

**BIOMARKERS: FROM STANDARDIZATION TO PERFORMANCE**

## BIOMARKERI: OD STANDARDIZACIJE DO IZVOĐENJA

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The 7<sup>th</sup> EFCC Symposium for Balkan Region under the title **Biomarkers: From Standardization to Performance** organized by the Society of Medical Biochemists of Serbia under the auspices of the International Federation of Clinical Chemistry (IFCC) and European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) will be held in Belgrade in June 2011. The Society as a member of the IFCC and EFCC greatly appreciates the role it has in the continuing development of our discipline according to the IFCC mission and the Strategic Plan. EFCC appointed Belgrade (Serbia) and the Society of Medical Biochemists of Serbia as the organizer of educational symposia for clinical chemists in the Balkan region and as a result of this decision six symposia have been organized up to now very successfully (1).

The first Symposium (Belgrade, June 2005) under the title **»Education, Management and Standards in Laboratory Medicine«** appointed the Present and future activities of EC4 (Rob Jansen), Education and training program of the IFCC in clinical chemistry and laboratory medicine (Willem Huisman), A practical tool for the management of quality in the medical laboratory – ISO 15189 (David Burnett), External quality assessment programs: past, present and future (Mario Plebani), and the process of Establishing reference laboratories in laboratory medicine (Lothar Siekmann). Also experts from the Balkan region (L. Crezante, D. Rizos, N. Majkić-Singh, S. Ignjatović, G. Kolios, A. Tzontcheva) presented their experiences regarding the topics of the Symposium in the Balkan region.

During the 2<sup>nd</sup> EFCC Symposium (Novi Sad, October 2006) held under the title **»New Diagnostic Tools and Quality in Laboratory Medicine«** the New diagnostic tools in clinical chemistry: Applications of SELDI-TOF MS, 2 D-HPLC and microarrays in protein profiling (Marja P. van Dieijen-Visser, Isabella Levrieri, Reinhard Hiller), the New biomarkers of diseases: Cardiac natriuretic peptides (Johannes Mair), Complexed PSA (Rainer Neumann), Bone remodeling (Jan Stepan), and Evidence-based approach (Svetlana Ignjatović, Nada Majkić-Singh) were discussed. A special section was devoted to the Application of quality indicators in a medical laboratory (Oswald Sonntag, Jakub Hejsek).

The 3<sup>rd</sup> EFCC Symposium (Belgrade, September 2007) titled **»Theory and Application of Evidence-Based Laboratory Medicine«** provided answers to the following questions: What is evidence based laboratory medicine? (Rita Horvath), How to ask the right questions? (Dunja Rogić), How should you read an article about a diagnostic test? (Svere Sandberg), What is a systematic review and how can it be performed? and How to appraise guidelines? (Rita Horvath), Is there a correlation between the methodological quality and the validity of contents of guidelines? (Joseph Watine), How to implement EBLM in everyday practice? (S. Sandberg). Also, special subjects addressed the matter of Diagnostic guidelines compared to therapeutic guidelines (Wytze Oosterhuis) and Simple statistics used in diagnostic test evaluations (Svere Sandberg & Diler Aslan) were presented.

The 4<sup>th</sup> EFCC Symposium (Belgrade, June 2008) was organized with the subject **»Impact of the Pre-analytical Phase on the Quality of the Laboratory Results«** where the latest findings regarding the application and significance of the impact of preanalytical factors on the quality of laboratory

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results were presented with the goal of preventing pre-analytical errors that can cause damage to the patients as well as the entire laboratory procedure (Victor Blaton, Nada Majkić-Singh, Sol Green, Pierangelo Bonini, Giuseppe Lippi). Safety measures during the process of collecting biological samples from patients were been discussed, e.g. during venipunctures, for the purpose of protecting the patients (Camilla Mattiuzzi). Besides presentations on the impact of the preanalytical phase in hematology (Giuseppe Banfi), sample stability was also reviewed (Gian Luca Salvagno), as well as the recommendations and ways of educating staff regarding the quality of diagnostic samples (Walter G. Guder). In order to achieve the best possible results, new approaches in laboratory medicine dealing with the application and philosophy behind the LEAN and SIX SIGMA techniques were laid out (Ana Stanković). Experts from Serbia, Romania, Bulgaria and Greece (Z. Šumarac, A. Tzontcheva, M. Cojocararu) presented their experiences regarding the application of the preanalytical phase technology in the Balkan region. Round table discussions on the topics presented served as the basis for reaching conclusions and guidelines in this area of laboratory medicine with the aim of achieving the best possible results to the benefit of patient treatment.

The idea of the 5<sup>th</sup> EFCC Symposium for Balkan Region (Belgrade, October 2009) under the title – **Proteins: from electrophoresis to proteomics** was to make a connection and show the continuation of different electrophoresis techniques for protein profiling to proteomics which is able to show the large-scale image of proteins, particularly their structures and functions. The program of the 5<sup>th</sup> Symposium covers: Agarose gel electrophoresis and capillary electrophoresis (Jean-Francois Giot), Lab-on-chip electrophoresis (Olgica Trenčevska), MAD-GE-Microplate array diagonal gel electrophoresis (Sanja Stanković), Isoelectrofocusing and PCR amplification-reverse hybridization assay in evaluation of alfa-1-antitrypsin deficiency (Anđelo Beletić), Proteomics techniques in biomarker discovery (Antonia Vlahou), Urinary proteome analysis using capillary electrophoresis coupled with mass spectrophotometry (Harald Mischak), Glucocorticoid receptor in health and disease (Gordana Matic), Molecular diagnosis of phenylketonuria (Sonja Pavlović), Experiences in clinical protein arrays: Biochip cardiac array technology (Grazyna Sypniewska), Cytokine and growth factor array (Hans J. van Pelt), Colorectal cancer array (Martin Crockard) and Multiparameter testing of colorectal cancer (Bernhard Risse).

The 6<sup>th</sup> EFCC Symposium for Balkan Region (Belgrade, October 2010) has been organized under the topic – **Implementing Laboratory Automation, Quality and Efficiency** where prominent foreign (Mario Plebani, Giorgio Da Rin, Jean-Michel Valid, Gerd Hafner, Gabriele Halwachs-Baumann, Divide Villa) and local experts (Nada Majkić-Singh, Svetlana Ignjatović and Vojislav Stoiljković) introduced to the

participants the means for achieving full automation and laboratory consolidation, with the goal of adhering to the philosophy of Lean and Six Sigma laboratory efficiency.

The 7<sup>th</sup> Symposium (Belgrade, June 2011) under the title **Biomarkers: From Standardization to Performance** is natural continuation of the knowledge from the previous Symposia. It will be marked with the lecture titles: What is biomarker? From discovery to clinical application (Nada Majkić-Singh), Standardization approaches and definition of performance requirements for heterogeneous biomarker assay (Mauro Panteghini), Defining biomarker performance and clinical validity (Patrick MM Bossuyt), Prospective biomarkers in cardiovascular events (Victor Blaton), How do apolipoproteins B and A perform as biomarker in acute coronary syndrome patients (Grazyna Sypniewska) and The role of copeptin (Dunja Rogić) and Myeloperoxidase (Sanja Stanković) as a cardiac biomarkers. The new biomarkers of molecular aging of proteins (Philippe Gillery), The biomarkers of diabetes complications (Diler Aslan), and Glycans as biomarkers (Miroslava Janković) will be presented. Screening biomarkers for fetal anomalies (Svetlana Ignjatović), Biomarker for bone turnover (Andrea Griesmacher) and A novel promising tumor markers combination for the prediction of ovarian cancer (Demetrios Rizos) will be discussed. The special lecture on Biomarkers, Biospecimen and European biobanking infrastructures for translation research will be discussed (Bernard Gouget).

The term biomarker in medicine most often stands for a protein measured in the circulation (blood) whose concentration indicates a normal or a pathological response of the organism, as well as a pharmacological response to the applied therapy. From a wider perspective, a biomarker is any indicator that is used as an index of the intensity of a disease or other physiological state in the organism. This means that biomarkers have a very important role in medical research and practice providing insight into the mechanism and course of a disease.

Regardless of their role, their clinical significance depends on their sensitivity, specificity, predictive value, and also precision, reliability, reproducibility, and the possibility of easy and wide application. For a biomarker to become successful, it must undergo the process of validation, depending on the level of use. It is very important for every suggested biomarker, according to its purpose or its nature, to possess certain characteristics and to meet the strict requirements related to sensitivity, accuracy and precision, in order for the proper outcome to be produced in the estimation of the state for which it is intended. Finally, the development of guidelines for biomarker application is very important, based on well defined and properly conducted assessments of biomarker determination, providing the means by which research is translated into practice and allowing evidence based on facts to promote the clinical application of new biomarkers (2–6).

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