Quest Diagnostics™

ClevelandHeartLab®
Know your risk.

Report Status: Final

TEST, MALESAM

Patient Information	Specimen Information	Client Information
TEST, MALESAM **DOB: 09/11/1958** **AGE: 61** Gender: Male Fasting: Not Fasting Phone: Patient ID:	Order ID: 1928400847 Requisition: 1928400847 Collected: 10/10/2019, 10:28 AM Received: 10/11/2019, 10:28 AM Reported: 10/14/2019, 11:55 AM	TEST PROVIDER - IT DEPT 12628 IT DEPT - CHL 6701 CARNEGIE AVE SUITE 500 CLEVELAND, OH 44103

Cardiometabolic Risk Report

Test Name	Current Result & Risk		Reference Range/Risk Categories			Units	Historical Result & Risk from / /
	Optimal	Non-Optimal	Optimal	Moderate	High		
INFLAMMATION							
Myeloperoxidase[10]	393		<470	470-539	≥540	pmol/L	
Lp-PLA$_2$ Activity[9]		128	≤123	N/A	>123	nmol/min/mL	
hs-CRP[4]		2.1	<1.0	1.0-3.0	>3.0	mg/L	
Microalbumin/Creatinine	3.7		<3.9	N/A	≥3.9	mg/g	
Microalbumin	5.9					mg/L	
Creatinine, Urine, Random	157.4			20.0-300.0		mg/dL	
ADMA (Asymmetric dimethylarginine)[1]	93		<100	100-123	>123	ng/mL	
SDMA (Symmetric dimethylarginine)	97			73-135		ng/mL	
OxLDL		66	<60	60-69	≥70	U/L	
F$_2$-Isoprostane/Creatinine[5]	0.65		<0.86	N/A	≥0.86	ng/mg	
F$_2$-Isoprostane	1.03					ng/mL	
Creatinine, Urine, Random	157.4			20.0-300.0		mg/dL	
LIPIDS							
Lipid Panel							
Cholesterol, Total	149		<200	N/A	≥200	mg/dL	
HDL Cholesterol	42		≥40	N/A	<40	mg/dL	
Triglycerides	102		<150	150-199	≥200	mg/dL	
LDL Cholesterol, Calculated	87		<100	100-129	>129	mg/dL (calc)	
Chol/HDL-C	3.5		≤3.5	3.6-5.0	>5.0	calc	
Non-HDL Cholesterol	107		<130	130-189	≥190	mg/dL (calc)	

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	Optimal	Non-Optimal	Optimal	Moderate	High		/ /	/ /
TG/HDL-C		2.4	<2.0	2.0-3.0	>3.0	calc		
Lipoprotein Fractionation, NMR								
LDL-P(11)		1200	<935	935-1816	>1816	nmol/L		
Small LDL-P	384		<467	467-820	>820	nmol/L		
LDL Size	21.2		>20.5	N/A	≤20.5	nm		
HDL-P		29.0	>32.8	29.2-32.8	<29.2	umol/L		
Large HDL-P		4.2	>7.2	5.3-7.2	<5.3	umol/L		
HDL Size		8.8	>9.0	8.7-9.0	<8.7	nm		
Large VLDL-P		5.3	<3.7	3.7-6.1	>6.1	nmol/L		
VLDL Size		49.4	<47.1	47.1-49.0	>49.0	nm		
METABOLIC								
TMAO (Trimethylamine N-oxide)(3)		7.4	<6.2	6.2-9.9	≥10.0	uM		
VITAMINS/SUPPLEMENTS								
Coenzyme Q10(2)	1.37		>0.35	N/A	≤0.35	ug/mL		
Vitamin B12	720			232-1245		pg/mL		
FATTY ACIDS								
OmegaCheck® (Whole Blood: EPA+DPA +DHA)(12)		4.3	≥5.5	3.8-5.4	≤3.7	% by wt		
Arachidonic Acid/EPA Ratio		51.7 H		3.7-40.7				
Omega-6/Omega-3 Ratio	9.5			3.7-14.4				
Omega-3 total	4.3					% by wt		
EPA	0.3			0.2-2.3		% by wt		
DPA	1.6			0.8-1.8		% by wt		
DHA	2.4			1.4-5.1		% by wt		
Omega-6 total	40.8					% by wt		

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Test Name	Current Result & Risk		Reference Range/Risk Categories			Units	Historical Result & Risk from	
	Optimal	Non-Optimal	Optimal	Moderate	High		/ /	/ /
Arachidonic Acid	**15.5**			8.6-15.6		% by wt		
Linoleic Acid	**21.5**			18.6-29.5		% by wt		

HYPERTENSION/HEART FAILURE

Troponin T, High Sensitivity (hs-TnT)		**6**	<6	6-22	>22	ng/L	

GENETIC CARDIOVASCULAR MARKERS

Test Name	Result	Comments (See Guidance Statements)
ApoE Genotype[6]	**3/4**	Apo E4 Carrier: associated with increased CVD risk. See Guidance Statements.
CYP2C19 Genotype[7]	***1/*2**	Intermediate Metabolizer. See Guidance Statements.
MTHFR Mutation[8]	**SEE NOTE**	RESULT: Positive for one copy of the C677T variant and one copy of the A1298C variant. 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.

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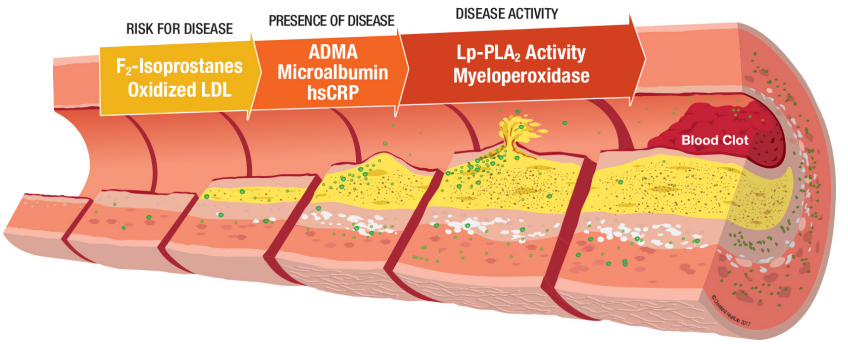
Inflammation Summary

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)	0.65 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)	93 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)	3.7 L

Your result in the desirable range suggests you have a low risk of 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)	2.1 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-PLA_2 Activity (nmol/min/mL)	128 H

You have high levels of Lp-PLA_2 Activity suggesting that you may have increased active cholesterol build-up.

Lp-PLA_2 Activity measures vascular-specific inflammation. When cholesterol enters and gets trapped in the vessel wall, inflammation occurs. Lp-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)	393 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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Cardiometabolic Comment Report

INFLAMMATION

Myeloperoxidase(10) — 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(9) — Lab: Z4M

Relative Risk: Optimal <=123 nmol/min/mL; High >123 nmol/min/mL.

hs-CRP(4) — Lab: Z4M

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).

SDMA (Symmetric dimethylarginine) — Lab: Z4M

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(5) — 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(11) — 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.

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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

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.

METABOLIC

TMAO (Trimethylamine N-oxide)[3] — 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)).

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 B12 — Lab: Z4M

FATTY ACIDS

OmegaCheck® (Whole Blood: EPA+DPA+DHA)[12] — 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 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).

Arachidonic Acid/EPA Ratio — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (3.7-40.7) replaces the previous reference range of <5.0.

Omega-6/Omega-3 Ratio — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (3.7-14.4) replaces the previous reference range of <4.5.

EPA — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (0.2-2.3% by wt) replaces the previous reference range of >2.0% by wt.

DPA — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (0.8-1.8% by wt) replaces the previous reference range of >1.0% by wt.

DHA — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (1.4-5.1% by wt) replaces the previous reference range of >4.0% by wt.

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Cardiometabolic Comment Report

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.

Arachidonic Acid — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (8.6-15.6% by wt) replaces the previous reference range of <9.0% by wt.

Linoleic Acid — Lab: Z4M

Please note new reference range effective April 22nd, 2019. This reference range (18.6-29.5% by wt) replaces the previous reference range of <20.0% by wt.

HYPERTENSION/HEART FAILURE

Troponin T, High Sensitivity (hs-TnT) — Lab: Z4M

High Sensitivity Troponin T (hs-TnT) levels exceeding the gender-specific 99th percentile upper reference limit (males >22 ng/L, females >14 ng/L) may indicate a recent acute myocardial infarction however hs-TnT results should always be assessed in conjunction with the patient's medical history, clinical examination, symptoms of cardiac ischemia, electrocardiogram results, and/or other cardiovascular disease (CVD) diagnostic findings. Elevations in hs-TnT can also be observed in other heart conditions. To distinguish between acute and chronic hs-TnT elevations, serial sampling and clinical correlation is recommended for interpretation. There is literature supporting any hs-TnT >=6 ng/L confers increased CVD relative risk (Oluleye OW, et al. Ann Epidemiol. 2013;23(2):66-73; Seliger SL, et al. Circulation. 2017;135(16):1494-1505).

Cardiovascular Genetics Detail Report

Guidance Summary

ApoE Genotype	**Lab: Z4M**
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.

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Cardiovascular Genetics Detail Report

Guidance Summary

CYP2C19 Genotype	**Lab: Z4M**
CYP2C19 Genotype	***1/*2**
GUIDANCE STATEMENTS	Intermediate Metabolizer. Indication for testing: Pharmacogenetic test (Clopidogrel Metabolism) 1. Targeted genetic analysis shows this patient carries a single non-functional CYP2C19 genetic variant that causes reduced metabolism of some drugs, including the prodrug clopidogrel. This patient is likely to be an intermediate metabolizer. Intermediate metabolizers have reduced CYP2C19 enzyme activity and may require alternative treatments or altered drug dosage of a drug metabolized by CYP2C19 for optimal therapeutic response, as clinically indicated.
GENERAL GUIDANCE	The clinical impact of the CYP2C19 genotype on the metabolism of specific drugs will vary based on non-genetic factors, such as hepatic and renal status, other medications used (including over-the-counter medications, herbals and other supplements), alcohol or illegal drug use, race, age, weight, diet, and diseases present in an individual patient. Detection of genetic variants does not replace the need for drug and clinical monitoring. Many medications serve as substrates, inhibitors, or inducers of the CYP2C19 enzyme, including some proton pump inhibitors, antidepressants, antimicrobials and anti-seizure medications. Co-administration of CYP2C19 inhibitors may convert patients to poor metabolizer status. Consultation with a clinical pharmacy professional to discuss drug and dose selection may be helpful in understanding the implications of these test results and management options. The CYP2C19 genotype test should be considered in context of other clinical criteria by a qualified physician. This test is not intended to be used as the sole means for clinical diagnosis or patient management decisions.
METHOD	The normal (wild-type) CYP2C19 allele is designated CYP2C19*1. This assay detects the wild type allele (CYP2C19*1) as well as 10 common mutations in the CYP2C19 gene: CYP2C19*2 (c.681G>A), CYP2C19*3 (p.W212X), CYP2C19*4 (c.1A>G), CYP2C19*5 (p.R433W), CYP2C19*6 (p.Arg132G1n), CYP2C19*7 (c.819+2T>A), CYP2C19*8 (p.Trp120Arg), CYP2C19*9 (p.Arg144His), CYP2C19*12 (p.X491CysextX26) and CYP2C19*17 (c.-806C>T). The CYP2C19 variants described above are detected by single nucleotide primer extension after multiplex-polymerase chain reaction (PCR) amplification of specific regions of the CYP2C19 gene. Fluorescent extension products are analyzed on an automated, capillary DNA sequencer.
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.
MTHFR Mutation	**Lab: Z4M**
MTHFR Mutation	**SEE NOTE**
GUIDANCE STATEMENTS	RESULT: Positive for one copy of the C677T variant and one copy of the A1298C variant. INTERPRETATION: This individual is compound heterozygous for the variants C677T and A1298C in the MTHFR gene. This result is not associated with a significantly increased risk for coronary artery disease, venous thromboembolism, or adverse pregnancy outcome. This assay cannot determine whether these two variants are on opposite chromosomes (trans) or on the same chromosome (cis).
GENERAL GUIDANCE	Reduced methylenetetrahydrofolate reductase (MTHFR) enzyme activity is a genetic risk factor for hyperhomocysteinemia, especially when present with low serum folate levels. Two common variants in the MTHFR gene result in reduced enzyme activity. The "thermolabile" variant C677T [NM 005957.3:c665C>T (p.A222V)] and A1298C [c. 1286A>C (p.E429A)] occur frequently in the general population. Mild to moderate hyperhomocysteinemia has been identified as a risk factor for coronary artery disease and venous thromboembolism. Hyperhomocysteinemia is multifactorial, involving a combination of genetic, physiologic and environmental factors. Recent studies do not support the previously described association of increased risk for coronary artery disease and venous thromboembolim with mild hyperhomocysteinemia caused by reduced MTHFR activity. Therefore, the utility of MTHFR variant testing is uncertain and is not recommended by the American College of Medical Genetics and Genomics (ACMG) or the American Congress of Obstetricians and Gynecologists (ACOG) in the evaluation of venous thromboembolism or adverse pregnancy outcome.
General (Cardiovascular Genetics)	

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Guidance Summary

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%.
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) 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.

(4) The AHA/CDC Guidelines recommend hs-CRP ranges for identifying Relative Cardiovascular Risk in patients ages >17 years: <1.0 mg/L Lower Relative Cardiovascular Risk; 1.0-3.0 mg/L Average Relative Cardiovascular Risk; 3.1-10.0 mg/L Higher Relative Cardiovascular Risk. For patients with higher cardiovascular risk, consider retesting in 1-2 weeks to exclude a benign transient elevation secondary to infection or inflammation from the baseline CRP value. Persistent elevations of >10.0 mg/L upon retesting may be associated with infection and inflammation. The AHA/CDC recommendations are based on Pearson TA et al. Circulation. 2003;107:499-511.

(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.

Patient Information	Specimen Information	Client Information
TEST, MALESAM **DOB: 09/11/1958** **AGE: 61** Gender: Male Fasting: Not Fasting Patient ID:	Order ID: 1928400847 Collected: 10/10/2019, 10:28 AM Received: 10/11/2019, 10:28 AM Reported: 10/14/2019, 11:55 AM	TEST PROVIDER - IT DEPT

(6) Real-Time Polymerase Chain Reaction (PCR). Analytic sensitivity and specificity of the genetic assays using this platform exceed 99.9%. 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 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.

(7) The normal (wild-type) CYP2C19 allele is designated CYP2C19*1. This assay detects the wild type allele (CYP2C19*1) as well as 10 common mutations in the CYP2C19 gene: CYP2C19*2 (c.681G>A), CYP2C19*3 (p.W212X), CYP2C19*4 (c.1A>G), CYP2C19*5 (p.R433W), CYP2C19*6 (p.Arg132G1n), CYP2C19*7 (c.819+2T>A), CYP2C19*8 (p.Trp120Arg), CYP2C19*9 (p.Arg144His), CYP2C19*12 (p.X491CysextX26) and CYP2C19*17 (c.-806C>T). The CYP2C19 variants described above are detected by single nucleotide primer extension after multiplex-polymerase chain reaction (PCR) amplification of specific regions of the CYP2C19 gene. Fluorescent extension products are analyzed on an automated, capillary DNA sequencer. 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 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.

(8) The C677T and A1298C variants are detected by amplification of the selected regions of MTHFR gene by polymerase chain reaction (PCR) and fluorescent probes hybridization to the targeted regions, followed by melting curve analysis with a real time PCR system. 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. Health care providers, please contact your local Quest Diagnostics genetic counselor or call 866-GENEINFO (866-436-3463) for assistance with interpretation of these results. 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.

(9) This test is performed by an enzymatic 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 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.

(11) 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.

(12) 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