Alka-Plex® Research Data - pH Sciences Holdings, Inc.

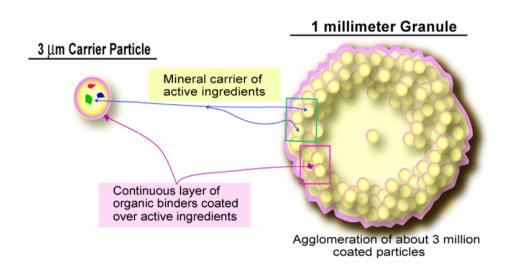
1.1 The Alka-*Plex* Granule

Alka-Plex has three distinguishing characteristics: (1) it reduces acidity in foods and beverages without damaging flavor; (2) it improves absorption of nutrients in the digestive tract; and (3) it balances the complex and critical acid-alkaline relationship in the human body.

1.1.1 The Structure of the Granule: Alka-*Plex* consists entirely of ingredients the U.S. Food and Drug Administration ("FDA") has designated as "GRAS" (generally recognized as safe).¹ It is a mineral-based, crystalline composition produced using the patented Exact Blending and Compounding ("EBC") Process[™]. The combination of GRAS ingredients and its precise composition permits the FDA to recognize **Alka-***Plex* as a New Dietary Ingredient ("NDI") under the Dietary Supplement and Health Education Act of 1994 ("DSHEA") regulations.

Alka-*Plex* granules are made by using microscopic calcium carbonate carrier particles to hold extremely reactive magnesium hydroxide, potassium chloride, and potassium hydroxide (i.e. magnesium and potassium salts). Calcium carbonate is chosen because it does not react with the magnesium and potassium salts and is a stable carrier for those components. The microscopic carrier particles are coated with micro-crystalline cellulose and croscarmellose sodium. Then the particles are assembled into granules using the EBC Process[™]. Diagram 1 is a schematic representation of the Alka-*Plex* granule.

<u>Diagram 1 – Schematic Representation of an Alka-Plex Granule</u>



¹ Federal Code of Regulations ("CFR") Title 21, Section 182.

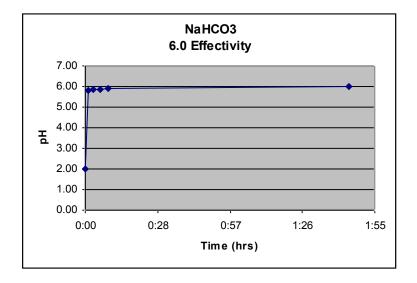
The particular characteristics of the **Alka-Plex** granule are built upon a central paradigm of material science that the structure (not the composition) largely controls the functions of the material. This is a concept that the discipline of chemistry often finds difficult to evaluate.

An example seems in order. Let's imagine that a determination was made that your favorite uncle needed pure carbon in his diet. Should you sprinkle graphite in his soup or diamonds? Both are pure carbon but each has a very different impact on your uncle if he eats them (not to speak of the impact on your pocket book).

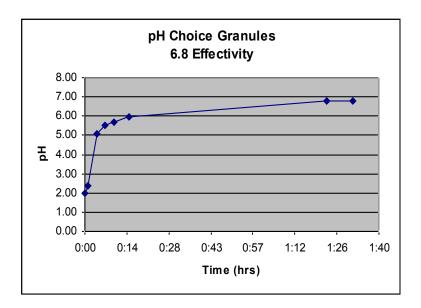
The schematic representation of the **Alka-***Plex* granule shows the microscopic calcium carbonate carrier particle; impregnated with unaltered, stabilized magnesium and potassium salts; coated with microcrystalline cellulose and croscarmellose sodium; and then assembled into a granule. Of course, there is much more to it than that. Like diamond, **Alka-***Plex* is a simple ingredient that is hard to make.

1.1.2 Granule Characteristics: The **Alka-***Plex* granule is unusually resilient. It does not disintegrate into a powder when pressed. The normally highly reactive salts are slow to react. The ingredient has an extraordinarily long shelf life (well in excess of the FDA mandatory three-year maximum) although it holds very reactive compounds.

In short, **Alka-Plex** is seven (7) times stronger than sodium bicarbonate (NaHCO₃) and it takes over an hour to release its active ingredients. The diagrams below offer a comparison of the **Alka-Plex** titration curve and the NaHCO₃ titration curve. The diagrams demonstrate the comparative slow release of **Alka-Plex** and its much stronger effect as an alkalizing agent.



<u>Diagram 2 – Titration Curves for Alka-Plex (pH Choice) and NaHCO₃</u>



The test starts with two beakers each with 150ml of room temperature hydrochloric acid (HCl) with standard 2.0 pH. Exactly .37 grams of **Alka-Plex** is added to one beaker and the same amount of sodium bicarbonate is added to the second beaker. The alkaline materials raise the pH levels of the hydrochloric acid over a period of time. The change in acidity is called the titration curve.

The resulting titration curves reveal interesting contrasts between the materials:

- Alka-*Plex* granules release the alkalizing agents in <u>two gradual steps</u> whereas the bicarbonate is one, almost instantaneous, reaction.
- Alka-*Plex* granules are tasteless and quickly neutralize the acids in foods and beverages. Bicarbonate is very difficult to blend with any food.
- Bicarbonate produces gas while neutralizing hydrochloric acid which, if released in the gut, produces discomfort. **Alka-***Plex* seldom produces gaseous discomfort.
- The first gradual **Alka-***Plex* release takes about 15 minutes to raise the pH of hydrochloric acid to 6.0. This is about the same acid neutralizing power as sodium bicarbonate. But, sodium bicarbonate raises the pH of hydrochloric acid in seconds, not minutes.
- The second **Alka-***Plex* release takes about one hour to raise the pH of hydrochloric acid to 6.8 (7.0 is neutral). Bicarbonate has no such second release.
- For comparison purposes, **Alka-***Plex* removes about seven times (7x) more free H⁺ ions than bicarbonate.
- The gradual release of the **Alka-***Plex* alkalizing agents probably results in greater absorption of alkalizing agents in the blood and through the intestinal tract. Therefore, significantly less **Alka-***Plex* is needed to impact body pH than is the case with bicarbonate.

• The hydroxyl ions (OH-) in **Alka-***Plex* are likely to be transported and absorbed through the small intestine more readily than the bicarbonate ion (HCO₃-) due to the much smaller ion size and the more gradual release of the **Alka-***Plex* ions.

Alka-Plex has unique characteristics (and is patent protected) but what function does it have that may be commercialized?

1.2 Function 1 – Reducing Acidity in Foods and Beverages with Alka-*Plex*

Coffee is an excellent example to describe the potential demand for **Alka-Plex** as a food acidity reducing product. It is estimated that 35-40 million American adults have decreased or eliminated coffee consumption because of stomach discomfort.² Certain acids in coffee are mucosa active. That means they damage stomach mucosal membranes. A small amount of **Alka-Plex** neutralizes the mucosa active acids without damaging flavor-enhancing acidic compounds in the coffee. **Alka-Plex** makes the coffee stomach friendly without damaging flavor.

Similarly, wine, tomato-based products, and certain salad dressings are seeing decreased consumption among baby boomers. The unifying reason is sensitivity to dietary acids.

Dietary changes over the last two centuries have resulted in a mismatch with genetically-determined nutritional requirements in humans.³ Estimates of the net systemic acid load on contemporary humans, when compared to the diet of pre-agricultural *Homo sapiens*, leads researchers to conclude that contemporary diets generate diet-induced arterial blood pH that ranges in the lower levels of "normal." Medical researchers refer to this as "low-grade metabolic acidosis." As a result, wide-spread, chronic low-grade metabolic acidosis is becoming prevalent in athletes and many persons over 30 years old.⁵

Almost 80 million Americans are in the baby boomer generation. They spend \$2 trillion annually. Of increasing concern to boomers is their health and their reaction to certain acidic foods. pH Sciences is offering two ingredients that we believe will be attractive to the food and beverage industry.

One example of **Alka-Plex** use is when it is added to water. The granules do not dissolve completely and can give water (and other drinks) a slightly cloudy appearance. When added to water, the granules can increase the pH level of the water to 10.5 without damaging the flavor. Several delivery systems are being considered for alkalizing water with **Alka-Plex** granules.

One dramatic test of **Alka-Plex** occurred in 2005. In 2005, Glacia Nova, a strategic partner of pH Sciences, introduced glacier water under the brand name "Akali®" which contains **Alka-Plex Liquid**TM. Akali has a 10.3 pH and a wonderfully clean, clear taste. It won a bronze metal in the prestigious Berkeley Springs Best Waters of the World competition at least in part because **Alka-Plex Liquid** was added to the water.

The Berkeley Springs bronze medal awarded to Akali is shown below.

² Proctor and Gamble Company announcement for Folgers® brand coffee, May 12, 2006.

³ Frassetto, L.; Morris, R.; Sellmeyer, D.; Todd, K. and Sebastian, A. Diet, evolution and aging: the pathophystologic effects of the post-agricultural inversion of the potassium-to-sodium and base-to-chloride ratios in the human diet, *European Journal of Nutrition* 40:5 200-213, 2001.

⁴ Ibid. (Quotation marks added.)

⁵ Ibid.

Diagram 3 – Berkeley Springs Award to Akali™ with Alka-Plex Liquid



3. Function 2 – Improving Absorption of Nutrients

pH Sciences is researching the unexpected characteristic of **Alka-Plex** to improve nutrient absorption in the gut. It is common knowledge that lipophilic compositions are easily absorbed across mucous membranes. For example, hand lotions are lipophilic (i.e. mixes easily with oils). They are easily absorbed by the skin. This is their chief advantage.

It is also common knowledge that hydrophilic compositions (i.e. mixes easily with water) are not easily absorbed by the skin. The component ingredients in Alka-Plex are classic hydrophilic materials, but **Alka-Plex** is easily absorbed by mucous membranes and can carry nutrients with it.

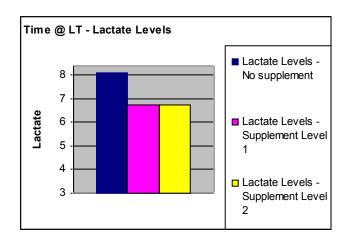
This is an area for on-going patent applications and will not be described further than to say:

- Studies at Montana State University concluded that bottled water containing Alka-Plex Liquid hyrates 21% better than water without Alka-Plex Liquid; and
- Yoli, a network marketing channel launch partner, is so impressed with the improved absorption of nutrients with **Alka-Plex** that Yoli is including **Alka-Plex** in all the products they make.

4. Function 3 – Balancing Systemic pH and Improving Performance for Competitive Athletes

1.4.1 **Athletic Performance:** pH Sciences is developing a group of products for world-class athletes, military personnel, and weekend warriors. There is compelling evidence that our investigational products for athletes permit them to continue beyond the standard limits of fatigue.

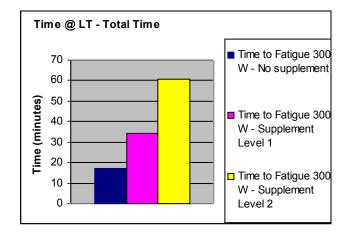
In a pilot study with one competitive athlete, a medical doctor measured blood lactate levels in the athlete working to exhaustion. Blood lactate levels rise as muscle pain and fatigue sets in. Diagram 4, entitled "Lactate Levels of a Competitive Athlete Working to Exhaustion," shows the lactate levels after an athlete worked to exhaustion on three tests. On the first test, the athlete was taking no **Alka-Plex**. In the last two tests, the athlete was taking **Alka-Plex**. **Alka-Plex** has a clear physiological impact on reducing the athlete's blood lactate levels. Lactate levels correlate with muscle pain and discomfort at exhaustion.



<u>Diagram 4 – Lactate Levels of a Competitive Athlete Working to Exhaustion</u>

Diagram 5, entitled "Work Performed by Same Competitive Athlete Working to Exhaustion" is shown below. As in diagram 4, the first bar is the result of an athlete taking no **Alka-Plex**. The second and third bars indicate the amount of time an athlete was able to work at VO₂ Max after taking **Alka-Plex** for one week. The work performed with **Alka-Plex** supplementation is startling. The tests indicate an athlete can perform considerably more work before reaching exhaustion while taking **Alka-Plex**.

<u>Diagram 5 – Work Performed by Same Competitive Athlete Working to Exhaustion</u>



Athletes, soldiers, and others working under severe physical stress may not tire as quickly, may have untapped reserves available to them, and their muscles are not likely to feel as much pain if they are taking **Alka-Plex**.

The data collected in the pilot study has been confirmed by a Montana State University double-blind, placebo-controlled study involving collegiate athletes.

pH Sciences is speculating that the "wall" marathon runners hit after 20 miles of running may be moved out considerably. New records may be set for athletes taking **Alka-Plex**. pH Sciences continues to research and develop second and third generation improvements to **Alka-Plex**.

The U.S. Anti-Doping Agency (USADA) has reviewed the Alka-*Plex* composition and has determined there are no prohibited ingredients in the product. The World Anti-Doping Agency (WADA) has issued a report with the same conclusion. Tests have shown improved endurance and stamina, faster muscle recovery, and less pain and less cramping in athletes taking various doses of Alka-*Plex*.

What works for healthy athletes also works for an aging population that is beginning to "feel" its age.

1.4.2 Improving Health of an Aging Population: Based on tests given to healthy athletes, **Alka-Plex** has been shown to help balance the complex mechanisms regulating pH levels and fundamental biochemical functions in the human body. A healthy human body works best, and its chemistry functions most effectively, when it is slightly alkaline. Blood pH in a healthy body lies within a narrow alkaline range of 7.35 to 7.45.

"Chronic, low-grade acidosis" arising from excess dietary acids must be distinguished from "acidosis" – a medical condition which occurs from a pH imbalance where blood pH drops below 7.35. Acidosis is life threatening. However, the human body performs heroic measures and compromises essential functions to keep blood pH in the narrow range of 7.35 to 7.45 pH. Therein lays many of the health problems that arise with "chronic, low-grade acidosis" associated with aging.

⁶ Wiederkebr, M. and Krapf, R. Metabolic and Endocrine Effects of Metabolic Acidosis in Humans. *Swiss Medical Weekly* 136: 127-132. 2001.

As we age, body functions become less efficient. Organs and body systems do not work as efficiently as they do for young people.⁷ The healthy acid/alkaline balance can easily lean toward too much acid creating acidic stress on the body.⁸ Also, metabolic events—ranging from marathon running to traumatic ailments—can unsettle the acid/alkaline balance. When the body's pH balancing systems are stressed the body reacts to keep blood pH levels within the low/normal range of 7.35. When this acidic stress is persistent, the condition is described as "chronic, low-grade acidosis."

pH Sciences has identified several **Alka-Plex** based products that relieve distress in certain body systems caused by chronic, low-grade acidosis. These broad applications arise from a systemic acid imbalance that is present in most people over 30 years old and is increasingly evident among people over 40.

• **pH Balancing for the Digestive System:** pH Sciences has developed the first new (patented) antacid in over twenty (20) years based on the **Alka-Plex** formula. Current antacid formulas are really buffers and rely on large amounts of calcium carbonate. Calcium may make the stomach feel better but it is a mere palliative. Worse, slow-acting but widely advertised proton pump inhibitors are detrimental to the digestive process and contribute to acidic stress.

pH Sciences' digestive formula is an extremely powerful alkalizing agent (eleven times more powerful than extra-strength TUMS®) and has essential minerals and considerably less calcium than any other antacid (there is increasing evidence that U.S. consumers are beginning to overdose on calcium). It improves and strengthens the digestive tract while providing immediate relief from acid indigestion.

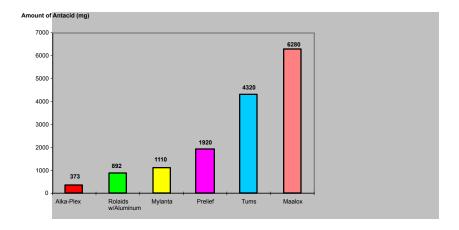
Pacific Testing Labs conducted a study comparing the amount of various antacids to neutralize a standard amount of hydrochloric (HCl) acid. The results are shown in the following diagram.

<u>Diagram 6 – Comparison of Various Antacids and Alka-Plex from Pacific Labs Tests</u>
(Study Performed by Pacific Testing Laboratories)

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⁷ **Frassetto, L., Morris, R. and Sebastian, A**. Effect of Age on Blood Acid. Base Composition in Adult Humans. *American Journal of Physiology* 271:1114-1122. 2000.

⁸ Lark, S., M.D. and Richards, J. The Chemistry of Success: Six Secrets of Peak Performance, Bay Books, pp43-55 1999.

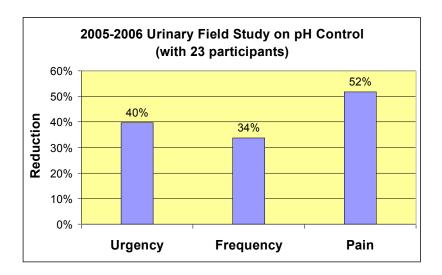


- Lower Digestive Tract Health: Alka-*Plex*, if delivered in correct doses and dissolve rates, is an effective agent to improve intestinal tract health and reduce the diarrhea and abdominal pain symptoms of certain symptoms associated with irritable bowel syndrome (IBS). IBS effects up to 15% of the population in Western countries and increases frequency with age. Pre-clinical trials are in the planning stage with a major naturopathic university.
- Urinary Tract Health: If delivered in correct doses and dissolve rates, Alka-*Plex* is an effective agent in reducing the symptoms of frequency and urgency of urination. About 68 million people in the U.S. suffer from urgency and frequency symptoms. The initial product tests targeted persons suffering from interstitial cystitis (IC), a particularly troubling condition with urinary urgency and frequency.

There are three primary symptoms of IC—urinary frequency (i.e. a need to urinate as often as every 20 minutes day and night), urinary urgency (i.e. an immediate, compelling need to urinate) and pelvic pain. IC is primarily a condition of middle aged women and often follows a traumatic event or child birth. There is no identified cause of IC and there are no effective cures for the condition. Urinary urgency and frequency is reduced by 34% within two weeks of taking Alka-Plex for most IC sufferers.

The following diagram shows data from a field study of a product, pH Control, made from **Alka-Plex**, given to persons diagnosed with IC.

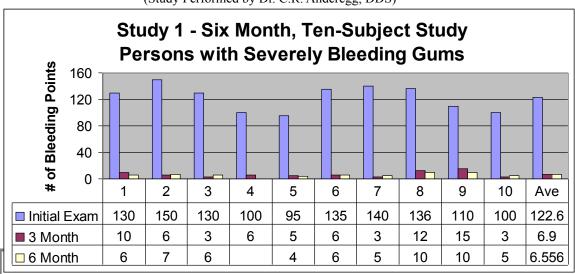
<u>Diagram 7 – Field Study Results of Bladder Improvements of IC Sufferers Taking Alka-Plex</u> (Study Performed by Tamer Laboratories)



• <u>Gum Health</u>: When delivered in toothpaste, Alka-Plex is an effective agent in reducing inflammation, infection, and bleeding in gums. Abnormal gum bleeding is often prevalent in persons with chronic, low-grade acidosis and is also associated with aging.

Three studies, including a double blind, placebo-controlled study at the University of Washington, has shown that an Alka-*Plex* based toothpaste reduces gum bleeding in as fast as two weeks. The data from one study is presented below. In that study, ten subjects with severely bleeding gums (an average of 122 bleeding points) were asked to brush once a day with Alka-Plex toothpaste. Bleeding was reduced to an average of seven (7) bleeding points.

<u>Diagram 8 – Field Study of Gum Health Improvement with Alka-Plex Toothpaste</u> (Study Performed by Dr. C.R. Anderegg, DDS)



- **Joint Health:** Gout, a condition associated with formation of painful uric acid crystals in joints and extremities, is quickly moderated and can be eliminated if **Alka-Plex** is added to the diet. This eliminates the need for drugs and their serious negative effects on heart health.
- Alka-Plex for Increased Absorption of Nutraceuticals: Alka-Plex, when combined with other botanical dietary supplements can improve the absorption of those products. For example, an important active ingredient in garlic (allicin) is quickly broken down by stomach acids. If it is combined with Alka-Plex, the stomach acids are neutralized, absorption is improved and over thirty (30) times more allicin is absorbed by the body.
- **pH Balancing for General Health:** pH Sciences is planning on releasing a group of products that promote healthy aging. As humans age, their ability to neutralize acids at the cellular level is reduced. Certain fundamental chemical functions in the body are changed or stop if intra- and inter-cellular pH levels tend toward 7.35. Highly acidic foods compound the problem. Wideranging ailments can begin to appear if intra- and inter-cellular acid/alkaline relationships are out of balance. Considerable research is being done in this area. About 4.5 million people turn 50 every year in the U.S. Baby boomers are turning toward health as a major concern. Baby boomers are driving a trend toward healthy aging just as they have driven many U.S. trends in the past.
 - Maintaining Health: After age 40, a metabolic pH imbalance often begins to appear in a person's body. That imbalance—chronic, low-grade metabolic acidosis—is associated with chronic discomfort in a wide range of body functions that are associated with the "aging process." These symptoms do not have to persist because Alka-Plex granules, when delivered appropriately, will alleviate many of the most troubling symptoms naturally.
 - <u>Improving Energy</u>: Alka-*Plex*, when taken in appropriate doses, increases energy levels and reduces muscle fatigue and soreness that often accompanies physical exertion.

Alka-*Plex* has several important functions and can address many different markets. The diverse markets call for marketing partners to introduce **Alka-***Plex* under their brand name and for pH Sciences to remain the premier manufacturer and technology leader making ingredients that balance body pH.

1.5 Raw Materials Sourcing

The raw ingredients for **Alka-Plex** are available from a broad range of sources that are easily available from U.S. sources. The ingredients are almost all available from natural sources and all are available in pharmaceutical grades. pH Sciences currently uses a natural source of calcium carbonate that is unusually pure. The Company intends to continue using that source and anticipates that significant growth in demand for **Alka-Plex** may create competitive demands for that calcium carbonate. Therefore, the Company is also pursuing long term strategies to secure key ingredient supplies.

1.6 Technology Patents

The following table lists the most relevant patents issued to Tamer Labs that have been purchased by pH Sciences.

<u>TABLE 1 – Select Patents Issued to Tamer Labs and Subsequently Purchased by pH Sciences</u>
(Patents Typically Have a 20-year Life From the Filing Date)

Patent #	Title of the Patent	Filing Date	Grant Date
6,102,213	Beverage filters for reducing coffee acidity	10/30/98	8/15/00
6,066,342	Antacid composition	12/20/96	5/23/00
6,045,843	Acid-reduced whole bean coffee process	6/03/98	4/04/00
6,143,221	Agglomerating and Drying Apparatus	3/12/99	11/07/00
6,270,708	Agglomerating and Drying Apparatus	2/23/00	8/07/01
6,495,180	Acid Reduced Whole Bean Coffee & Process	2/28/00	12/17/02
6,669,928	Periodontal Composition	5/04/00	12/30/03

Copies of the purchase agreement and related license agreement between pH Sciences and Tamer Labs and the patents issued to Tamer Labs are included in the due diligence materials and are available upon request. All of the issued patents and any subsequent patents issued to Tamer, which contain intellectual property important to pH Sciences as it exploits its designated markets, are included in the license agreement. Patents filed on or after June 8, 1995 have a 20-year term from the filing date. The key pH Sciences patents expire in late 2016 to 2020. Additional provisional patents and patents pending are being pursued in the following areas:

- Composition and method for reducing acidosis and related conditions in mammals using a strong base; and
- Specific applications for use of a slow release alkaline composition.

Management believes these additional patents will be important for the long-term growth of pH Sciences.

1.7 Clinical Research

Clinical research, especially with healthy subjects like athletes, is an important component to the Company's objective of capturing the global category of alkalization for healthy aging and sports performance. The general research strategy for the Company is to monitor consumer responses to **Alka-Plex**; identify potential areas of research through anecdotal evidence; conduct detailed literature research in the area; plan a pilot study if the literature supports a possible application for **Alka-Plex**; and, depending on the results in the pilot study, undertake a clinical trial using standard double-blind, placebo-controlled run by an independent laboratory or university.

The pilot study prepared by Dr. Emily Cooper, M.D., from the Seattle Performance Medicine Clinic is one such study. It is entitled, "Elite Bicyclist Pilot Study Using Two Levels of Alka-Plex® Supplementation" and contains detailed physiological data on two subjects exercising to exhaustion while taking **Alka-Plex**. Daniel Heil, Ph.D., a professor at Montana State University Human Performance Lab has concluded a clinical trial and is submitting his report for peer review analysis. His clinical trial confirms the pilot study conducted by Dr. Cooper.

Similarly₂ pH Sciences has undertaken a literature review of dietary impacts on chronic metabolic acidosis and clinical treatments of the condition. The literature review, conducted by Joseph Pizzorno, ND, (the founder of Bastyr University) and Dr. Lynda Frassetto, MD, (a researcher from the University of California Medical Center in San Francisco, has been submitted to peer review analysis and publication in

a medical journal. This sort of research is fundamental to pH Sciences establishing its reputation at the leader in the field of alkalization for healthy aging and athletic performance.