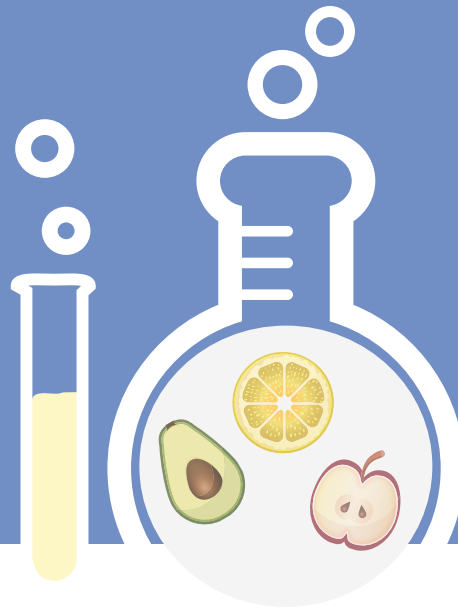# MOSAIQUES THERAPEUTICS

**CLINICAL BIOMARKER PATTERN**

INFORMATION

- Nutritional Health Claims
- Application to EFSA for scientific opinion
- CE-MS based Proteomic Profiling
- Using the CE-MS technology to prove health benefits of food

HEALTH CLAIMS OPEN UP NEW MARKET POTENTIALS

A successful health claim application to the European Foods Safety Authority (EFSA) is a significant achievement that can take years of product research and development, and requires appropriate and controlled trials. Health claims can open up new markets and a positive scientific opinion can provide a competitive differentiator and add value to a product.
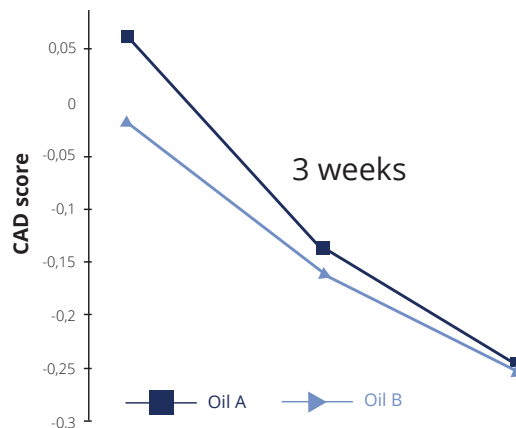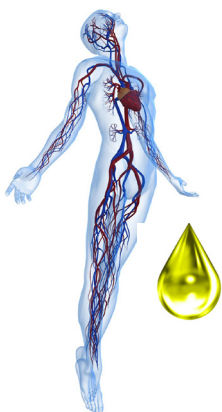
DIETARY EFFECTS ON A CHRONIC DISEASE

Health claims require scientific evidence for substantiation by the EFSA. However, standard methodologies lack the sensitivity and selectivity to show significant effects in nutritional studies. Mosaiques has developed a range of biomarker tests for a number of chronic diseases. In two studies the application of the biomarkers has demonstrated significant effects on these diseases after a dietary supplementation.

BENEFICIAL IMPACT OF OLIVE OIL

60 healthy volunteers were split into two groups and asked to consume either 20 ml of a low phenolic oil or 20 ml of olive oil having a high phenolic content. After only three weeks a significant beneficial effect on the coronary artery disease (CAD) biomarker could be demonstrated.

3 weeks

CAD score: 0,05 / 0 / -0,05 / -0,1 / -0,15 / -0,2 / -0,25 / -0,3

Oil A   Oil B

mosaiques therapeutics

HOW TO PROVE WHICH FOOD IS TRULY RESPONSIBLE FOR HEALTH BENEFITS

The burden of chronic diseases is rapidly increasing worldwide. Eating a healthy diet is seen as a way to prevent or delay the onset of these diseases. But to claim a product is healthy there must be proof.

Mosaiques has developed a range of biomarker tests for a number of chronic diseases. Among these are tests for diabetes, coronary artery disease (CAD)[1] and chronic kidney disease (CKD)[2,3]. These tests are based on a range of peptides that are excreted in urine and form a "biomarker fingerprint" or signature for the health of an individual. These biomarkers were developed for clinical diagnostic purposes and to inform clinicians on treatment progression. They have high specificity and sensitivity for each disease. The clinical biomarker patterns have been validated in a number of blinded studies [4,5]. They can detect the onset of a disease before any symptoms develop.

The tests can also be used to show a significant effect on these chronic diseases after a dietary change. Mosaiques has piloted the use of clinical biomarkers in dietary intervention studies. The initial investigation was on a polyphenol rich (P-R) drink verses placebo. The data indicated that the P-R drink may have benefits for cardiovascular health[6]. The second study was set up to examine the effect of the phenolics in olive oil on heart health and provided proof that the intake of 20 ml of olive oil per day can have a statistically significant effect on the biomarker of CAD, independent of phenolic content [7].

This type of data forms the basis for a strong health claim application with considerably less effort than the conventional approaches, including a smaller number of volunteers. It is also an example of how one product can be tested alongside another to provide information of improved performance due to formulation changes.

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[3] Zurbig et al., 2012. Urinary Proteomics for Early Diagnosis in Diabetic Nephropathy. Diabetes 61, 3304-3313.
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