CellSentials Premarketing Evaluation: Biochemical Marker Evaluation

Executive Summary

For a four-week trial period, healthy adults consumed the new CellSentials formulas. At the end of the trial, we saw statistically significant improvements in three key areas of health: vitamin D status, blood quality, and cardiovascular health-related markers. These results indicate that the new CellSentials formulas deliver important health benefits in a relatively short amount of time.

The Biochemical Marker Evaluation measured whether consuming the new CellSentials for four weeks had any effects of on a number of different biochemical markers of human health. Twenty participants were enrolled in the study, which was performed at the Sanoviv Medical Institute in Rosarito, Mexico. Blood samples were evaluated from participants before and after the four-week trial period. In this time, a number of biochemical markers exhibited statistically significant ($p<0.05$; paired t-test) changes. These are listed in Table 1.

Table 1 - List of biochemical markers that changed significantly (i.e., $p<0.05$) in participants consuming the CellSentials for 4 weeks. n=20 participants

Biochemical	Average Values (±SD)		Paired T-test
Marker	Before	After	p-value
Vitamin D (25 hydroxy)	26.8 (10.9)	34.5 (13.5)	< 0.001
Homocysteine	8.3 (2.2)	5.3 (1.3)	< 0.001
HDL cholesterol	51.2 (10.5)	55.2 (11.8)	0.007
Total/HDL ratio	3.7 (1.1)	3.5 (1)	0.014
LDL/HDL ratio	2.3 (0.9)	2.2 (0.9)	0.043
RBC	4.7 (0.4)	4.7 (0.4)	0.011
Hematocrit	42.1 (3.8)	41.3 (3.5)	0.014
MCHC	33 (0.7)	33.5 (0.8)	0.020
MCH	29.3 (1.3)	29.7 (1.3)	0.037

Vitamin D Status

When compared to Essentials, the CellSentials contain an additional 200 IU of vitamin D in a daily dose, for a total of 2000 IU per day. Participants' average circulating vitamin D levels increased from 26.8 ng/mL (67 nmol/l) to 34.5 ng/mL (86 nmol/l). A range of 30 to 40 mg/mL has been widely accepted as the optimal target for maintaining health in adults. The results of this evaluation indicate that the increase of vitamin D in the new CellSentials are more effective for helping generally healthy consumers achieve recommended levels.

Blood Quality

Changes in markers indicative of red blood cell count (RBC), hematocrit, mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) were observed following the four-week CellSentials

trial. Each of these indices can be a measure of iron, as well as B vitamin status or metabolism, and all measures (i.e., the before and after measures) stayed within healthy, normal ranges. These observations are most likely due to increased intake of the B vitamins, especially vitamin B6, since there is no iron in the CellSentials. These results may be clinically significant, since these markers are indicative of a change in blood quality. The CDC has recently suggested that over 10% of the population is deficient in vitamin B6, with women between 11 and 59 having the lowest B6 levels. As such, in this study, it appears that the CellSentials are improving blood quality by way of a significant increase in B vitamin intake.

Cardiovascular Health

High plasma levels of homocysteine have been associated with elevated risk for cardiovascular disease. After four weeks of supplementation with the CellSentials, decreased homocysteine levels were observed. Adequate folic acid and vitamin B12 status has been associated with healthy homocysteine levels.

Additionally, significant increases in high density lipoprotein (HDL) cholesterol were also observed, resulting in improvements in the Total/HDL and LDL/HDL ratio, all of which are important for reducing the risk of heart disease. This is a finding that deserves particular attention since: a) we are unaware of any previous evidence that consumption of a multivitamin-mineral/phytochemical supplement increases HDL levels in healthy individuals, and b) a unique finding that deserves further inquiry.

Summary

Consumption of the CellSentials for four weeks increased vitamin D status and also improved markers related to blood quality and cardiovascular health. These changes are associated with positive health benefits and merit further investigation, as they may represent a novel attribute of the CellSentials.