

Patient Information	Specimen Information	Client Information
TEST, SAMPLE1 DOB: 08/30/1968 AGE: 51 Gender: Male Fasting: Not Fasting Phone: Patient ID:	Order ID: 1927300198 Requisition: 1927300198 Collected: 09/29/2019, 11:59 AM Received: 09/30/2019, 11:59 AM Reported: 09/30/2019, 2:45 PM	HUMPHREY BACCHUS, CCN, P.T. 13323 INVIVO CLINICAL UNIT 1, THE NEW WAREHOUSE LIBBY'S DRIVE, STROUD GLOUCESTERSHIRE, EN GL5- 1RN

Cardiometabolic Risk Report

Test Name	Current		Reference Range/Risk Categories			Units	Historical	
	Result & Risk		Optimal	Moderate	High		Result & Risk from	
	Optimal	Non-Optimal					//	//
INFLAMMATION								
Myeloperoxidase ⁽⁸⁾		556	<470	470-539	≥540	pmol/L		
Lp-PLA ₂ Activity ⁽⁷⁾	68		≤123	N/A	>123	nmol/min/mL		
hs-CRP ⁽⁵⁾	0.7		<1.0	1.0-3.0	>3.0	mg/L		
Microalbumin/Creatinine		9.4	<3.9	N/A	≥3.9	mg/g		
Microalbumin	7.3					mg/L		
Creatinine, Urine, Random	128.3			20.0-300.0		mg/dL		
ADMA (Asymmetric dimethylarginine) ⁽¹⁾		126	<100	100-123	>123	ng/mL		
SDMA (Symmetric dimethylarginine)	108			73-135		ng/mL		
OxLDL	53		<60	60-69	≥70	U/L		
F ₂ -Isoprostane/Creatinine ⁽⁶⁾	0.43		<0.86	N/A	≥0.86	ng/mg		
F ₂ -Isoprostane	0.55					ng/mL		
Creatinine, Urine, Random	128.3			20.0-300.0		mg/dL		
LIPIDS								
Lipid Panel								
Cholesterol, Total		206	<200	N/A	≥200	mg/dL		
HDL Cholesterol	56		≥40	N/A	<40	mg/dL		
Triglycerides	110		<150	150-199	≥200	mg/dL		
LDL Cholesterol, Calculated		128	<100	100-129	>129	mg/dL (calc)		
Chol/HDL-C		3.7	≤3.5	3.6-5.0	>5.0	calc		
Non-HDL Cholesterol		150	<130	130-189	≥190	mg/dL (calc)		

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	Result & Risk		Optimal	Moderate	High		Result & Risk from	
	Optimal	Non-Optimal					//	//
TG/HDL-C		2.0	<2.0	2.0-3.0	>3.0	calc		
Lipoprotein Fractionation, NMR								
LDL-P ⁽¹⁰⁾		1379	<935	935-1816	>1816	nmol/L		
Small LDL-P	248		<467	467-820	>820	nmol/L		
LDL Size	21.6		>20.5	N/A	≤20.5	nm		
HDL-P	41.2		>32.8	29.2-32.8	<29.2	umol/L		
Large HDL-P	8.1		>7.2	5.3-7.2	<5.3	umol/L		
HDL Size	9.5		>9.0	8.7-9.0	<8.7	nm		
Large VLDL-P	3.2		<3.7	3.7-6.1	>6.1	nmol/L		
VLDL Size	35.6		<47.1	47.1-49.0	>49.0	nm		
Apolipoproteins								
Lipoprotein (a)	18		<75	75-125	>125	nmol/L		
METABOLIC								
Glucose ⁽³⁾	87		65-99	100-125	<65 OR ≥126	mg/dL		
HbA1c	5.5		<5.7	5.7-6.4	>6.4	%		
Estimated Average Glucose	111		<117	117-137	>137	mg/dL		
TMAO (Trimethylamine N-oxide) ⁽²⁾	5.1		<6.2	6.2-9.9	≥10.0	uM		
VITAMINS/SUPPLEMENTS								
Coenzyme Q10 ⁽⁴⁾	1.56		>0.35	N/A	≤0.35	ug/mL		
Vitamin D, 25-Hydroxy by LC-MS/MS ⁽⁹⁾		6.0	≥30.0	20.0-29.9	<20.0 OR >150.0	ng/mL		
FATTY ACIDS								
OmegaCheck® (Whole Blood: EPA+DPA +DHA) ⁽¹¹⁾	9.2		≥5.5	3.8-5.4	≤3.7	% by wt		

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Test Name	Current		Reference Range/Risk Categories			Units	Historical	
	Result & Risk		Optimal	Moderate	High		Result & Risk from	
	Optimal	Non-Optimal					//	//
Arachidonic Acid/EPA Ratio	5.1							
Omega-6/Omega-3 Ratio	5.2							
Omega-3 total		9.2				% by wt		
EPA		3.0 H				% by wt		
DPA		3.1 H				% by wt		
DHA	3.1					% by wt		
Omega-6 total		41.7				% by wt		
Arachidonic Acid	15.4					% by wt		
Linoleic Acid		15.2 L				% by wt		

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		Reference Range	Units	Lab	Historical Results	
	In Range	Out of Range				//	//
ROUTINE PANELS							
Comprehensive Metabolic Panel							
Glucose ⁽³⁾	87		65-99	mg/dL	Z4M		
Calcium, Total	9.4		8.5-10.5	mg/dL	Z4M		
Sodium	141		136-145	mmol/L	Z4M		
Potassium	4.4		3.5-5.1	mmol/L	Z4M		
Chloride	103		95-108	mmol/L	Z4M		
CO ₂ (Carbon Dioxide, Bicarbonate)	25		21-33	mmol/L	Z4M		
BUN (Blood Urea Nitrogen)	10		8-23	mg/dL	Z4M		
Creatinine	0.83		0.72-1.30	mg/dL	Z4M		
Albumin	4.4		3.5-5.5	g/dL	Z4M		
Total Protein	6.9		6.1-8.0	g/dL	Z4M		

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Results (Non-Cardiometabolic)

Test Name	Current Result		Reference Range	Units	Lab	Historical Results	
	In Range	Out of Range				//	//
Globulin	2.5		1.8-3.8	g/dL	Z4M		
ALP (Alkaline Phosphatase)	41		<150	U/L	Z4M		
ALT (Alanine Amino Transferase)	7		<51	U/L	Z4M		
AST (Aspartate Amino Transferase)	11		<41	U/L	Z4M		
Bilirubin, Total	0.2		<1.3	mg/dL	Z4M		
eGFR, Non-African descent	102		>60	mL/min/ 1.73 m ²	Z4M		
eGFR, African descent	118		>60	mL/min/ 1.73 m ²	Z4M		

THYROID FUNCTION

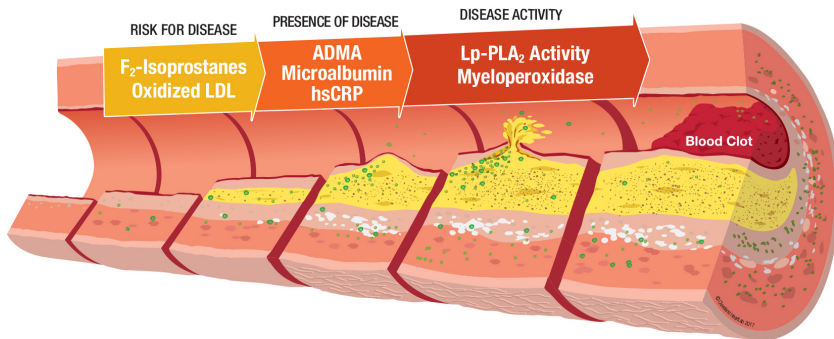
Thyroid Stimulating Hormone (TSH)	1.110		0.400-4.500	uIU/mL	Z4M		
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Inflammation Summary

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		Presence of Disease		Disease Activity	
Test	Result	Test	Result	Test	Result
F₂-Isoprostanes/Creatinine (ng/mg)	0.43 L	ADMA (ng/mL)	126 H	Lp-PLA₂ Activity (nmol/min/mL)	68 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.		You have high levels of ADMA in your blood suggesting you may have low nitric oxide levels and endothelial (vessel wall lining) 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.		Your result is in the desirable range suggesting that you may have limited 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.	
Oxidized LDL (OxLDL) (U/L)	53 L	Microalbumin/Creatinine (ng/mg)	9.4 H	Myeloperoxidase (MPO) (pmol/L)	556 H
Your result is in the desirable range, suggesting that you have low levels of OxLDL. 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.		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.		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 <ul style="list-style-type: none"> 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. 		hsCRP (mg/L)	0.7 L	Legend: "L" or Low Risk UND = Undetectable "M" or Moderate Risk "H" or High Risk TNO = Test Not Ordered TNP = Test Not Performed INC = Incomputable	
Your result in the desirable range suggests that you have low amounts of general inflammation in your body. 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.					

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Cardiometabolic Comment Report

INFLAMMATION

Myeloperoxidase⁽⁸⁾ 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-PLA₂ Activity⁽⁷⁾ Lab: Z4M
 Relative Risk: Optimal <=123 nmol/min/mL; High >123 nmol/min/mL.

hs-CRP⁽⁵⁾ 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.)

F₂-Isoprostane/Creatinine⁽⁶⁾ 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⁽¹⁰⁾ 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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Cardiometabolic Comment Report

HDL-P Relative risk: Optimal >32.8; Moderate 29.2-32.8; High <29.2 umol/L. Reference range is 21.1-43.4 umol/L.	Lab: Z4M
Large HDL-P Relative risk: Optimal >7.2; Moderate 5.3-7.2; High <5.3 umol/L. Reference range is >3.5 umol/L.	Lab: Z4M
HDL Size Relative risk: Optimal >9.0; Moderate 8.7-9.0; High <8.7 nm. Reference range is 8.3-10.5 nm.	Lab: Z4M
Large VLDL-P Relative risk: Optimal <3.7; Moderate 3.7-6.1; High >6.1 nmol/L. Reference range is <16.0 nmol/L.	Lab: Z4M
VLDL Size Relative risk: Optimal <47.1; Moderate 47.1-49.0; High >49.0 nm. Reference range is 41.1-61.7 nm.	Lab: Z4M
Lipoprotein (a) 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 Tsimika S. JACC 2017;69:692-711.	Lab: Z4M

METABOLIC

Glucose⁽³⁾ Lab: Z4M
HbA1c Lab: Z4M For the purpose of screening for the presence of diabetes: <5.7% is consistent with the absence of diabetes; 5.7-6.4% is consistent with increased risk for diabetes (prediabetes); >= 6.5% is consistent with diabetes. This assay result is consistent with a decreased risk of diabetes. Currently, no consensus exists regarding use of hemoglobin A1c for diagnosis of diabetes in children. According to American Diabetes Association (ADA) guidelines, hemoglobin A1c <7.0% represents optimal control in non-pregnant diabetic patients. Different metrics may apply to specific patient populations. Standards of Medical Care in Diabetes (ADA).
Estimated Average Glucose Lab: Z4M 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;31:1473-1478).

TMAO (Trimethylamine N-oxide)⁽²⁾

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)).
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VITAMINS/SUPPLEMENTS

Coenzyme Q10⁽⁴⁾ 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⁽⁹⁾ 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)⁽¹¹⁾ Lab: Z4M
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Cardiometabolic Comment Report

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 $\geq 5.5\%$ by wt defines a population at low relative risk, 3.8-5.4% by wt defines a population at moderate relative risk, and $\leq 3.7\%$ 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.

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.

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) The American Diabetes Association (ADA) defines Diagnostic Criteria for Diabetes Mellitus within the Standards of Medical Care in Diabetes 2018, Diabetes Care 2018 Jan; 41(Supplement 1): S1-S2. The following ranges for Fasting Glucose Values are recommended as Diagnostic Criteria for Diabetes Mellitus: <100 mg/dL Normal, 100-125 mg/dL Fasting Impaired, and ≥ 126 mg/dL Diabetes. The value for diagnosis of diabetes (≥ 126 mg/dL Fasting) must be confirmed by testing on a subsequent day.

(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

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(5) 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.

(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, 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.

(7) 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.

(8) 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.

(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 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.

(11) 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.

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