Quest Diagnostics™

ClevelandHeartLab®
Know your risk.

Report Status: Final

TEST, FEMALE SAMPLE

Patient Information	Specimen Information	Client Information
TEST, FEMALE SAMPLE **DOB: 01/10/1964** **AGE: 55** Gender: Female Fasting: Not Fasting Phone: Patient ID:	Order ID: 1908400248 Requisition: 1908400248 Collected: 03/24/2019, 11:14 AM Received: 03/25/2019, 11:14 AM Reported: 03/25/2019, 1:55 PM	TEST PROVIDER - IT DEPT 12628 IT DEPT - CHL 6701 CARNEGIE AVE SUITE 500 CLEVELAND, OH 44103

Cardiometabolic Risk Report

Test Name	Current Result & Risk: Optimal	Current Result & Risk: Non-Optimal	Reference Range/Risk Categories: Optimal	Moderate	High	Units	Historical Result & Risk from / /	/ /
INFLAMMATION								
Myeloperoxidase(14)	392		<470	470-539	≥540	pmol/L		
Lp-PLA$_2$ Activity(4)		82	<75	N/A	≥75	nmol/min/mL		
High-sensitivity CRP		2.6	<1.0	1.0-3.0	>3.0	mg/L		
Microalbumin/Creatinine		9.7	<7.5	N/A	≥7.5	mg/g		
Microalbumin	9.4					mg/L		
Creatinine, Urine, Random	97.2			20.0-300.0		mg/dL		
ADMA (Asymmetric dimethylarginine)(1)	99		<100	100-123	>123	ng/mL		
SDMA (Symmetric dimethylarginine)	95			73-135		ng/mL		
OxLDL		66	<60	60-69	≥70	U/L		
F$_2$-Isoprostane/Creatinine(7)	0.59		< 0.86	N/A	≥ 0.86	ng/mg		
F$_2$-Isoprostane	0.57					ng/mL		
Creatinine, Urine, Random	97.2			20.0-300.0		mg/dL		
LIPIDS								
Lipid Panel								
Cholesterol, Total	175		<200	N/A	≥200	mg/dL		
HDL Cholesterol	57		≥50	N/A	<50	mg/dL		
Triglycerides	125		<150	150-199	≥200	mg/dL		
LDL Cholesterol, Calculated	95		<100	100-129	>129	mg/dL		
Chol/HDL-C	3.1		≤ 3.5	3.6-5.0	> 5.0	mg/dL		
Non-HDL Cholesterol	126		<130	130-189	≥190	mg/dL		

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TG/HDL-C		2.2	< 2.0	2.0-3.0	> 3.0	mg/dL		
Lipoprotein Fractionation, NMR								
LDL-P(13)		1620	< 935	935-1816	>1816	nmol/L		
Small LDL-P		580	< 467	467-820	> 820	nmol/L		
LDL Size		19.2	>20.5	N/A	≤20.5	nm		
HDL-P	36.8		>32.8	29.2-32.8	<29.2	umol/L		
Large HDL-P	7.7		>7.2	5.3-7.2	<5.3	umol/L		
HDL Size	9.1		>9.0	8.7-9.0	<8.7	nm		
Large VLDL-P		6.2	<3.7	3.7-6.1	>6.1	nmol/L		
VLDL Size		48.6	<47.1	47.1-49.0	>49.0	nm		
Apolipoproteins								
Lipoprotein (a)(3)		110	< 75	75-125	>125	nmol/L		
METABOLIC								
Glucose	97			65-99		mg/dL		
HbA1c	5.6		<5.7	5.7-6.4	>6.4	%		
Estimated Average Glucose(8)	114		<117	117-139	>139	mg/dL		
TMAO (Trimethylamine N-oxide)(5)		12.2	< 6.2	6.2-9.9	≥10.0	uM		
Insulin Resistance Panel w/Score								
Insulin Resistance Score(10)	21		< 33	33-66	> 66			
Insulin, Intact, LC/MS/MS(11)	5.4		≤ 16	N/A	> 16	uIU/mL		
C-peptide, LC/MS/MS(12)	1.80		≤ 2.16	N/A	> 2.16	ng/mL		
VITAMINS/SUPPLEMENTS								
Coenzyme Q10(2)	1.15		> 0.35	N/A	< 0.36	ug/mL		

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	Optimal	Non-Optimal	Optimal	Moderate	High		/ /	/ /
Vitamin D, 25-Hydroxy by LC-MS/MS[15]		28.2	≥ 30.0	20.0-29.9	<20.0 OR >150.0	ng/mL		
FATTY ACIDS								
OmegaCheck® (Whole Blood: EPA+DPA+DHA)[9]		3.5	≥5.5	3.8-5.4	≤3.7	% by wt		
Arachidonic Acid/EPA Ratio		8.4 H		<5.0				
Omega-6/Omega-3 Ratio		11.2 H		<4.5				
Omega-3 total	3.5					% by wt		
EPA		1.6 L		>2.0		% by wt		
DPA		0.4 L		>1.0		% by wt		
DHA		1.5 L		>4.0		% by wt		
Omega-6 total	39.3					% by wt		
Arachidonic Acid		13.5 H		<9.0		% by wt		
Linoleic Acid		27.1 H		<20.0		% by wt		
PLATELET FUNCTION								
11dhTxB2/Creatinine[6]		1895	≤1500			pg/mg Cr		
11dhTxB2	2431					pg/mL		
Creatinine, Urine, Random	97.2			20.0-300.0		mg/dL		
HYPERTENSION/HEART FAILURE								
Galectin-3	10.5		<17.9	17.9-25.9	>25.9	ng/mL		
NT-proBNP	142		<372	N/A	≥372	pg/mL		

GENETIC CARDIOVASCULAR MARKERS		
Test Name	**Result**	**Comments (See Guidance Statements)**
KIF6 Genotype[SJC]	Trp/Trp	Homozygous noncarrier: See Guidance Statements.
9p21 Genotype[SJC]	RESULT	Heterozygous carrier (rs10757278 and rs1333049). Increased 9p21 associated CVD risk. See Guidance Statements.
rs10757278[SJC]	ag	
rs1333049[SJC]	gc	
ApoE Genotype[SJC]	3/4	Apo E4 Carrier: associated with increased CVD risk. See Guidance Statements.

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	Optimal	Non-Optimal	Optimal	Moderate	High		/ /	/ /
Test Name		**Result**	**Comments (See Guidance Statements)**					

4myheart Diet & Exercise Coaching Program: Need help achieving and maintaining an optimal weight? Managing stress? Trying to improve physical fitness levels? The 4myheart program provides support and personalized lifestyle guidance to help improve heart health. Please talk to your provider, visit 4myheart.com or call 1-800-432-7889 opt 2 to learn more.

Medical Information For Healthcare Providers: If you have any questions about any of the tests in our Cardiometabolic Risk Report, please call Cleveland HeartLab Client Services at 866.358.9828, option 1 to arrange a consult with our clinical education team.

Results (Non-Cardiometabolic)

Test Name	Current Result In Range	Current Result Out of Range	Reference Range	Units	Lab	Historical Results / /	Historical Results / /
ROUTINE PANELS							
Comprehensive Metabolic Panel							
Glucose	97		65-99	mg/dL	Z4M		
Calcium, Total	10.1		8.5-10.5	mg/dL	Z4M		
Sodium	142		136-145	mmol/L	Z4M		
Potassium	4.2		3.5-5.1	mmol/L	Z4M		
Chloride	98		95-108	mmol/L	Z4M		
CO_2 (Carbon Dioxide, Bicarbonate)	27		21-33	mmol/L	Z4M		
BUN (Blood Urea Nitrogen)	18		8-23	mg/dL	Z4M		
Creatinine		1.18 H	0.55-1.00	mg/dL	Z4M		
Albumin	4.6		3.5-5.5	g/dL	Z4M		
Total Protein	7.2		6.1-8.0	g/dL	Z4M		
Globulin	2.7		1.8-3.8	g/dL	Z4M		
ALP (Alkaline Phosphatase)	57		<150	U/L	Z4M		
ALT (Alanine Amino Transferase)	42		<46	U/L	Z4M		
AST (Aspartate Amino Transferase)	32		<41	U/L	Z4M		
Bilirubin, Total	0.9		<1.3	mg/dL	Z4M		
eGFR, Non-African descent	73		>60	mL/min/ 1.73 m²	Z4M		
eGFR, African descent	84		>60	mL/min/ 1.73 m²	Z4M		

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Results (Non-Cardiometabolic)

Test Name	Current Result		Reference Range	Units	Lab	Historical Results	
	In Range	Out of Range				/ /	/ /
THYROID FUNCTION							
Thyroid Stimulating Hormone (TSH)	1.950		0.400-4.500	ulU/mL	Z4M		

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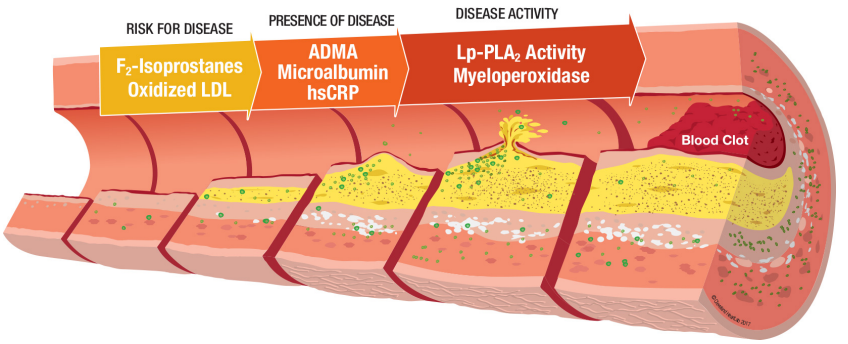
Inflammation Summary

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.



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

Risk for Disease

Test	Result
F_2-Isoprostanes/Creatinine (ng/mg)	0.59 L

Your result in the desirable range suggests the levels of oxidation in your body are low.

Your body needs F_2-Isoprostanes for basic functions like making muscle. In excess, F_2-IsoPs caused by inactivity, smoking and processed foods increase oxidation and blood vessel damage.

Test	Result
Oxidized LDL (OxLDL) (U/L)	66 M

You have modest levels of OxLDL suggesting your diet and/or lifestyle habits may be affecting your health.

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.

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.

Presence of Disease

Test	Result
ADMA (ng/mL)	99 L

Your ADMA result in the desirable range suggests optimal nitric oxide levels and low risk of endothelial dysfunction.

ADMA is a chemical in your blood that reduces nitric oxide, a molecule needed to keep a healthy endothelium (the cells that line your blood vessels). High levels of ADMA indicate unhealthy cells in the blood vessel and may identify risk of cardiovascular disease.

Test	Result
Microalbumin/Creatinine (ng/mg)	9.7 H

You have modest to high levels of albumin in your urine suggesting you may have endothelial damage.

Microalbumin measures the health of the endothelium, a thin layer of cells lining blood vessels. Risk factors can damage that lining in the kidneys causing them to leak albumin, a protein not normally found in urine.

Test	Result
hsCRP (mg/L)	2.6 M

You have modest levels of hsCRP suggesting that you may have increased vascular inflammation. Your provider may order a repeat test and/or consider the presence of cardiovascular disease.

hsCRP measures inflammation in the body. Increases of hsCRP are seen with recent illness, injury, a virus, infection, periodontal (gum) disease and with cardiovascular disease.

Disease Activity

Test	Result
$Lp\text{-}PLA_2$ Activity (nmol/min/mL)	82 H

You have high levels of $Lp\text{-}PLA_2$ Activity suggesting that you may have increased active cholesterol build-up.

$Lp\text{-}PLA_2$ Activity measures vascular-specific inflammation. When cholesterol enters and gets trapped in the vessel wall, inflammation occurs. $Lp\text{-}PLA_2$ Activity may identify active cholesterol build-up inside the vessel wall and the progression of cardiovascular disease.

Test	Result
Myeloperoxidase (MPO) (pmol/L)	392 L

Your result is in the desirable range suggesting that you may have a low probability of plaque rupture if cardiovascular disease is present.

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.

"L" or Low Risk
UND = Undetectable
"M" or Moderate Risk
"H" or High Risk
TNO = Test Not Ordered
TNP = Test Not Performed
INC = Incomputable

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INFLAMMATION

Myeloperoxidase[14] Lab: Z4M

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 have 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[4] Lab: Z4M

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).

Microalbumin/Creatinine Lab: Z4M

In the Framingham Heart Study, it was shown that healthy individuals (defined as non-hypertensive, non-diabetic, and without prevalent CVD) with elevated microalbumin had approximately 3x greater risk for developing cardiovascular disease. These levels were gender-specific and noted to be >=3.9 mg/g cr for men and >=7.5 mg/g cr for women (1). A persistent microalbumin >30 mg/g cr 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).

ADMA (Asymmetric dimethylarginine)[1] Lab: Z4M

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).

OxLDL Lab: Z4M

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[7] Lab: Z4M

Elevated urinary F2-Isoprostanes are associated with an increased risk of coronary heart disease (CHD) (1). (Reference: 1-Schwedhelm et al. Circulation. 2004; 109: 843-848).

LIPIDS

LDL Cholesterol, Calculated Lab: Z4M

Desirable range <100 mg/dL for primary prevention; <70 mg/dL for patients with CHD or diabetic patients with >= 2 CHD risk factors. LDL-C is now calculated using the Martin-Hopkins calculation, which is a validated novel method providing better accuracy than the Friedewald equation in the estimation of LDL-C. Martin SS et al. JAMA. 2013;310(19): 2061-2068 (http://education.QuestDiagnostics.com/faq/FAQ164)

Non-HDL Cholesterol Lab: Z4M

For patients with diabetes plus 1 major ASCVD risk factor, treating to a non-HDL-C goal of <100 mg/dL (LDL-C of <70 mg/dL) is considered a therapeutic option.

LDL-P[13] Lab: Z4M

Relative risk: Optimal <935; Moderate 935-1816; High >1816 nmol/L. Reference range is 592-2404 nmol/L.

Small LDL-P Lab: Z4M

Relative risk: Optimal <467; Moderate 467-820; High >820 nmol/L. Reference range is <1408 nmol/L.

LDL Size Lab: Z4M

Relative risk: Optimal >20.5; High <20.6 nm. Reference range is 20.0-22.3 nm.

HDL-P Lab: Z4M

Relative risk: Optimal >32.8; Moderate 29.2-32.8; High <29.2 umol/L. Reference range is 21.1-43.4 umol/L.

Large HDL-P Lab: Z4M

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Relative risk: Optimal >7.2; Moderate 5.3-7.2; High <5.3 umol/L. Reference range is >3.5 umol/L.

HDL Size — Lab: Z4M

Relative risk: Optimal >9.0; Moderate 8.7-9.0; High <8.7 nm. Reference range is 8.3-10.5 nm.

Large VLDL-P — Lab: Z4M

Relative risk: Optimal <3.7; Moderate 3.7-6.1; High >6.1 nmol/L. Reference range is <16.0 nmol/L.

VLDL Size — Lab: Z4M

Relative risk: Optimal <47.1; Moderate 47.1-49.0; High >49.0 nm. Reference range is 41.1-61.7 nm.

Lipoprotein (a)[3] — Lab: Z4M

Risk: Optimal <75 nmol/L; Moderate 75-125 nmol/L; High >125 nmol/L. Cardiovascular event risk category cut points (optimal, moderate, high) are based on Marcovina et al. Clin Chem. 2003;49:1785 and Nordestgaard et al. European Heart J. 2010;31:2844 (results of meta-analysis and expert panel recommendations).

METABOLIC

HbA1c — Lab: Z4M

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).

TMAO (Trimethylamine N-oxide)[5] — Lab: Z4M

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 have defined the following cut-offs for TMAO to assess relative risk of a cardiovascular event: A cut-off of <6.2 uM defines a population at low risk for a cardiovascular event relative to those above this level. 6.2-9.9 uM defines a population at moderate risk for a cardiovascular event (two-fold increased risk of MACE at 3 years) relative to those with TMAO <6.2 uM (1). Given the dose-dependent relationship between TMAO and cardiovascular event risk demonstrated across multiple clinical subgroups (2), those above the upper limit of the Cleveland HeartLab 95% population interval (>=10.0 uM) are defined as high risk for a cardiovascular event relative to those with TMAO <6.2 uM. (References: 1-Tang et al. N Engl J Med. 2013; 368:1575-1584. 2-Heianza Y, et al. J Am Heart Assoc. 2017;6(7)).

Insulin Resistance Score[10] — Lab: Z4M

Reference range <67. Insulin Sensitive <33; Impaired Insulin Sensitivity 33-66; Insulin Resistant >66. A score below 33 is optimal. The insulin resistance score correlates with steady state glucose levels achieved during an insulin suppression test, a standard research test for insulin resistance. The score is based on insulin and C-peptide results (Abbasi, F., Shiffman, D., Tong, C.H., Devlin, J. J., Reaven, G. M., McPhaul, M. J. (2017) Identification of Insulin Resistance in Apparently Healthy Individuals. Manuscript in preparation).

Insulin, Intact, LC/MS/MS[11] — Lab: Z4M

Insulin concentration can be converted to pmol/L by applying the conversion factor: 1 uIU/mL = 5.97 pmol/L For additional information, please refer to http://education.QuestDiagnostics.com/faq/FAQ170 (This link is being provided for information/ educational purposes only.)

VITAMINS/SUPPLEMENTS

Coenzyme Q10[2] — Lab: Z4M

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.

Vitamin D, 25-Hydroxy by LC-MS/MS[15] — Lab: Z4M

Please note new risk range effective March 18th, 2019. This risk range (>=30.0 ng/dL) replaces the previous risk range of 30.0-80.0 ng/dL. Therapy is based on measurement of Total 25-OHD, with levels <20 ng/mL indicative of Vitamin D deficiency, while levels between 20 ng/mL and 30 ng/mL suggest insufficiency. Optimal levels are >=30 ng/mL. Vitamin-D is fat-soluble and therefore inadvertent or intentional ingestion of excessively high amounts could be toxic. Studies in children and adults suggest blood levels would need to exceed 150 ng/ml before there is any concern. Holick MF, Binkley NC, Bischoff-ferrari HA, et al. Evaluation, treatment, and prevention of vitamin D deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011;96(7):1911-30.

FATTY ACIDS

OmegaCheck® (Whole Blood: EPA+DPA+DHA)[9] — Lab: Z4M

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

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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).

Omega-6 total — Lab: Z4M

Cleveland HeartLab measures a number of omega-6 fatty acids with AA and LA being the two most abundant forms reported.

PLATELET FUNCTION

11dhTxB2/Creatinine[6] — Lab: Z4M

Normalized levels of 11-Dehydro Thromboxane B2 <=1500 pg/mg cr indicate aspirin effect and >1500 pg/mg cr indicate lack of effect.

HYPERTENSION/HEART FAILURE

Galectin-3 — Lab: Z4M

Galectin-3 may be used to help identify individuals at risk of future chronic heart failure due to hypertension. The risk ranges are as follows: low risk <17.9 ng/mL; moderate risk 17.9-25.9 ng/mL; high risk >25.9 ng/mL.

NT-proBNP — Lab: Z4M

Please note new risk range effective March 18th, 2019. This risk range (<372 pg/mL) replaces the previous risk range of <126 pg/mL.

Cardiovascular Genetics Detail Report

Guidance Summary

KIF6 Genotype — **Lab: SJC**

KIF6 Genotype	Trp/Trp
GUIDANCE STATEMENTS	Homozygous noncarrier: Indication for testing: Aid in the assessment of cardiovascular disease risk. Interpretation: This patient is homozygous for KIF6 719Trp and does not carry the KIF6 719Arg allele. The 719Arg polymorphism in the kinesin-like protein 6 (KIF6) gene [Human Genome Variation Society nucleotide position NM 145027.4:c.2155T>C] has been associated with increased coronary heart disease (CHD) risk. This polymorphism has also been associated with CHD event reduction from atorvastatin and pravastatin therapy in certain clinical settings. Carriers of the 719Arg allele, either 719 Arg/Arg or 719 Trp/Arg, have a similar increased CHD risk of up to 55% and observed CHD event reduction with atorvastatin and pravastatin therapy in study populations of predominantly Caucasian men and women over 45 years old. Current studies indicate that carriers of the 719Arg allele in an African-American population are at higher risk for CHD and that this risk is likely of similar magnitude to that observed in a Caucasian population. However, the degree of risk and the response to atorvastatin and pravastatin therapy in African-American carriers of 719Arg have not been precisely quantified.
GENERAL GUIDANCE	1. Non genetic factors contribute to coronary heart disease (CHD), cardiovascular disease (CVD), or myocardial infarction (MI) risk. Examples of such factors include smoking, hypertension, age, diabetes, elevated blood lipid levels, obesity and sedentary lifestyle. 2. Other genetic factors (e.g. family history of heart disease) may contribute to CHD, CVD, or MI risk. 3. These genetic test results should be considered in context of other clinical criteria by a qualified physician. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. 4. Genetic consultation for this individual may be helpful in understanding the genetic implications of these test results and management options.

Patient Information	Specimen Information	Client Information
TEST, FEMALE SAMPLE **DOB: 01/10/1964** **AGE: 55** Gender: Female Fasting: Not Fasting Patient ID:	Order ID: 1908400248 Collected: 03/24/2019, 11:14 AM Received: 03/25/2019, 11:14 AM Reported: 03/25/2019, 1:55 PM	TEST PROVIDER - IT DEPT

Cardiovascular Genetics Detail Report

Guidance Summary

9p21 Genotype	**Lab: SJC**
rs10757278	**ag**
rs1333049	**gc**
GUIDANCE STATEMENTS	Heterozygous carrier (rs10757278 and rs1333049). Increased 9p21 associated CVD risk. Indication for testing: Aid in the assessment of cardiovascular disease risk. Interpretation: This patient has increased 9p21 associated cardiovascular disease (CVD) risk. This patient carries one copy of the 9p21 associated CVD risk allele. About 50% of individuals in the Caucasian population have the same genotype as this patient and also carry one copy of the 9p21 associated CVD risk allele. Individuals who carry one copy of the 9p21 associated CVD risk allele have more 9p21 associated CVD risk than individuals who in the Caucasian population) and less 9p21 associated CVD risk than individuals who carry two copies of the 9p21 associated CVD risk alleles (about 23% of individuals in the Caucasian population). Carriers of one copy of the 9p21 associated risk allele are at 1.25 fold higher 9p21 associated heart disease risk compared to those who carry no copies of the 9p21 risk allele. Carriers of two copies of the 9p21 associated risk allele are at 1.56 fold higher 9p21 associated heart disease risk compared to those who carry no copies of the 9p21 risk allele (Palomaki GE, Melillo S, Bradley LA, "Association Between 9p21 Genomic Markers and Heart Disease, A Meta-analysis", JAMA, 2010; 303(7): 648-656). The 9p21 genetic markers used in this test associate with increased CVD risk, including an association with myocardial infarction (MI) and early onset MI, age <50 (men), <60 (women). A higher risk result does not mean that the patient has had or will develop cardiovascular disease (CVD) or MI, and a lower risk result does not mean the patient is immune to disease. This is a genetic risk test more analogous to the laboratory measurement of another CVD risk biomarker (e.g. LDL-cholesterol), and this 9p21 test is not a determinative genetic test like for Huntington's disease. When interpreting results, it is suggested that clinicians consider that 50% of the Caucasian population carries one copy of the 9p21 associated CVD risk allele, 23% of the Caucasian population carries two copies of the 9p21 associated CVD risk alleles, and there are multiple factors used in evaluating CVD risk in an individual patient. A patient's overall CVD risk can be estimated using a risk classification scheme that utilizes both clinical and laboratory information (e.g. Framingham Risk Score, Reynolds Risk Score), and the 9p21 genetic test can further refine a risk estimate. These 9p21 results apply to Caucasian individuals of European ancestry, as more research is needed in order to extend to African-American or other ethnic populations. SEE BELOW FOR SNP INFORMATION.
ApoE Genotype	**Lab: SJC**
ApoE Genotype	**3/4**
GUIDANCE STATEMENTS	Apo E4 Carrier: associated with increased CVD risk. Indication for testing: Aid in the assessment of cardiovascular disease risk. Interpretation: This patient has the ApoE genotype of E3/E4. The E4 allele can be associated with increased LDL-C levels and therefore an increased risk for coronary heart disease (CHD) compared to individuals with the E3/E3 genotype
GENERAL GUIDANCE	1. Non genetic factors contribute to coronary heart disease (CHD), cardiovascular disease (CVD), or myocardial infarction (MI) risk. Examples of such factors include smoking, hypertension, age, diabetes, elevated blood lipid levels, obesity and sedentary lifestyle. 2. Other genetic factors (e.g. family history of heart disease) may contribute to CHD, CVD, or MI risk. 3. These genetic test results should be considered in context of other clinical criteria by a qualified physician. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. 4. Genetic consultation for this individual may be helpful in understanding the genetic implications of these test results and management options.
General (Cardiovascular Genetics)	
GENERAL GUIDANCE	1. Non genetic factors contribute to coronary heart disease (CHD), cardiovascular disease (CVD), or myocardial infraction (MI) risk. Examples of such factors include smoking, hypertension, age, diabetes, elevated blood lipid levels, obesity and sedentary lifestyle. 2. Other genetic factors (e.g. family history of heart disease) may contribute to CHD, CVD, or MI risk. 3. These genetic test results should be considered in context of other clinical criteria by a qualified physician. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. 4. Genetic consultation for this individual may be helpful in understanding the genetic implications of these test results and management options.
METHOD	Real-Time Polymerase Chain Reaction (PCR). Analytic sensitivity and specificity of the genetic assays using this platform exceed 99.9%.

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LIMITATIONS	Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data. This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.

Footnotes

(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, Inc. 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.

(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, Inc. 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) Although the test is performed by a U.S. FDA approved/cleared reagent, the manufacturer has not determined the efficacy of this test when performed on certain specimen type/collection device/etc. The performance characteristics of this test were determined by Cleveland HeartLab, Inc. The Cleveland HeartLab, Inc. is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

(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, Inc. 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, Inc. 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) Although the test is performed by a U.S. FDA approved reagent, Cleveland HeartLab has extended sample stability up to 5 days based on data provided by manufacturer. The performance characteristics of this test were determined by the Cleveland HeartLab, Inc. The Cleveland HeartLab is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity clinical laboratory testing.

(7) 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, Inc. 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) 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).

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(9) 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, Inc. 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.

(10) This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. Test performed by: Quest Diagnostics Nichols Institute, 33608 Ortega Highway, San Juan Capistrano CA 92675-2042, Laboratory Medical Director: J M Nakamoto MD, PhD, CLIA ID: 05D0643352.

(11) This test was developed, and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. Test performed by: Quest Diagnostics Nichols Institute, 33608 Ortega Highway, San Juan Capistrano CA 92675-2042, Laboratory Medical Director: J M Nakamoto MD, PhD, CLIA ID: 05D0643352.

(12) Test performed by: Quest Diagnostics Nichols Institute, 33608 Ortega Highway, San Juan Capistrano CA 92675-2042, Laboratory Medical Director: J M Nakamoto MD, PhD, CLIA ID: 05D0643352.

(13) This test is performed by a Nuclear Magnetic Resonance 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.

(14) 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, Inc. 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.

(15) 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, Inc. 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.

PERFORMING SITE:

Z4M CLEVELAND HEARTLAB INC, 6701 CARNEGIE AVENUE SUITE 500, CLEVELAND, OH 44103-4623 Medical Director: Bill G. Richendollar, MD, CLIA: 36D1032987

SJC Quest Diagnostics Nichols Institute, 33608 Ortega Highway, San Juan Capistrano CA 92675-2042, Laboratory Medical Director: I Maramica MD, PhD, MBA, CLIA ID: 05D0643352.