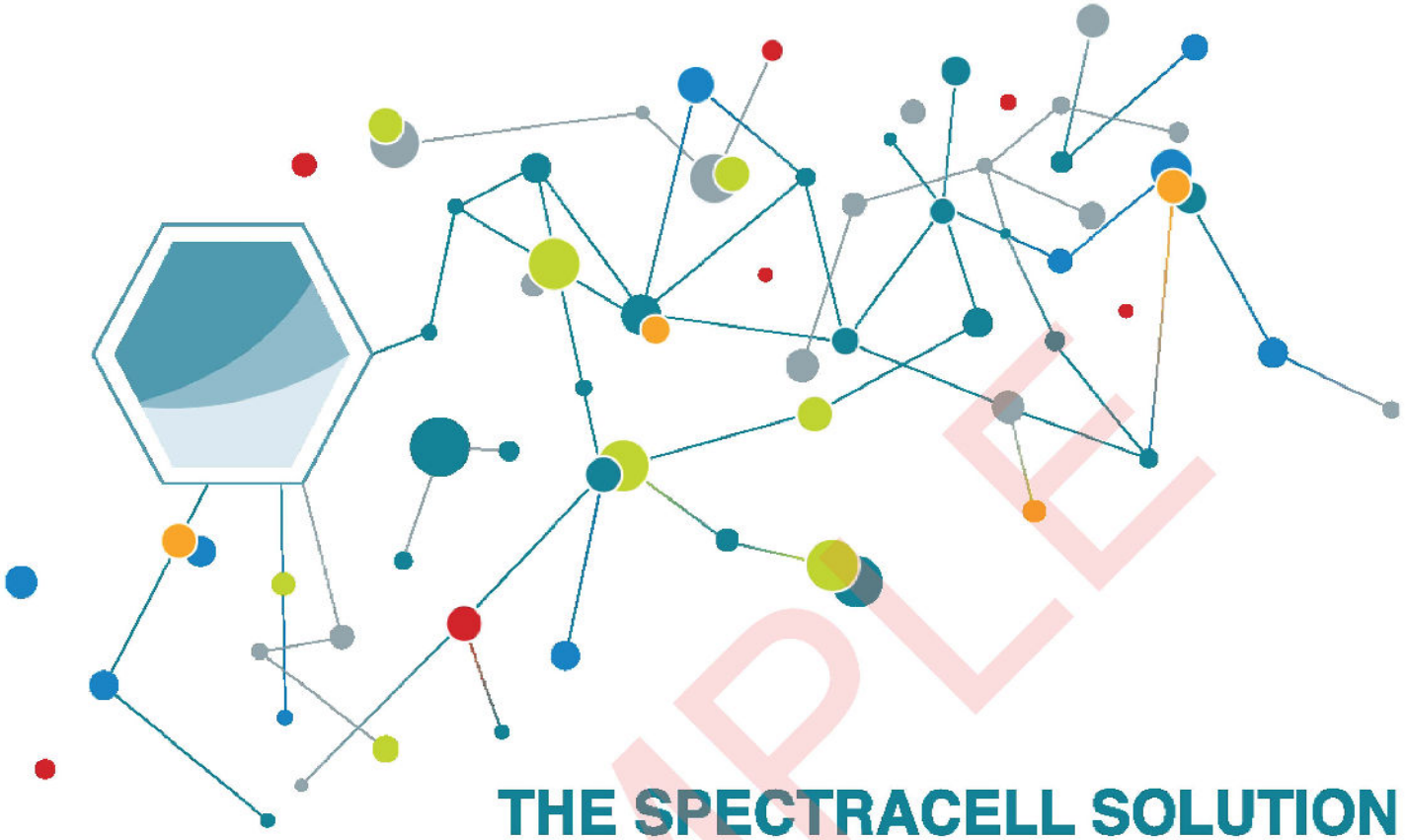

THE SPECTRACELL SOLUTION

Driven *by Science.* Inspired *by You.*

Patient: Doe, Jane

Accession ID: 0000000

Provider: Sample Provider, MD

Order Status: Complete

CardioMetabolic Panel
OmegaCheck

10401 Town Park Drive, Houston, TX 77072
1(800) 227-5227 | support@spectracell.com | www.spectracell.com

SpectraCell Laboratories
Science + Health + Solutions

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PATIENT

NAME	AGE
Doe, Jane	**59**
DOB	GENDER
2/25/1960	**Female**
PATIENT ID	
00-000-00000	

SPECIMEN

ACCESSION ID	DATE COLLECTED
0000000000	**04/17/2019**
ORDER ID	DATE RECEIVED
0000-00000000000-000000	**04/18/2019**
	DATE REPORTED
	08/19/2019

PROVIDER

ACCOUNT ID	CLIENT NAME
000000	**Sample Provider, MD**
ADDRESS	
123 S. Any Street **ANYWHERE, TX 77000**	

Normal | Borderline | Out of Range

Lipoprotein Particle Numbers

Tests	In Range	Out of Range	Reference Range	Units
VLDL Particles		**123**	<85	nmol/L
Total LDL Particles		**905**	<900	nmol/L
Non-HDL Particles		**1028**	<1000	nmol/L
Remnant Lipoprotein		**236**	<150	nmol/L
Dense LDL III		**390**	<300	nmol/L
Dense LDL IV	55		<100	nmol/L
Total HDL Particles		**5925**	>7000	nmol/L
Buoyant HDL 2b		**1769**	>1500	nmol/L

Lipid Panel

Tests	In Range	Out of Range	Reference Range	Units
Total Cholesterol	198		<200	mg/dL
Triglycerides		**344**	30-150	mg/dL
HDL		**34**	>40	mg/dL
LDL		**108**	40-130	mg/dL
Non-HDL Cholesterol		**164**	<160	mg/dL

Vascular Inflammation

Tests	In Range	Out of Range	Reference Range	Units
Insulin, Serum	16.1		<21.0	µIU/mL
hs-CRP		**2.69**	<3.00	mg/L
Lipoprotein(a)	4.6		<30.0	mg/dL
Apolipoprotein B		**99**	40-100	mg/dL
Apolipoprotein A1	124		>115	mg/dL
Homocysteine		**30**	<11.0	µmol/L

PATIENT: **Doe, Jane** PROVIDER: **Sample Provider, MD** DATE REPORTED: **08/19/2019** ACCESSION ID: **0000000000**

Metabolic Syndrome Traits

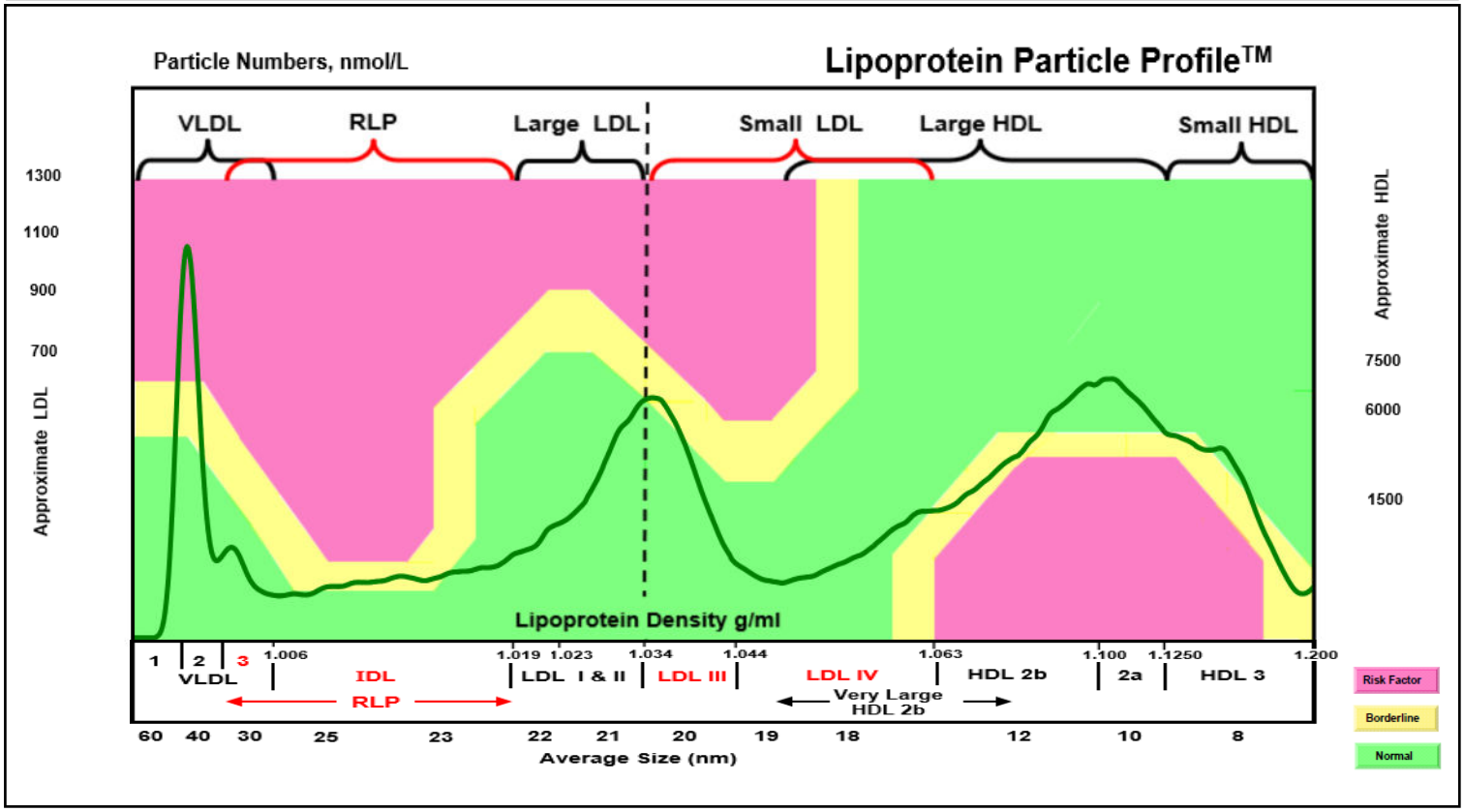
Tests		In Range	Out of Range	Reference Range	Units
Metabolic Syndrome Traits			1	Zero	

A diagnosis of metabolic syndrome is confirmed if any three of the following traits exist in a patient: (1)high triglycerides [>150mg/dL]*; (2)low HDL [<40mg/dL in men, <50mg/dL in women]*; (3) elevated small dense LDL III and LDL IV [>400 nmol/L]*; (4) high fasting glucose [>100mg/dL]; (5) high blood pressure [>130/85]; (6) high waist circumference [>40 inches in men, >35 inches in women]. *Included in this section of report.

CardioMetabolic Risk Assessment

Tests		In Range	Out of Range	Reference Range	Units
CardioMetabolic Risk Assessment			High		

The CardioMetabolic Risk Assessment is an indication of your risk for developing cardiovascular disease, including stroke and diabetes. It is a composite value derived from laboratory test results and may not capture all of the individual risk factors for a particular patient. Additional elements that can impact risk that are not included are weight, blood pressure (hypertension), smoking, inflammation, medical history and family history. The risk score is provided to supplement, not supplant, the clinical utility of individual biomarkers and other clinical indications. The CardioMetabolic Risk Assessment is not intended to provide a single indicator of risk. Treatment decisions should be based on the totality of available information.



PATIENT: **Doe, Jane** PROVIDER: **Sample Provider, MD** DATE REPORTED: **08/19/2019** ACCESSION ID: **0000000000**

Pre-Diabetes

Normal | Borderline | Out of Range

Tests	In Range	Out of Range	Reference Range	Units
Insulin, Serum	16.1		<21.0	µIU/mL
Glucose		118	70-99	mg/dL
Hemoglobin A1c		6.6	<5.6	%
HOMA-IR		4.7	<3.0	
Estimated Average Glucose		143	<117	mg/dL
C-Peptide	5.8		0.7-7.1	ng/mL
Adiponectin *	14.7		5.5-28.0	µg/mL
Leptin *		78.7	0.0-25.0	ng/mL
hs-CRP		2.69	<3.00	mg/L
Triglycerides		344	30-150	mg/dL
HDL		34	>40	mg/dL

Type 2 Diabetes Risk Assessment

Tests	In Range	Out of Range	Reference Range	Units
Type 2 Diabetes Risk Assessment		Moderate		

The type 2 diabetes risk assessment is an indication of your risk for developing type 2 diabetes. It is a composite value derived from laboratory test results and demographics and may not capture all of the individual risk factors for a particular person. It is provided to supplement, not supplant, the clinical utility of individual biomarkers and other clinical indications. The Type 2 Diabetes Risk Assessment is not intended to provide a single indicator of risk. You should discuss these results with your provider. Treatment decisions should be based on the totality of available information.

* The performance characteristics of this test were determined by SpectraCell Laboratories. The U.S. Food & Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

PATIENT: **Doe, Jane** PROVIDER: **Sample Provider, MD** DATE REPORTED: **08/19/2019** ACCESSION ID: **0000000000**

OmegaCheck

Risk Categories Optimal | Moderate | High

Cleveland HeartLab; 6701 Carnegie Ave, Ste 500; Cleveland; OH; 44103;Bill G. Richendollar, MD

Tests	In Range	Out of Range	Flag	Relative Risk	Reference Range	Units
OmegaCheck (Whole Blood: EPA+DPA +DHA)		**4.1**		**MOD**	>5.4	% by wt
Arachidonic Acid/EPA Ratio	31.6				3.7-40.7	
Omega 6/Omega 3 Ratio	9.7				3.7-14.4	
Omega-3 Total	4.0					% by wt
EPA	0.5				0.2-2.3	% by wt
DPA-3	1.3				0.8-1.8	% by wt
DHA	2.2				1.4-5.1	% by wt
Omega-6-Total	38.9					% by wt
Arachidonic Acid		**15.8**	H		8.6-15.6	% by wt
Linoleic Acid	20.0				18.6-29.5	% by wt

RISK CATEGORIES – Increasing blood levels of long-chain omega 3 fatty acids is 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 for sudden cardiac death were established for OmegaCheck:

OmegaCheck equal or above 5.5% = LOW relative risk
OmegaCheck between 3.8% and 5.4% = MODERATE relative risk
OmegaCheck equal or below 3.7% = HIGH relative risk

DOSAGE INFORMATION – Evidence suggests that daily consumption of fish oil containing 3 grams or less of EPA and DHA does not significantly raise the risk of increased bleeding time beyond the normal range. A daily dosage of 1 gram of EPA and DHA may lower triglycerides by about 7-10% within 2 -3 weeks.[1]

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

CLINICAL RELEVANCE – Omega 3 fatty acids influence enzyme and hormone systems throughout our entire body, and although they have gained attention primarily from their superb cardiovascular benefits, they alleviate symptoms of many other conditions. They are especially beneficial for reducing inflammation and may benefit the immune, respiratory, reproductive and neurological systems as well.

FATTY ACID CONSUMPTION – The conversion of essential fatty acids into DHA and EPA is inefficient in the human body, and can be exacerbated by nutrient deficiencies and high levels of other fatty acids present in the blood, as fatty acids will compete for incorporation into cell membranes. Depending on which fatty acids are consumed and absorbed – whether omega 6, omega 3, saturated, or trans – those present at high levels can potentially displace fatty acids present in lower amounts. The best way to ensure adequate levels of omega 3 fats is through consumption. Ingestion of omega 3 fats via food or supplements is a very effective way to increase their levels throughout the body. In most tissues, there is a linear dose response to supplementation.[2]

FATTY ACID RATIOS – In general, omega 6 fatty acids contribute to inflammation while omega 3 fatty acids reduce whole body inflammation. Our Paleolithic ancestors, who were completely free of degenerative diseases maintained an omega 6 to omega 3 ratio around 2:1. The higher this ratio, the more systemic inflammation that is present, which ultimately causes pain and an acceleration of degenerative disease.

[1]Albert et al. Blood levels of long-chain n-3 fatty acids and the risk of sudden death. N Engl J Med 2002;346:1113-1118.
[2]Arterburn et al. Distribution, interconversion, and dose response of n-3 fatty acids in humans. Am J Clin Nutr 2006;83(6 Suppl);1467S-1476S.

**Flags: H = Out of Range High; L = Out of Range Low

Lipoprotein Particle Profile (Component Summaries)

This information is provided for educational purposes.

Lipoprotein Particle Numbers – Lipoproteins are ball-shaped proteins in the blood that transport fats (lipids) throughout the body. The fact that lipoproteins – not the cholesterol that is carried within them – causes cardiovascular disease by penetrating the endothelial lining of the arteries, becoming oxidized and contributing to arterial plaque, has been well established. Further, the most effective treatment will depend on which lipoproteins are elevated, so measuring lipoprotein particle numbers enables a clinician to (1) determine accurately the level of cardiometabolic risk and (2) how best to treat it.

Remnant Lipoprotein (RLP) – This highly atherogenic lipoprotein causes platelet aggregation and impairs vascular relaxation. Unlike other LDL particles which have to be oxidized before they are taken into the arterial intima by macrophage cells, RLP can contribute to plaque buildup even when not oxidized. Foam cells (the sticky contributors to arterial plaque) contains high levels of RLP. Treatment with omega 3 fatty acids can be efficacious.

Dense LDL III and LDL IV – These lipoproteins are small and can thus more easily penetrate and damage the lining of the arteries due to their size, causing plaque and atherosclerosis. They are highly correlated to cardiovascular disease.

HDL2b – This is a protective lipoprotein that indicates how well cholesterol is being cleared by the liver (reverse cholesterol transport system). HDL is made in the liver as HDL3 and as it travels through the body accumulating cholesterol it becomes the larger and lipid-enriched HDL2b. It positively correlates with heart health.

Lipid Panel – The lipid panel measures cholesterol, not lipoproteins (which carry cholesterol). Although directly measuring the actual number of lipoproteins (versus the amount of cholesterol inside them) is widely recognized as a superior tool in assessing cardiometabolic health, clinicians and patients tend to be familiar with a standard lipid panel and its historical use. It is important to note that half of all people who have a heart attack will have cholesterol values that fall in the normal range. Thus, the lipid panel is most useful when viewed in the context of other biomarkers, particularly lipoprotein particle numbers. Elevated triglycerides and low HDL-cholesterol are highly correlated to metabolic syndrome and increase the risk of heart disease significantly.

Vascular Inflammation – Cardiovascular disease is generally considered an inflammatory process and the analytes included here are important determinants of cardiometabolic risk, particularly with respect to vascular inflammation.

Insulin – Insulin is a hormone made by beta cells (β-cells) in the pancreas and secreted in response to elevated blood sugar. Its main function is to regulate plasma glucose levels within a narrow range and is correlated to the efficiency with which a person can metabolize carbohydrates. If one becomes de-sensitized to the action of insulin (insulin resistant), more is needed to achieve adequate glucose-lowering effects, thus altering metabolism to favor fat storage over efficient energy production. High fasting insulin indicates insulin resistance and possible pre-diabetes. Stimulatory hormones (i.e. adrenaline, cortisol) can also raise insulin levels.

hs-CRP – High Sensitivity C-reactive Protein (hs-CRP) is an acute phase protein that reflects the presence of inflammation in the body. High CRP, regardless of cause, is strongly correlated to the risk of sudden cardiac death and low-grade chronic systemic inflammation raises the risk of metabolic syndrome, heart disease, diabetes and other degenerative diseases.

Lipoprotein(a) – This unique lipoprotein is particularly dangerous because it inhibits the formation of plasmin which is an enzyme that dissolves blood clots. High levels of Lp(a) are strongly linked to thrombosis significantly raising the risk of blood clots and associated cardiac events. It can also penetrate the arterial lining, become oxidized and build plaque, thus contributing to atherosclerosis independent of its thrombotic potential.

Apolipoprotein B – ApoB100 is a protein produced in the liver that attached to the surface of all low-density lipoproteins (LDL), regardless of type. Every molecule of VLDL, RLP, Lp(a) and LDL has exactly one, and only one apoB100 molecule attached to it and thus, apoB reflects the level of atherogenic lipoproteins in the blood.

Apolipoprotein A1 – ApoA1 is a protein that is attached to the surface of all high-density lipoproteins (HDL) and is thus reflective of the amount of protective lipoproteins in the blood. It facilitates the removal of fats (cholesterol) from arterial walls by enabling its transport back to the liver for eventual excretion. Like HDL, low levels raise risk of heart disease.

Homocysteine – A metabolic intermediate, this protein is dangerous at high levels because it indicates poor methylation (detoxification) ability. Homocysteine will also act as an arterial abrasive, physically damaging the endothelial lining of blood vessels. High levels are strongly linked to kidney and heart disease, stroke and dementia.

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Pre-Diabetes (Component Summaries)

This information is provided for educational purposes.

Insulin – Insulin is a hormone made by beta cells (β-cells) in the pancreas and secreted in response to elevated blood sugar. Its main function is to regulate plasma glucose levels within a narrow range and is correlated to the efficiency with which a person can metabolize carbohydrates. If one becomes de-sensitized to the action of insulin (insulin resistant), more is needed to achieve adequate glucose-lowering effects, thus altering metabolism to favor fat storage over efficient energy production. High fasting insulin indicates insulin resistance and possible pre-diabetes. Stimulatory hormones (i.e. adrenaline, cortisol) can also raise insulin levels.

Glucose – Blood glucose (also known as blood sugar) is a snapshot of the amount of glucose circulating in blood. Since the body's tendency toward homeostasis tightly regulates blood sugar levels, too much or too little blood sugar can be indicative of a metabolic abnormality. Abnormally low fasting low blood sugar levels (hypoglycemia) can be caused by certain medications, excess alcohol intake, hormone deficiencies, severe illness, pancreatic tumors or severely restricted caloric intake. High fasting glucose levels can be indicative of a person with decreased sensitivity to endogenous insulin, which is a hallmark of insulin resistance, and eventually diabetes.

HOMA-IR – The Homeostatic Model Assessment of Insulin Resistance is mathematically derived from fasting insulin and glucose results. HOMA-IR assesses how well the glucose-insulin feedback loop is functioning. High HOMA-IR indicates some degree of insulin resistance or beta cell dysfunction. A value of 1 means 100% insulin sensitivity (which is good); Under 1 suggests beta cells are very efficient; Over 3 indicates some insulin resistance; Over 4 suggests a significant portion of beta cells are damaged.

Hemoglobin A1c (HbA1c, Glycated Hemoglobin) – HbA1c is considered a relatively long-term marker of blood sugar levels of the previous 2-3 months, but weighted heavily for the previous 2-3 weeks. Excess glucose that is not taken up into tissues will remain in the bloodstream and damage (in a process called glycation) hemoglobin proteins also in the blood. Thus, HbA1c is appropriate for assessing both blood sugar levels over time as well as the amount of damaging advanced glycation end products (AGEs), commonly considered a marker of accelerated aging. In diabetics, high levels strongly increase the risk of diabetic complications such as heart disease, neuropathy, retinopathy (blindness) and nephropathy (kidney disease).

Estimated Average Glucose (eAG) – This is an estimate of the average glucose levels for the previous 2-3 months that is mathematically derived from HbA1c. It is sometimes more intuitively understood than HbA1c since it is reported in the same units as fasting glucose (mg/dL) and can thus be compared directly.

C-Peptide – C-Peptide (connecting peptide) is a measure of endogenous insulin production. It is useful in distinguishing between type 1 diabetes (an autoimmune disorder where the pancreas cannot make insulin) and type 2 diabetes (a metabolic disorder where the pancreas can make insulin but the body is resistant to it), and possible causes of hypoglycemia or insulinomas.

Adiponectin – Although this hormone is produced by fat cells (adipocytes), paradoxically it is inversely correlated to body fat. It regulates metabolism by telling cells to burn glucose and fatty acids for fuel. Thus, high levels are generally good. Low adiponectin increases the risk of metabolic abnormalities associated with diabetes. Adiponectin works synergistically with leptin to maintain insulin sensitivity.

Leptin – Called the satiety hormone, leptin is produced in fat cells and sends signals to the brain (hypothalamus) to suppress hunger after eating, thus regulating appetite in healthy people. Leptin should normally be low with a temporary increase after meals. In obesity, due to the higher number of adipocytes, disproportionately high levels of leptin are needed to suppress appetite. This is called leptin resistance. Chronically high leptin indicates the appetite feedback mechanism is dysfunctional.

hs-CRP – High Sensitivity C-reactive Protein (hs-CRP) is an acute phase protein that reflects the presence of inflammation in the body. High CRP, regardless of cause, is strongly correlated to the risk of sudden cardiac death and low-grade chronic systemic inflammation raises the risk of metabolic syndrome, heart disease, diabetes and other degenerative diseases.

Triglycerides – Through a complex metabolic interaction, elevated triglycerides promote the formation of atherogenic, small-dense LDL which damage arterial walls and increase risk of heart disease and stroke. A strong inverse correlation exists between triglycerides and HDL. High triglycerides are indicative of abnormal lipoprotein metabolism.

HDL Cholesterol – High density lipoproteins (generally considered healthy) carry cholesterol that is being cleared by the liver for removal from the body. Low HDL is associated with metabolic syndrome and increases risk of pre-diabetes.