmosterol	64	0	90	120	
Absorption Markers					
Beta-Sitosterol	191	0	100	180	HIGH
Campesterol	247	0	150	260	

Cholesterol Balance Score		Over Absorber		Over Producer
Production/Absorption	0.3	0.2	0.5	1.1

Interpretation:
· OPTIMAL cholesterol production and HIGH absorption may be associated with elevated LDL-C levels and increased heart disease risk.

Consideration:
· Lifestyle modification and ezetimibe therapy if LDL-C lowering is indicated.

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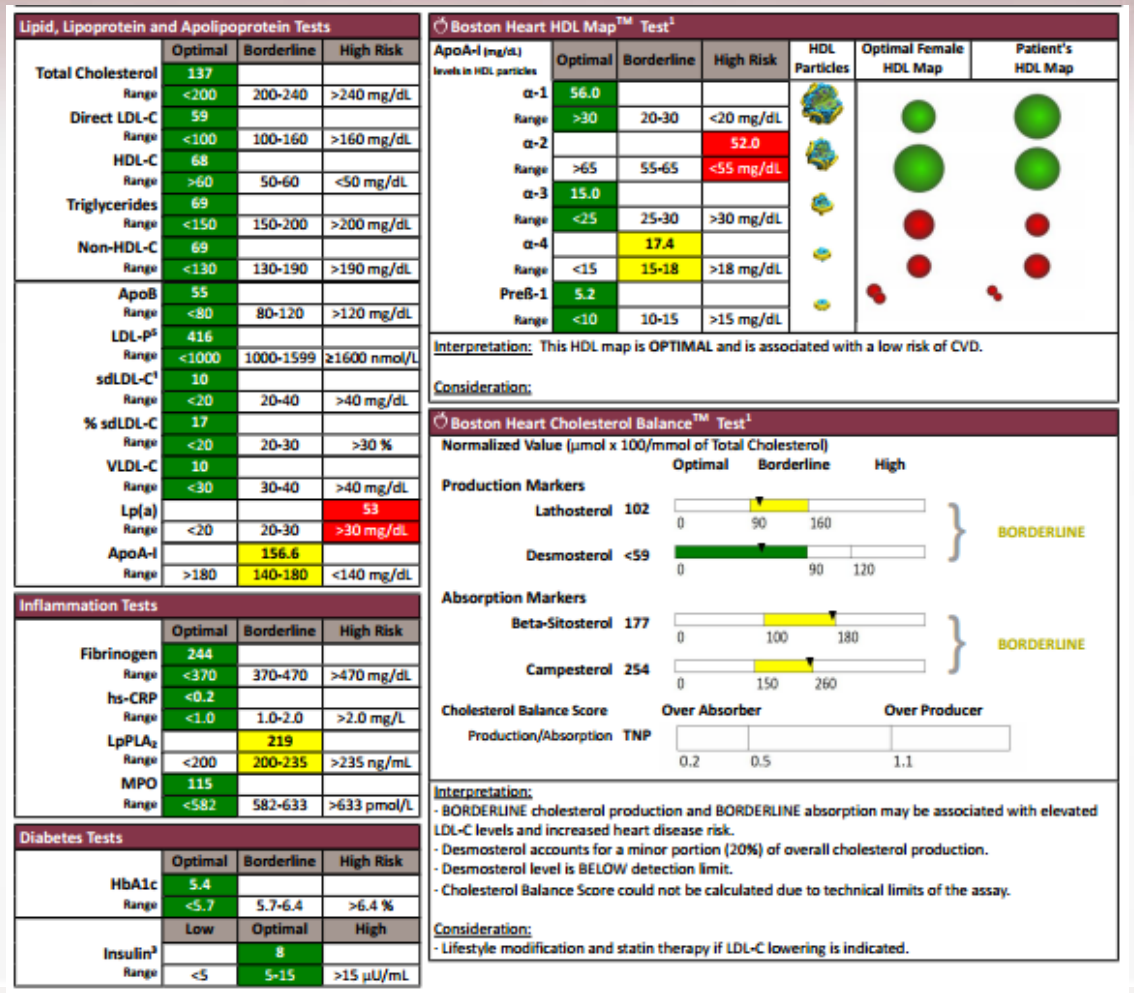
Continued Improvement Post-Lifestyle April 2014

Barbara Green

Barbara continued to follow her lifestyle and supplement recommendations and her weight went down to 121 lbs.

Lp(a) decreased by half in latest test results from last month.



Lipid, Lipoprotein and Apolipoprotein Tests

	Optimal	Borderline	High Risk
Total Cholesterol	137		
Range	<200	200-240	>240 mg/dL
Direct LDL-C	59		
Range	<100	100-160	>160 mg/dL
HDL-C	68		
Range	>60	50-60	<50 mg/dL
Triglycerides	69		
Range	<150	150-200	>200 mg/dL
Non-HDL-C	69		
Range	<130	130-190	>190 mg/dL
ApoB	55		
Range	<80	80-120	>120 mg/dL
LDL-P[5]	416		
Range	<1000	1000-1599	≥1600 nmol/L
sdLDL-C[1]	10		
Range	<20	20-40	>40 mg/dL
% sdLDL-C	17		
Range	<20	20-30	>30 %
VLDL-C	10		
Range	<30	30-40	>40 mg/dL
Lp(a)			53
Range	<20	20-30	>30 mg/dL
ApoA-I		156.6	
Range	>180	140-180	<140 mg/dL

Inflammation Tests

	Optimal	Borderline	High Risk
Fibrinogen	244		
Range	<370	370-470	>470 mg/dL
hs-CRP	<0.2		
Range	<1.0	1.0-2.0	>2.0 mg/L
$LpPLA_2$		219	
Range	<200	200-235	>235 ng/mL
MPO	115		
Range	<582	582-633	>633 pmol/L

Diabetes Tests

	Optimal	Borderline	High Risk
HbA1c	5.4		
Range	<5.7	5.7-6.4	>6.4 %
	Low	Optimal	High
Insulin[3]		8	
Range	<5	5-15	>15 µU/mL

Boston Heart HDL Map™ Test[1]

ApoA-I (mg/dL) levels in HDL particles	Optimal	Borderline	High Risk	HDL Particles	Optimal Female HDL Map	Patient's HDL Map
α-1	56.0					
Range	>30	20-30	<20 mg/dL			
α-2			52.0			
Range	>65	55-65	<55 mg/dL			
α-3	15.0					
Range	<25	25-30	>30 mg/dL			
α-4		17.4				
Range	<15	15-18	>18 mg/dL			
Preß-1	5.2					
Range	<10	10-15	>15 mg/dL			

Interpretation: This HDL map is **OPTIMAL** and is associated with a low risk of CVD.

Consideration:

Boston Heart Cholesterol Balance™ Test[1]

Normalized Value (µmol x 100/mmol of Total Cholesterol)

Optimal | Borderline | High

Production Markers

Lathosterol 102 (0 | 90 | 160)

Desmosterol <59 (0 | 90 | 120) — BORDERLINE

Absorption Markers

Beta-Sitosterol 177 (0 | 100 | 180)

Campesterol 254 (0 | 150 | 260) — BORDERLINE

Cholesterol Balance Score: Over Absorber | Over Producer

Production/Absorption TNP (0.2 | 0.5 | 1.1)

Interpretation:
- BORDERLINE cholesterol production and BORDERLINE absorption may be associated with elevated LDL-C levels and increased heart disease risk.
- Desmosterol accounts for a minor portion (20%) of overall cholesterol production.
- Desmosterol level is BELOW detection limit.
- Cholesterol Balance Score could not be calculated due to technical limits of the assay.

Consideration:
- Lifestyle modification and statin therapy if LDL-C lowering is indicated.

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Barbara— Summary and Conclusion

CONCLUSION

- After the Lifestyle Program:
  - Weight of 153 lbs reduced to 121 lbs
  - Lab improvements:
    - ✦ HDL-C increased from 40 to 68
    - ✦ ApoA-I increased from 129.8 to 156.6
    - ✦ α-1 HDL increased from 16.1 to 56
  - "This program really changed my life and my diet…I feel confident, healthy and 10 years younger."
- Continues to follow lifestyle & supplement recommendations

Thank you!

Q&A