

## **Human Clinical Trial Evaluating the Safety and Efficacy of intraMAX® A Randomized, Gold Standard, Double-Blind Placebo Controlled Study**

Melonie Montgomery, MSHN, Director of Research, Fenestra Research Labs

### **intraMAX Clinical Study and Test Results**

An Independent Trial: Neither the owner of Fenestra Research nor any of its employees have financial ties to Drucker Labs, the formulator and manufacturer of intraMAX and therefore Fenestra Research provided a non-biased study on Drucker Labs' supplement intraMAX in terms of not having a financial interest in producing a desired outcome.

### **Discussion:**

The purpose of this study was to evaluate an all-natural, all-in-one essential nutrient supplement product, intraMAX, with respect to helping normalize and improve cellular functions.

This was a 30-day, 125-person study with subjects drawn from a large population of people with various cellular imbalances. The subjects were randomized into two groups. The placebo group was made up of 75-subjects. Subjects in both Group A (live product group) and Group B (placebo group) were provided and instructed to take one cap full of product twice daily on an empty stomach with a full glass of purified water. Instructions also included: no eating or drinking for at least one-half hour of taking the product and no pharmaceuticals (unless it was a medical emergency) or nutraceuticals for at least two hours after consuming the product.

The Optimal Wellness Test is a revolutionary Anti-Aging and Wellness Analyzer developed by Fenestra Research Labs. It is an analytical, mathematically based test that actually measures wellness in every organ and system of the human body within 0.02 accuracy. What Fenestra Research has established is a simple, reproducible, mathematically based system to determine if a natural product results in the human body moving closer to or further from Wellness parameters. This makes it possible for Health-Care Professionals to establish, determine, and provide improved cellular health for patients objectively.

The Clinical study subjects were tested on week 0 (visit 1) to evaluate their suitability for inclusion in the study. Accepted subjects entered into a 1-week "Baseline Preparation" period designed to eliminate all non-prescription drugs, all OTC (over-the-counter) supplements, and to prepare for baseline testing. At week 1 (visit 2), subjects returned for baseline Optimal Wellness Tests at which time they received their water product, group instruction and individual instructions on expected protocol. Second testing was done on the 2nd week (visit 3) when the Optimal Wellness Test was repeated. Final tests were taken on week 4 (visit 3). At each visit specific protocol for this study was reviewed with each subject. Bi-weekly phone contacts were made to each subject to insure compliance with this study's protocol.

### **Subjects:**

- |                  |                               |                        |
|------------------|-------------------------------|------------------------|
| 1. Gender _____  | 2. Age _____                  | 3. Race _____          |
| 72 women: 53 men | a. 18 from 18-25 years of age | a. 40 Caucasian        |
|                  | b. 25 from 25-32 years of age | b. 28 African American |
|                  | c. 22 from 32-40 years of age | c. 24 Asian            |
|                  | d. 30 from 41-48 years of age | d. 33 Hispanic         |
|                  | e. 20 from 48-53 years of age |                        |
|                  | f. 10 from 53-60 years of age |                        |

### **Results:**

A simple non-paired t-test comparing the differences between baseline and final parameter values for the live product group showed statistically significant changes in salivary ORP (Oxidation-Reduction Potential), pH, toxicity, and urinary specific gravity, carbohydrate digestion, and cellular respiration (see detailed descriptions of these markers below). Statistical analysis of these data shows a consistent picture between treatment groups over time. Results were race, sex, and age independent.

### **Cellular pH**

pH is a measurement of the concentration of hydrogen ions within the various body fluids. The lower the pH, the more acidic the solution; conversely, the higher the pH, the more alkaline the solution is. The pH is measured on a logarithmic scale, meaning that for each charge of one pH unit, there is a tenfold change in the concentration of H<sup>+</sup> ions in the fluids. The normal range for venous blood is 7.30 to 7.35. This slightly alkaline pH is due to the reservoir of bicarbonate ions in the blood that act as physiologic buffers and maintain the normal pH range. The perfect number for fasting urine and saliva is 6.4. These fluids tend to be more acidic due to the removal of acid that is taking place in these body fluids.

### **ORP (Oxidation-Reduction Potential)**

The oxidation-reduction potential is a true value. It is the actual measure of the fluids milli-volt (mV) potential, the measurement of the fluid's ability to donate or accept electrons. The higher the ORP, the more reduced intermediates are in the specimen, meaning the fluid is active, charged, and has the ability to create energy. When the fluid is oxidized, the fluid has lost its capacity to create energy.

### **Cellular Toxicity**

Toxicity is an assessment of what the body contains too much of which causes a toxic relationship between the substance and the cellular body. Here we have several different mathematical representations of ammoniums, nitrates, salts, oxygen, ureas, and other toxic materials that may be present in the body. Significant changes in toxicity have not been observed in studies less than three months in duration. Both nitrates' and ammoniums' numbers influence the electromagnetic picture of the body fluids. Together they determine the amount of energy being lost from the

system. Nitrate and ammonium are related to digestion, and they provide a view of the amount of usable energy being produced by digestion. The chemical reaction that takes place between food and digestive enzymes is vital to Wellness. The correct balance of water, calcium, and oxygen in the body is necessary for usable energy to be the result.

The nitrate and ammonium particles are the result of poor digestion. For the liver to make energy, the liver incites the urea cycle to occur. The body cannot use amino acids that have not been digested properly. Another cause of ammonium production is bacterial metabolism in the intestinal lumen. This released ammonium is absorbed and transported to the liver. The liver treats the nitrates and ammoniums as toxins because the poor digestion has rendered the byproduct unusable. This unusable material is converted into urea and stored in the body. Urea can only be stored for 72 hours before it becomes toxic. At that time the urea is broken down to urea salts of Nitrate and Ammonium Nitrogen. The numbers for perfect digestion are 3 nitrate and 3 for ammonium.

#### **Cellular Specific Gravity**

With bodily fluids, specific gravity is a function of the types and amounts of solids found in solution. The more there is of a substance in solution, which is heavier than the water, the higher the specific gravity will be. With dehydration, whether it is intra or extra-cellular, the specific gravity of fluids is higher because the water content goes down as the solids go up; the converse is true for increased hydration.

#### **Cellular Carbohydrate Digestion**

Many of the vital chemical reactions that take place in the cell require energy, which is derived from the oxidation of the glucose. Within the cell. Measuring and evaluating carbohydrate metabolism provides you with a thorough look at the cellular functions and limitations of the body.

#### **Cellular Respiration**

Cellular respiration is the series of metabolic processes by which living cells produce energy through the oxidation of organic substances. This measurement provides us a look at the most efficient way for cells to produce energy stored in food. Cellular respiration is a catabolic pathway for the production of adenosine triphosphate (ATP), a high-energy molecule, necessary for working cells. We provide a mathematical measurement of the body's ability to produce energy and predict how that ability can be enhanced as well as increase its efficiency.

#### **NO ADVERSE EVENTS WHATSOEVER WERE REPORTED DURING THE STUDY**

Statistic (on average overall)	Group A (intraMAX® Group)	Group B (Placebo Group)
Improved Cellular pH	<b>1.8</b>	No Significant Change
Improved Cellular ORP (Reduced "Free-Radical" damage and reduced aging)	<b>42%</b>	No Significant Change
Decreased Cellular Toxicity	<b>18%</b>	No Significant Change
Improved Cellular Specific Gravity (Lymph, Kidneys, and Energy)	<b>32%</b>	No Significant Change
Improved Cellular Carbohydrate Digestion	<b>27%</b>	No Significant Change
Improved Cellular Respiration (Krebs Cycle, ATP)	<b>22%</b>	No Significant Change

#### **Conclusion:**

intraMAX Is Effective:

Details of the efficacy results supported by the clinical study's findings on intraMAX can be grouped into 4 areas:

#### **Energy:**

- All subjects on the product reported more energy throughout the day.
- intraMAX promotes significant improvement in cellular respiration, and thus enhances energy levels.

#### **Cellular Function:**

- Helps achieve proper composition of body pH. This improved level of acidity in the body promotes better overall functioning.
- Helps achieve proper activation and assimilation of vitamins, minerals, amino acids, enzymes, glycogens, etc.
- Augments the hydration level which is essential for normal bodily function.
- The subjects were tested on Specific Gravity to determine the effects of intraMAX on hydration.

#### **Detoxification:**

- Assists with proper detoxification of intercellular metabolic wastes, and therefore leads to reduced levels of toxicity in the body.
- May help normalize the body's cellular functions.

#### **Optimal Wellness:**

- Helps with digestive enzymes and optimal digestion (especially carbohydrate digestion), which is essential to wellness.
- Helps the body's natural, normal anti-inflammatory response.
- Some subjects had improved kidney health.
- There was a strong anti-oxidant effect vs. oxidative stress, by neutralizing "free radical" damage.

Based on these clinical comparisons and the complete lack of known adverse side effects, interaction, or contra-indications from the ingredients in the product, intraMAX was shown to be a safe and highly effective means of improving one's nutrition while helping to maintain or improve cellular systems' functions.