Epimune Complex Research: Effective and Comprehensive Support for Immune Function



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Open-label, pilot study

30 days: 2 Epimune Complex capsules per day **25 subjects:** 20-57 years of age; 15 men and 10 women; 18 Hispanic/Latino, 5 Caucasian, 2 Asian



Trend increase in salivary immunoglobulin A (IgA)

Overall increase in multiple immune markers

Statistically significant increase
in red-blood-cell zinc

Statistical and clinically significant increase in leptin

To assess the effect of Epimune Complex consumption on immune markers, Standard Process designed an openlabel pilot study. This type of trial does not use a control group (open label) and is used to identify areas for further research (pilot study). While an open-label pilot study does not result in clinical recommendations, it is a great way to identify interesting findings for further examination.

Sponsored by Standard Process and managed by a contract research organization, this Institutional Review Board-approved study examined how Epimune Complex affects both the white blood cells of the immune system and surrogate markers of their activity. Subjects had blood drawn at the beginning of the study and again at the end. These samples were tested for a number of biomarkers thought to indicate immune function and activity.

Primary Objective: Assess Effect of Epimune Complex on Immune Markers:

- > Salivary IgA
- > Complete blood count (CBC)
- > Immunoglobulin E (IgE)
- > Cluster of differentiation (CD)4/8
- > CD19
- > Cytokines
- > Red-blood-cell zinc

Ingredients in Epimune Complex

EpiCor®: contains a variety of active compounds such as beta-glucans, mannan-oligosaccharides, nucleotides, amino acids, and vitamins

Mushroom powders: whole food powders of the mycelium of *Grifola frondosa* (maitake) and *Coriolus versicolor* (turkey-tail) mushrooms

MaitakeGold 404°: contains polysaccharides found in the mycelium of maitake mushrooms

Calcium lactate: highly digestible calcium that supports numerous actions in the body (involved in cell signaling)

Zinc rice chelate: highly bioavailable and needed throughout the body (plays a structural role in proteins and helps protect cell membranes while influencing cell communication, hormone release, and cell death, among other actions)

Acerola: a rich source of vitamin C, which supports the immune system through peripheral means (supports mucosa, cell function, skin, blood vessels, and other tissue via its role in collagen synthesis and antioxidant activity; may help re-form other vitamins, like vitamin E)

Results

The information presented below is excerpted from the unpublished research report.

- Salivary IgA: As an antibody, IgA acts as a sentinel for foreign matter. The report states, "In this study, Salivary IgA increased by 11.4% after 30 days of exposure to the test product [Epimune Complex]. This increase from baseline did not reach statistical significance."1
- Overall increase in multiple immune markers throughout immune system: To begin to identify exactly how Epimune Complex interacts with the body, this study examined white blood cells and the immune system's communication molecules, cytokines. The report states, "The Epimune Complex product appears to increase immune markers in the humoral and cellular immune system."
- Red-blood-cell zinc: The report states, "In this study, RBC Zinc increased by increased by 26.4% after 30 days of exposure to the test product [Epimune Complex].

 This increase from baseline was statistically significant (p = 0.014)."

 Future research is needed to determine if raising this particular marker of zinc is supportive of overall health.²
- > **Leptin:** The report states, "In this study, leptin increased by 36.9% after 30 days of exposure to the test product [Epimune Complex]. This increase from baseline DID reach statistical significance [p = 0.036] and has potential implications for the management of satiety as well as in immune function regulation." This finding, which is both statistically and clinically significant, was an interesting surprise and requires more research to determine the mechanism of action.³

- 1. This finding is consistent with the results of a study based on one ingredient (EpiCor) where salivary IgA trended up at four weeks and became statistically significant at eight weeks: Jensen et al. 2008. *The Open Nutrition Journal*, 2:68-75.
- **2.** Zinc is an important cofactor in many processes associated with immune system function in general. In red blood cells:
- Zinc may support cell membrane strength. (O'Dell, BL. 2000. J Nutr. 130(5):1432S-436S)
- Zinc may provide protection from oxidative damage. (Wood, M. October 29, 2002. United States Depart. of Agriculture, Agricultural Research Service)
- **3.** Leptin is a protein involved in communication between the body and the brain regarding fat storage and metabolism.

More research on these findings is needed, but this pilot study provides valuable insight into how Epimune Complex works with the human body's natural immune response.