

# Human Clinical Trial

Evaluating the Safety and Efficacy of

## DiaMetrix™

A Randomized, Double-Blind  
Placebo Controlled Study

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### CONFIDENTIAL INFORMATION

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## **1.0 STUDY PURPOSE**

The purpose of this study was to determine the effect of an all-natural herbal dietary supplement product, DiaMetrix™, on blood glucose levels, triglycerides, cholesterol, and blood pressure.

## **2.0 STUDY OVERVIEW**

DiaMetrix™ is an all natural herbal dietary supplement designed for blood glucose support. The product is composed of: Vitamin C (ascorbic acid) 10 mg, Biotin USP 100 mcg, Chromium (chelate), Proprietary (Db)<sup>2</sup>™ Complex 1600 mg, dicalcium phosphate, croscamellose sodium, stearic acid, silicon dioxide, magnesium stearate hydroxypropyl methylcellulose (HPMC). This was a ninety day, 100-participant, double-blind study (47 men and 53 women [all menstruating] ages 23 to 50; 33 black, 32 caucasian, 25 asian, 10 hispanic) using participants drawn from a large diverse population of people in or near the Las Vegas, NV area. (33 Black, 32 Caucasian, 25 Asian, 10 Hispanic) with chronic uncontrolled blood glucose (people with fasting blood glucose levels between 160 mg/dL and 225 mg/dL with a mean of 16 mg/dL). The participants were randomized (names placed in hat and alternately drawn) into two groups of 50 participants. Participants in both Group A (live product group) and Group B (placebo group) were instructed to take two tablets three times daily, or three tablets two times daily if only two meals, approximately 15 minutes before meals. Participants in Group B were the control group and were given a placebo (vegetarian tablet, magnesium citrate, silicon). Participants in Group A were provided live product. Participants were instructed to take product only if they ate a meal.

All study participants completed the study.

## **3.0 PROTOCOL**

### **3.1 SCREENING AND FOLLOW-UP**

Following an initial screening at Visit 1 (week 0), participants entered a 1-week baseline period (participants were to refrain from taking any unnecessary OTC's, prescription drugs or natural products that they were not already taking for the remainder of the study. Ibuprofen, tylenol, and aspirin were allowed). Participants who met all inclusion criteria and none of the exclusion criteria during the intake at Visit 2 (week 1) were then provided either the placebo or DiaMetrix™ along with a protocol describing daily dosing to follow for the duration of the study. The second evaluation on Visit 3 (week 3) was performed following standard procedures and the study's protocol was again reviewed with each participant on an individual basis. The third evaluation of the participants took place on Visit 4 (week 5). The fourth evaluation of the participants took place on visit 5 (week 9). Final evaluations of test participants were completed on visit 6 (week 13) of the study.

At initial screening, 14 of the participants reported mild headaches and "not feeling well." All participants were attempting to control their glucose levels with diet and exercise. Diet and exercise were not monitored during the study, but all participants were instructed to make no changes in their diet, activities, or water intake during the duration of the study at the initial screening and at subsequent evaluations.

### **3.2 INCLUSION CRITERIA**

- Participants who have signed a written informed consent consistent with required guidelines and met prior to participation in the trial.
- Participants 18 years of age or older, either sex.
- Blood sugar imbalance must have been presented for a minimum of the last consecutive six (6) months at a frequency of at least twenty (20) times each month based on participant's daily glucometer readings.
- Participants whose Optimal Wellness Test (OWT) indicated they were at least 35% out of balance for standard wellness with respect to blood sugar balance and Brix Balance indicators (the red zone).
- Participants who were able to follow the protocol as designed by Syntratech Corporation and Fenestra Research labs.
- Not currently using any pharmaceutical remedies (oral, injection or otherwise) for their blood sugar control.
- Generally good health.

### **3.3 EXCLUSION CRITERIA**

- History of head trauma.
- History of serious diseases or illness diagnosed at this time.
- Known moderate to severe renal insufficiency.
- Recent history (<6 months prior to Visit 1) of myocardial infarction.
- Participants who regularly use oxygen therapy.
- \* Participants with known active tuberculosis.
- Participants with treated basal cell carcinoma.
- Participants with a history of cancer within the last 5 years.
- Participants who have undergone thoracotomy with pulmonary resection within 1 year prior to the trial.
- Participants who are currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit (Visit 1).
- Participants currently prescribed diuretic medications, cardiac stimulants, or any other prescribed or non-prescribed medication that may, in the opinion of the Fenestra research staff, alter testing results.
- Use of opiate analgesics prescribed or otherwise obtained for any treatment reason including migraine treatment, or for recreation.
- History of drug addiction.

- History of alcohol addiction within six (6) months of this study period.
- Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
- Patients diagnosed as HIV-positive, diagnosed with AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea.
- Patients with uncontrolled hypertension (e.g. BP>160/100).
- Patients with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.

## 4.0 TESTS

### Fasting Blood Glucose (FBG)

Through an elaborate system, glucose levels are controlled by insulin and glucagons. A glucose test is part of a routine urinalysis. Urine glucose tests are also used to monitor the effectiveness of diabetes therapy; however, this is largely supplanted today by a finger stick to determine blood glucose levels.

Glucose is filtered from the blood by glomeruli in the kidney. Normally, all of the glucose is reabsorbed in the proximal renal tubules. When the blood glucose levels exceed the capability of the renal threshold to absorb the glucose (normally around 180 mg/dL), it begins to spill over into the urine (glycosuria). As blood glucose levels increase further, greater amounts of glucose are spilled into the urine. In participants who do not have diabetes, glycosuria can occur with a normal serum glucose level when kidney disease affects the renal tubule. The renal threshold for glucose becomes abnormally low, and glycosuria occurs.

Approximately 7 ml of venous blood in a red top tube was collected from each participant at each blood draw.

<b>Fasting Blood Glucose</b>	<b>Status</b>	<b>Health Impact</b>
Less than 100 milligrams per deciliter (mg/dL)	Normal	Healthy level
Between 100 and 125 mg/dL	Prediabetes or borderline diabetes	Increased risk of cardiovascular disease and future diabetes
126 mg/dL or higher, measured on two different days	Diabetes	Risk of damage to the eyes, kidneys, blood vessels, heart and nerves as well as cognitive decline and dementia

Verified by National Institutes of Health Clinical Center (CC) January 2007

## Optimal Wellness

The Optimal Wellness Test (OWT), using the standard thirty-nine specific cellular measurements, was performed on day one, day fourteen, day thirty, day sixty, and day ninety. Three cc's of urine and saliva were taken from each participant on each occasion of the study.

OWT provides analysis of:

Test	Urine	Saliva	Blood
pH	X	X	X
rH2 (oxidation and reduction)	X	X	
r (resistivity)	X	X	
C (conductivity)	X	X	
Nitrate	X		
Ammonia	X		
Brix (refractometry)	X		X
Specific Gravity	X	X	
Oxidative Stress	X	X	X
Cellular Respiration	X	X	
Renall Balance	X	X	
Hepatic Balance	X	X	
Digestion	X	X	
Hydration	X	X	
Toxicity	X	X	
Adrenal Balance	X	X	
Protein Digestion	X	X	
Carbohydrate Digestion	X	X	
Blood Sugar Balance	X	X	X
Anabolic State	X	X	
Catabolic State	X	X	
Surface Tension	X	X	

## Weight

Being overweight or obese is a leading risk factor for type 2 diabetes. Weight was recorded on all participants at all 6 visits using a monthly calibrated weight scale. Starting weights ranged from 143 to 327 lbs., with a mean of 211.

## **Glucose Challenge**

The oral glucose tolerance test (OGTT) measures the body's ability to use a type of sugar, called glucose. The test is usually used to test for diabetes, insulin resistance, and sometimes reactive hypoglycemia.

Fasting blood glucose (FBG) should be below 110 mg/dL. Fasting levels between 110 and 126 mg/dL are borderline ("impaired fasting glycemia or pre-diabetes"), and fasting levels repeatedly at or above 126 mg/dL are diagnostic of diabetes.

The 2-hour glucose level should be below 140 mg/dL. Levels between this and 200 mg/dl indicate "impaired glucose tolerance." Glucose levels above 200 mg/dL at 2 hours confirm a diagnosis of diabetes.

Hypoglycemia is a condition characterized by an abnormally low level of blood glucose. Like fever, hypoglycemia isn't a disease itself, it's an indicator of a health problem, that if left untreated, can lead to coma and death. Blood glucose levels of less than 50mg/dL are generally considered hypoglycemic.

Each participant's FBG was taken at the initial visit. All were given a test tablet (half active product and half placebo), followed by a standard 50 g carbohydrate load drink.

Blood plasma readings were taken at 30-min., 120-min., and 180-min. intervals.

## **Total Cholesterol**

Cholesterol plays both positive and negative roles in the body. Cholesterol is the principle lipid associated with arteriosclerotic vascular disease. It is required however, for the production of steroids, sex hormones, bile acids, and cellular membranes in the body. Almost 75% of the cholesterol in the body is bound to low-density lipoproteins (LDL's), and 25% is bound to high density lipoproteins (HDL's).

Participant's blood was taken after a 12-14 hour fasting period. No alcohol was consumed for at least 24 hours before blood was drawn. 5-19 ml of arterial blood was collected into a red-top tube.

## **Lipoproteins**

HDL's are carriers of cholesterol. Science suspects that the purpose of HDL's is to remove cholesterol from the peripheral tissues and transport it to the liver for excretion; HDL's may have a protective effect by preventing cellular uptake of cholesterol and lipids.

LDL's are rich in cholesterol. Cholesterol carried by the LDL's can be deposited into the peripheral tissues and is associated with an increase risk of atherosclerotic heart and vascular disease. High levels of LDL's are atherogenic. LDL levels are derived by subtracting HDL readings plus one fifth of the triglycerides from the total cholesterol.

$LDL = \text{Total cholesterol} - (\text{HDL} + \text{Triglycerides}/5)$

## Triglycerides (TGs)

TGs are a form of fat that exist within the bloodstream. They are transported by very low-density lipoproteins (VLVDs) and low-density lipoproteins (LDL's). TGs are part of a lipid profile that evaluates cholesterol and lipoproteins. This test is performed as a fasting (12-14 hour) blood test on the participant. No alcohol is permitted for 24 hours before the test is done. A venous blood draw in a red-top tube of 5-10 ml was collected from each participant at each test interval.

### Normal findings:

Adult female over 19	40-128 mg/dL
Adult male over 19	40-138 mg/dL
Critical values	>400 mg/dL

## Blood Pressure

Blood pressure (strictly speaking: vascular pressure) refers to the force exerted by circulating blood on the walls of blood vessels, and constitutes one of the principal vital signs. The systolic arterial pressure is defined as the peak pressure in the arteries, which occurs near the beginning of the cardiac cycle; the diastolic arterial pressure is the lowest pressure (at the resting phase of the cardiac cycle).

Typical values for a resting, healthy adult human are approximately 120 mm Hg systolic and 80 mm Hg diastolic (written as 120/80 mmHg, and spoken as "one twenty over eighty"), with large individual variations. Hypertension refers to arterial pressure being 140/90 mm Hg or higher, as opposed to hypotension, when it is abnormally low.

High blood pressure increases the risk for heart disease and stroke.

Blood pressure was taken by medical professionals with a minimum of 20 years experience using a sphygmometer and stethoscope. Blood pressure measurements were taken an average of three times after a minimum rest of at least 15 minutes.

## **A1c, also known as: Hemoglobin A1c, HbA1c, Glycohemoglobin, Glycated hemoglobin, Glycosylated hemoglobin**

The A1c test evaluates the average amount of glucose in the blood over the last 2 to 3 months. It does this by measuring the concentration of glycosylated hemoglobin. As glucose circulates in the blood, some of it spontaneously binds to hemoglobin A (the primary form of hemoglobin in adults). Hemoglobin is a red protein that carries oxygen in the red blood cells. Once the glucose is bound to the hemoglobin, it remains there for the life of the red blood cell (about 120 days). The more glucose that is in the blood, the more that binds to hemoglobin. This combination of glucose and hemoglobin is called A1c (or hemoglobin A1c or glycohemoglobin). A1c levels do not change quickly but will shift as older red blood cells die and younger ones take their place.

A 1% change in an A1c result reflects a change of about 30 mg/dL (1.67 mmol/L) in average blood glucose. For example, an A1c of 6% corresponds to an average glucose of 135 mg/dL (7.5 mmol/L), while an A1c of 9% corresponds to an average glucose of 240 mg/dL (13.5 mmol/L).

The A1c test provides a picture of the average amount of glucose in the blood over a few months period of time. It can help a patient and their healthcare professional to know if the measures they are taking to control the patient's blood sugar balance are effective. Blood was drawn on day one and day ninety of this study for analysis. An arterial blood sample was

obtained by inserting a needle into an artery of the participant's arm and a standard A1c vial of blood was collected by a healthcare professional.

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated conclusively that risks for complications in patients with diabetes are directly related to glycemic control, as measured by glycated hemoglobin (GHb). Many diabetes organizations worldwide now recommend GHb targets in terms of DCCT/UKPDS hemoglobin A1c (HbA1c). However, in 1993 there was a lack of comparability of GHb test results among methods and laboratories that represented a major obstacle to meaningful implementation of specific guidelines for diabetes care. The National Glycohemoglobin Standardization Program (NGSP) was implemented to enable laboratories to report DCCT/UKPDS-traceable GHb/HbA1c results.

Fenestra Research Labs adheres to guidelines specified by The National Glycohemoglobin Standardization Program.

#### **4.1 RESCUE MEDICATIONS AND FOOD INTAKE**

All participants were instructed to contact their regular healthcare professional if they had any unusual or uncomfortable symptoms during the course of this study. All participants in the study were instructed to make no changes to their daily consumption of food or liquid relating to the amount, volume, or type consumed.

NOTE: Compliance to the protocol was monitored and maintained through bi-weekly phone calls with Fenestra Labs Clinical Studies personnel as well as in-person office visits as described above.

### **5.0 CLINICAL DATA STATISTICAL METHODS**

The Clinical Data collected during this study is the sole property of Syntratech Corporation and any oral inquires about that data should be referred directly to them.

#### **5.1 OPTIMAL WELLNESS TEST (OWT) ANALYSIS**

Certain physiologic parameters indicative of various states of blood sugar and electrolyte imbalances were measured during this study using OWT apparatus and calculation algorithms. OWT apparatus and calculation algorithms are proprietary and were developed by Fenestra Research Labs. All measurements were taken at baseline, day fourteen, day thirty, day sixty, and day ninety.

Parameters measured in urine, saliva, and blood included: Brix, ORP (redox potential), and r (resistivity). Parameters measured only in urine in addition to the above included: s.g. (specific gravity),  $\text{NO}_3^-$ ,  $\text{NH}_3$ , °Brix, and C (conductivity).

There was no statistically significant change in any parameter measured for the placebo Group B (placebo). The measures that showed significant in-group change from baseline to finish were limited to Group A (live) and are shown in Table 1 on next page.

Further studies are planned to determine if these measures or others within the scope of OWT capability can be either indicative or predictive for certain characteristics of reduction or control of blood sugar balance, triglyceride balance, cholesterol balance, healthy weight control, and or blood pressure regulation.

**Table 1**

Group	Test	*Difference of Means	Wilcoxon paired sample test significance
A	B-Brix	-21.5%	p<0.0001
A	S-ORP	+6.4%	p<0.0001
A	B-ORP	-22.5%	p<0.0001
A	U-ORP	-15.3%	p<0.0001
A	U-Brix	-33.2%	p<0.0001
A	S-Brix	-20.9%	p=0.001

\*Baseline vs Finish

**A1C ANALYSIS**

The live product group, Test Group A, measured an average change from baseline to day ninety of -3.04% in their A1c test results. The A1c tests were run three times on each participant at baseline and at the ninety day interval, with the average of those three times being used for this calculation. This is a very significant change in A1c results for each of these test participants in a lower, or positive direction.

The placebo group, Test Group B, measured an average change from baseline to day ninety of +0.25% in their A1c test results. The A1c tests were run three times on each participant at baseline and at the ninety day interval with the average of those three times being used for this calculation. This change indicated participant's blood glucose numbers moved in a higher, or negative direction.

While the study showed dramatic A1c reductions for every participant in Test Group A (all participants ended with a A1c of 5 or less), none of the participants ended with an A1c reading of less than 4.2. Baseline readings showed a maximum deviation among active group participants of 1.6 percent, with an ending maximum deviation of only .8 percent. These findings were quite unexpected and suggest an enhanced blood glucose regulating mechanism among participants that used the test product. (Table 2 on page 10)

**HEMOGLOBIN A1c (HbA1c) Human**

Protein Conc: >1 mg/dL  
Purity: >90%  
Source: Human Erythrocytes

**TRIGLYCERIDES ANALYSIS**

The triglyceride levels in Group A (live product) showed a significant change from baseline to day ninety, decreasing by an average of 52.02 (-52.02) points by the end of the study. Group B (placebo) showed an increase in triglycerides over the course of the study by an average of 16.80 (+16.80) points.

The average positive change in triglycerides for Group A was -20.26%. The average change for Group B moved into a more negative health range by an average of +6.60%. (Table 2 on page 12 and 13)

## **BLOOD GLUCOSE ANALYSIS**

The Fasting Blood Glucose measurements of Group A showed a positive average change from baseline to day ninety of -54.55%, indicating a significant positive change for all test participants in this group.

The FBG measurements of Group B indicated an average change of +4.23%, showing a negative change for most participants in this group. (Table 2 on page 12 and 13)

## **GLUCOSE CHALLENGE TEST**

The Glucose Challenge Test measurements of Group A indicated an average change at the 120-min mark of -86.6 points, indicating a significant positive change for all test participants in this group.

Group B measurements indicated an average negative change at the 120-min mark of +25.0 points.

At the 120-min mark, every study participant in Group B saw an increase in blood glucose, while every participant in Group A saw a decrease in blood glucose. Importantly, none of the participants in Group A recorded a reading below 63 mg/dL. The exclusion of any hypoglycemic incidents in the glucose challenge test is significant. Additionally, the 180-min readings in Group A were nearly identical to the 120-min readings (109.5 vs. 110.0), while the readings for participants in Group B continued to increase at these same intervals (221.9 vs. 225.8).

## **LOW DENSITY LIPOPROTEINS (LDLs)**

The LDL measurement of Group A indicated a positive change from baseline to day ninety of the study by an average of -34.26%.

The LDL measurement of Group B indicated a positive change from baseline to day ninety of the study by an average of -20.10%. (Table 2 on page 12 and 13)

## **HIGH DENSITY LIPOPROTEINS (HDLs)**

The HDL measurement of Group A indicated a negative change from baseline to day ninety of the study by an average of -15.93%.

The HDL measurement of Group B indicated a negative change from baseline to day ninety of the study by an average of -8.18%. (Table 2 on page 12 and 13)

The unexpected lowering of HDLs in Group A was not considered significant nor an adverse event since the overall drop in total cholesterol was much larger for Group A than it was for Group B, resulting in a much larger improvement in both the total cholesterol/HDL and LDL/HDL ratios for Group A compared to Group B.

## **TOTAL CHOLESTEROL ANALYSIS**

The total cholesterol measurement of Group A indicated a positive change from baseline to day ninety of the study by an average of -29.10%.

The total cholesterol measurement of Group B indicated a positive change from baseline to day ninety of the study by an average of -13.33%.

The total cholesterol to HDL cholesterol ratio is a number that is helpful in predicting an individual's risk of developing atherosclerosis. The number is obtained by dividing the total cholesterol value by the value of the HDL cholesterol. (High ratios indicate higher risk of heart attacks, low ratios indicate lower risk).

High total cholesterol and low HDL cholesterol increases the ratio, and is undesirable. Conversely, high HDL cholesterol and low total cholesterol lowers the ratio, and is desirable. An average ratio would be about 4.5. Ideally we want to be better than average if we can. Thus the best ratio would be 2 or 3, or less than 4.

Another ratio is LDL/HDL. The LDL/HDL ratio is actually a purer ratio than total cholesterol/HDL, because LDL is a measure of "bad" cholesterol and HDL is a measure of "good" cholesterol, whereas the total cholesterol is the sum of HDL, LDL, and the VLDL. Adding up the values for the HDL, LDL and VLDL makes up the total cholesterol measurement.

The total cholesterol/HDL ratio of both test groups improved: Group A improved 15.61% and Group B 5.52%. Likewise, the LDL/HDL ratio of both test groups improved: Group A improved 21.87% and Group B 12.76%. (Table 2 on page 12 and 13)

## **BLOOD PRESSURE**

Group A saw a positive change from baseline to day ninety of the study by an average of 25% and 5% (systolic/diastolic) respectively. Group B saw a neutral and slightly negative change from baseline to day ninety of the study by an average of 0% and 1%. (Table 2 on page 12 and 13)

While it is to be expected that the higher of two groups measured for blood pressure would see the biggest change given the same testing variable, the difference between Group A and Group B is significant.

Analytical methods for all blood parameter tests were conducted by Fenestra Research Labs following standard blood draw protocol.

## **6.0 ADDITIONAL OBSERVATIONS**

In Group A (live product), an average weight loss of 9 lbs. was seen over the ninety-day study period. Although this weight loss was measured, it was in no way anticipated or expected in this study group as participants were instructed to maintain their previous eating and drinking habits from pre-study. Participants expressed no changes in hunger or appetite, no changes in cravings or consumption of sweets or treats. There was no significant weight change in Group B (placebo) participants.

A significant reduction in the average systolic blood pressure numbers, and a smaller reduction in average diastolic blood pressure numbers were measured in Group A participants. The decrease in both average systolic and diastolic readings moved participants into a more healthy blood pressure range. Further studies are planned to analyze and predict participant blood pressure changes. No significant change in blood pressure was seen in Group B participants.

None of the participants reported needing any rescue medication during the course of the study. None of the participants reported any negative or bad symptoms during the course of the study.

## **7.0 ANECDOTAL OBSERVATIONS**

Group A participants expressed no changes in hunger or appetite, no changes in cravings or consumption of sweets or treats. Twenty-five of the participants in Group A reported feeling better than they had felt in years after using the test product for only two weeks. Fifty percent of the participants in Group A reported feeling more energy after one month on the test product. Twelve participants in Group A reported after using the test product for one month, they could eat sweets and not have their blood glucose numbers increase more than 10 points for the next ten hours.

Group B reported no similar observations.

## **8.0 CONCLUSIONS**

DiaMetrix™ has proven itself to be a very safe and effective product for blood sugar management.

Statistical analysis of these data shows a consistent picture across treatment groups and over time. Group A's blood glucose, triglycerides, blood pressure, total cholesterol, LDL/HDL ratio, total cholesterol/HDL ratio, and even weight increasingly moved into a more positive state over time as the participants continued using the test product.

Based on these clinical comparisons and the complete lack of known adverse side effects, interactions, or contra-indications from the herbal ingredients in the test product, we conclude that DiaMetrix™ was shown to be a safe and highly effective means of promoting healthy blood sugar balance naturally in the body.

**Table 2: Results of 90 Day, Placebo-Controlled Trial of DiaMetrix™**

	<b>Placebo</b>	<b>DiaMetrix™</b>
<b>HbA<sub>1c</sub> (%), Mean</b>		
<b>Baseline</b>	<b>7.70</b>	<b>7.70</b>
Baseline SD	.5	.5
Baseline Coeff/Var(%)	6.00%	7.00%
Change at day 90	0.25	-3.04
<b>Day 90 HbA<sub>1c</sub></b>	<b>7.95</b>	<b>4.66</b>
Day 90 SD	.6	.3
Day 90 Coeff/Var(%)	7.00%	6%
Proportion Achieving HbA <sub>1c</sub> ≤7%	2.00%	100%
Proportion Achieving HbA <sub>1c</sub> ≤6%	0.00%	100%
Proportion Achieving HbA <sub>1c</sub> ≤5%	0.00%	100%
Proportion Achieving HbA <sub>1c</sub> ≤4.5%	0.00%	32.0%
<b>FBG (mg/dL), Mean</b>		
<b>Baseline</b>	<b>196.92</b>	<b>196.60</b>
Baseline SD	17.4	17.5
Baseline Coeff/Var(%)	9.00%	9.00%
Change at day 90 (points)	8.32	-107.24
Change at day 90 (%)	4.23%	-54.55%
<b>Day 90 FBG</b>	<b>205.24</b>	<b>89.36</b>
Day 90 SD	20.2	9.2
Day 90 Coeff/Var(%)	10.00%	10.00%
<b>Glucose Challenge Test</b>		
<b>Baseline</b>	<b>196.9</b>	<b>196.6</b>
Baseline SD	17.4	17.5
Baseline Coeff/Var(%)	9.00%	9.00%
<b>30-Min</b>	<b>205.1</b>	<b>110.1</b>
30-Min SD	18.5	24.1
30-Min Coeff/Var(%)	9.00%	22.00%
<b>120-Min</b>	<b>221.9</b>	<b>110.0</b>
120-Min SD	14.6	23.0
120-Min Coeff/Var(%)	7.00%	21.00%
<b>Body Weight Change (lbs), Mean</b>		
<b>Baseline</b>	<b>211.56</b>	<b>211.38</b>
Baseline SD	53.6	54.7
Baseline Coeff/Var(%)	25.00%	26.00%
Change at day 90 (lbs)	0.02	-9.28
Change at day 90 (%)	.01%	-4.39%
<b>Day 90 Body Weight</b>	<b>211.58</b>	<b>202.10</b>
Day 90 SD	52.8	54.0
Day 90 Coeff/Var(%)	25.00%	27.00%
<b>Triglycerides (mg/dL), Mean</b>		
<b>Baseline</b>	<b>254.54</b>	<b>255.18</b>
Baseline SD	46.5	48.1
Baseline Coeff/Var(%)	18.00%	19.00%
Change at day 90 (points)	16.80	-52.02
Change day 90 (%)	6.60%	-20.26%
<b>Day 90 Triglycerides</b>	<b>271.34</b>	<b>203.16</b>
Day 90 SD	48.3	42.4
Day 90 Coeff/Var(%)	18.00%	21.00%

**Table 2 (cont): Results of 90 Day, Placebo-Controlled Trial of DiaMetrix™**

	<b>Placebo</b>	<b>DiaMetrix™</b>
<b>LDL (mg/dL), Mean</b>		
<b>Baseline</b>	<b>193.17</b>	<b>230.74</b>
Baseline SD	50.7	61.0
Baseline Coeff/Var(%)	21.00%	25.00%
Change at day 90 (points)	-38.82	-79.05
Change at day 90 (%)	-20.10%	-34.26%
<b>Day 90 LDL</b>	<b>154.35</b>	<b>151.69</b>
Day 90 SD	30.3	33.5
Day 90 Coeff/Var(%)	20.00%	22.00%
<b>HDL (mg/dL), Mean</b>		
<b>Baseline</b>	<b>57.26</b>	<b>56.76</b>
Baseline SD	29.8	29.8
Baseline Coeff/Var(%)	52.00%	52.00%
Change at day 90 (points)	-4.68	-9.04
Change at day 90 (%)	-8.18%	-15.93%
<b>Day 90 HDL</b>	<b>52.58</b>	<b>47.72</b>
Day 90 SD	10.5	9.3
Day 90 Coeff/Var(%)	20.00%	19.00%
<b>Total Cholesterol (mg/dL), Mean</b>		
<b>Baseline</b>	<b>301.34</b>	<b>338.54</b>
Baseline SD	89.4	96.9
Baseline Coeff/Var(%)	30.00%	29.00%
Change at day 90 (points)	-40.14	-98.50
Change at Day 90 (%)	-13.33%	-29.10%
<b>Day 90 Total Cholesterol</b>	<b>261.20</b>	<b>240.04</b>
Day 90 SD	29.2	32.8
Day 90 Coeff/Var(%)	11.00%	14.00%
T Cholesterol/HDL Ratio (baseline)	5.26	5.96
T Cholesterol/HDL Ratio (day 90)	4.97	5.03
T Cholesterol/HDL Ratio Change (%)	-5.52%	-15.61%
LDL/HDL Ratio (baseline)	3.37	4.07
LDL/HDL Ratio (day 90)	2.94	3.18
LDL/HDL Ratio Change (%)	-12.76%	-21.87%
<b>Blood Pressure (mm Hg), Mean</b>		
<b>Baseline</b>	<b>155/76</b>	<b>171/75</b>
Baseline SD	25.1/8.7	19.9/9.9
Baseline Coeff/Var(%)	16.00/11.00%	12.00/13.00%
Change at day 90 (points)	0/1	-25/-5
Change at day 90 (%)	0/7%	-14.6/-6.7%
<b>Day 90 Blood Pressure</b>	<b>155/77</b>	<b>146/70</b>
Day 90 SD	18.9/5.2	14.6/3.2
Day 90 Coeff/Var(%)	12.00/7.00%	10.00/4.00%