Summary report of

Clinical evaluation of the accuracy of Vitastiq device for tracking vitamin and mineral trend in human body

Commissioned by Vitastiq d.o.o.
Performed by Vizera d.o.o.

December 20, 2017

EXECUTIVE SUMMARY

PRIMARY TARGET OF THE STUDY

The primary analysis of the study was to determine the Vitastiq device accuracy and performance. Additionally, the study evaluated which results/information (obtained by Vitastiq device or well-established blood test analyses) had bigger impact on people's life style changes, such as food intake and exercise.

The *Clinical evaluation of the accuracy of Vitastiq device for tracking vitamin and mineral trend in human body* was conducted from May 2017 to November 2017 at Adria lab d.o.o. in Ljubljana. The contract research organization coordinating the study was Vizera, d.o.o., Slovenia.

This was a single site evaluation study of Vitastiq device accuracy in 45 healthy men and women over the age 18. Participants completed a home diary which included all readings for selected minerals and vitamins once per day – in the mornings, after waking up. Subject's reported about physical activities, and food intake during every week. Study duration for individual volunteer included 57-day (± 4) test period.

A total of 45 Vitastiq personal devices were used by volunteers for two months. The Vitastiq device was evaluated during three site visits: on day 1, 29 ± 4 days and 57 ± 4 days and 54 ± 4 home use days (every day between first and last day of the study except on visit days). During site visit days, blood sampling was collected and analysed, and at the same time the Vitastiq readings by two investigators and participant were performed.

ACCURACY OF VITASTIQ READINGS

The goal was to achieve at least 70% Vitastiq accuracy performance. Analysis showed that Vitastiq readings accuracy was higher than 70% for potassium, calcium, magnesium, zinc, selenium, folic acid, vitamin A, vitamin B12, and vitamin E. For Investigator 1 sodium and iron accuracy levels above 70% could not be confirmed. On the other hand, the analysis showed that the accuracy of Vitastiq readings for vitamin D was lower than 70%.

DIFFERENCES IN BLOOD TEST RESULTS AMONG VISITS AND CHANGES IN DIET

Blood levels for calcium, selenium, Vitamin A, Vitamin B12 and Vitamin E were changing during the study period.

The majority of the participants did not change the diet between the visits. However, 8 participants (18%) reported their change in the diet between the first and second visit and 4 of them (50%) related this change to the readings obtained from the Vitastiq device.

ETHICS AND REGULATORY APPROVAL

ETHICAL CONDUCT OF THE STUDY

The study was performed in accordance with the current version of the declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland, October 2000). The trial was conducted in agreement with the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practise (GCP).

PATIENT INFORMATION AND CONSENT

Each subject signed the informed consent before she/he participated in the study. The informed consent process fully apprised the subjects of the risks and benefits to them and to society for participating in the study.

SUBJECT IDENTIFICATION AND PRIVACY

Unique numbers were used to identify each subject screened and each subject enrolled. The unique numbers were the only identifying information on the study forms. A master list of subject names, and their subject IDs and all singed IFC's were kept by the Investigator at the study site.

REGULATORY APPROVAL

The study was performed in compliance with the requirements of the local authority. Considering that this is a device for personal use (not medical device), the approval of the Ethics Committee was sufficient. The study gained full regulatory approval from the on 16 May 2017, with the following number 0120-252/2017/4.