

COMPLETE REPORT

PATIENT INFORMATION		SPECIMEN INFORMATION		PRACTITIONER INFORMATION	
Name TEST, PATIENT B	Age 42	Order ID 1726100292		Name TEST PROVIDER - IT DEPT	
Patient ID	Gender Female	Collection Date/Time 09/17/2017, 3:45 PM		Client ID 13456 IT TEST LOCATION	
Fasting Status Not Fasting	DOB 07/18/1975	Received Date/Time 09/18/2017, 3:52 PM		Address 6701 CARNEGIE AVENUE SUITE 500 CLEVELAND, OH 44103	
Ethnicity	BMI	Report Date/Time 09/20/2017, 1:20 PM			

INFLAMMATION

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Myeloperoxidase ⁽⁷⁾		556		HIGH	<470	pmol/L		
Based on a high risk sub-population (N=920) defined as ambulatory stable patients without acute coronary syndrome who underwent elective diagnostic coronary angiography (1) and a reference range study of apparently healthy donors, we've defined the following cut-offs for MPO: A cut-off of <470 pmol/L defines an "apparently healthy" population at lower risk for a cardiovascular event, 470-539 pmol/L defines a population at intermediate risk for a cardiovascular event (2-fold increased risk of MACE at 3 years), and >= 540 pmol/L defines a population with an increased risk for a cardiovascular event. (Reference: 1. Tang et al. Am J Cardiol. 2013; 111:465-470 and personal communication with Tang et al).								
Lp-PLA ₂ Activity ⁽³⁾	68			LOW	<75	nmol/min/mL		
Based on the documented clinical utility of Lp-PLA2 Activity to assess risk of CHD (1), the following cut-off has been defined for Lp-PLA2 Activity: A cut-off of >=75 nmol/min/mL defines a population with increased relative risk of developing CHD. (Reference: 1-The Lp-PLA2 Studies Collaboration. Lancet. 2010; 375: 1536-1544).								
ADMA (Asymmetric dimethylarginine) ⁽¹⁾		108		MOD	<100	ng/mL		
Elevated ADMA levels are associated with significant subclinical atherosclerosis while elevated SDMA levels are associated with kidney function and strongly correlate with reduced eGFR. Available prospective studies suggest an increased risk of cardiovascular disease with higher ADMA concentrations (1). Based on an internal reference range study using 180 'apparently healthy,' non-smoking donors, CHL has defined the following cut-offs for ADMA: A cut-off of <100 ng/mL defines an 'apparently healthy' population at a relatively low risk for a cardiovascular event, 100-123 ng/mL defines a population at intermediate risk for a cardiovascular event, and >123 ng/mL defines a relatively high risk population. (Reference: 1-Willeit P. et al. J Am Heart Assoc. 2015; 4: e001833).								
SDMA (Symmetric dimethylarginine)	96				73-135	ng/mL		

LIPIDS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Lp(a)	18			LOW	<30	mg/dL		
NMR LIPOPROFILE®								
LDL Particle Number		1042		MOD	<1000	nmol/L		
LDL Cholesterol, Calculated		113		MOD	0-99	mg/dL		
LDL-C is inaccurate if patient is non-fasting.								
HDL-C	75			LOW	≥40	mg/dL		
Triglycerides	54			LOW	0-149	mg/dL		
Cholesterol, Total	199			LOW	100-199	mg/dL		

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	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
HDL-Particle Number	43.5			LOW	≥30.5	umol/L		
Small LDL-Particle Number	<90			LOW	≤527	nmol/L		
LDL Size	21.7				>20.5	nm		
Small LDL-P and LDL Size are associated with CVD risk, but not after LDL-P is taken into account. These assays were developed and their performance characteristics determined by LipoScience. These assays have not been cleared by the US Food and Drug Administration. The clinical utility of these laboratory values have not been fully established.								
Large VLDL-P	1.8			LOW	≤2.7	nmol/L		
Large HDL-P	12.9			LOW	≥4.8	umol/L		
VLDL Size		50.7		MOD	≤46.6	nm		
HDL Size	9.8			LOW	≥9.2	nm		
LP-IR Score ⁽⁸⁾	23			LOW	≤45	0-100		

METABOLIC

	In Range	Out of Range	Flag**	Relative Risk	Reference/Optimal Range	Units	Previous Result	Date
HbA1c	5.4			LOW	<5.7	%		
American Diabetes Association (ADA) guidelines indicate that individuals with a HbA1c of 5.7%-6.4% are at a higher risk for developing diabetes and cardiovascular disease. The risk of diabetes rises disproportionately as HbA1c rises. Accordingly, interventions should be more intensive for those with HbA1c levels above 6.0%. HbA1c at or greater than 6.5% is considered diagnostic of diabetes. (Reference: Diabetes Care 2011;34:e75-e80).								
Estimated Average Glucose ⁽⁵⁾	108			LOW	<117	mg/dL		
TMAO (Trimethylamine N-oxide) ⁽⁴⁾		6.6		MOD	<6.2	uM		
Based on a population (N=4007) defined as ambulatory stable patients without acute coronary syndrome who underwent elective diagnostic coronary angiography (1) and a reference range study of apparently healthy donors (N=180), we've defined the following cut-offs for TMAO to assess relative risk of a cardiovascular event: A cut-off of <6.2 uM defines an "apparently healthy" population at lower risk for a cardiovascular event, 6.2-9.9 uM defines a population at intermediate risk for a cardiovascular event (2-fold increased risk of MACE at 3 years), and ≥10.0 uM defines a population with an increased risk for a cardiovascular event. (Reference: 1-Tang et al. N Engl J Med. 2013; 368:1575-1584).								

VITAMINS/SUPPLEMENTS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Coenzyme Q10 ⁽²⁾	1.46			LOW		ug/mL		
Population reference range: 0.36 to 1.59 ug/mL. Studies have suggested that serum levels of Coenzyme Q10 at > 2.0 ug/mL show an anti-hypertensive effect.								

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FATTY ACIDS

	In Range	Out of Range	Flag**	Relative Risk	Optimal	Units	Previous Result	Date
OmegaCheck™ (Whole Blood: EPA+DPA+DHA) ⁽⁶⁾	9.2			LOW	≥5.5	% by wt		
<p>Increasing blood levels of long-chain n-3 fatty acids are associated with a lower risk of sudden cardiac death (1). Based on the top (75th percentile) and bottom (25th percentile) quartiles of the CHL reference population, the following risk categories were established for OmegaCheck: A cut-off of ≥5.5% by wt defines a population at low relative risk, 3.8-5.4% by wt defines a population at moderate relative risk, and ≤3.7% by wt defines a population at high relative risk of sudden cardiac death. The totality of the scientific evidence demonstrates that when consumption of fish oils is limited to 3 g/day or less of EPA and DHA, there is no significant risk for increased bleeding time beyond the normal range. A daily dosage of 1 gram of EPA and DHA lowers the circulating triglycerides by about 7-10% within 2 to 3 weeks. (Reference: 1-Albert et al. NEJM. 2002; 346: 1113-1118).</p>								
Arachidonic Acid/EPA Ratio		5.1	H		<5.0			
Omega-6/Omega-3 Ratio		4.5	H		<4.5			
Omega-3 total	9.2					% by wt		
EPA	3.0				>2.0	% by wt		
DPA	3.1				>1.0	% by wt		
DHA		3.1	L		>4.0	% by wt		
Omega-6 total	41.7					% by wt		
Cleveland HeartLab measures a number of omega-6 fatty acids with AA and LA being the two most abundant forms reported.								
Arachidonic Acid		15.4	H		<9.0	% by wt		
Linoleic Acid	15.2				<20.0	% by wt		

ROUTINE PANELS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Comprehensive Metabolic Panel								
Glucose	87				65-99	mg/dL		
Calcium, Total	9.4				8.5-10.5	mg/dL		
Sodium	141				136-145	mmol/L		
Potassium	4.4				3.5-5.1	mmol/L		
Chloride	103				95-108	mmol/L		
CO ₂ (Carbon Dioxide, Bicarbonate)	25				21-33	mmol/L		
BUN (Blood Urea Nitrogen)	10				8-23	mg/dL		
Creatinine	0.83				0.55-1.00	mg/dL		

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	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Albumin	4.4				3.5-5.5	g/dL		
Total Protein	6.9				6.1-8.0	g/dL		
Globulin	2.5				1.8-3.8	g/dL		
ALP (Alkaline Phosphatase)	41				<150	U/L		
ALT (Alanine Amino Transferase)	7				<46	U/L		
AST (Aspartate Amino Transferase)	11				<41	U/L		
Bilirubin, Total	0.2				<1.3	mg/dL		
eGFR, Non-African descent	87				>60	mL/min/ 1.73 m ²		
eGFR, African descent	101				>60	mL/min/ 1.73 m ²		

OUT OF RANGE RESULTS SUMMARY

	Result	Flag**	Relative Risk	Reference/ Optimal Range	Units	Previous Result	Date
INFLAMMATION							
Myeloperoxidase	556		HIGH	<470	pmol/L		
ADMA (Asymmetric dimethylarginine)	108		MOD	<100	ng/mL		
LIPIDS							
LDL Particle Number	1042		MOD	<1000	nmol/L		
LDL Cholesterol, Calculated	113		MOD	0-99	mg/dL		
VLDL Size	50.7		MOD	≤46.6	nm		
METABOLIC							
TMAO (Trimethylamine N-oxide)	6.6		MOD	<6.2	uM		
FATTY ACIDS							
Arachidonic Acid/EPA Ratio	5.1	H		<5.0			
Omega-6/Omega-3 Ratio	4.5	H		<4.5			
DHA	3.1	L		>4.0	% by wt		
Arachidonic Acid	15.4	H		<9.0	% by wt		

Comments

(1) This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified

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to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(2) This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(3) This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(4) This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(5) The estimated average glucose value is an adjunct to the treatment of both Type I and Type II Diabetes. It is not intended for the diagnosis or risk assessment of patients without diabetes. (Reference: Nathan DM et al. Diabetes Care 2008;31:1473).

(6) This test is performed by a Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(7) This test is performed by a turbidimetric immunoassay method. This test was developed and its performance characteristics determined by the Cleveland HeartLab, Inc. It has not been cleared or approved by the U.S. FDA. The Cleveland HeartLab is regulated under Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

(8) LP-IR Score is inaccurate if patient is non-fasting. The LP-IR score is a laboratory developed index that has been associated with insulin resistance and diabetes risk and should be used as one component of a physician's clinical assessment. Neither the LP-IR score nor the subclasses listed above have been cleared by the US Food and Drug Administration. Test performed by: LabCorp Burlington, 1447 York Court, Burlington, NC 27215-3361, Laboratory Medical Director: William F Hancock, MD.

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Your medical provider has gone *beyond* standard testing to examine your inflammation levels so you can Know Your Risk[®] for heart attack and stroke!

Lowering blood pressure, blood sugar and cholesterol reduces risk, but 50% of heart attack or stroke victims have *normal* cholesterol levels. Measuring inflammation levels can help identify *hidden risk* so your provider can catch the beginning or treat advanced stages of vascular disease. Always review your results and treatment considerations with your medical provider.

PATIENT B TEST

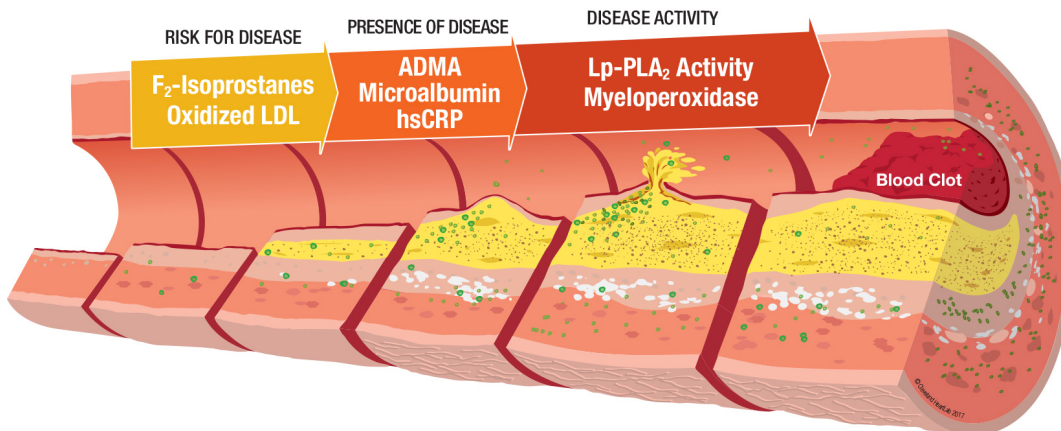
Gender Female

DOB 07/18/1975

Patient ID

Medical Provider

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Disclaimer: The information provided here is for educational purposes only, and the results provided should be reviewed and interpreted by the treating physician. This Patient Report is generated when three or more of the inflammation tests listed below are ordered, or for repeat tests due to a sample problem.

Risk for Disease

Test	Result
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F₂-Isoprostanes/ Creatinine (ng/mg)	TNO
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This urine test was not ordered.

Your body needs F₂-Isoprostanes for basic functions like making muscle. In excess, F₂-IsoPs caused by inactivity, smoking and processed foods increase oxidation and blood vessel damage.

Oxidized LDL (OxLDL) (U/L)	TNO
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This blood test was not ordered.

OxLDL measures oxidized damage to LDL cholesterol (bad cholesterol). High levels trigger inflammation, increasing your risk of developing metabolic syndrome and your future risk of plaque build-up.

Presence of Disease

Test	Result
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ADMA (ng/mL)	108 M
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You have modest levels of ADMA in your blood suggesting you may have low nitric oxide levels and endothelial dysfunction.

ADMA is a chemical in your blood that reduces nitric oxide production needed to keep a healthy endothelium (the cells that line your blood vessels). High levels of ADMA indicate damage to these cells.

Microalbumin/ Creatinine (mg/g)	TNO
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This urine test was not ordered.

Microalbumin measures the health of the endothelium, a thin layer of cells lining blood vessels. Risk factors can damage that lining in the kidneys leading to abnormal release of albumin into the urine, which is linked to increased risk of cardiovascular or kidney disease.

hsCRP (mg/L)	TNO
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This blood test was not ordered.

hsCRP measures inflammation in the body. Increases of hsCRP are seen with recent illness, tissue injury, if you are fighting a virus or infection, with periodontal (gum) disease as well as with cardiovascular disease.

Disease Activity

Test	Result
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Lp-PLA₂ Activity (nmol/min/mL)	68 L
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Your result is in the desirable range suggesting that you may have limited active cholesterol build-up.

Lp-PLA₂ Activity measures vascular-specific inflammation. When cholesterol enters and gets trapped in the vessel wall, inflammation occurs. Lp-PLA₂ Activity may identify active cholesterol build-up inside the vessel wall and the progression of cardiovascular disease.

Myeloperoxidase (MPO) (pmol/L)	556 H
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You have high levels of MPO that suggest you may have vessel damage and increased risk of plaque rupture which may lead to a heart attack.

MPO identifies vulnerable plaque due to the breakdown of cells lining the blood vessel. This breakdown leads to white blood cells attacking the vessel wall and marks the progression of cardiovascular disease.

Your Lifestyle Considerations

- Limit your intake of processed foods, exercise regularly and if you smoke, quit.
- Eat foods rich in anti-oxidants and high in fiber, and consider a heart healthy Mediterranean-style diet.
- Limit foods high in sugar and salt (sodium) to reduce the damage to your endothelium (vessel lining).
- Your provider may order an imaging test to identify cardiovascular disease.
- Strive for optimal oral health to reduce inflammation associated with periodontal disease.

"L" or Low Risk
UND = Undetectable

"M" or Moderate Risk

"H" or High Risk

TNO = Test Not Ordered
TNP = Test Not Performed
INC = Incomputable

