

# PRELIMINARY CLINICAL EVALUATION OF SCOOP OF GREENS™ PRODUCT IN SUBJECTS WITH TYPE II DIABETES MELLITUS

### Title:

Preliminary research - Effect of Scoop of Greens™ product on blood glucose in human subjects with Insulin Dependent Diabetes Mellitus and Non-Insulin Dependent Diabetes Mellitus (Type 2).

### **Study Directors:**

This clinical evaluation was carried out under the direction of Dr. Sandy D. Corlett of Diabetes Resource Center, Inc., Buford, Georgia.

### **Aims and Objectives:**

To evaluate the effects of Scoop of Greens™ on glycemic response in people with Type 2 Diabetes Mellitus.

### **Product Description:**

Scoop of Greens™ is a 100% plant based, certified organic, non-pasteurized whole food concentrate, which naturally contains essential vitamins, minerals, amino acids, antioxidants, essential fatty acids, lignans, fiber, a rich source of chlorophyll, trace minerals, and enzymes that are necessary to life, and the ability to help regulate the bodies pH balance.

### **Subjects:**

Subjects selected were individuals with clinically established cases of Diabetes Mellitus (Type 2), male or female, between the age of 20-65 years, with ideal body weight (+20%), and no diagnosed complications. The subjects were under glycemic control with either oral hypoglycemic agents, or insulin therapy or both. All the subjects were on a Standard American Diet.



# **Dosage and Duration:**

The subjects were initially screened and randomly assigned to the Scoop of Greens<sup>™</sup> product regimen. Test product was provided to each subject to consume one half hour between breakfast and lunch, and one half hour between lunch and dinner. Throughout the duration of study – subjects consumed one scoop two times daily with one 8 ounce glass of water.

### **Study Protocol:**

The product was given individually. An initial fasting blood sample was drawn before protocol, and a final fasting blood sample drawn at the end of protocol. These blood samples were used for the measurement of glycemic parameters. Physical parameters such as body weight, body mass index, height, medications, and diet were measured and recorded for each subject. Blood glucose levels were self monitored every morning before breakfast, lunch, dinner, and at bedtime, by the subjects drawing capillary blood and using a glucose meter.

### **Biochemical Analysis:**

The initial and final blood samples of all the subjects before and after the consumption of the product were analyzed for glycosylated hemoglobin (HbA1C), fasting plasma glucose.

### **Statistical Analysis of the data:**

All the parameters were statistically analyzed, using changes from baseline values (0-time) to the end of study according to analysis of variances. The Phase I study commenced with 7 subjects and concluded with 3 subjects.

# **Results and Discussion**

Tables 1 - 7 summarize the study of Type 2 diabetic subjects on glycemic parameters. Tables 5 - 7 summarizes Average Percentage Changes on all Type 2 diabetic subjects.

### Type 2 Study:

A total of 7 subjects with clinically established Type 2 Diabetes Mellitus were randomly selected and given a specified amount of Scoop of Greens<sup>™</sup> product to consume for a 90-day period with an undefined diet. Total of 3 subjects completed Phase I, 90-Day protocol.



# **Glycemic Response:**

At the conclusion of the 90 days, the Blood Glucose results showed there was an overall average A1C decrease of 6.02% for all subjects. More specifically, the results showed that at 21 days all subjects had significant decreases in fasting blood glucose, with an average percentage change of 19.88%. The most remarkable decrease was at the end of 90 days. All subjects, which adhered strictly to nutrition, fitness and diabetes care recommendations given by Diabetes Resource Center throughout the study, decreased fasting blood glucose levels by 53.44%. The subject which showed the least change was due to blood sugars commencing and concluding within near to normal blood glucose levels between 70 and 110 mg/dl with an occassional elevation to 150 mg/dl. Albeit this subjects blood glucose showed a stabilization at the conclusion of three months. All tests conducted on capillary blood self-monitored by blood glucose meter.

This preliminary data on glycemic response parameters suggest that the Scoop of Greens<sup>™</sup> product has significant potential as nutritional support in the management and control of blood glucose in diabetes mellitus. However, further studies are required to confirm these preliminary results, and to better understand the long-term effects of the Scoop of Greens<sup>™</sup> product on glucose metabolism, and diabetes.

### Table One: 90 Day Research Study (A1C)

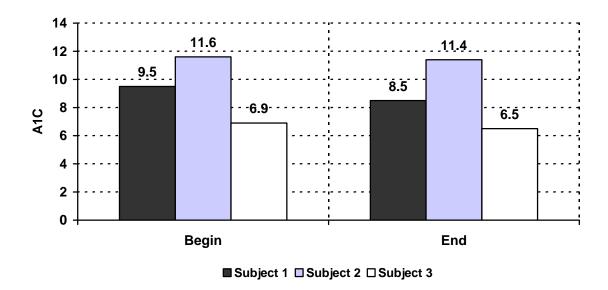
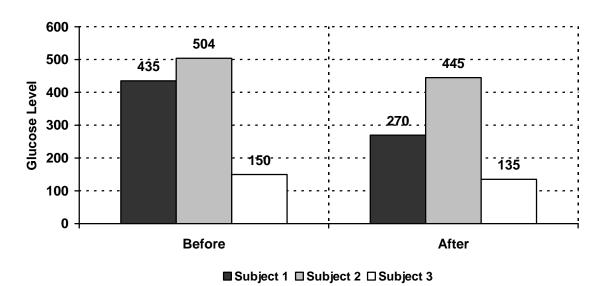
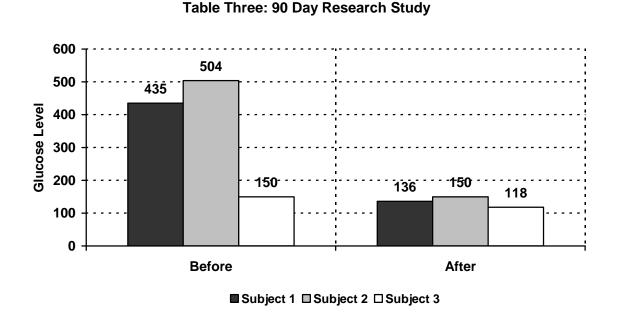




Table Two: 21 Day Research Study







**Table Four: A1C Comparision (90 Day Research)** 

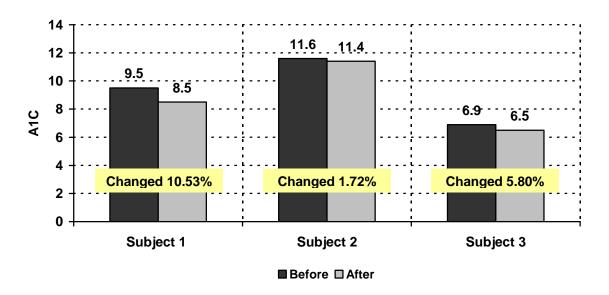


Table Five: Comparision (21 Day Research Study)

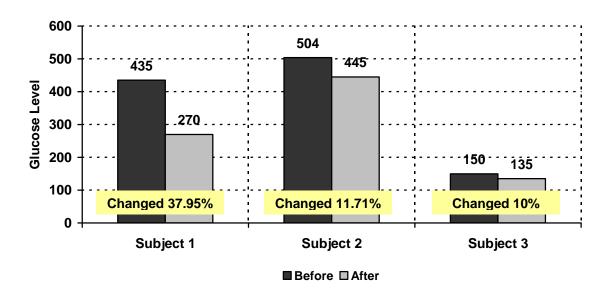
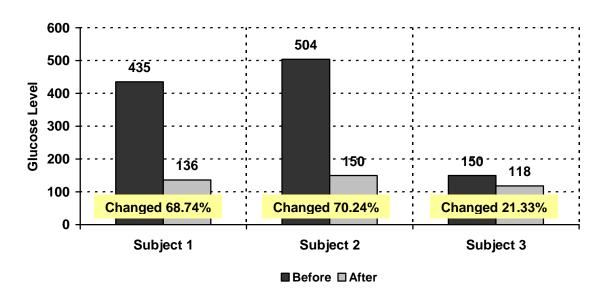




Table Six: Comparision (90 Day Research Study)



**Table Seven** 

Subject:	A1C			FBS - 21 DAYS			FBS - 90 DAYS		
	Begin	End	% Change	Before	After	% Change	Before	After	% Change
Subject 1	9.5	8.5	10.53%	435	270	37.93%	435	136	68.74%
Subject 2	11.6	11.4	1.72%	504	445	11.71%	504	150	70.24%
Subject 3	6.9	6.5	5.80%	150	135	10.00%	150	118	21.33%
			6.02%			19.88%			53.44%

A1C Test - 90 days, FBS - 21 days and 90 days

A1C - 4%-65 mg/dl, 5-100 Typical Non-Diabetic Range, 6-135, 7-170 ADA Target for Diabetes in Control, 8-205 (8 or >) Action suggested according to ADA guidelines, 9-240, 10-275, 11-310, 12-345"