

# **A Study of the Effects of Oral Dietary Supplementation of Ai/E<sup>10</sup><sup>®</sup> Upon Natural Killer Cell Activity in a Healthy Human Population**

Quantum Research, Inc., Scottsdale, Arizona, September 1, 2001

## **Abstract**

Seven women and five men, mean age 43, were monitored over 90 days for changes in Natural Killer (NK) Cell Activity and their responses to a "Symptom Evaluation" general health questionnaire. Each participant consumed 100 mg of the dietary ingredient **Ai/E<sup>10</sup><sup>®</sup>** by capsule b.i.d. as recorded by compliance questionnaire.

## **Objective**

To evaluate changes in NK cell activity (Lytic units) experienced by healthy people using **Ai/E<sup>10</sup><sup>®</sup>** on a regular basis and to simultaneously review changes in their responses to a symptom evaluation.

## **Findings**

A significant elevation ( $p=.001$ ) of NK cell activity from a pre-study mean of 30 LU (Lytic Units) to a post study mean of 101 LU was measured for the study group over a ninety-day period while taking 100 mg of **Ai/E<sup>10</sup><sup>®</sup>** b.i.d.

A significant reduction ( $p=.019$ ) in the numerical value average of "symptoms" per participant from the baseline was experienced when comparing the average from the beginning and the end of the study. The pre-study general health "Symptom Evaluation" numerical value average per participant was 121 and the post-study average of was 82, indicating that the use of **Ai/E<sup>10</sup><sup>®</sup>** by the study participants correlated with significance to a 32% reduction in reported health symptoms.

## **Conclusion**

This study suggests a positive relationship between the oral consumption of **Ai/E<sup>10</sup><sup>®</sup>** and increases in Natural Killer cell activity and the reported reduction of general health symptoms without the support of addition nutrition supplementation, medication or lifestyle alterations. As Natural Killer cell activity is associated with immune system health, **Ai/E<sup>10</sup><sup>®</sup>** can be an important and significant contribution to the health and well-being of healthy people.

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## **Background**

Human immune system dysfunction is an emerging world health crisis. Declining immune system performance, a function easily measured by blood test, continues to appear as the source of the most severe, degenerative and chronic disease.

Medical research has identified Natural Killer (NK) cells as a critical component of the immune system and revealed that low Natural Killer cell activity is present in most severe, chronic and degenerative diseases. This study was designed to determine the effect of the refined lacteal complex **Ai/E<sup>10</sup>**® on Natural Killer cell function over a 90-day period with a population of participants who in all respects appeared and judged themselves to be healthy.

No additional nutritional supplement or health improvement program was included and participants were advised not to alter their normal lifestyle during the study period. The study results suggest a positive correlation between the consumption of **Ai/E<sup>10</sup>**® provided to the participants and improvement of their Natural Killer (NK) cell activity.

**Ai/E<sup>10</sup>**® is produced by patented process and proprietary method developed and researched since the 1950's<sup>1</sup>, and has been used since 1993 to provide immune system support. Several clinical studies have demonstrated the efficacy of the substance for supporting immune system function and increasing Natural Killer (NK) cell function<sup>2</sup> and a double blind study has revealed the immune modulation effects of **Ai/E<sup>10</sup>**® within a 15-day study period<sup>3</sup>.

The improvement and support of healthy immune function has come to the forefront in the quest for addressing the alarming rise in serious, degenerative and chronic diseases<sup>4</sup>. Absent an intact and efficient immune system the possibility for contracting a serious or degenerative disease becomes likely, if not a certainty.

The primary function of the immune system is to eliminate infectious agents and minimize the damage such agents might cause<sup>5</sup>. There is an ever-increasing degradation of immune function due to the prevalence of four primary factors that effect immune function that can be associated with the worldwide decline in well being. Those factors are:

1. Stress (mental, emotion, physical),
2. Nutritional deficiencies,
3. Infections,
4. Toxins<sup>6</sup>.

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## **Background (continued)**

Daily exposure to environmental pollutants, the stressful lifestyles of modern society, inadequate nutritional intake, and the continual exposure to pathogenic micro-organisms place most people at risk. These factors and demands can and do overwhelm the capacity of the immune system of many individuals. Even those people whose immune systems are not overwhelmed undoubtedly experience a diminished standard of living through reduced immune performance.

When the immune system is overwhelmed the communication pathways are compromised and remain compromised until re-established. If the communication networks are not restored there is little opportunity for the immune system to regain full defensive capability.

Re-establishing immune integrity through traditional nutrition shows very little promise. Traditional nutrition relies upon biochemical activity as a method of supporting the function of the immune system. However, the traditional nutrition approach fails due to the inability of biochemical activity to reestablish immune communication pathways.

Communication in the immune system is accomplished through the cytokine mechanism. These messenger molecules must be activated to energize the communication capability that is necessary for immune system reliability<sup>7</sup>.

An indicator that can be used to determine the status of the immune system is Natural Killer (NK) cell activity. Low Natural Killer cell activity is present in most illness and can be an indicator of developing disease or declining health. Natural Killer cells have been of interest to medical research since the early 1970's. Their role in immune health has been well established and they play an important role in immune function. NK cell activity can be evaluated with blood testing<sup>8</sup>.

NK cells attack a broad range of virally infected or tumor cells and activated NK cells produce a variety of cytokines, including interferons, interleukins, TNF, hematopoietic cell growth factors and other growth factors. There is substantial evidence that indicates the involvement of NK cells in the interactions of the immune system with the neuroendocrine axis<sup>9</sup>. They also appear to be responsible for activities at the interface between the immune system and the reproductive and neurological systems.

## **Background (continued)**

NK cells are not restricted to immune surveillance against infectious agents or tumor metastases but have a broadly based involvement in a variety of essential biological processes ranging from reproduction to coping with daily stress<sup>10</sup>.

Chronically low levels of NK cell activity occur in association with a variety of diseases, including cancer, acquired or congenital immunodeficiencies, severe life-threatening viral infections, autoimmune diseases and behavioral disorders<sup>11</sup>.

An eleven-year study on 3,625 people indicated that a medium to high level of NK cell activity reduces cancer risk and that low NK activity is associated with increased cancer risk<sup>12</sup>. Natural Killer cells appear to play an important role in human health, as there is a strong correlation between low NK activity and disease. Accordingly, augmenting NK cell activity through dietary supplementation appears to be an excellent health maintenance option.

There are a number of natural and synthetic substances that will temporarily stimulate NK cell activity<sup>13</sup>. However, immune system response appears to be more enveloping and effective when achieved through the modulation process rather than stimulation or depression<sup>14</sup>.

NK stimulation versus immune modulation with a resulting increase in NK activity has three major distinctions:

1. Stimulation will cause an initial rise in NK activity but after a short period of time the stimulation will diminish and the NK activity will return to baseline or below.
2. Stimulation has a limited effect on the immune system and does not affect the immune system as a whole.
3. Stimulation has limited effects on overall health.

Conversely, immune modulation that harnesses the body's ability to regulate will have an all-encompassing immune response that is not limited to one specific area of immune response. Regulation, upward or downward, in accordance with the needs of the body will be achieved.

**Ai/E<sup>10</sup>**<sup>®</sup> has a long history of empirical and antidotal evidence, as well as clinical studies on humans that have proven its effectiveness as an immune modulator that triggers the appropriate immune response. Although the pathways of

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### **Background (continued)**

initiation by **Ai/E<sup>10</sup>**® are not clearly understood there appears to be an activation effect on B cells, T cells, macrophages, interleukins, interferons, TNF and other cytokines.

The cytokine launch initiated in immune modulation produces a “spreading effect” that causes an increase in Natural Cell activity<sup>15</sup>. This study examines the Natural Killer activity changes after the commencement of daily usage of **Ai/E<sup>10</sup>**® for the express purpose of determining the effects of **Ai/E<sup>10</sup>**®, an immune modulator, on Natural Killer cell function and participant general health symptoms.

### **Eligibility Criteria**

The following eligibility criteria were applied to human subjects self-evaluated as healthy or reasonably so. They were required to be between the ages of 21 and 65 years, not suffering from severe or degenerative diseases, not currently experiencing any high stress circumstances, not taking any pharmaceutical medications for severe, chronic or degenerative diseases and not pregnant.

They were advised not to alter their eating habits or lifestyle just because they were in the study. Dietary supplements were acceptable if they were currently taking any, as well as the use of any medications or health care treatments that were deemed necessary during the course of the study.

### **Study Design**

Twelve participants were included in the study that was comprised of seven women and five men ranging in age from 24 years to 63 years. Each participant completed a symptom evaluation form just prior to commencement of the study and provided a blood sample for a Natural Killer Function Test. Each participant received a two week supply of 100 mg capsules of **Ai/E<sup>10</sup>**® along with a compliance form to record date and time of consumption. Participants were instructed to take one capsule twice daily, one in the AM and one in the PM.

Every two weeks each participant returned to the research site to submit the compliance form, participate in a short interview and receive another two weeks supply of the product.

After approximately 90 days of taking **Ai/E<sup>10</sup>**® a Natural Killer cell Function test and Symptom Evaluation Form were completed for each participant.

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## **Study Design (continued)**

Each participant received a six months supply of an **Ai/E<sup>10</sup>**® product for agreeing to participate, comply and complete the study.

### **Materials**

**Ai/E<sup>10</sup>**® is a refined lacteal complex produced from privately managed dairy cows that receive specific antigen infusions to the cow's udder.

Antigen infusion is a patented process of immunological stimulation that produces a particular array of immuno-dynamic molecules in a dairy cow that can be ingested by other mammals to support an immune response that enhances the functional capabilities of the immune system. **Ai/E<sup>10</sup>**® was presented as dried, encapsulated powder bottled for the study.

### **Natural Killer Cell Function Test**

Natural Killer (NK) cell activity and measurement of NK cell numbers can be evaluated by flow cytometry. Until the recently NK cell activity was measured by Cr-labeled leukemia cell line, K562, as target cells and peripheral blood mononuclear cells as effector cells. However, developments in flow cytometry technology can now use K562 cells as the target cells that are labeled with fluorescent dye instead of radioactive chromium. The advantages of this method are increases in specificity, sensitivity and the absence of radioactivity in the assay<sup>16</sup>. The results of NK assays are expressed as lytic units (LU) and the normal range is between 20 and 250 LU<sup>17</sup>.

### **Symptom Evaluation**

The 241 health questions and/or symptoms listed in the Study Questionnaire were self evaluated by participants with a numerical value of 3 for symptoms experienced frequently, 2 for occasionally, 1 for rarely and 0 for never. A numerical value was determined by totaling the numbers of the participant's survey to establish a before and after comparison.

These numbers were used to determine the percentage of symptomatic change that occurred at the completion of the study. Because this symptom evaluation is a very subjective process with a high degree of variance from individual to individual it may be considered an indicator of trend rather than an objective scientific tool for improvement evaluation.

## Study Findings

### Natural Killer Cell Activity

A significant elevation ( $p=.001$ ) of NK cell activity from a pre-study mean of 30 LU (lytic units) to a post study mean of 101 LU was measured for the study group over a ninety-day period while taking 100 mg of **Ai/E<sup>10</sup>**® b.i.d.

Appendix 1 details “before” and “after” Natural Killer cell activity measured in lytic units (LU) for each participant.

### Symptom Evaluation

A significant reduction ( $p=.019$ ) in the numerical value average of “symptoms” per participant from the baseline was experienced. The pre-study general health “Symptom Evaluation” numerical value average per participant was 121 and the post-study average of was 82, indicating that the use of **Ai/E<sup>10</sup>**® by the study participants correlated with significance to a 32% reduction in reported health symptoms.

Symptom evaluation details for each individual divided into groups of male and female is shown in Appendix 1.

### Discussion and Comments on Findings

There has been a great deal of clinical, anecdotal and empirical evidence accumulated that demonstrates the effectiveness of **Ai/E<sup>10</sup>**® for immune system support for “sick” people. However, until now, there had not been a study that evaluated the effect of the extracts on the average individual who is not suffering from any severe or degenerative health problems.

This group study was designed to determine the effect of **Ai/E<sup>10</sup>**® on a general population that was “healthy”. This group was not under any type of health care treatment and agreed not to alter any lifestyle regimen just because they were a study participant. They were instructed to live life as usual, but if they needed any medical attention or other health services while on the study they were instructed to follow their normal routine.

This study focused upon the change in Natural Killer cell activity initiated by **Ai/E<sup>10</sup>**® in a healthy (self-evaluated) population of humans. The effect of **Ai/E<sup>10</sup>**® on Natural Killer cell activity has been documented in several studies where it was included in a holistic treatment regimen. The investigators in those studies concluded that the modulation effect along with a dramatic increase in Natural

## **Discussion and Comments on Findings (continued)**

Killer cell activity could only have been the result of the addition of **Ai/E<sup>10</sup>**<sup>®</sup>. This was indicated since the same treatment regimen had not produced similar laboratory results (blood test monitored immunological responses) in the past. Also, the fact that patient outcomes in those studies were far superior to the same treatment regimens without **Ai/E<sup>10</sup>**<sup>®</sup> further reinforces the correlation.

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