Mass spectrometry (MS) has been an important tool in trace element, steroid analysis, newborn screening and other small analytes for almost 50 years but the technology has become amenable for diagnostic work in hospital laboratories only in the last 15 years. The operation of an MS is controlled through the computer with user friendly procedures. Liquid chromatography (LC) coupled with MS systems is now in wider use than gas chromatography because of the ability to make the determination without preparation of thermostable derivatives. The development of ionisation of analytes in the LC eluate with removal of solvents was the key to success of LC-MS/MS. Electrospray is probably the commonest technique for ionisation but charged particles are also produced by photo-ionisation and chemical ionisation. For quantitative work an internal standard is required. A stable isotope labelled form of the analyte is the ideal compound because the system detects the different mass forms. The combination of two mass spectrometers (LC-MS/MS) improves the specificity of the analysis.

by John W Honour, Institute for Women’s Health, University College London, United Kingdom

HOT TOPICS IN LABORATORY MEDICINE

Mass spectrometry in Laboratory Medicine

by John W Honour, Institute for Women’s Health, University College London, United Kingdom

In this current issue of the EFLM EuroLabNews John W Honour enumerates on Mass Spectroscopy in Laboratory Medicine and Giuseppe Lippi gives us an overview of Web-based access to scientific information in the EFLM countries, in the regular section of Laboratory Hot Topics. Ferruccio Ceriotti, Chair of the EFLM WG on Harmonisation (WG-H) highlights their persuals for improving the harmonisation of reference intervals used by European laboratories. Furthermore, Ralf Lichtinghagen, Chair of the EFLM Education and Training Committee reports on the activities of the EFLM Committee “Education and Training”: establishment of the EFLM e-learning platform. Ana-Maria Simundic, EFLM Executive Board Secretary, interviews Wim Huisman, Chair of EFLM Quality and Regulations Committee and talk about the IVD Regulation 2017/746. Maria Stella Graziani and Juan Robles Bauza on behalf of the EFLM Communication Committee and the Promotion & Publications WG present an excerpt on the EFLM Symposia at EuroMedLab, Athens. Honoured awardees and bursaries are highlighted from the above-mentioned meeting. Maria Stella Graziani, Chair of the EFLM Communications Committee presents a recent addition to the EFLM publications list. As a regular column of the EuroLabNews, changing of the guard and other important news from National Societies has as usual made this issue more colourful. Attendees may mark their calendars to attend stimulating meeting as mentioned in the Calendar of Events.

Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews

In this current issue of the EFLM EuroLabNews John W Honour enumerates on Mass Spectroscopy in Laboratory Medicine and Giuseppe Lippi gives us an overview of Web-based access to scientific information in the EFLM countries, in the regular section of Laboratory Hot Topics. Ferruccio Ceriotti, Chair of the EFLM WG on Harmonisation (WG-H) highlights their persuals for improving the harmonisation of reference intervals used by European laboratories. Furthermore, Ralf Lichtinghagen, Chair of the EFLM Education and Training Committee reports on the activities of the EFLM Committee “Education and Training”: establishment of the EFLM e-learning platform. Ana-Maria Simundic, EFLM Executive Board Secretary, interviews Wim Huisman, Chair of EFLM Quality and Regulations Committee and talk about the IVD Regulation 2017/746. Maria Stella Graziani and Juan Robles Bauza on behalf of the EFLM Communication Committee and the Promotion & Publications WG present an excerpt on the EFLM Symposia at EuroMedLab, Athens. Honoured awardees and bursaries are highlighted from the above-mentioned meeting. Maria Stella Graziani, Chair of the EFLM Communications Committee presents a recent addition to the EFLM publications list. As a regular column of the EuroLabNews, changing of the guard and other important news from National Societies has as usual made this issue more colourful. Attendees may mark their calendars to attend stimulating meeting as mentioned in the Calendar of Events.
In general, parent ions from the first MS pass to a collision chamber whence fragment ions are analysed in the second MS (see Figure) that are particular to the molecular structure and not a fragment common to the group of compounds (e.g. steroids). Selected reaction monitoring (SRM) is the basis of targeted analysis. The ion response for the analyte is compared with the signal from the internal standard. Ideally two independent transitions are monitored with quantifier and qualifier roles for the analyte and the internal standard. There are risks that results will be subject to interferences from matrix effects where the ionisation of the analyte is impacted by a substance eluting at the same retention time that can lower or increase the signal from the analyser. The internal standard is likely affected by interferences to the same extent as the analyte. A number of checks for possible interfering substances are necessary, not all likely compounds are available. For many endogenous compounds and drugs there are metabolites to consider. The beauty of any MS analysis above immunoassay is the presentation of data in the form of chromatograms, mass spectra and plots of ion ratios that demonstrate the quality of the analysis. In an immunoassay the data only indicate reaction with an antibody.

LC-MS/MS now has a footprint less than 2 square metres, and is capable of high volume throughput, though not in the same league as say producing results for plasma sodium concentration on an automated analyser. A sample will be injected directly to the LC column or into a sample preparation station that may include ability for solid phase extraction. LC column dimensions have been reduced in order to keep analysis time to a few minutes. The analyst needs to take care that isomers and epimers are separated. A drawback is the need for a 6 or 8 point calibration in each run. LC-MS/MS is often said to be expensive but a business case will demonstrate that the equipment and running costs per sample are low and competes with the cost of an analysis by immunoassay. A challenge for many laboratories will be the proper validation of a method for accreditation. The cost of this exercise should be added to the up-front costs of acquiring the instrumentation. Training of staff needs investment with a programme to meet the requirements for accurate chemical analysis. Users must be trained to identify problems in the LC-MS/MS system through observation of leaks, pressure changes and retention time shifts. There need to be rules for interpretation of peaks against high noise levels, tailing or fronting of peaks and overlapping peaks. The data system for MS methods is a powerful resource in quality control. The user can review parameters from each analysis (e.g. consistency of peak areas of the internal standard, ion ratios and of retention times) making it easy to detect problems with the analysis compared with earlier runs. When maintenance, changes in reagents, new columns are effectively recorded then differences in analytical performance are highlighted from the data review.

The improved specificity of the results will be appreciated by clinical users but the results are numerically lower than previously experienced and new reference ranges are required. For example the literature in 2016/7 indicates that a plasma cortisol concentration in the standard adrenocorticotrophin stimulation test at 30 minutes can be around 350 nmol/L, not the 550 nmol/L that has been applied for 50 years. MS with SRM is used for therapeutic drug monitoring, drugs of abuse detection and toxicology. The analysis of deoxiribonucleic acid (DNA) and ribose nucleic acid (RNA) is now applied to DNA polymorphisms, sequences, haplotypes, methylation and RNA expression. Proteins can be enzymatically digested to produce fragments of size suitable for MS analysis. MS-based proteomics has emerged as a powerful tool to complement genomic approaches for epigenetic research. MS analysis of 16S RNA has already been replacing classical methods of bacterial classification in clinical laboratories. Tissue slices can also be analysed by fast atom bombardment and desorption spray MS to achieve histological images. Accurate mass determination with time-of-flight (TOF) MS also extends the range of possible analytes. This will become more widely used. One perceived advantage is the ability for retrospective analysis of full scan data for non-targeted analysis to extend the range of determinations.

In conclusion, high throughput tandem mass spectrometry has numerous benefits in a clinical laboratory. The limitations must be weighed for each clinical analyte to determine suitability in the lab. Standardisation and harmonisation will need to be addressed for the best outcome for patients. The use of commercial kits does not produce identical results because there are many variables in the LC-MS/MS system between users. Undoubtedly running a MS method is more challenging than the operation of other analyzers in a clinical laboratory. MS has nevertheless come of age in the clinical laboratory, though proof of full capability to the clinical service is awaited.

**Figure 1.**
Ions are introduced into the first MS which is set to allow the passage of a single target ion. The collision cell is slightly pressurised with argon. Collisions take place and the target is fragmented. MS2 is a filter that separates the fragments and the signal from one ion is measured.
HOT TOPICS IN LABORATORY MEDICINE

Web-based access to scientific information in the EFLM Countries

by Giuseppe Lippi, Section of Clinical Biochemistry, University of Verona, Verona, Italy

Due to the growing and already widespread popularity of the Internet as a free, easy and virtually incomparable means for obtaining any type of information, the general public, as well as healthcare professionals and scientists, have substantially revolutionized their approach to collecting scientific and medical information. This has become mostly possible due to the availability of a number of scientific search engines that can be accessed through the Web, so allowing rapid and efficient identification of documents, articles, recommendations and official guidelines on a kaleidoscope of medical topics.

Although the use of the most common Web-based scientific search engines such as PubMed, Scopus, Web of Science and - more recently - Google Scholar, has become commonplace in our daily activity, no reliable information is available on which of these tools are the mostly accessed across Europe. Google Trends (Google Inc. Mountain View, CA, United States) is a free Internet tool, which pools data about the volume of Google searches during a given period of time and a specific geographic location. Essentially, the final output generated with this analysis, conventionally defined “Google Trends score”, reflects the volume of Google searches for a certain term. In brief, the highest is the score, the largest is the popularity of the search term. Google Trends can hence be reliably exploited to approximate the volume of searches for the most common Web-based scientific search engines throughout the Countries affiliated with the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), so obtaining reliable information on how scientific information is searched by the different Nations. If one enters the search terms "PubMed", "Scopus", "Web of Science" and “Google Scholar” in Google Trends, using geographic (i.e., European Countries) and time limits (i.e., the past four years, between June 2013 and June 2017), the cumulative Google Trends score that can be obtained is shown in figure 1. Notably, PubMed seems to be the most accessed scientific search engine (total score, 225), closely followed by Google Scholar (total score, 194), whereas the volume of searches for Scopus (total score, 25) and Web of Science (total score, 17) is nearly 10 times lower. Notably, these volume of searches are not alike in a worldwide analysis conducted during the same period, wherein Google Scholar becomes first (total score, 1792), followed by PubMed (total score, 1023), Scopus (total score, 112) and Web of Science (total score, 89). A sub-analysis of the different European Countries for which a Google Trends score is available is shown in table 1. PubMed and Google Scholar are again the most accessed searched terms in most European Countries, with the exception of Slovakia and Ukraine (Scopus is ranked first) and Russia, where all the four databases seem to be equally searched.

The results are not really surprising or unexpected. Medline (interface PubMed) and Google Scholar have a big advantage over the two other scientific search engines available in the Internet. These Web-based tools are both free, since they do not require personal or institutional subscriptions, and can hence be accessed with no restriction by whoever is seeking to collect any kind of scientific or medical information. On the other hand, Scopus/EMBASE and Web of Science need an institutional subscription and are hence almost unavailable to the general public. The fact that the use of Google Scholar has continuously grown during the past decade, displaying a nearly 3-fold increase, also leads to an important consideration. This freely accessible web search engine not only includes peer-reviewed academic journals and books, but also conference papers, theses, dissertations, abstracts, and other type of scholarly literature such as court opinions. Unlike Google Scholar, PubMed/Medline is maintained by the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH). Therefore, the sources of scientific and medical information are directly controlled by a Literature Selection Technical Review Committee. Specifically, the process of PubMed indexing requires that journals should demonstrate the quality of editorial work, thus including aspects contributing to objectivity, credibility and quality of the contents. All these aspects are not necessary for being indexed in Google Scholar and this raises some doubts as to whether the increasing popularity of Google Scholar may be seen as a threat or an opportunity for the scientific community.

![Figure 1](image1.png)

**Figure 1.**
Google Trends score for the different scientific search engines in Countries affiliated with the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). The relative percentage is given in Table 1.

<table>
<thead>
<tr>
<th>Country</th>
<th>PubMed/Medline</th>
<th>Scopus/EMBASE</th>
<th>Web of Science</th>
<th>Google Scholar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>45%</td>
<td>5%</td>
<td>0%</td>
<td>50%</td>
</tr>
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<td>0%</td>
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<td>5%</td>
<td>48%</td>
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<td>0%</td>
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<tr>
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<td>44%</td>
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<td>Russia</td>
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<tr>
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<td>Slovakia</td>
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<td>Slovenia</td>
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<td>45%</td>
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<td>23%</td>
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<td>Ukraine</td>
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<td>0%</td>
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<tr>
<td>United Kingdom</td>
<td>22%</td>
<td>2%</td>
<td>2%</td>
<td>73%</td>
</tr>
</tbody>
</table>

**Table 1.**
Most searched Web-based scientific search engines across the different Countries affiliated with the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).
Survey of the EFLM Working Group on Harmonisation of Total Testing Process

Campaign for improving the harmonisation of reference intervals used by European laboratories

Deadline to reply: 10 September 2017
Click here to access the survey

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has created the Working Group on Harmonization in Total Testing Process with the aim to promote and spread the harmonization activities carried out, or currently on-going, in the different national societies of Europe.

Following the survey on Harmonisation activities, the WG-H intends to start a campaign for improving the harmonisation of reference intervals used by European laboratories. To set a background from which to start, we prepared this short questionnaire (10 questions) focusing on the reference intervals used for the most commonly performed tests. Aim of the survey is to understand which are the origin of the reference intervals presently in use and if the partitioning criteria for the use of reference intervals are the same all over Europe.

We invite you or your laboratory leaders to fill in this questionnaire, which takes no more than 10 minutes. Please note that it is not possible to save your answers and go back later, so please fill in the whole questionnaire before you press “Finish” to save and send your filled-in questionnaire.

Entered data are handled anonymously (the identity of your laboratory is not requested).

Click here to access the survey and enter your replies

Thanks a lot for filling in this survey!

With kindest regards,

Ferruccio Ceriotti
Chair EFLM WG-H

PLEASE CIRCULATE THIS MESSAGE TO OTHER LABORATORIES IN YOUR COUNTRY HELPING US TO COLLECT A SIGNIFICANT NUMBER OF REPLIES FROM EACH COUNTRY!

About the EFLM WG “Harmonisation of Total Testing Process”

Created by EFLM in 2015, the aim of this Working Group is to act as a collector of the harmonization initiatives arising from other EFLM WGs or Task and Finish Groups and from National Society Members active in the field and to disseminate them to all the EFLM Member Societies attempting to monitor their application and effects. The WG surveys and promotes the use of harmonised nomenclature for measurands and promotes the use of amount of substance units in the European countries and the implementation of common reference intervals for the measurands where this approach is feasible.

The WG is chaired by Ferruccio Ceriotti (Central Laboratory, Ospedale Maggiore Policlinico, Milano, IT) and WG Full Members are: Gijs den Besten (Dept of Clinical Chemistry Isala Hospital, Zwolle, NL), Lora Dukic (Dept of Medical Laboratory Diagnostics, University Hospital “Sveti Duh”, Zagreb, HRK), Mesude Yilmaz Falay (Dept of Hematology, Ankara Numune Training and Research Hospital, Ankara, TR) and Irena Kostovska (Inst. of Medical and Experimental Biochemistry, Fac. of Medicine, University “Ss. Kiril and Metodij”, Skopje, MK). Volodymyr M. Protsenko from Ukraine has just been appointed as Corresponding Member. We invite those EFLM National Societies interested to nominate a Corresponding Member for this WG to contact the EFLM Office at eflm@eflm.eu).
The EFLM Education and Training Committee (C-ET) includes two working groups: the WG Congresses and Postgraduate Education (WG-CPE; Chair: Evgenija Homskak) and the WG Distance Education and e-Learning (WG-DE; Chair: Daniel Rajdl). The WG-CPE is working to promote education within the field of Laboratory Medicine in Europe; the WG-DE task is to establish efficient distance learning channels between EFLM and its member societies. In addition, a Task and Finishing Group on Continuous Professional Development Crediting System (TFG-CPD; Chair: Elizabeta Topic) has been recently established. The task of this TFG of experts is to produce a document on accreditation of CPD events in Clinical Chemistry and Laboratory Medicine and to develop a CPD crediting system for medical and non-medical Specialists in Laboratory Medicine.

Under the chairmanship of Daniel Rajdl, the WG-DE offers web seminars on hot topics in Laboratory Medicine. EFLM laboratory professionals wishing to attend the webinars may now register on the recently created EFLM-e-learning platform (https://elearning.eflm.eu). Each lecture is given by an expert speaker in the field and chaired by a moderator. After the presentation, participants have the opportunity to ask questions to the speaker live. The 2017 forthcoming webinars will take place on September 26 (Reliable estimates of biological variation- the way forward, by Aasne Karine Aarsand), on October 19 (Hepatic fibrosis assessment using multiparametric biomarker tests, by Ralf Lichtinghagen) and on November 14, (Harmonisation of pre-analytical phase in Europe, by Ana-Maria Simundic). The registration to the webinars are already open on the EFLM e-learning platform.

For admission to the European Market IVD’s (In Vitro Diagnostic materials and equipment) have to adhere to specific demands as formulated in the IVD Directive98/79/EC. This is made visible by a CE symbol. Many have been convinced for a long time that this directive has to be updated. About 10 years ago, stakeholders were asked for their opinion continuing discussion led to a new regulation acceptable to the European Commission, the respective countries and the European Parliament. In the official paper of the EC of 5 May, the new IVD Regulation was published, valid from May 26 2017. A link to this publication has been placed at our EFLM website.

**AMS: What are the main differences between the old directive and the new regulation?**

**WH:** First a formality, but with consequences. As the name indicates, this is a Regulation and not a Directive. A Regulation leaves much less possibilities for countries to deviate. It has a stronger legal position than a Directive.

However, major differences exist between the old and the new text well. There is more attention to risk in relation to patient safety in the classifications (A-D) of the IVDs; Clinical Effectiveness and requires clinical studies to demonstrate this. Hence there are specific demands in relation to the quality system of the manufacturers, especially in relation to Risk Management. The majority of the IVDs will be placed in class B. The documentation concerning these IVDs and the quality management system of the manufacturer has to be approved by a Notified Body (NoBo). This is a certifying body, which has to fulfill the demands comparable to becoming accredited, but nominated as such by an European country for this specific task; judging the claims for a specific type of IVD for conformity assessment. For class C and D stricter demands in relation to the role of the NoBo are formulated.

The demands for being accepted as a NoBo are much stricter than it used to be. Knowledge about the specific product has to be present; the list of accepted NoBo’s will be published. In house produced tests are only allowed if no CE marked IVD with justifiable needed requirements is on the market. The laboratory which develops such a test must have a quality management
of the regulation?  

AMS: Do you want to add some remarks?  

WH: Although the Regulation is an extensive document it is worthwhile to read at least specific parts. It concerns the preambles (for instance 29 about in house tests, 38 about UDI, and 41 about Eucomed) to have an idea about what is intended. Chapter I gives scope and definition (it indicates the Regulation is not for External Quality material or research products). Chapter III is about identification and traceability. Chapter VI is about clinical evidence, performance evaluation. Chapter VI is about Post Market Surveillance. Especially informative is Annex I under 9 about the performance requirements, traceability, and under 20 requirements regarding information supplied. Here one finds under 20 4.1 u-w the batch to batch variation.

AMS: When will the Regulation become effective?  

WH: For becoming effective the industry has 5 years. The period they have to adopt the demands formulated in this IVD Regulation ends 26 May 2022. The products produced under the IVD Directive98 will be no longer be available after 26 May 2024. This seems a very long time, but quite a lot of actions have to be taken. The NoBos have to be nominated and published, they have to change their quality system and include sufficient competence, they have to assess many more IVDs than before. The industry will have to adjust their quality management system, they have to put much more effort in the risk management, they must set up clinical studies for many IVDs, but above all they have to set up the Unique Device Identification system for all IVDs they produce. They have to set up the post-market-surveillance system. They must make sure they can provide all needed information for each specific IVD. The EC has to set up the database system of Eucomed and have made it publically available.

AMS: What are the classifications used for the IVDs?  

WH: Class D: transmutable agents in blood, high risk transmutable agents, specific blood groups. Class C: rest of the blood groups, infectious agents, tests for sexual transmittable diseases, tests for pre and post natal screening, genetic related tests, drugs, screening in life-threatening situations, and self-testing (except pregnancy tests, urine tests, fertility tests and cholesterol). Class A: specimen receptacles, reagents for buffers, media for bacterial cultivation, instrumentation as such. Class B: all others.

AMS: Will the new Regulation affect the quality of the products the laboratory will use?  

WH: Many of the requirements for the products were already formulated in the present Directive. Some aspects are more strictly formulated like traceability and clinical effectiveness. For us it is very important that the manufacturer has to make the information about the validation and acceptable batch to batch differences available for the laboratories which use these products. Besides they have to show continuous improvement and updated information for the products once they are on the market, the post market surveillance system will facilitate this. The stringent demands in relation to the NoBo’s, which is quite justified, and the fact that the majority of the IVDs (more than 80% instead of the present 20%) have to be assessed, will have a positive influence.

AMS: Do we expect improvements in the quality of our services as a consequence of the regulation?  

WH: I expect it will facilitate and improve the work we do. For risk management we have to do this in our laboratories to comply with ISO15189, the manufacturers have to supply us with information about the residual risks left when the product is placed on the market. The information about validation and traceability will make it easier to perform verification in the laboratory. Unfortunately the term Measurement Uncertainty is not mentioned in the regulation, but because the provided information, including the allowed batch to batch differences, it will be easier for the laboratory to decide if a specific test fulfills the requirement needed for the patient in that situation. For developing an in house method specific requirements concerning its quality have been formulated.

AMS: Do you think our profession had a role in the development of the regulation?  

WH: We have reacted to the questionnaire about areas for improvement of the Directive98. We focused on traceability, availability of information, changing the classification system, in a way it was more focused on patient safety and in house testing. We sent around papers to the societies to approach the persons in their countries who were involved in writing this regulation. In some countries extensive contacts were accomplished. Quite a lot of our wishes are fulfilled, but not only because our efforts. A specific point concerning information about the allowed lot to lot differences can be considered as our exclusive lobbying result. Concerning the in house tests we are glad with the possibility offered in relation to the classes (also C and D), and the demand for their validation with specific mentioning of the ISO15189, but not with the restriction to “if not available as an IVD”.

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“EuroMedLab Athens 2017”: New technologies in Laboratory Medicine

by Alexander Haliassos, President of the EuroMedLab Athens 2017 Congress

During the past decades, Laboratory Medicine has brought a “revolution” in the field of medicine, contributing significantly to prevention as well as management of medical conditions. At the same time, however, a number of dilemmas, both scientific and ethical are pushed to the surface. Aiming at broadening the cognitive field and deepening on cutting-edge matters, through creative dialogue, reflection and exchanges on latest developments and innovations in Laboratory Medicine, scientists recently participated in “EuroMedLab Athens 2017” - 22nd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine held in Athens, at the Megaron Athens International Conference Centre. It was organized by the Greek Society of Clinical Chemistry – Clinical Biochemistry (GSCC-CB) together with IFCC and EFLM.

“EuroMedLab Athens 2017” welcomed 5578 participants, 3312 delegates and 2266 visitors, who came from 97 countries all over the world.

This experience started from the believing that hosting such an important Congress in Athens would have contributed not only to the city’s promotion, but also to the promotion and recognition of the academic and clinical work that is taking place in Greece. The scientific program included, inter alia, 33 symposia, six “meet the expert” sessions, an author’s workshop, 35 educational workshops sponsored by IVD companies, the welcome address and four satellite meetings.

The program also included four thematic satellite symposia. Two symposia on “Metabolic Bone Diseases” and “Inborn Errors of Metabolism” were held on Saturday June 10th, while the thematic satellite meeting on Diabetes was held in collaboration with the Hellenic Diabetes Association on June 15th-16th.

Another highlight in the Congress program involved the debates between world-class scientists. They were open to the general public and covered interesting subjects, such as:
- Lessons from 30 years of cancer screening.
- The ethics of gene editing
- Direct to consumer testing (DCT) Ethical issues and confidentiality
- Antidoping testing. Should we allow doping if it is medically safe and accessible to all?

Summing up on the scientific program of the Congress, the main thematic units were:
- Standardization of the laboratory testing procedure from collection of biological samples to result announcement.
- Management of laboratory tests carried out outside clinical laboratories (Point-of-Care testing)
- New technologies and their contribution to the diagnosis of diseases
- Personalized Medicine.

An important technological exhibition of equipment and clinical laboratory supplies was added, with the participation of more than 70 companies that exposed the continuous technical development and the sophisticated perfection of the diagnostic systems in the laboratories. The participation of young scientists, the professionals of the future, starting from IFCC Task Force of Young Scientists, was made feasible through the volunteers and the bursaries programs offered by EFLM, IFCC and GSCC-CB.

The organizers tried hard to prepare a really fantastic social program, which was attended with big enthusiasm by the delegates and enhanced the wonderful atmosphere of the congress. Based on the impressions and comments by those who participated in EuroMedLab 2017 in Athens, this was one of the most successful congresses ever held in Greece.

NEWS FROM EFLM COMMITTEES

EFLM Symposia at EuroMedLab (Athens, 2017, June 11-15)

by Maria Stella Graziani and Juan Robles Bauza on behalf of the EFLM Communication Committee and the Promotion & Publications WG

The three symposia organized by EFLM at 2017 EuroMedLab covered topics of pivotal importance in Laboratory Medicine. The first one, held on Monday 12, was related to Harmonisation. Harmonisation is a fundamental aspect of quality in Laboratory Medicine; it involves all the steps of the total testing process (pre-analytical, analytical, post-analytical) but includes any aspect of our profession and ranges from laboratory accreditation to professional development to uniform recognition of the profession in Europe. The symposium was specifically dedicated to these aspects. The speakers were all chairs of EFLM functional units devoted to work in these specific areas.

The first topic concerns the pre-analytical phase: we had the pleasure to listen to Ana-Maria Simundic, chair of the EFLM WG on preanalytical phase. The important and long-lasting experience of the EFLM WG on preanalytical phase specifically on the harmonisation of the venous blood sampling in Europe was presented in details, and was focused in particular to the description of the recommendations issued by the WG in these years. The issuing of recommendations will be of great help in harmonizing the pre-analytical phase activities across Europe.

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The second presentation was about harmonisation of medical laboratory accreditation, by Wim Huisman, chair of the EFLM Committee Quality & Regulation. The speaker explained that the harmonization of a quality management system for medical laboratories starts by using the same standard. In Europe only one institute in each country is allowed to perform accreditation. These National Accreditation Bodies cooperate in EA (European cooperation on Accreditation) and they have a mutual recognition for most of the standards we use. EFLM has been working in this field for almost 20 years in the firm belief that harmonization helps the medical laboratories to attain the quality of information the patients deserve. Gilbert Wieringa, chair of the EFLM Profession Committee, presented the EFLM efforts to press the EU Commission for acceptance of a Common Training Framework that recognises the role of the ‘Specialist in Laboratory Medicine’. The importance of a Common Training Framework is that it acts as a passport to allowing free professional migration across EU borders at ‘specialist’ level under EU Commission Directive 2013/55/EU. The recent (end of 2016) integration of the European Register (EC4) into the EFLM infrastructure will facilitate the management of applications to hold the title European Specialist in Laboratory Medicine (EUSpLM).

The forth presentation was by Elizabeta Topic, chair of the EFLM TFG on Continuous Professional Development (CPD) crediting system. We heard about the need to ensure harmonisation of life-long education in Laboratory Medicine. The CPD programs introduced in the majority of EFLM countries vary in contents, accessibility, and impact on relicensing. The recently created TFG is aimed to solve this problem, standardizing, harmonizing and implementing common rules for the CPD crediting system. Harmonized CPD crediting systems in EFLM national societies will lead to the same high quality of Laboratory Medicine in all EFLM countries, in the face of free movement of laboratory specialists and patients throughout Europe.

The audience (more than 200 attendees) was very attentive and the number of questions from the participants to the speakers testified to the interest in the topics.

The other two EFLM symposia were about the Performance Specifications in Laboratory Medicine, and took place on Wednesday 14th.

There were 3 conferences in the morning session, the first was given by Mauro Panteghini and entitled ‘Defining performance specification in laboratory testing’. Prof Panteghini illustrated the importance of measurements in clinical laboratories that produce results needed in the diagnosis and/or monitoring of patients. All laboratory results are characterized by some uncertainty. What degree of quality is needed and what measurement errors can be tolerated without jeopardizing patient safety should therefore be precisely defined and specified for each analyte having clinical use.

The next presentation, ‘The new EFLM biological variation database based on a critical appraisal checklist’ was given by Sverre Sandberg, on behalf of the EFLM Task and Finish Group Biological Variation Database. Prof Sandberg explained that data regarding biological variation are used for many different purposes; the two most common are to set laboratory performance specifications and to generate reference intervals as well as reference change values for the improvement of verification and validation tasks. Therefore, it is crucial to generate a comprehensive database on the EFLM website with essential information about the biological variation and derived performance specifications for different measurands.

The last morning lecture, by Ferruccio Ceriotti, was about the ‘Criteria for allocation of laboratory tests to the three Milan models for performance specifications’. The three different models from the EFLM Strategic Conference in Milan 2014 were presented. Model 1 was based on the effect of analytical performance on clinical outcome; Model 2 was based on components of biological variation of the measurand and Model 3 was based on the state-of-the-art of the measurement.

In the afternoon, this interesting symposium continued with three more conferences. The first of them was given by Wytze Oosterhuis, and was entitled ‘Are total error and uncertainty of measurement two sides of the same coin? Different aspects of the uncertainty and error quantification methods were presented, together with their advantages and disadvantages.

The second presentation was about the Performance Specifications in EQAS, by Graham Jones. He emphasized that the satisfactory participation of laboratories in external quality assurance schemes (EQAS) is both a regulatory requirement and a vital tool to ensure analytical quality in medical laboratories.

Finally, the last presentation was about the ‘Specifications in extra-analytical phases’, given by Mario Plebani who highlighted that the main priority in the current healthcare scenario should be to address errors in laboratory testing, that account for a significant proportion of diagnostic errors. Valuable quality indicators and extra-analytical performance specifications are currently required for guidance in improving all total testing process steps.

This symposium on performance specifications was a complete and indubitable success, testified by the large number of attendees (more than 200 participants in each session) and the questions afterwards, which led to a very enriching and informative debate.
Our Awardees

Awards sponsored by the EFLM illustrate our dedication to support original research and scientific excellence. This year, the acknowledgment of EFLM honours were for:

**Prof. Callum G. Fraser**

*Div. of Cancer, Ninewells Hospital and Medical School, Dundee (UK)*

**9th EFLM-Roche Scientific Award for Laboratory Medicine**

*for his important achievements as a Scientist in Laboratory Medicine and his extraordinary and energetic contribution to the promotion of the art and science of biological variation*

**Prof. Andreas R. Huber**

*Kantonsspital Aarau, Institut for Laboratory Medicine, Aarau (CH)*

**4th EFLM-Abbott Diagnostics Award for Excellence in Outcomes Research in Laboratory Medicine**

*for the article: “Biomarkers from distinct biological pathways improve early risk stratification in medical emergency patients: the multinational, prospective, observational TRIAGE study CrossMark”*

**Dr. Thomas Kaier**

*The Rayne Institute, St Thomas’ Hospital, London (UK)*

**1st EFLM-HyTest Cardiac Marker Award for remarkable scientific work in the field of cardiovascular diseases**

*for the article: “Quantifying the Release of Biomarkers of Myocardial Necrosis from Cardiac Myocytes and Intact Myocardium”*
Our Bursaries

10 European Young Scientists were awarded with an ELFM bursary covering travel and accommodation

the registration was kindly offered by the Congress Organizing Committee.

Gizem Calibasi (TR)
Jelena Culej (HR)
Wendy Den Elzen (NL)
Isabel Fort Zoltan (SP)
Horvath-Szalai (HU)

Miroslava Rabajdova (SK)
Benoit Rucheton (FR)
Marie-Louise Schleck (BE)
Elisabetta Sotgiu (IT)
Sandra Vladimirov (RS)

The EFLM President, Prof. Sverre Sandberg, and some members of the Executive Board with bursaries recipients during the get-together at the EFLM booth in Athens.
This is an important study by the EFLM WG on Biological Variation (BV), reporting on within-subject and between-subject BV for 9 commonly measured serum enzymes. The enrolled subjects came from a number of European Countries and the samples were collected in a biobank created by the EuBiVAS (European Biological Variation Study). The enzymes were measured by contemporary methods following a protocol designed to minimize analytical imprecision and enable traceability using frozen sera with target values assigned by reference methods. All within-subject and some between-subject BV estimates were lower than those reported in the online BV available database. The enzymes studied in the paper demonstrated a rather stable activity in healthy individuals for at least 10 weeks, and no clear differences were observed in enzyme activity between groups from Turkey, Norway, The Netherlands, Spain, and Italy. These observations confirm that the obtained data are widely applicable across healthcare systems and that they can be used to deliver analytical performance specifications to be used internationally, in accordance to model 2 (BV based) proposed by the 1st EFLM Strategic Conference held in Milano (Italy) in 2014. The full list of the EFLM publications is available on www.eflm.eu under EFLM Publications, where you can download the full papers.

NEWS ABOUT AND FROM EFLM NATIONAL SOCIETIES

New Full Member in EFLM: the Kosova Association of Clinical Chemistry (KACC)

Following the admittance to membership of the “Kosova Association of Clinical Chemistry - KACC” as a Full Member of IFCC, the status of KACC as Provisional Member of EFLM has been automatically transformed to Full EFLM Membership as per EFLM Articles of Association.

New Provisional Member in EFLM: Slovak Society for Laboratory Medicine (SSLM)

The Slovak Society for Laboratory Medicine (SSLM), chaired by Prof. Gustav Kovac, has been endorsed by the EFLM General Meeting in Athens on June 11, as a Provisional Member of EFLM in addition to the Full Member of EFLM for the Slovak Republic which is the Slovak Society of Clinical Biochemistry.

Provisional membership automatically turns to Full or Affiliate EFLM membership once the National Society becomes a member of IFCC.

EFLM counts now 40 Full National Society Members, 1 Affiliate Member and 1 Provisional Member.

For the detailed list of Members, you can visit: https://www.eflm.eu/site/page/a/1046

News from the Spanish Society of Laboratory Medicine (SEQCML)

Report of the Course “How to perform oral presentations in biomedicine”

When speaking in front of an audience, only 15% of what actually reaches the public corresponds to the spoken message. In contrast, more than half the information retained by listeners lies in nonverbal communication. Indeed, the lecturer’s posture, gestures and eye contact tell a lot more about how he/she feels than mere words.

These courses organized by the Esteve Foundation on How to perform oral presentations in biomedicine attempt to address all the aspects directly related to this skill. No matter how good the content selection is, how clearly and orderly the data are presented and how
and prof. William Au (China). The participation of prof. Sedef Yenice and prof. Elizabeta Topic was supported by the Visiting Lecturers Program of IFCC. Many of the Romanian speakers were teachers at the medical faculties of Bucharest, Cluj Napoca, Târgu Mureș, Timisoara, Iași. As our association is very interested in motivating young laboratory professionals, many communications were presented by young colleagues, most of them PhD fellows. Two awards were granted, one for the best poster, and one for professional activity.

The scientific programme covered a large area of themes in laboratory medicine (clinical chemistry, microbiology, hematology, genetics, molecular biology) presented in 58 posters, 21 oral communications and 21 plenary reports. The posters and the slides for the oral presentations were written in English. Many of the presentations focused on continuous professional development for laboratory professionals, quality assessment, standardization, technology, instrumentation and method evaluation, performance criteria of laboratory tests, showing the interest of the participants in the improvement of our professional activity.

During the discussions that followed the presentations, the participants had the opportunity to share their experience and to identify solutions for the scientific or technical issues they are confronted to in their everyday practice.

Congress abstracts were published in a supplement of Romanian Journal of Laboratory Medicine (RRML).

As our profession is in a permanent partnership with the clinical diagnostic industry, during the congress an exhibition of reagents, equipment, supplies, software was organized by 19 companies. There were also 9 workshops organized by IVD providers, which were an excellent opportunity for the development and transfer of technical innovations to clinical laboratory professionals.

The scientific quality and the diversity of the presentations, the excellent organization, the appealing social programme, as well as the unique charm of the city of Timisoara, with its historical monuments, beautiful architecture, multicultural heritage and friendly life style fully contributed to the success of this scientific and professional event.

**NEWS FROM EFLM NATIONAL SOCIETIES**

**News from the Romanian Association of Laboratory Medicine (RALM)**

2nd Conference of the Romanian Association of Laboratory Medicine – Timisoara 10-13 May 2017

by Ioana Brudască, RALM President

The 2nd Romanian Association of Laboratory Medicine (RALM) Conference was held between 10-13 May 2017 in Timisoara. The congress was organized under the auspices of IFCC and EFLM and in collaboration with the Romanian Society of Microbiology, the Romanian Society of Hematology and the Universities of Medicine and Pharmacy of Timisoara, Târgu Mureș, Cluj Napoca, Iași, Buchurești.

The congress was attended by over 550 participants (medical doctors, scientists, and lab technicians working in medical laboratories). Four speakers from abroad were invited to the conference: prof. Sedef Yenice (Turkey), prof. Elizabeta Topic (Croatia), prof. Gabor Kovacs (Hungary)
**Calendar of EFLM events and events under EFLM auspices**

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<td>Belgrade (SRB), 21 - 22 September 2017. Laboratory Medicine Management: Leadership skills for effective Laboratory. <a href="http://www.dnmj.org.rs">http://www.dnmj.org.rs</a></td>
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<td>1ères Journées Francophones de Biologie Médicale</td>
<td>Bordeaux (FR), 27-29 September 2017. <a href="http://www.acnbh.fr">www.acnbh.fr</a></td>
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<td>Annual meeting of the European Society for Pharmacogenomics &amp; Personalised Therapy (ESPT)</td>
<td>Catania (IT), 4-7 October 2017. <a href="http://www.2017ESPTcongress.eu">www.2017ESPTcongress.eu</a></td>
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<td>19-23 May 2019</td>
<td>EuroMedLab 2019 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine Barcelona, Spain</td>
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<td><strong>EPMA World Congress 2017</strong></td>
<td>1 issue per year</td>
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<td>Valletta (Malta), 14-17 September 2017</td>
<td>1000 €</td>
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<td>Predictive, Preventive &amp; Personalised Medicine</td>
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**Boost your brand and increase your company’s visibility through the EFLM Newsletter!**

EuroLabNews is the digital bi-monthly newsletter of EFLM targeting more than 4,500 laboratory medicine professionals and is also published on the EFLM website. The Newsletter features information on EFLM initiatives and activities of its functional units, news from EFLM National Society members and includes a calendar of the major events in the Clinical Chemistry and Laboratory Medicine field.

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