Abstract

The word biomarker comes from English and the exact translation means biological marker or biological indicator. The National Institutes of Health defines a “biomarker” as a property that is objectively measured and evaluated as an indicator of normal biological processes, including pathogenic processes, or an indicator of a pharmaceutical response to a therapeutic intervention.

All biological samples undergo gradual degradation. It is therefore necessary to know the conditions under which the biomarker molecule is stable, which is important for the needs of correct interpretation of laboratory results. The stability of individual biomarkers is highly variable and it is characterized as the time during which the initial content of the analyte in the sample does not change while maintaining precisely defined conditions.

In this thesis, the pre-analytical influences on the result of the laboratory examination are described in detail, the thesis also summarizes the current general knowledge about the stability of biomarkers, the important role of biobanks is mentioned here and the need for testing the stability of biomarkers according to the recommendations of the world leader in biobanking - the international company ISBER is explained.

The practical part of the thesis is focused on studies of the stability of biomarkers commonly used to diagnose rare ovarian tumors, to diagnose polycystic ovary syndrome, as well as to estimate the ovarian response to hormonal stimulation during in vitro fertilization (IVF) and to diagnose prostate cancer.

The aim of the practical part is to determine the optimal pre-analytical conditions for Anti-Müllerian hormone (AMH) and prostatic markers and to assess the effect of observing the correct pre-analytical conditions on the clinical and diagnostic use of these biomarkers.

The achieved results demonstrated that AMH concentrations remain relatively stable in various pre-analytical conditions. The worst results are shown by the group of plasma and serum samples stored at 22 °C, as well as plasma samples during repeated thawing and also during storage at 4 °C. The results show falsely low AMH levels, which can lead to over-diagnosis of gonadotropins for ovarian stimulation in IVF. The risk is the development of ovarian hyperstimulation syndrome and its serious complications.

The achieved results further demonstrated the great stability of tPSA under various stress conditions, on the other hand, the stability of fPSA and [−2]proPSA proved to be low. The concentration of fPSA decreased over time during exercise conditions, while the concentration of [−2]proPSA, on the contrary, increased. Since [−2]proPSA is used in the calculation of PHI, any increase will affect the final value of this index. Failure to comply with the correct pre-analytical conditions results in falsely diagnosed PCa and the associated high diagnostic stress of the patient.

Based on the results achieved, it is possible to issue specific recommendations for laboratories.

Key words: biomarker, stability, preanalytical conditions, serum, plasma, AMH, PSA, fPSA, [-2]proPSA, PHI, prostate carcer, immunochemical analysis