

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

EFLM Connects National Societies of Clinical Chemistry and Laboratory Medicine and Creates a Platform for all European "Specialists in Laboratory Medicine"



Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews



This summer issue of the EuroLabNews commences with a short report highlighting the launch of the EFLM Biological Variation Database at the EuroMedLab conference in Barcelona this May by Aasne Karine Aarsand, Chair of the WG-BV and Sverre Sandberg, Chair of the TG-BVD. This time around the Hot Topic column discusses the importance of Quality in Laboratory

Medicine by Ada Aita and colleagues. Joanna Sheldon shall be presenting a webinar titled Harmonisation of Autoimmune tests on the 24th of September, 2019. Also among the forthcoming events, the Symposium CELME 2019 shall be held between the 3rd and 4th of October, 2019 in Prague organized jointly by the EFLM and Czech Society of Clinical Biochemistry. The EFLM announces the admission of the Faculty of Pathology - Royal College of Physicians of Ireland as a new Affiliate Member. The Romanian Association of Laboratory Medicine report changing of the guard. The Society of Medical Biochemists of Serbia present the highlights of the 15th Belgrade Symposium for Balkan Region held this April, the Spanish Society of Laboratory Medicine present their report on the 23rd EuroMedLab Congress in Barcelona this May, the Romanian Association of Laboratory Medicine summarize the activities of their 3rd Congress held this June. Jasna Lenicek Krleza and colleagues present the National recommendations for Harmonisation of Post-analytical phase on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine. Daniel Rajdl, Chair of the Communication Committee gives an update of the EFLM publications. The IFCC corner summarizes happenings in Laboratory Medicine with a global perspective. Last but not least, the Calendar of Events lists all events in our field.

HOT TOPICS IN LABORATORY MEDICINE

Speaking of Quality in Laboratory Medicine

by Ada Aita^{1,2}, Laura Sciacovelli¹, Mario Plebani^{1,2}

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It was estimated that the probability of a person having an airplane crash is 1 in a million, while the probability of a person experiencing an error during health care is 1 in 300. Medical record reviews demonstrated that 6-17% of all adverse events in hospital is due to diagnostic errors, so they took the eighth place on the WHO list of 10 facts affecting patient safety. This percentage appears higher in low- and middle-income than in high-income countries because of the limited resources in terms of laboratory equipment, qualified professionals and health information technologies (1). Thus supporting that: a) patient safety still remains a concern to be managed, despite the efforts made to redesign the healthcare system after discouraging data published by Institute of Medicine (IOM) in "To Err Is Human" (2,3); and b) quality of health care organizations is related to a set of sociotechnical components including personnel, organization, technology and systems that have to work in sync to provide a positive outcome for patients.

In the healthcare system, Laboratory Medicine was largely seen as an isolated department providing a low-risk service for other departments impacting less than 3% of a nation's healthcare expenditure (4-6). However, laboratory medicine results often integrated with radiology and pathological anatomy reports represent, in most of cases, the starting point in the patient care process.

To be continued on page 2

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The reliability of laboratory information is then fundamental to not affect the patient outcome. This means that errors occurring in whichever step of laboratory testing could compromise the entire patient care process leading to incorrect, delayed or missed diagnosis/treatment. For this reason, Quality in laboratory medicine has been defined as “the guarantee that each and every step in the total testing process is correctly performed, thus ensuring valuable decision making and effective patient care” (7).

In the last decades the role of laboratory professionals has deeply changed. An active, competent and aware involvement is required and the concerns described following have to be taken into account.

Laboratory without walls

The landmark paper on errors in laboratory medicine published by Plebani and Carraro in 1997 (8) paved the way for studies in this field, so that the number of papers published on PubMed increased over the years (41 in 1997 vs 3681 in 2018) allowing professionals to know error rates and phases involved, causes and impact on outcome. In view of these studies several strategies to report, monitor, analyse and prevent laboratory errors have been adopted since the 2000s. Automation, information technologies, improved laboratory technology and assay standardization have contributed to reducing errors, initially at analytical steps (ten-fold reduction), and more generally in the entire process within laboratory walls (9). The next step in the journey towards quality in laboratory medicine is to improve steps at clinical interface performed outside the laboratory walls or not under the direct control of laboratory staff, moving from the “laboratory errors” to “diagnostic errors” point of view (10). Studies on pre-pre-analytical phase demonstrated that failure to order appropriate diagnostic tests, including laboratory tests, resulted in 55% of observed missed/delayed diagnosis in ambulatory setting (11-13) and 58% of errors in emergency departments (14). Studies on post-post-analytical phase demonstrated that incorrect interpretation of laboratory reports provided a large percentage of errors in ambulatory setting and in emergency departments (15). These data demonstrate that a significant number of failures occurs in the interface between clinical practice and laboratories supporting the notion that quality must be not enclosed within laboratory walls, but laboratory professional should cooperate with physicians to ensure the safest patient management.

Lab professionals knowledge and competence as a driver for the quality

Cognitive factors (inadequate training, carelessness, stress) still remain the main cause of diagnostic errors (16). In this regard, WHO proposes the adoption of educational interventions as the first error reducing strategy. In 2011, WHO Multi-professional Patient Safety Curriculum Guide was published in several languages to assist professors in the on-going training of all health care professionals on patient safety topic (17). WHO also organizes a series of meetings aimed not only at training but also at creation and dissemination of a culture oriented towards risk prevention and management. Last year, WHO organized, in cooperation with Clinical Risk Management Centre and Patient Safety of the Tuscany Region (Italy), a meeting entirely dedicated to the new generations of physicians and specialists, which was attended by over 200 specialists from 30

different countries. At European level, the syllabus formulated by EFLM includes “quality, health and safety of the patient” among the fundamental aspects on which the young Laboratory professional must be trained so that he can operate as a leader and participate in the transformation of the service as a quality service (18).

In conclusion, the role and activities of laboratory have progressed in parallel with sociocultural and economic evolutionism so every day clinical laboratories generate billions of interpretative reports by means of a multistep process. It is then of utmost importance for clinical laboratories to maintain quality along the entire testing process, including not only analytical but also extra-analytical steps within and outside laboratory walls. Personnel represent a key element in defining well-established quality assurance tools to build a failure-resistant system able to ‘catch’ mistakes before they become a problem, so the training of new generations on quality and safety issues is fundamental.

Speaking of quality in Laboratory Medicine the take home message is “it is, and always it will be an unfinished journey”.

References

1. World Health Organization (WHO). http://www.who.int/features/factfiles/patient_safety/en/. Accessed: 1 July 2019.
2. Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Source Washington (DC): National Academies Press (US), 2000.
3. Becich MJ, Gilbertson JR, Gupta D, Patel A, Grzybicki DM, Raab SS. Pathology and patient safety: the critical role of pathology informatics in error reduction and quality initiatives. *Clin Lab Med* 2004;24:913-43, vi. Review.
4. Kalra J. Medical errors: impact on clinical laboratories and other critical areas. *Clin Biochem* 2004;37:1052-62.
5. Plebani M. Quality and future of clinical laboratories: the Vico's whole cyclical theory of the recurring cycles. *Clin Chem Lab Med* 2018;56:901-908.
6. The Lewin Group Under subcontract to Battelle Memorial Institute; Wolcott J, Schwartz A, Goodman C, The Lewin Group, eds. *Laboratory Medicine: A National Status Report*. The Lewin Group (US), 2008.
7. Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. *Clin Biochem Rev* 2012;33:85-8.
8. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem* 1997;43:1348-51.
9. Plebani M. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem* 2010;47:101-10.
10. Plebani M. Diagnostic Errors and Laboratory Medicine - Causes and Strategies. *EJIFCC*. 2015;26:7-14.
11. Hickner J, Graham DG, Elder NC, Brandt E, Emsermann CB, Dovey S, et al. Testing process errors and their harms and consequences reported from family medicine practices: a study of the American Academy of Family Physicians National Research Network. *Qual Saf Health Care* 2008;17:194-200.
12. Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med* 2006;145:488-96.
13. Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. *BMC Fam Pract* 2007;8:32-42.
14. Kachalia A, Gandhi TK, Puopolo AL, Yoon C, Thomas EJ, Griffey R, et al. Missed and delayed diagnoses in the emergency department: a study of closed malpractice claims from 4 liability insurers. *Ann Emerg Med* 2007;49:196-205.
15. Roy CL, Poon EG, Karson AS, Ladak-Merchant Z, Johnson RE, Maviglia SM, et al. Patient safety concerns arising from test results that return after hospital discharge. *Ann Intern Med* 2005;143:121-8.
16. Plebani M. System-related and cognitive errors in laboratory medicine. *Diagnosis* 2018;5:191-196.
17. World Health Organization (WHO). http://www.who.int/features/factfiles/patient_safety/en/. Accessed: 1 July 2019.
18. Jassam N, Lake J, Dabrowska M, Queraltó J, Rizos D, Lichtinghagen R, et al. *The European Federation of Clinical Chemistry and Laboratory Medicine syllabus for postgraduate education and training for Specialists in Laboratory Medicine: version 5 - 2018*. *Clin Chem Lab Med*. 2018;56:1846-1863.

EFLM Biological Variation Database official launch

by Aasne Karine Aarsand, Chair of the EFLM Working Group "Biological Variation", and Sverre Sandberg, Chair of the EFLM Task Group "Biological Variation Database"

The EFLM is happy to announce that the EFLM Biological Variation Database is now live. The database, available via the EFLM homepage and at <https://biologicalvariation.eu/> was launched during the Euromedlab in Barcelona in May 2019 and delivers updated, evidence-based biological variation (BV) estimates to users worldwide. BV data have many important applications in laboratory medicine. However, the literature describing studies of BV stretches back over 45 years, and widely varying estimates are observed for many measurands. With this background, the EFLM established the Task (and Finish) Group for the Biological Variation Database (TG-BVD). The TG-BVD, in collaboration with the Working



Fig 1. From the left: Chair of the TG-BVD, Sverre Sandberg, EFLM president Michael Neumaier and chair of the WG-BV, Aasne Karine Aarsand officially launching the EFLM Biological Variation Database.

Group on BV (WG-BV), have developed a standard for evaluating studies on BV; the Biological Variation Data Critical Appraisal Checklist (BIVAC), a Minimum Dataset for BV studies and a meta-analysis approach for delivery of global BV estimates. In the EFLM Biological Variation Database, BV studies for measurands of interest are identified by systematic literature searches, with relevant publications being appraised by the BIVAC. Meta-analysis is thereafter performed for BIVAC-compliant studies with similar study characteristics. At the launch, **over 1500 BV data sets** and nearly 500 publications were already included in the database. All data, including the Minimum Dataset and results from the appraisal by the BIVAC, are available for review by users. Global estimates are presently published for **80 measurands**, with quality review and

appraisal of new measurands being continuously ongoing. When critical appraisal is performed for a new measurand, data from appraised publications are published, but global BV estimates will only first be available when all relevant studies reporting BV data for the measurand in question have been assessed.

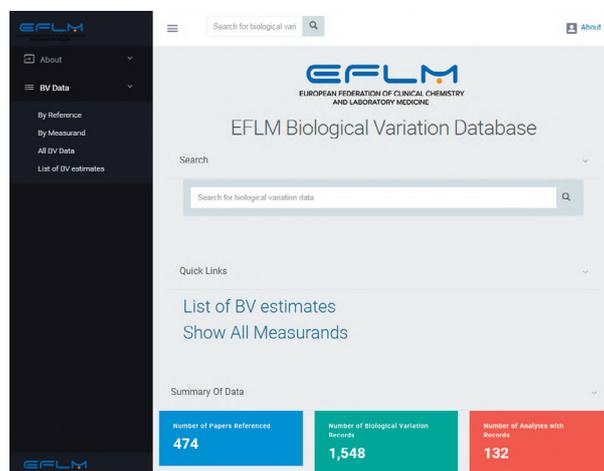


Fig 2. User interface of the EFLM Biological Variation Database. In the future, we will add functionality such as calculations of analytical performance specification (APS) and reference change values (RCV), improve the user interface including sign up for updates and deliver meta-analysis results for population subgroups/different sampling intervals.

EFLM OFFICE INFORMS

New EFLM Affiliate Member: Faculty of Pathology - Royal College of Physicians of Ireland

by Silvia Cattaneo, EFLM Office



FACULTY OF PATHOLOGY

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

On 19 May 2019 in Barcelona, the EFLM General Meeting has voted the admission of the "Faculty of Pathology - Royal College of Physicians of Ireland (RCPI)" as new Affiliate Member of EFLM. About RCPI - The Faculty of Pathology is the professional and training body for Pathology in Ireland, working to ensure the highest standards in laboratory medicine.

Established in 1982, the Faculty of Pathology is one of six postgraduate specialist training bodies based in the Royal College of Physicians of Ireland. They have over 300 Fellows, including international Fellows, who are experienced Consultant Pathologists and leading experts in their field. The Faculty of Pathology is accredited by the Medical Council of Ireland, proud to meet the strict standards required to deliver postgraduate specialist training in five Pathology specialties.

The offered training programmes are:

- Basic Specialist Training: Histopathology;
- Higher Specialist Training: Chemical Pathology, Clinical Microbiology, Haematology, Histopathology, Immunology.

Click here to know more

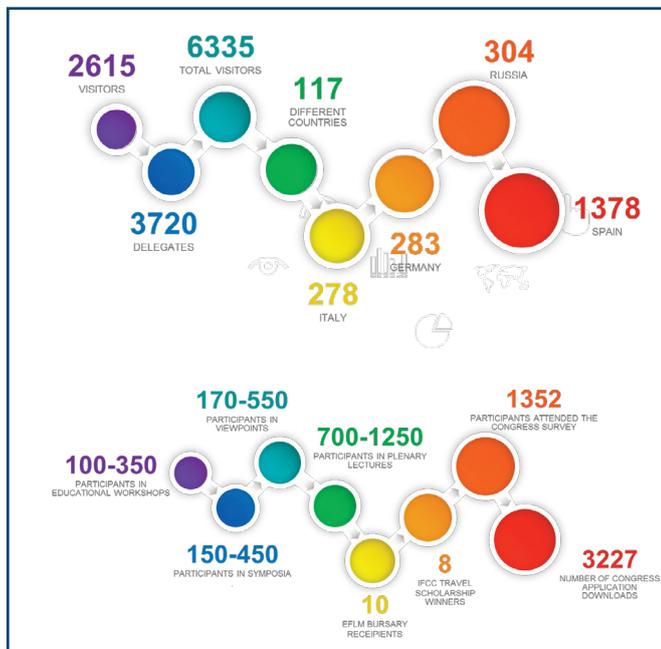


Barcelona hosted the 23rd EuroMedLab Congress, the most important scientific event for Laboratory Medicine in Europe, from May 19 to 23 at the CCIB (International Convention Center of Barcelona). Organized by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and the Spanish Society of Laboratory Medicine (SEQC^{ML}), this biennial meeting was an opportunity to show the latest advances in research and clinical science in the various areas of Laboratory Medicine. With 1,563 communications received from 83 different countries, the communications record from previous editions has been broken, with notable contributions from Spanish professionals, given that one in three communications were sent by professionals from our country. More than 100 speakers from numerous countries around the world participated, including 33 Spaniards, with a very high scientific level addressing current issues in the different disciplines of Laboratory Medicine, such as clinical biochemistry, hematology, microbiology, immunology, and molecular biology. The total number of attendees exceeded 6,000 professionals, including congress registrants and visitors to the commercial exhibition, which is a new record compared to previous editions. Likewise, the Congress included more than 70 scientific activities distributed over four plenary sessions, in addition to 20 symposiums, seven monographic sessions, 40 educational workshops, and an inaugural conference in which Dr. Manuel Serrano, leader of the Laboratory of Cellular Plasticity and Disease of the IRB Barcelona, addressed advances in understanding of the mechanisms of aging and senescent cells and their possible clinical applications, with the paper entitled Recent Progress on the Mechanisms of Aging and its Medical Applications. In addition, among the topics covered during the five days of the Congress were epigenetics applied to cancer, the microbiome, big data and information security, CRISPR, diabetes, kidney, liver and thyroid diseases, sepsis, in vitro fertilization, cerebrovascular and cardiac disease, personalized immunosuppression, congenital metabolic errors, non-invasive prenatal tests through the analysis of circulating fetal DNA, and dyslipidemia. Likewise, there was time to discuss issues related to professional and organizational development, quality in the clinical laboratory based on the 20-year experience of the Spanish Society of Laboratory Medicine, point-of-care-testing, professional development for young scientists, and aspects of regulation from new legislation at the European level. For its part, and as part of the Congress activity, the Spanish Society of Laboratory Medicine also carried out two satellite symposiums in advance. The first of them on Quality and Laboratory Medicine, and more specifically on the updating of the Biological Variation data table and its use to ensure the clinical usefulness of laboratory results. And the second focused on standardization in the hematology laboratory, and which shared the challenges facing the clinical laboratory in detecting these diseases in an increasingly globalized world, highlighting the importance of consensus on the values analyzed and the need to use optical means to detect some pathologies. During the Congress there was also a large commercial exhibition where 42 in vitro diagnostic companies presented their latest developments related to Laboratory Medicine. Congress attendees had the opportunity to interact with their colleagues and professionals from other countries. In addition, coinciding with the Congress, numerous meetings of the various working groups of the societies organizing the Congress were held, with a high participation of professionals. Both the scientific program and the activities presented, and the high level of participation, give good proof of the success of the celebration of the 23rd EuroMedLab Congress in Barcelona. This success has been possible thanks to the effort, work, and enthusiasm of many professionals of the SEQC^{ML} who for more than two years have participated in both the organizational and scientific parts of the Congress. "We must be proud that at the international level they have trusted us to carry out this Congress, 16 years after the only time it had been held in Spain. Precisely because of this, it has been a great challenge and responsibility to carry it out impeccably, taking care of each and every detail at a scientific and organizational level," concluded Dr. Imma Caballé, president of the Congress and the SEQC^{ML}.

PAST EFLM EVENTS

EuroMedLab 2019 by figures

by Merve Gungoren, Chair of the EFLM Working Group "Promotion and Publications"



Report on EuroMedLab by the Spanish Society of Laboratory Medicine (SEQC^{ML})



About the Spanish Society of Laboratory Medicine (SEQCML)

SEQCML

Sociedad Española de Medicina de Laboratorio

The Spanish Society of Laboratory Medicine (SEQCML), founded in 1976, currently includes more than 2,500 professionals, and its main objective is to bring together all scientists interested in the field of Laboratory Medicine, to promote the dissemination of scientific and technical publications, to organize meetings, courses and congresses of a national and international nature, to cooperate with other Scientific Societies, and to defend and promote the specialties within Laboratory Medicine as well as its associates. Likewise, the Society wishes to contribute to the study and recommendation of standardized methods and the establishment of guidelines and recommendations for training in the field of Laboratory Medicine. More information at www.seqc.es.



Fig 1. Snapshots of SEQCML booth during the Congress



Fig 2. Members of SEQCML Board



Fig 3. Members of Congress Organising and Scientific Programme Committees



Fig 4. EuroMedLab Presidents in Paris, Athens, Barcelona and Munich



Symposium CELME 2019

by Merve Gungoren, Chair of the EFLM Working Group
"Promotion and Publications"

Symposium CELME 2019: CUTTING EDGE LABORATORY MANAGEMENT IN EUROPE, Emerging Challenges in Laboratory Medicine" will be held in October 3-4, 2019 in Prague. Organized by EFLM and Czech Society of Clinical Biochemistry and under auspices of IFCC, this event will provide an atmosphere to share the latest innovative thinking in the delivery of the best laboratory medicine activities. Participants can learn from expert innovators presenting new ways of solving the financial, quality and organizational problems.

If you want to lead your laboratory service to 'first class' performance, then join us and experience the shared opinion of like-minded professionals.

Number of attendees is limited, only 120 seats. Registration fee is 200 EUR.

For more information: <http://celme2019.cz/index.php>

FORTHCOMING EFLM EVENTS

EFLM Webinar: Harmonisation of Autoimmune tests

by Darko Cerne, Chair of the EFLM WG Distance Education and eLearning

EFLM is happy to remind you that the attendance to the webinars is free of charge and that the recording of the lectures will be available afterwards on at the EFLM elearning platform for those unable to attend.

Speaker: Joanna Sheldon (UK)

Moderator: Tommaso Trenti (IT)

Date: 24th September 2019 at 18:00 CET

The importance of standardisation is only just being realised and addressed in autoantibody measurements. Immunoglobulins have a high degree of molecular heterogeneity, there are subclasses of IgG and IgA, and the affinity and avidity of antigen-antibody binding can vary both between and within individuals. An immune stimulus may generate a monoclonal, oligoclonal or polyclonal response and this pattern of response will vary between individuals and even within an individual over the disease course. There are multiple methods available for autoantibody detection which will vary in their abilities to detect different types of immunoglobulins. Finally, the antigen to which we are trying to measure antibodies is usually a protein with its own molecular heterogeneity which may also be influenced by the source of the antigens and the preparation process. Considering these complexities, it is unsurprising that there is marked variation in autoantibody concentrations measured with different methods. However, the increasing reliance on automated quantitative autoantibody results has made standardisation or harmonisation of these tests vital. The IFCC through a working group and more recently a committee have been integral to investigating and producing certified materials for IgG anti myeloperoxidase (ERM-DA476/IFCC) and IgG anti proteinase 3 (ERM-DA483/IFCC) with values assigned in mg/L, traceable to ERM Da 470k/IFCC (the certified reference materials for IgG). Evaluation of patient samples showed that use of these materials will give a significant reduction in the spread of the numerical results over different methods. However, there was only 30% concordance between positivity and negativity of results when interpreted with respect to each methods reference ranges. The introduction of certified reference material (CRM) will be the essential first step in standardisation of autoantibody testing and although it does not solve every issue, it should give us a point of reference to identify the other components of the methods that need to be harmonised before we can have comparability in autoantibody results.

HOW TO REGISTER

Registration at elearning platform.

Did you miss any EFLM webinar?

Do not worry: The recorded version of all EFLM webinars is available at <https://elearning.eflm.eu/>

New posted recorded webinar: Monitoring of Internal Quality Control System Using Patients' Data (Speaker: Abdurrahman Coskun, TR)

Changing of the Guard in EFLM National Societies

Romanian Association of Laboratory Medicine (AMLR)

Dr. Cristina Mambet (Stefan S Nicolau Institute of Virology, Bucharest) is the new President of the Romanian Association of Laboratory Medicine replacing Dr. Ioana Brudasca who will now act as EFLM National Representatives replacing Mrs Constanta Popa.

A warm welcome to Dr. Mambet and a thank you to the outgoing President, Dr. Brudasca, and to the outgoing EFLM National Representative, Mrs Popa, for the support to EFLM activities during these last years.

NEWS FROM EFLM NATIONAL SOCIETIES

15TH Belgrade Symposium for Balkan Region - Laboratory Medicine Management: Leadership Skills for Effective Laboratory

by Dr. Snežana Jovičić, Society of Medical Biochemists of Serbia

The Belgrade Symposium organized by the Society of Medical Biochemists of Serbia, held on 11 and 12 April, and continued the fourteen years long tradition of EFLM Symposiums for Balkan Region. The 15th Belgrade Symposium for Balkan Region continued tradition of gathering laboratory medicine professionals from the Balkan countries in order to share experience and discuss topics of mutual interest, therefore the new title of the Symposium was "Neighboring Countries: the Same Professional Aim". However, the borders of the Symposium expanded beyond the Balkans, and this regional meeting had also speakers

from Italy, Austria, Slovenia, Croatia, Hungary, Cyprus, and Israel. The Symposium was organized under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Balkan Clinical Laboratory Federation (BCLF), Ministry of Education, Science and Technological Development of Serbia and Ministry of Health of Serbia. During two days and within eight sessions, eminent foreign and local experts introduced participants to the latest developments in laboratory medicine planning and organization, type of medical laboratory and strategy, laboratory medicine management, leadership skills, accreditation and competencies, laboratory standards in Balkan countries, as well as challenges in laboratory medicine that we meet today. After the opening ceremony and welcome addresses of the EFLM President-Elect, prof. Ana-Maria Šimundić; EFLM Secretary, prof. Giuseppe Lippi; BCLF President, dr Jozo Čorić, and prof. Vesna Matović, the President of the Pharmaceutical Association of Serbia, the Symposium was opened with the session hosted by the IFCC Emerging Technologies Division. Professors Bernard Gouget and Damien Gruson presented how we can use e-health tools in medical laboratories to obtain better outcomes, as well as the benefits of digital tools and machine learning in laboratory medicine. The Symposium continued with the inspiring session dealing with leadership skills. The characteristics and skills necessary for a leader in laboratory medicine, all the aspects of project management important in laboratory medicine practice, and the importance of communication between the clinical laboratory and its users were presented by Professors Ana-Maria Šimundić, Giuseppe Lippi, and Graham Beastall. The central part of the Symposium was sharing experiences between regional countries in implementing laboratory standards, harmonization, and teaching and training in laboratory medicine. Experiences from Slovenia, Croatia, Serbia, Bosnia and Herzegovina, Montenegro, Albania, North Macedonia, and Bulgaria were presented by Evgenija Homšak, Jasna Leniček-Krleža, Svetlana Ignjatović, Ermin Begović, Najdana Gligorović-Barhanović, Anyla Bulo Kasneci, Danica Labudovic, and Margaritka Bončeva. The second day of the Symposium was opened by two sessions dedicated to laboratory organization and planning. Very important and provocative issue of management of laboratory tests demands through personal experience was presented by prof. Dunja Rogić. Prof. Nataša Bogavac-Stanojević presented her work where she showed through cost-effectiveness analysis that the increase in laboratory use could actually decrease hospital costs. The use of six sigma for risk management and the optimal design of analytical quality control in clinical laboratory practice were presented by Adriana Unić. Also, the current views on measurement uncertainty in everyday practice were presented by dr Neda Milinković. Laboratory role in accreditation of healthcare institutions by the Agency for Accreditation of Healthcare Institutions in Serbia was presented from two points of view, of a surveyor (prof. Zorica Šumarac) and a chief of accredited laboratory (dr Vera Lukić). The challenges met in laboratory medicine covered evolving regulatory challenges in in vitro diagnostics, presented by prof. Tomris Ozben. Prof. Marielle Kaplan presented the efforts in national harmonization program of critical values communication in Israel. We were introduced with the assessment of medical residents' skills in choosing appropriate laboratory request and subsequent interpretation of laboratory tests results in a Romanian university center by prof. Ioana Brudașcă. Dr Dragana Pap presented the challenges and perspectives of QMS, and the road map for achieving standardization in laboratory medicine. The final sessions dealt with specific areas of laboratory medicine, namely current positions in laboratory testing in hemostasis, laboratory drug management, and latest results in endocrine disruptor research. About the latest protocols in laboratory diagnostics of anticoagulation, laboratory testing of lupus anticoagulant using different aPTT reagents, and assessment of hipercoagulable state in normal pregnancy and preeclampsia using global haemostatic assays talked prof. Andrea Griesmaher, prof. Violeta Dopsaj, and Sanja Lalić-Ćosić. The contribution of laboratory to therapeutic drug monitoring, challenges, and perspectives, integration of pharmacogenomics in clinical practice, as well as the latest research results in pharmacogenomics of the antidepressants of the SSRI group were presented by prof. Nicholas Pappgeorgakis, Angela Melpidou, Andriani Grigoratou, and prof. Vesna Pešić. The Symposium was closed with the presentation of the latest research results on endocrine disrupting chemicals inducing oxidative stress, their effect on organisms, and particularly the influence of di-2-ethylhexyl phthalate on the oxidative stress tissue damage and on the

fatty acids composition, by prof. Nuriye Nuray Ulusu and dr Duygu Aydemir. The two day Symposium with over 250 participants pointed out the same issues and problems that laboratory medicine professionals in this region meet in their every day work and practice, provoking discussions and exchange of opinion. The positive impressions of all the participants demonstrated that these local meetings addressing the practical issues that we are all facing and exchanging experience are necessary in laboratory medicine practice, and that the local problems are rather common to all than local.



Fig 1. Chairs of the Opening Session: Dr Bernard Gouget (France) and Dr Snežana Jovičić (Serbia)



Fig 2. Speakers and chairs of the 15th Belgrade Symposium for Balkan region



Fig 3. Speakers and chairs of the 15th Belgrade Symposium for Balkan region



Fig 4. Speaker's dinner



NEWS FROM EFLM NATIONAL SOCIETIES

Harmonisation of Post-analytical phase in Croatia: national recommendations from the Working Group for Post-analytics on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine

by Jasna Lenicek Krljeza, Lorena Honovic, Jelena Vlastic Tanaskovic, Sonja Podolar, Vladimira Rimac, Anja Jokic, members of the working group

The post-analytical phase is the final phase of the total testing process and involves evaluation of laboratory test results; release of test results in a timely manner to appropriate individuals, and modification, annotation or revocation of results as necessary to support clinical decision-making. The Working Group for Post-analytics of the Committee for Scientific Professional Development of the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) presented recommendations for the post-analytical phase published in *Biochemia Medica* (DOI: 10.11613/BM.2019.020502). The aim of these recommendations is to encourage the implementation of certain procedures to simplify and harmonise the post-analytical phase of laboratory work. The recommendations are intended for laboratory experts who are responsible for the timely and accurate release of laboratory test results. In Croatia, such experts are mandated by regulations concerning the medical biochemistry profession to hold a master's degree or specialisation in medical biochemistry and laboratory medicine. According to the same regulations, they must complete successfully the relevant board certification exam, and possess a valid license for practice issued from the Croatian Chamber of Medical Biochemists (CCMB). These recommendations are based on CCMB regulations and recommendations, the International Organization for Standardization (ISO) 15189:2012 (Medical laboratories - Requirements for quality and competence), national recommendations of the CSMBLM laws and policies of the Republic of Croatia and recent literature. In addition, the recommendations are aligned with specific requirements of the medical biochemistry profession at the national level in the Republic of Croatia. This recommendation includes 20 recommendations divided by procedures in the post-analytical phase of clinical laboratory work which are an integral part of ISO 15189:2012, thereby allowing rigorous quality control of post-analytical part of laboratory work. Procedure 1 is an evaluation of test results which include a comparison with reference intervals, comparison with previous results, additional procedures such as sample dilution, repeat testing,

communication with a physician/clinical department about possible causes of unexpected results and/or about the need for new sampling, reflex testing, reflective testing. Procedure 2 refers to the decision to release test results and includes the competences of decision-making laboratory personnel. In procedure 3 recommendations explain the preparation of the laboratory test report, the content and layout of the laboratory test report. Procedure 4 refers to releasing of the laboratory test report and includes some of the rules for automated selection and reporting of test results. Procedure 5 describes the reporting of test results. Procedure 6 (Sample storage and disposal) and procedure 7 (Archiving of laboratory documentation) describe minimum sample storage conditions for traceability purposes and minimum archiving conditions of laboratory documentation according to CCMB recommendations. These recommendations include post-analytical quality indicators: turnaround time, errors during transcription of results/ incorrect laboratory reports and notification of critical results (procedure 8.). Finally, the recommendations include 7 appendices to facilitate everyday application in a laboratory environment. For procedures not clearly defined by CCMB, the recommendations have been formulated based on the literature specified. In cases where the literature does not provide a clear viewpoint, the recommended procedures have been defined based on the consensus opinion of the Working Group.

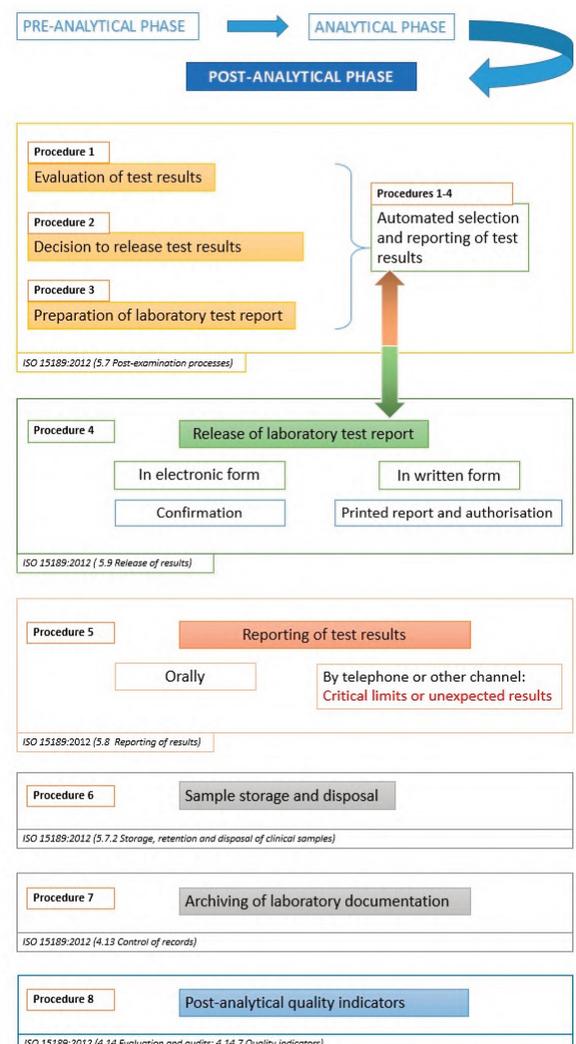


Fig 1. Procedures in the post-analytical phase of clinical laboratory work. (With permission of Croatian Society of Medical Biochemistry and Laboratory Medicine; published in *Biochem Med (Zagreb)* 2019;29(2):020502.)

The 3rd Congress of the Romanian Association of Laboratory Medicine, Iași 03-5 June 2019

by Dr.Cristina Mambet, RALM president



The 3rd Romanian Association of Laboratory Medicine (RALM) Congress, 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 Bucharest, Târgu Mures, Cluj Napoca, Iași, and Timișoara, took place on 3-5 June in Iași. The congress was attended by 798 participants including medical doctors, scientists and lab technicians working in medical laboratories. Four speakers from abroad were invited to give their lecture at the congress: Prof. Dr. Tomris Ozben (Turkey), Prof. MUDr. Vladimír Palička (Czech Republic), Prof. Dr. Hans H. Maurer (Germany), and Prof. Dr. Alain G. Verstraete (Belgium). Also, 14 invited speakers from Romanian academic institutions significantly contributed to the scientific program of the congress. Their lectures provided an updated information on topics such as in vitro diagnosis and regulatory changes in laboratory medicine, bone marker evaluation in patients undergoing hemodialysis, methods for determination of drugs and their metabolites in emergency toxicology, genomic analysis in modern medicine, markers of tumor cell metabolism, killer immunoglobulin-like receptors in allogeneic hematopoietic stem cell transplantation, new approaches to antibiotic resistance, and many others (some pictures are presented in Appendix 1 to this report).

The scientific program of the congress comprised 7 sessions of plenary reports (21) and brief oral communications (17), and 4 poster sessions at which a total number of 41 electronic posters were presented. The posters and the slides for the oral presentations were written in English and conference abstracts were published in a supplement of Romanian Journal of Laboratory Medicine. The content of the presentations referred to topics of interest in clinical chemistry, hematology, immunology, microbiology, molecular biology, quality management and laboratory automation. Many communications focused on practical issues concerning clinical relevance of laboratory tests, standardization, new instrumentation and method evaluation, reference ranges and clinical decision limits in laboratory result interpretation, emphasizing the interest of the participants in adding value to our professional activity. The participants had the opportunity to ask questions and make comments after presentations, and also to share their experience in a particular field.

As RALM manifests a strong interest in encouraging and motivating young laboratory professionals, many communications and posters were presented by young colleagues, most of them PhD fellows. RALM also initiated last year an internal grant competition for young scientists, consisting in 3000 euros. The grant was assigned to Dr. Mare Anca from Târgu Mureș University of Medicine, Pharmacy, Science and Technology.

During the congress an exhibition of equipment, reagents, supplies, software was held, being involved 22 IVD companies. In addition, diagnostic industry organized 10 workshops that introduced new technologies and clinical assays. After closing ceremony the general assembly of RAML took place and members elected the new RAML Board. The scientific quality and the variety of topics included in the program, the organization of the congress in a historic cultural institution, as well as the attractive social program led to a successful scientific and professional event.



UPDATES ON EFLM PUBLICATIONS

Updates of the EFLM Publication list

by Daniel Rajdl, Chair of the EFLM Communication Committee;
Aasne Karine Aarsand, Chair of the Working Group: Biological Variation and Janne Cadamuro, member of the Working Group: Preanalytical Phase

European Biological Variation Study (EuBIVAS): Within- and Between-Subject Biological Variation Data for 15 Frequently Measured Proteins

Carobene A, Aarsand AK, Guerra E, Bartlett WA, Coskun A, Díaz-Garzón J, Fernandez-Calle P, Jonker N, Locatelli M, Sandberg S, Ceriotti F; European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation. *Clin Chem* 2019 doi:10.1373/clinchem.2019.304618. Available from: *Clin Chem* 2019 doi:10.1373/clinchem.2019.304618. Available from: <http://clinchem.aaccjnls.org/cgi/doi/10.1373/clinchem.2019.304618>

Critical appraisal of biological variation studies by the Biological Variation Data Critical Appraisal Checklist (BIVAC) created by the EFLM Working Group on Biological Variation (WG-BV) indicate that the quality of many published articles reporting biological variation is poor. The EuBIVAS study, a large-scale biological



variation study, driven by the same working group has now published new, rigorously determined, biological variation estimates for 15 commonly measured proteins: α 1-acid glycoprotein, α 1-antitrypsin, albumin, β 2-microglobulin, ceruloplasmin, complement component 3, complement component 4, C-reactive protein, cystatin C, haptoglobin, IgA, IgG, IgM, soluble transferrin receptor, and transferrin. For most of these proteins, the within-subject estimates (CVi) were significantly lower than previously published, whereas between-subject estimates were comparable. This generally results in lower reference change values (RCV) and stricter analytical performance specifications for these analytes. The biological variation estimates of these analytes will be included in the EFLM Biological Variation Database at <https://biologicalvariation.eu/>.

Biological variation data for lipid cardiovascular risk assessment biomarkers. A systematic review applying the biological variation data critical appraisal checklist (BIVAC).

Díaz-Garzón J, Fernández-Calle P, Minchinela J, Aarsand AK, Bartlett WA, Aslan B, Boned B, Braga F, Carobene A, Coskun A, Gonzalez-Lao E, Jonker N, Marques-Garcia F, Perich C, Ricos C, Simón M, Sandberg S.

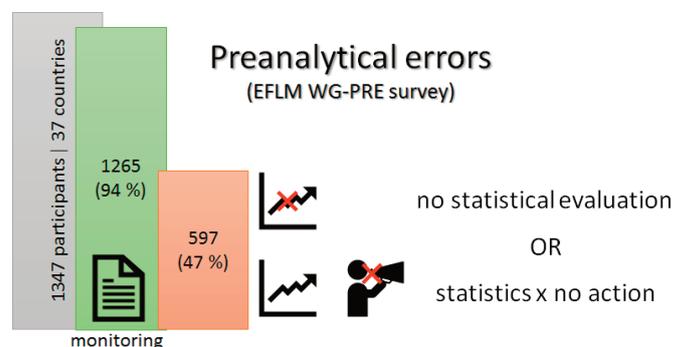
Clin Chim Acta. Elsevier; 2019 Aug 1;495:467–75. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0009898119318649>

The second publication from the WG-BV and the Task Group for the Biological Variation Database has used the BIVAC to appraise published biological variation studies of cardiovascular risk assessment biomarkers (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides and apolipoproteins A1 and B) and delivered meta-analysis derived estimates for these measurands based on BIVAC compliant studies. This review shows that there is a lack of BIVAC compliant studies and to provide biological variation reference data in different subpopulations, new studies must be initiated. The new meta-analysis derived estimates for lipid biomarkers will be included in the EFLM Biological Variation Database (<https://biologicalvariation.eu/>).

European survey on preanalytical sample handling – Part 1: How do European laboratories monitor the preanalytical phase? On behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE)

Cadamuro J, Lippi G, von Meyer A, Ibarz M, van Dongen Lasen E, Cornes M, Nybo M, Vermeersch P, Grankvist K, Guimaraes JT, Kristensen GBB, de la Salle B, Simundic AM
Full-Text at Biochemia-Medica available here.

The first part of results from this interesting survey depicts that the vast majority (94 %) of the 1,347 participating laboratories from 37 countries is monitoring preanalytical errors. However, there is large heterogeneity in which errors are monitored and how. Additionally, almost half of the laboratories (47 %) do not statistically evaluate these data or take no action after evaluation (Figure). The optimistic part of the survey is that almost everybody is interested in a guideline for measurement and evaluation of preanalytical variables (92 %), and in preanalytical e-learning programs or webinars (84 %), a clear assignment to the WG-PRE to further provide recommendations, guidelines, information and tools, aiming to harmonize/standardize the preanalytical phase in Europe.



European survey on preanalytical sample handling – Part 2: Practices of European laboratories on monitoring and processing haemolytic, icteric and lipemic samples. On behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE)

Cadamuro J, Lippi G, von Meyer A, Ibarz M, van Dongen Lasen E, Cornes M, Nybo M, Vermeersch P, Grankvist K, Guimaraes JT, Kristensen GBB, de la Salle B, Simundic AM
Full-Text at Biochemia-Medica available here.

The second part of results from the WG-PRE survey monitors assessment, management and follow-up actions of haemolysis, icterus and lipemia (HIL) in routine blood samples. Most laboratories measured HIL indices (43%), but still a large amount of facilities are performing obsolete visual inspection of samples either as only method (30%) or in combination with automatic detection (28%). Only a quarter of responders performing automated HIL checks used internal quality controls. In haemolytic or icteric or lipemic samples, most responders (70%) only rejected HIL-sensitive parameters, whilst about 20% released all test results with general comments on haemolysis/lipemia/icterus. Interestingly, 10% of laboratories stating to be accredited according to the ISO 15189 regulation were not monitoring preanalytical errors in general or HIL in particular. Generally, there was a significant heterogeneity in strategies for monitoring and treating haemolytic, icteric or lipemic samples in Europe.

IFCC Distinguished Awards for the IFCC WorldLab Congress, Seoul (KR) 2020 Call for nominations

by Maurizio Ferrari, Chair, IFCC Awards Committee

The IFCC confers its Distinguished Awards to scientists and clinicians who work in clinical chemistry and laboratory medicine or related disciplines. These triennial

awards are the highest honours that our Federation can bestow to colleagues worldwide in recognition of their outstanding achievements, to publicize their exceptional research and other contributions that have improved medical and healthcare, and to stimulate and encourage other scientists to accelerate their efforts in advancing clinical chemistry and laboratory medicine:

1. IFCC Distinguished Clinical Chemist Award – sponsor: Yashraj Biotechnology Ltd.
2. IFCC-Henry Wishinsky Award for Distinguished International Service since 1990 (IFCC Distinguished International Services Award 1981-1987) – sponsor: Siemens Healthineers.
3. IFCC Award for Distinguished Contributions in Education – sponsor: Abbott Laboratories.
4. IFCC Award for Significant Contributions in Molecular Diagnostics – sponsor: Abbott Laboratories.
5. IFCC Distinguished Award for Laboratory Medicine and Patient Care – sponsor: Sekisui Diagnostics.
6. IFCC-Robert Shaffer Award for Outstanding Achievements in the Development of Standards for Use in Laboratory Medicine – sponsors: NIST CLSI.
7. IFCC Distinguished Award for Contributions to the Cardiovascular Diagnostics – sponsor: HyTest.
8. IFCC-G rard Siest Award Young Scientist Award for Distinguished Contributions in Pharmacogenetics – sponsor: Biologie Prospective.
9. IFCC Distinguished Women Scientist Award for Contribution to In Vitro Diagnostics – sponsor: Yashraj Biotechnology Ltd.
10. IFCC Young Investigator Award – sponsor: IFCC.

For a more detailed description, click here. The closing date for receipt of nominations is 30 November 2019



The IFCC Working Group on Volatolomics - by Larry Kricka, US, WG-Vol Chair

The Working Group on Volatolomics (WG-Vol) is part of the Emerging Technology Division (ETD) that provides current awareness of emerging technologies likely to have important clinical diagnostic applications in the near future - one of those emerging technologies is volatolomics (i.e., breath analysis). The terms of reference for the WG are to develop a survey on the diagnostic applications of volatolomics (breath analysis) and to develop periodic updates of the volatolomics survey over the next 3 years. For all information, click here.

IFCC President election result

The ballot for the substitution of the IFCC President, following the unfortunate death of Prof. Morris, was concluded, June 30. The voting unanimously confirmed the Executive Board recommendation to appoint Prof. Maurizio Ferrari as President, beginning his term on July 1. The President-Elect will transition into the role of President during the 2020 year at a date mutually agreed upon between the EB and the President-Elect. 52 societies voted (out of 88 having the right to vote). Full details of the ballot may be found from the independent company that conducted the ballot: <https://secure.electionbuddy.com/results/6EFTVWVKVRNVV>. We congratulate Prof. Maurizio Ferrari in his role.

The IFCC Committee on Point-of-Care Testing - Meeting in Barcelona - by Adil I. Khan, US, C-PoCT Chair

Barcelona hosted the meeting of the IFCC Committee on Point-of-Care Testing (C-POCT) – which comprises thirty-three members from all around the world. C-POCT members look at different aspects of point-of-care testing and provide international leadership by developing clinical practice guidelines or educational materials where none exists or there is lack of clear direction. For all updates click here.

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here. **Apply for EFLM auspices!** For more information visit: <https://www.eflm.eu/site/page/a/1048/> or email eflm@eflm.eu

EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with the Finnish Society of Clinical Chemistry



Helsinki (FI) 18-19 September 2019 [Click here for information](#)

Cardiac Biomarkers Symposium - High Sensitive Troponin: Present and Future

Tel Aviv (IL) 24-26 September 2019, [Click here for information](#)

MSACL 2019 EU

Salzburg (AT) 22-26 September 2019, [Click here for information](#)

16 Jahrestagung der Deutschen Gesellschaft f r Klinische Chemie und Laboratoriumsmedizin (DGKL)

Magdeburg (DE) 25-28 September 2019, [Click here for information](#)

XIVth Congress of Czech Society of Clinical Biochemistry with International Participation

Pilsen (CZ) 22-24 September 2019, [Click here for information](#)

41st National Conference LABAC

Paris (FR) 1 October 2019 [Click here for information](#)

EFLM webinar: Harmonisation of Autoimmune tests



On-line 24 September 2019 [Click here for information](#)

4th ACTC (Advances in Circulating Tumor Cells) - Liquid Biopsy: Latest Advances and Future Challenges

Corfu (GR) 2-5 October 2019 [Click here for information](#)

CELME 2019: Emerging Challenges in Laboratory Medicine EFLM Symposium in collaboration with the Czech Society of Clinical Biochemistry
Prague (CZ) 3-4 October 2019 [Click here for information](#)



EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with the Association of Association of Clinical Biochemists in Ireland
Athlone (IR) 7 November 2019 [Click here for information](#)



EFLM webinar: How should a medical laboratory specialist prepare for accreditation according to the ISO 15189
On-line 8 October 2019 [Click here for information](#)



The Value of Laboratory Medicine into Clinical Medicine
Erice (IT) 7-9 November 2019 [Click here for information](#)

LABKVALITA 2019 - Biennial Conference with international participation on Quality in Laboratory Testing
Nový Smokovec (SK) 10-11 October 2019, [Click here for information](#)

JIB 2019: Journées de l'innovation en biologie
Paris (FR) 21-22 November 2019 [Click here for information](#)

EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with the Association of Laboratory Specialists and Organizations «Federation of Laboratory Medicine
Moscow (RU) 14 October 2019 [Click here for information](#)



13th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "The Internal Quality Control in the Traceability Era"
Milan (IT) 28 November 2019 [Click here for information](#)

5th ESPT Congress Precision Medicine and Personalised Health
Seville (SP) 16-18 October 2019 [Click here for information](#)

Journées de biologie pratique
Paris (FR) 7-8 December 2019 [Click here for information](#)

EQALM Symposium 2019
Ljubljana (SL) 17-18 October 2019 [Click here for information](#)

EFLM webinar: Essential Leadership Management for Laboratory Professionals
On-line, 17 December 2019 [Click here for information](#)



EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with the Royal Belgian Society of Laboratory Medicine
Bruxelles (BE) 18-19 October 2019 [Click here for information](#)



International Congress on Quality in Laboratory Medicine
Helsinki (FI) 6-7 February 2020 [Click here for information](#)

International Conference on Laboratory Medicine "From Bench to Diagnostic-Therapeutic Pathways"
Padova (IT) 23 October 2019 [Click here for information](#)

XXXVII Nordic Congress in Medical Biochemistry
Trondheim (NO) 9-12 June 2020 [Click here for information](#)

EFLM Postgraduate Course on "How to write a good scientific and professional article" in collaboration with the Turkish Biochemical Society
Antalya (TR) 26-27 October 2019 [Click here for information](#)



3rd EFLM Strategic Conference "Demand Management"
Zagreb (HR), 27-28 November 2020, [Click here for information](#)



Joint Congress of 27th Balkan Clinical Laboratory Federation (BCLF) Congress and 30th National Biochemistry Congress (NBC) of TBS
Antalya (TR) 27-31 October 2019 [Click here for information](#)

EuroMedLab 2021 - 24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Munich (DE) 16-20 May 2021 [Click here for information](#)



3^{èmes} Journées Francophones de Biologie Médicale
Monaco (MC) 6-8 November 2019 [Click here for information](#)

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