PATIENT INFORMATION		SPECIMEN INFORMATION	PRACTITIONER INFORMATION
Name **TEST, PATIENT A**	Age **50**	Order ID **1601200402**	Name **DOCTOR TEST, M.D.**
Patient ID **123456789**	Gender **Female**	Collection Date/Time **01/12/2016, 12:09 PM**	Client ID **TEST TEST LOCATION**
Fasting Status **Not Fasting**	DOB **06/02/1965**	Received Date/Time **01/12/2016, 12:08 PM**	Address **6701 CARNEGIE AVENUE , SUITE 500** **CLEVELAND, OH 44103**
Ethnicity **Hispanic/Latino**	BMI **27**	Report Date/Time **01/12/2016, 4:30 PM**	

INFLAMMATION

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Myeloperoxidase (3)		480		MOD	<470	pmol/L	238	10/01/2015
Based on a high risk population 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 low 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 high risk population. (Reference: 1. Tang et al. Am J Cardiol. 2013; 111:465-470).							
Lp-PLA$_2$ (The PLAC® Test)	125			LOW	≤ 200	ng/mL	151	05/27/2015
High-sensitivity CRP		1.5		MOD	<1.0	mg/L	2.3	05/27/2015
Microalbumin/Creatinine ratio	2.1			LOW	<7.5	mg/g	16.4	05/27/2015
Please note new reference range of <3.9 mg/g for men and <7.5 mg/g for women. This reference range replaces <30.0 mg/g. A 3-fold increase in CVD has been found in men with Microalbumin/Creatinine ratios >=3.9 mg/g and in women with ratios >=7.5 mg/g in the Framingham Heart Study (1). A persistent Microalbumin/Creatinine ratio >30 mg/g indicates a loss in kidney function and is used in the diagnosis of chronic kidney disease (2). (References: 1-Arnlov et al. Circulation 2005; 112: 969-975. 2-Fox et al. Nephrology 2013; 1:21).							
Microalbumin	4.2					mg/L	38.1	05/27/2015
Creatinine, Urine	203.0				20.0-300.0	mg/dL	158.3	08/24/2015
OxLDL	34			LOW	<60	U/L	65	05/27/2015
Based on a recent study of an 'apparently healthy' and non-metabolic syndrome population-1, the following cut-offs have been defined for OxLDL: A cut-off of <60 U/L defines a population with a low relative risk of developing metabolic syndrome, a range of 60 to 69 U/L defines a population with a moderate relative risk (2.8 fold) and >=70 U/L defines a population with a high relative risk (3.5-fold). (Reference: 1-Holvoet et al. JAMA. 2008; 299: 2287-2293.)							
F$_2$-Isoprostane/Creatinine Ratio (6)	0.27			LOW	<0.86	ng/mg	0.13	05/27/2015
F$_2$-Isoprostane	0.55					ng/mL	0.31	05/27/2015
Creatinine, Urine	203.0				20.0-300.0	mg/dL	158.3	08/24/2015

ENDOTHELIAL FUNCTION

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
ADMA (Asymmetric dimethylarginine) (2)	92			LOW	<100	ng/mL	42	08/04/2015
SDMA (Symmetric dimethylarginine)	108				73-135	ng/mL	56	08/04/2015

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LIPIDS

	In Range	Out of Range	Flag**	Relative Risk	Reference Range	Units	Previous Result	Date
Total Cholesterol	170			LOW	<200	mg/dL	215	03/24/2015
LDL-Calculated	94			LOW	<100	mg/dL	124	03/24/2015
Direct HDL Cholesterol		48		HIGH	≥50	mg/dL	60	03/24/2015
Triglycerides	140			LOW	<150	mg/dL	153	03/24/2015
Non-HDL Cholesterol	122			LOW	<130	mg/dL	155	03/24/2015
Apolipoprotein A1	135			LOW	>130	mg/dL	153	10/15/2015
Apolipoprotein B	59			LOW	<100	mg/dL	56	10/15/2015
Per the ACC and ADA recommendation, the goal ApoB level for high risk patients is <90 mg/dL and <80 mg/dL for very high risk patients, respectively. (Reference: Brunzell et al. J Am Cardiol 2008;51:1512).								
ApoB/ApoA Ratio	0.44			LOW	<0.70		0.37	10/15/2015
sdLDL (1)	25.1			LOW	≤40.0	mg/dL	25.1	03/24/2015
Lp(a)		35		HIGH	<30	mg/dL	35	03/24/2015

METABOLIC

	In Range	Out of Range	Flag**	Relative Risk	Reference/ Optimal Range	Units	Previous Result	Date
OxLDL	34			LOW	<60	U/L	65	05/27/2015
Based on a recent study of an 'apparently healthy' and non-metabolic syndrome population-1, the following cut-offs have been defined for OxLDL: A cut-off of <60 U/L defines a population with a low relative risk of developing metabolic syndrome, a range of 60 to 69 U/L defines a population with a moderate relative risk (2.8 fold) and >=70 U/L defines a population with a high relative risk (3.5-fold). (Reference: 1-Holvoet et al. JAMA. 2008; 299: 2287-2293.)								
TMAO (Trimethylamine N-oxide) (5)		10.4		HIGH	<6.2	uM	5.8	12/04/2015
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 low risk, 6.2-9.9 uM defines a population at intermediate risk, and >=10.0 uM defines a population at high risk for a cardiovascular event (2-fold increased risk of MACE at 3 years). (Reference: 1-Tang et al. N Engl J Med. 2013; 368:1575-1584).								

FATTY ACIDS

	In Range	Out of Range	Flag**	Relative Risk	Optimal	Units	Previous Result	Date
OmegaCheck™ (Whole Blood: EPA+DPA+DHA) (4)	6.9			LOW	≥5.5	% by wt		
The risk categories for OmegaCheck are based on the top (75th percentile) and bottom (25th percentile) quartiles of the CHL reference population. Consumption of foods rich in omega-3 fatty acids or supplements containing omega-3 fatty acids (EPA, DHA or DPA) may increase omega-3 fatty acid levels measured by OmegaCheck, and decrease the risk of sudden death								

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	In Range	Out of Range	Flag**	Relative Risk	Optimal	Units	Previous Result	Date
due to cardiovascular disease.* 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. *Albert CM et al. N Engl J Med. 2001; 346: 1113-1118.								
Arachidonic Acid/EPA Ratio	**4.5**				<5.0			
Omega-6/Omega-3 Ratio		**6.3**	**H**		<4.5			
Omega-3 total	**6.9**					% by wt		
EPA		**2.0**	**L**		>2.0	% by wt		
DPA		**1.0**	**L**		>1.0	% by wt		
DHA		**3.9**	**L**		>4.0	% by wt		
Omega-6 total	**43.3**					% 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		**9.0**	**H**		<9.0	% by wt		
Linoleic Acid		**20.0**	**H**		<20.0	% by wt		

OUT OF RANGE RESULTS SUMMARY

	Result	Flag**	Relative Risk	Reference/ Optimal Range	Units	Previous Result	Date
INFLAMMATION							
Myeloperoxidase	480		**MOD**	<470	pmol/L	238	10/01/2015
High-sensitivity CRP	1.5		**MOD**	<1.0	mg/L	2.3	05/27/2015
LIPIDS							
Direct HDL Cholesterol	48		**HIGH**	≥50	mg/dL	60	03/24/2015
Lp(a)	35		**HIGH**	<30	mg/dL	35	03/24/2015
METABOLIC							
TMAO (Trimethylamine N-oxide)	10.4		**HIGH**	<6.2	uM	5.8	12/04/2015
FATTY ACIDS							
Omega-6/Omega-3 Ratio	6.3	**H**		<4.5			
EPA	2.0	**L**		>2.0	% by wt		
DPA	1.0	**L**		>1.0	% by wt		
DHA	3.9	**L**		>4.0	% by wt		
Arachidonic Acid	9.0	**H**		<9.0	% by wt		
Linoleic Acid	20.0	**H**		<20.0	% by wt		

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Comments

(1) A reagent that is designated by the manufacturer as "for research use" was used for this test. Its performance was established and confirmed by the Cleveland Heartlab. This test is not cleared or approved by the U.S. FDA. The results are not intended to be used as the sole means for clinical diagnosis and patient monitoring. The Cleveland Heartlab is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

(2) Elevated ADMA levels are associated with significant subclinical atherosclerosis while elevated SDMA levels are associated with kidney function and strongly correlate with reduced eGFR. Please visit http://www.clevelandheartlab.com/our-science/educational-materials for references. Available prospective studies suggest an increased risk of cardiovascular disease with higher ADMA concentrations. 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 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 high risk population. (Reference: Willeit P. et al. Asymmetric dimethylarginine and cardiovascular risk: Systematic review and meta-analysis of 22 prospective studies. J Am Heart Assoc. 2015; 4: e001833). 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 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.

(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) 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.

(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.

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