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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



In the present issue, Consultant Immunologist Dr. Joanna Sheldon explores the challenges in harmonizing autoantibody testing under the Hot Topic column. Rita Andrea Horvath and Andrew St John, members of the EFLM Working Group on Test Evaluation, present a report on the EFLM-AACB Workshop "Value of Biomarker" held in Sydney in

March this year where they discuss the possibilities of how to improve the process of test development. Daria Pasalic, Chair of the EFLM Education and Training Committee reports the activities of the committee in the past six months. Call for nomination for 3 full members and a young scientist member is advertised by the EFLM Preanalytical Phase Working Group. Another exciting opportunity for young participants is presented as an EFLM bursary programme to attend the 5th EFLM Conference on Preanalytical Phase to be held in Zagreb on 22-23 March, 2019. MariaStella Graziani, Chair of the EFLM Communications Committee, provides an update on the EFLM publications list. The National Society of Spain outlines their latest professional activities. Additionally first experience of EFLMLabX is presented by the Medical University of Bialystok, Poland. The 5th EFLM-UEMS Conference in Turkey and EuroMedLab in Barcelona are some of the exciting upcoming events enlisted in the Calendar of Events.

HOT TOPICS IN LABORATORY MEDICINE

Harmonisation in autoantibody testing: a dream or a reality?



by Dr Joanna Sheldon PhD, FRCPath
Consultant Immunologist, St. George's Hospital, London, UK

Detection and quantification of autoantibodies is firmly embedded in diagnostic laboratories. These tests contribute to the diagnosis, treatment and management of patients with autoimmune diseases. Over the last three decades, the requesting of autoantibody testing has increased dramatically. Considering the incidence and prevalence of many autoimmune type diseases had not change significantly, the demand and increase in demand seems inappropriate.

March this year where they discuss the possibilities of how to improve the process of test development. Daria Pasalic, Chair of the EFLM Education and Training Committee reports the activities of the committee in the past six months. Call for nomination for 3 full members and a young scientist member is advertised by the EFLM Preanalytical Phase Working Group. Another exciting opportunity for young participants is presented as an EFLM bursary programme to attend the 5th EFLM Conference on Preanalytical Phase to be held in Zagreb on 22-23 March, 2019. MariaStella Graziani, Chair of the EFLM Communications Committee, provides an update on the EFLM publications list. The National Society of Spain outlines their latest professional activities. Additionally first experience of EFLMLabX is presented by the Medical University of Bialystok, Poland. The 5th EFLM-UEMS Conference in Turkey and EuroMedLab in Barcelona are some of the exciting upcoming events enlisted in the Calendar of Events.

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Editorial information:

Newsletter Editor: Dr. Harjit Bhattoa, Faculty of Medicine, Dept of Laboratory Medicine, University of Debrecen, Hungary

EFLM Executive Board:

M. Neumaier, S. Sandberg, AM. Simundic, G. Lippi, H. Storm, T. Guimaraes, T. Zima

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For example, ANCA vasculitis is classified as rare disease [affecting less than 200,000 people (US) or less than 1 in 2000 of the population (Europe)]. Pearce et al. reported the annual incidence of ANCA associated vasculitis in the whole of the UK as 1835 cases or approximately 35 new cases per week (1). It is hard to relate this to my laboratory which serves a population of approximately 1.3 million people where we receive over 200 ANCAs requests per week. This apparent indiscriminate requesting is seen across many autoantibody specificities and in many laboratories across world; maybe this is also an area where harmonisation is needed. Never the less, this increase in workload, consolidation and de-skilling of laboratories is driving autoantibody testing methods away from labour intensive qualitative analysis requiring training and experience towards automated and tracked quantitative testing. The reporting of an autoantibody concentration with units and a reference range gives the impression that these are robust results in terms of analytical and clinical validity. Unfortunately this is not the case, autoantibodies have had limited standardisation and there are no reference methods.

We have a rather simplistic perception that because we use a common name for an analyte, every method measures the same thing in the same way and all results for that analyte will be comparable. Autoantibody quantification is complex with the potential to introduce variability in every aspect of the analytical process. Figure 1 shows the possible sources of variation in an autoantibody test, but also reminds us that each method or manufacturer is working in a closed loop without any external or independent point of reference. To reduce the variability of autoantibody testing, we need to better understand these variations and identify the areas where harmonisation will have a positive impact.

Every method will test for antibodies in the patient's serum that react to normal cellular components. The relevant antigens may be from crude tissue preparations, purified from tissue, or may even be recombinant. It is easy to believe that there will be differences between these three preparation processes, but differences are also likely within a preparation type e.g. between manufacturers and between lots.

The exact definition of the autoantibodies, the measurands, is difficult. Typically, we test for IgG autoantibodies, but all immunoglobulin classes can be autoantibodies. Each individual person will make a different spectrum of polyclonal immunoglobulins that can all bind to the antigen of interest. Between individuals, the polyclonal immunoglobulins may differ regarding the target epitopes, antibody affinity and avidity, isotype etc. It is also reported that within an individual, during the course of their disease and management, the epitope specificity of the autoantibodies can change.

The methods available for quantification of antibodies show considerable variation in the assay characteristic e.g. isotype specificity, assay speed and temperature, and even the pH of the analytical phase. This all leads to inconsistencies in how the different methods detect different types of immunoglobulins of different affinities or avidities. In reality, different methods are often measuring slightly different versions of the same analyte. Materials *called* standards for autoantibodies have been available for some years but external quality assurance reports for an autoantibody, with an apparently common standard would show that use of the 'standards' does not generate harmonised results. Some analytes show up to 1000x variation between the lowest and highest values for a single sample! We also know that in addition to the enormous variation in the *concentrations* given by different methods, the interpretation of the result with respect to the manufacturer's reference range is not consistent. Samples from certain patients give different interpretation of results across various methods.

Considering all these issues, it is not surprising that standardisation of autoimmune serology is a major challenge and it was the IFCC Scientific Division who took on the task by forming the Working Group on Harmonisation of Autoantibody Testing (WG-HAT) in 2010. The group had a broad remit; in addition to trying to prepare certified reference materials, it is also aimed to develop a better understanding of the causes of high variation in autoantibody testing. Certified reference materials for IgG anti myeloperoxidase and IgG anti proteinase 3 were produced by the Institute for Reference Materials and Measurements (IRMM) and are now available (2,3).

The studies leading to the certification of these materials produced robust data by analysing over 30 samples and 11 different methods. It showed that not all samples behaved in the same way; more than 60% of samples showed some differences in result interpretation between methods and there was no consistent pattern. This kind of discrepancy will not be solved by introducing a common standard but it has generated another phase of investigation. The group is currently trying to identify the epitope reactivity of these samples which may reveal why the samples behave inconsistently between methods. The October issue of CCLM (4) is devoted to standardisation

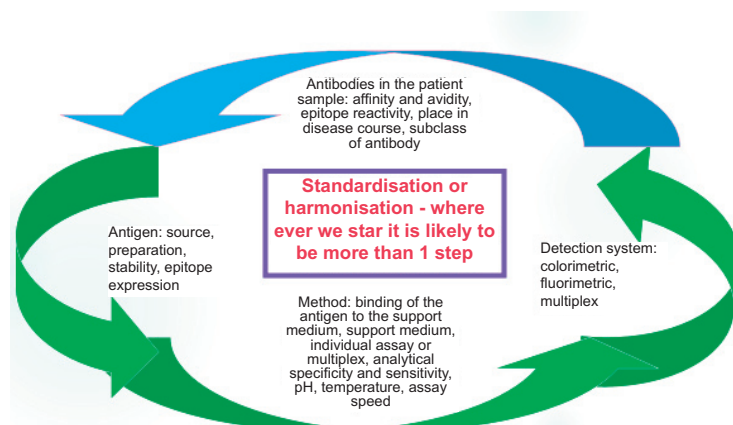


Figure 1. Sketch of the possible sources of variation in an autoantibody testing

and harmonisation in laboratory medicine. It is encouraging to see that nine papers are dedicated to the harmonization of autoimmune testing putting this previously ignored area of laboratory testing firmly on the standardisation/harmonisation map.

Producing a certified reference material is a major undertaking and although there are many complex steps, it is generally within the control of a small group who all have the same focus. Introducing a new reference material is a completely different challenge. There must be interaction with the reagent manufacturers and producers, medical device approval agencies e.g. FDA (USA) or European Community, laboratories, clinicians, patient focus associations, professional societies, etc. To achieve harmonisation or standardisation, all these groups must be on board with the process and benefits.

So, is harmonisation in autoantibody testing a dream or a reality? It is certainly not a reality, but we have made some huge steps forward. There is general agreement that we need to harmonise or standardise these tests. We know some of the possible causes of variation and we need to investigate them further. Reference materials are now available that fulfil the rigorous requirements of a certification process, but as we develop our understanding of the complex behaviours of autoantibodies, we may need to adapt or improve what we have. To make the dream into reality, we need to adopt these reference materials understanding that true standardisation of autoantibody tests is unlikely to be a simple one-step process.

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2. Monogioudi E, Hutu DP, Martos G, Tuddenham E, Sheldon J, Schimmel H, et al. The Certification of Anti-myeloperoxidase Immunoglobulin G in Human Serum ERM® — DA476/IFCC, EUR 27092 EN, European Commission, Luxembourg, 2015 (ISBN 978-92-79-45349-6).
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4. *Clinical Chemistry and Laboratory Medicine (CCLM)* Volume 56, Issue 10 (October 2018).

NEWS FROM THE EFLM WORKING GROUP ON TEST EVALUATION

How can we improve the process of test development?

A report on the EFLM-AACB Workshop “Value of Biomarker”, Sydney, March 2018

by Rita Andrea Horvath and Andrew StJohn, Members of the EFLM Working Group on Test Evaluation

The process of test development where supposedly promising biomarkers are developed into useful medical tests is known to be flawed. Consider how many new tests have been added to the laboratory repertoire in recent years? Leaving aside genomic based testing the answer is very few despite many new potential markers entering the pipeline. This unproductive process contributes to a reputed \$200 million dollars being wasted every year on failed biomarker research. Laboratory professionals play a key role in this process albeit usually towards the end, but what can they do to improve the situation?

To answer this question more than fifty professionals from all the sectors involved in biomarker development including the laboratory, industry, biomarker researchers and health policy makers, gathered together at a 2-day Workshop in Sydney in March. The Workshop entitled “Assessing the Value of Biomarkers” was delivered by the Test Evaluation Working Group (TE WG) which is a collaboration between the Australasian Association of Clinical Biochemistry (AACB) and the European Federation of Laboratory Medicine (EFLM). The Sydney Workshop was modelled on an inaugural workshop run in Leiden, The Netherlands in 2016.

The Sydney Workshop was opened by Adam Elshaug, who is Professor of Health Policy at the University of Sydney and a key member of the Government’s Medicare Review Taskforce. His talk placed the workshop in the context of the Australian environment where the government is looking to increase the value of healthcare through many different initiatives of which developing and implementing better pathology testing is but one.

Having set the scene, members of the TE Working Group explained the concepts and tools that have been developed as part of a cyclical framework for evaluation of clinical effectiveness of new medical tests. The aim of the workshop has been to go beyond the theory of evidence-based medicine and provide practical strategies and tools that laboratory professionals can use to assess biomarkers, both in the development phase and also during implementation in their own laboratories. Details of these activities are available on the Working Group’s website (<https://www.eflm.eu/site/page/a/1158>).

The key concepts covered in the lectures included the understanding that test development is not just a linearly staged step-wise process from discovery to implementation, as we might like to believe. It is more of an interplay of various components of the test evaluation cycle, all of which are primarily driven by how the test is going to be used in a clinical pathway.

Much biomarker development proceeds with no clear understanding of the unmet need or – “why and for what purpose are we using this test?” A key achievement of the TE WG is to develop a checklist which can be used for both new and existing tests to identify the unmet need for a medical test; if such a checklist is used appropriately and early in the translational pipeline, it would help prevent what turn out to be many ineffective tests being launched in the marketplace. This checklist can be found in an interactive form at



<https://elearning.eflm.eu/course/view.php?id=11>. The Working Group invites people to use this checklist and provide feedback on their experience.

Another important concept addressed by the speakers is that while analytical and clinical performance specifications are of themselves important, equally significant is that they interact and, consideration of this leads to the iterative nature of test development. Lectures covered how analytical and clinical performance criteria could be set with yet again the clinical pathway and the use of the test being central to such considerations. This is because high analytical quality of a test does not guarantee that the test will work well in clinical practice and, vice versa, a clinically useful test does not always need to achieve the highest possible analytical quality if the test plays a small part in a complex multi-test diagnostic pathway. Lectures on clinical pathway mapping, diagnostic trial design, health economics and a perspective from the IVD industry were also part of the lecture programme.

A key component of the workshop was to go beyond enunciated theory and ask the delegates to apply what they had heard in the lectures to exercises where they worked with their table colleagues on interactive assignments based on real life case scenarios.

The Workshop concluded with two Australian speakers who reviewed specific initiatives that are taking place in Australia in terms of improving value, namely the greater use of decision support to help test requesters, and the need for a Centre of Excellence to conduct translational research in the area of laboratory medicine.

At the completion of each day the delegates were asked to provide feedback on the talks and assignments, and over the two days, the feedback was uniformly good but also identified areas for improvement in future workshops.

At the end of such a Workshop the question is inevitably what next? How do we translate knowledge into action and eventually improve the process of test development and implementation? One action is to consider incorporating the key elements of this workshop into the training curriculum of trainee scientists and pathologists.

Another action is to devote more resources to this important area of laboratory medicine and a proposal is currently being considered by the AACB Executive to have a dedicated Value of Pathology Working Group or Committee. Tasks for such a group would be in part to continue the contribution of the AACB to the EFLM's TE WG but there is also a need to translate the concepts and tools developed by that group into local practice.

If interested in this topic and would like to attend similar courses in the future or if your national society or professional organisation is interested in hosting such an event, please contact the chair of the EFLM Test Evaluation Working Group, Christa Cobbaert, at C.M.Cobbaert@lumc.nl.



Prof. Ken Sikaris giving a lecture on the role of clinical decision support in delivering value



Prof Rachael Morton lecturing on health technology assessment and cost effectiveness of tests

EFLM Education and Training Committee – Report on a six-month activity

by Daria Pasalic, Chair of the EFLM Education and Training Committee

Since the first months of 2018, the structure of the Committee underwent a re-organisation. At the beginning of 2018, I have been appointed as chair of the Committee and left my previous position as member of the Working group on Congresses and Postgraduate Education (WG-CPE). At the same time, two additional functional units under the Committee umbrella have been established: the WG on Laboratory Medicine Crediting Points (WG-LMCP), chaired by Patrick Twomay and the Task Group on EFLM European Syllabus (TG-EuSy), chaired by Ralf Lichtinghagen.

The two other well established WGs (Congresses and Postgraduate Education chaired by Evgenija Homsak and Distance Education and e-Learning chaired by Daniel Rajdl) have continued their important work.

Working Group: Congresses and Postgraduate Education

1) The **EFLM project of exchanging practice in Laboratory Medicine (EFLMLabX)** has been activated after three years of preparation. In many EFLM countries, there is a need to acquire additional practical knowledge and skills in different fields of laboratory medicine (LM). This project gives the opportunity to laboratory medicine professionals either to offer or find training in specific fields of LM. All relevant information and offerings can be found at <https://eflmlabx.eflm.eu/en>. Since the beginning of this year, 10 countries with 12 laboratories offering 17 different practices/topics were included as providers: Belgium, Croatia, Czech Republic, France, Netherlands, Poland, Portugal, Slovenia, Spain and United Kingdom. This project still needs visibility to improve the database of practice providers and to motivate the users, especially young trainees: currently only 3 specialists applied and completed the training.

2) A new EFLM educational tool has been proposed: the **“brand mark” Postgraduate Courses (PGE)**. These courses are planned to be 1-2 days long, educational, and low budget (not profitable), with maximum two lecturers for a small group (up to 50 participants) and oriented to applicative knowledge in form of Workshops. Their aim is to be attractive for young trainees, residents and specialists. The topics, the programme, and the speakers will be proposed by the WG-CPE. The courses will be organized in different European countries upon application. Two application options are planned: a single National Society (NS) can request to host the course in its country offering to cover the related costs or, as an alternative, EFLM (once a year) will select a NS, among those that applied to host the course, and will pay for the faculty (travel expenses and accommodation for the speakers). Applications will be evaluated by the EFLM Executive Board, according to established criteria. The first two courses proposed by the WG-CPE are “Biostatistics” and “How to write a scientific paper” More relevant information will be posted on the EFLM website soon.

3) A survey on **“Understanding and implementation of MedTechCode in EFLM-member societies”** was conducted among NS representatives and received 25 (out of 40 NSs) replies. A second survey on the same topic was addressed to individual members of EFLM NS and 322 replies were obtained. The goal of the two surveys was to investigate the previous and current practice in terms of cooperation between professionals or scientific societies and IVD industry, as well as to know the impact of the MedTech Europe Code in the educational practice. At the moment WG-CPE members are preparing the publication of the results of the surveys.

4) For the EFLM Application to become a **Trusted Partner Ethical Medtech**, 4 EFLM officers were involved: Ian Watson, Merve Sibel Gungoren, Silvia Cattaneo and Ciriaco Carru.

Working Group: Distance Education and e-Learning

WG-DE recently launched the EFLM e-Learning platform <https://elearning.eflm.eu/> that provides a common framework for all online EFLM educational activities. Over one year of its existence, it attracted more than 1.500 newly registered participants. The growing educational content of the platform consists of:

- **live webinars** – in 2018, WG-DE organized 8 live webinars that are available as recordings and handouts. After passing an educational questionnaire, participants can obtain a certificate of participation. The same number of live webinars on actual topics is planned for next year.
- **recordings from congresses** – selected presentations from EuroMedLab in Athens (2017) and the majority of presentations from the 2nd EFLM Strategic Conference “The end of laboratory medicine as we know it?” were recorded, processed and published by the WG-DE in the e-Learning platform. Recordings from selected forthcoming congresses will be available on the platform.
- **e-learning courses** – a new interactive course “Unmet clinical needs” developed by EFLM Test Evaluation Working Group (TE-WG) was launched in Spring 2018. Other EFLM WGs are planning to create new e-learning courses. WG-DE closely collaborates with the Task Group EFLM European Syllabus on the realization of recordings, processioning and publication of lectures organized by the TG.

Task Group: EFLM European Syllabus

This new established TG chaired by Ralf Lichtinghagen, has the task of organising EFLM European Syllabus Courses which should support the continuous educational process for young laboratory professionals in EFLM countries. On the basis of the EFLM European Syllabus, it should be possible to recapitulate the required knowledge in a reasonable time, in order to be able to collect CPD points at the same time. The courses will be realised in cooperation with the WG-DE for the technical realization of the project thus including post-processing, upload on the EFLM e-learning platform and support for using e-learning authoring tools. The Task group will manage, together with the lecturers, the creation of autodidactic questionnaires. In cooperation with WG-LMCP, the courses will be certificated and attendants will get credit points for attendance and for participation. The practical realisation of this project is expected to start at the beginning of 2019.



UPCOMING EFLM EVENTS



10-13 OCTOBER 2018

"LABORATORY MEDICINE AT THE CLINICAL INTERFACE"

TITANIC BEACH LARA HOTEL, ANTALYA – TURKEY

Under the Auspices of



Do not miss to participate at the
**5th EFLM-UEMS European
Joint Congress in Laboratory Medicine**
*"Laboratory Medicine
at the Clinical Interface"*
in **Antalya (TR)**
from **October 10 to 13, 2018!**

**Click here to view the full
scientific programme**

PERSONALIZED MEDICINE

Friday October 12th | 16:40-17:40



MARIO PAZZAGLI

THE ROLE OF LABORATORY
MEDICINE IN PERSONALIZED AND
PRECISION MEDICINE



YESIM OZARDA

PERSONALIZED REFERENCE
INTERVALS

MEDICAL GUIDELINES AND CLINICAL DECISION MAKING

Thursday October 11th | 14:45-16:15



MICHEL LANGLOIS

MEDICAL GUIDELINES MAY NOT
ALWAYS BE COMPATIBLE WITH
LABORATORY PRACTICE

A HARMONISED APPROACH TO GENERATING AND APPLYING BIOLOGICAL VARIATION DATA

Friday October 12th | 09:00 - 10:30



SVERRE SANDBERG

BIOLOGICAL VARIATION, FROM
THEORY TO PRACTICE, THE
PROJECTS OF EFLM



WYTZE OOSTERHUIS

LABORATORY AND CLINICAL
COOPERATION IN ENHANCING
CLINICAL DECISION MAKING



ANNA CAROBENE

EUROPEAN BIOLOGICAL VARIATION STUDY
(EUBIVAS): SAMPLE COLLECTIONS FROM HEALTHY
VOLUNTEERS FROM SIX EUROPEAN LABS FOR
BIOLOGICAL VARIATION ESTIMATES' UPDATE



ANA MARIA SIMUNDIC

DEMAND MANAGEMENT
(TEST UTILIZATION)



ABDURRAHMAN COSKUN

BIOLOGICAL VARIATION OF CBC TESTS: THE
EFFECT OF TURNAROUND TIME

<http://eflm-uems-antalya2018.org/>

EFLM Working Group "Preanalytical Phase" - deadline to send nominations: 31 October 2018

This Working Group was established in 2013 with the aim to achieve harmonization in the preanalytical phase across European member societies. This group headed by now-President-Elect Ana-Maria Simundic, has been very successful e.g. performing surveys that have led to various recommendations like the definition of fasting status, patient and blood tubes identification issues, colour coding and validation of blood collection tubes, the sequential order of draw, hemolysis detection and management, quality assurance of HIL indices and others. Also, WG-PRE has organized four European conferences to promote the visibility of Preanalytics in laboratory diagnostics. As all members of WG-PRE will be finishing their terms by the end of 2018, the group needs to be refurbished in all positions. At this time, EFLM is calling for the nomination of:

⇒ **3 full members**

⇒ **1 young scientist member (must be below 35 years of age at the time of nomination).**

In order to complement the successful work on guidelines and recommendations of the past, the EB of EFLM has decided to put major emphasis and support future collaborative laboratory studies in areas of Preanalytics, also with the goal of attracting public grant funding. Accordingly, the scientific profile of the nominates candidates will be highly considered. The EFLM EB expects that the nominated group members are willing to interact with scientists within the EFLM to further said collaborative project activities.

The WG terms of reference are available at www.eflm.eu. For all the above mentioned positions, the term of office will be for 2 years (1 Jan 2019 - 31 Dec 2020). The position could be renewable for other two more terms if the work for the Group is deemed essential at that time. The work is mainly conducted by e-mail and teleconferencing, the WG usually meets once per year.

Procedure for applications: each EFLM National Society Member in good standing with the membership fee can submit one nomination using the form circulated to the National Society's representatives to be sent back to silvia.cattaneo@eflm.eu. A brief plan of the applicant's contribution to the aims and objectives of the relevant Working Group has to be included in the form. Together with the application, a short CV should also be submitted underlining the qualifications and prior experience and publications in the relevant area. Candidates have to be officially recommended by their National Society through a formal letter of support. Applicants who are not selected as full members may be eligible for corresponding membership.

EFLM BURSARY PROGRAMME

EFLM BURSARY PROGRAMME TO ATTEND THE

5th EFLM CONFERENCE ON PREANALYTICAL PHASE

"Preanalytical challenges - time for solutions"



<http://www.preanalytical-phase.org/>

This is to inform you that EFLM is promoting a bursary programme for young scientists attending the 5th EFLM Conference on Preanalytical Phase to be held in Zagreb on 22-23 March 2019.

A limited number of bursaries is available, the bursaries will cover the cost of the travel and 2-night accommodation for a maximum of Eur 750,00. EFLM bursary recipients will also receive the free conference registration and a free on-line yearly subscription to CCLM, kindly offered by W. de Gruyter.

Eligible candidates must come from an EFLM Member Society and meet the following criteria:

- Young participants (≤ 35 y at the date of the conference);
- Having a poster abstract accepted as First Author (deadline for abstract submission December 1, 2018)

Applications must be submitted through the dedicated application form (downloadable from www.eflm.eu) and accompanied by the following documentation:

- 1) Copy of the ID or passport,
- 2) Document proving the membership to the National Society,
- 3) Notification of poster acceptance (acceptance/rejection will be sent by the conference organizers within January 13)

Applications have to be sent to silvia.cattaneo@eflm.eu within January 31, 2019.

We assume that people submitting the application for the bursary have already decided to attend the conference (having an abstract accepted). So we expect that non-selected applicants do not withdrawn the abstract. Thanks!

With kindest regards,

Daria Pasalic

Chair of the EFLM Education and Training Committee



UPDATES OF THE EFLM PUBLICATION LIST

Quite a number of interesting papers by EFLM functional units have been published recently

by Maria Stella Graziani, Chair of the Communication Committee

This is a very important achievement of EFLM and its WG on pre-analytical phase and a joint effort between EFLM and COLABIOCLI

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling.

Simundic AM, Bolenius K, Cadamuro J, Church S, Cornes MP, van Dongen-Lases EC, Eker P, Erdeljanovic T, Grankvist K, Joao Tiago JT, Hoke R, Ibarz M, Ivanov H, Kovalevskaya S, Kristensen GBB, Lima-Oliveira G, Lippi G, von Meyer A, Nybo M, de la Salle B, Seipelt C, Zorica Sumarac, Vermeersch P on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WGPRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI).

Clin Chem Lab Med 2018 doi 10.1515/cclm-2018-0602

The document provides practical guidance for ensuring a safe and patient-centred blood collection. The target audience for the recommendation (based on the best available evidence) are healthcare staff members directly involved in blood collection. To facilitate implementation of the recommendation, the WG-PRE has prepared a number of tools that are freely available at the EFLM web site dedicated page (<https://www.eflm.eu/site/page/a/1194>). Professionals are encouraged to adopt the procedure and download and use the tools to establish a quality system and to maintain and continuously improve the quality of a harmonized procedure for blood collection across Europe and South America.

Two more papers by the very active WG on Biological variation.

Biological variation estimates for prostate specific antigen from the European Biological Variation Study; consequences for diagnosis and monitoring of prostate cancer.

Carobene A, Guerra E, Locatelli Ma, Vito Cucchiara Vc, Alberto Briganti A, Aarsand AK, Coşkun A, Díaz-Garzón J, Fernandez-Calle P, Røraas T, Sandberg S, Jonker N, Ferruccio Ceriotti C, on behalf of the EFLM Working Group on Biological Variation

Clin Chim Acta 2018;486:185-91.

Providing Correct Estimates of Biological Variation—Not an Easy Task. The Example of S100- Protein and Neuron-Specific Enolase.

Carobene A, Guerra E, Locatelli M, Ceriotti F, Sandberg S, Fernandez-Calle P, Coskun A, Aarsand AK on behalf of the EFLM Working Group on Biological Variation.

Clin Chem 2018; doi: 10.1373/clinchem.2018.292169.

These two papers present robust data on biological variation (BV) of prostate specific antigen, protein S100 and Neuron-Specific Enolase, confirming once again that the adoption of the Biological Variation Data Critical Appraisal Checklist (BIVAC), recently published by the same group allows obtaining reliable Reference Change Values and more stringent analytical performance specifications with significant clinical implications for patient monitoring.

A stimulating review on the role of personalized medicine

Personalized laboratory medicine: a patient-centered future approach.

Prodan Zitnik I, Cerne D, Mancini I, Simi L, Pazzagli M, Di Resta C, Podgornik H, Repic Lampret B, Trebusak Podkrajsek K, Sipeky C, van Schaik R, Brandslund I, Vermeersch P, Schwab M, Marc J on behalf of EFLM/ESPT Working Group of Personalised Laboratory Medicine Clin Chem Lab Med doi.org/10.1515/cclm-2018-0181.

The review is focused to illustrate the growing importance of personalized medicine within laboratory medicine profession in the near future. This specific approach will allow a more effective diagnostics with more effective and safer treatments: to reach these goals, however there is an urgent need of a more stringent cooperation between different disciplines within laboratory medicine.

SEQC^{ML}

Sociedad Española de Medicina de Laboratorio

NEWS FROM EFLM NATIONAL SOCIETIES

News from the Spanish Society of Laboratory Medicine (SEQC^{ML})

XVI Conferences of the Scientific Committee of the Spanish Society of Laboratory Medicine (SEQCML)

The use of biomarkers improves the diagnosis and treatment of autoimmune diseases

- The new edition of the SEQCML Scientific Committee Conferences has allowed professionals to update their knowledge of biological markers
- The use of these techniques in the clinical laboratory to detect neurological and hormonal autoimmune diseases, among the highlighted topics
- In the conference, which included six courses, the techniques of massive DNA sequencing were also examined in depth

Madrid, May 24, 2018 - In recent years there have been important advances in the development and incorporation into the clinical laboratory of new biomarkers-biological indicators that can be used in medicine to understand the processes that are taking place in an organism. These advances mean that healthcare professionals specializing in this field are in constant need of updating their knowledge. With this in mind, the XVI Conference of the Scientific Committee of the Spanish Society of Laboratory Medicine (SEQCML) was held, in which experts in different areas of the laboratory gave a total of six courses to help spread awareness of the latest developments in this field.

These courses addressed aspects such as biomarkers applied to endocrine or neurological diseases and the massive sequencing of DNA, and sought to increase attendees' skills and knowledge of these analytical techniques, which allow identification of diseases via the presence of different molecules in the body. The clinical usefulness of the different biomarkers was analyzed, in both the diagnosis and the management of these diseases. New recommendations and protocols were also presented.

One of the highlights of this new edition of the Scientific Committee Conferences was the use of these biomarkers to detect autoimmune neurological diseases. One of the courses, organized by the SEQCML Committees of the Biochemistry of Immunological Diseases and of Neurochemistry and Neurological Diseases, sought to expand knowledge in this "continuously developing area". "New autoantibodies associated with neurological autoimmune diseases are constantly being described; at the same time that the clinical application of new and existing markers is being analyzed and reviewed," explains Dr. Concepción González, Head of the Clinical Biochemistry Section of the Virgen Macarena University Hospital (Sevilla), who participated in the aforementioned course.

An autoantibody is an antibody developed by the immune system that acts directly against one or more antigens of the individual itself. As explained by Dr. José Luis García de Veas, a specialist in Clinical Analysis and Clinical Biochemistry at the Campus de Salud University Hospital (Granada), each year between two and four new autoantibodies are identified that are associated with diseases such as autoimmune encephalitis or paraneoplastic neurological syndromes, among others. "This has allowed us to significantly improve the diagnosis and treatment of these pathologies, and therefore it is necessary to stay up-to-date in this area". In this course, the autoantibodies associated with the aforementioned diseases were presented as well as the techniques used to identify them. This course was recommended, in addition to laboratory professionals, for neurologists who care for these patients, "as they will have a vision of what the autoimmunity laboratory can provide depending on the patient's pathology", concludes Dr. García de Veas.

Hormonal markers

Another topic that was a focus of the courses of the SEQCML XVI Conference of the Scientific Committee was the analyses applied to hormonal diseases and endocrine system. The course 'Protocols of diagnostic orientation and monitoring in endocrine pathology' offered specific information on the different biochemical tests available today to analyze endocrine pathologies and diagnostic algorithms suitable for diagnosis and monitoring in these diseases.

"In recent years many laboratories have expanded their activity in hormonal measurements. This has created a need for professionals to be involved in the development of diagnostic protocols, with the aim of adapting to the new scientific guidelines and ensuring that a greater number of clinicians (specialists or family doctors) make the request for testing in a more rationalized way", explained Dr. Eulàlia Urgell, of the Biochemistry service of the Santa Creu and Sant Pau Hospital (Barcelona) and Dr. Roser Ferrer, of the Vall d'Hebron University Hospital (Barcelona), both coordinators of the course.

"This course responds to the need to stay up-to-date and offer a broad and specific training on the protocols used and endorsed by different scientific societies for diagnostic orientation and monitoring in endocrine pathology. A series of objectives to be developed have been established in order to offer a tool for the different biochemical tests currently available, so as to be more efficient and effective in the diagnosis and monitoring of the most common endocrine pathologies," they explained.

DNA sequencing

Lastly, another of the key topics of the conference was genome sequencing. In the course 'Massive sequencing: methodological aspects and interpretation of data', the currently available sequencing platforms were presented, along with the methodology used by each of them and their limitations, emphasizing the genetic alterations that massive sequencing does not allow us to detect. In addition to briefly explaining the bioinformatic analyses that are carried out in this type of study, the course explained how the analysis of the data generated by this computational process is carried out at present.

"Massive sequencing by itself is a very new technology, of recent implementation in public centers for genetic diagnosis. But in addition, commercial kits, bioinformatic analysis, and databases are evolving and improving by leaps and bounds, which is allowing for increasingly high quality analysis," explains Dr. Pilar Carrasco Salas, of the Genetics Unit of the Juan Ramón Jiménez Hospital (Huelva), who noted that the course she offered was aimed at those professionals who dedicate or want to dedicate themselves to the diagnosis of hereditary diseases.

The SEQC^{ML}

The Spanish Society of Laboratory Medicine (SEQCML) -founded in 1976- now includes more than 2,500 professionals and has as its main objective to bring together all interested scientists in the field of the Clinical Laboratory, to promote the dissemination of scientific and technical publications, to organize meetings, courses, and congresses of national and international character, and to cooperate with other scientific societies. Likewise, the Society aims to contribute to the study and recommendation of standardized methods and to establish guidelines and recommendations for training in the field of Laboratory Medicine.
For more information: www.seqc.es



Fundación JL Castaño
SEQC

XVI JORNADAS COMITÉ CIENTÍFICO

6 Cursos organizados por Comisiones de la SEQC^{ML}

24 – 25 de Mayo de 2018

MADRID

SEQC^{ML}



Snapshots of different courses during the SEQCML Scientific Committee Conferences

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3-5 October 2018

26th Meeting of Balkan Clinical Laboratory Federation and the 6th National Congress of the Macedonian Society for Medical Biochemistry and Laboratory Medicine

Skopje, Macedonia

<http://www.bclf.info/index.htm>

11-13 October 2018

16th EEKX-KB National Congress of Clinical Chemistry

Paris (FR)

<http://www.eekx-kb.gr/>

4-6 October 2018

9th Russian Conference on Clinical Hemostasiology and Hemorheology

St Petersburg, Russia

<http://coith2018.com/en/main>

16-17 October 2018

2^{èmes} Journées Francophones de Biologie Médicale

Paris (FR)

www.jfbm.fr

10-13 October 2018

5th EFLM-UEMS Joint Congress

Laboratory Medicine at the clinical interface

Antalya, Turkey

<http://eflm-uems-antalya2018.org/>



7-8 December 2018

JBP 2018 - Journees de Biologie Praticienne

Paris (FR)

mf.gaudeau.toussaint@gmail.com

16-18 October 2018

**50th National Congress of S.I.Bio.C. - Laboratory Medicine
"Innovation in Laboratory Medicine"**

Naples, Italy

<http://congresso.sibioc.it/2018/home>

24-27 December 2018

ICB 2018 - 2nd International Congress on Biomedicine

Tehran, Iran

<http://www.icb2018.com/>

18-19 October 2018

EQALM Symposium 2018

Zagreb, Croatia

www.eqalm.org

7-8 February 2019

International Congress on Quality in Laboratory Medicine

Helsinki, Finland

<https://www.labquality.fi/en>

24-26 October 2018

LABCLIN 2018 - XII National Congress of Clinical Laboratory

Bilbao, Spain

www.labclin2018.es

22-23 March 2019

**5th EFLM-BD European Conference on Preanalytical Phase
Biannual Conference organized by the EFLM Working Group on
"Preanalytical Phase" in collaboration with BD**

Zagabria, Croatia

<http://www.preanalytical-phase.org/>



26-30 October 2018

**International Biochemistry Congress 2018 / 29th National
Biochemistry Congress of TBS**

Bodrum, Turkey

<https://www.biyokimyakongresi.org/>

4-5 April 2019

**10th European Symposium on Clinical Laboratory and In Vitro Diagnostic
Industry 'The clinical laboratory in the pregnancy monitoring'**

Barcelona, Spain

<http://www.iec.cat/jornades/laboratoridclinic2019.asp>

30 October 2018

**International Conference on Laboratory Medicine "Laboratory
Medicine: 25 years on"**

Padova (IT) <http://www.lccongressi.it/laboratorymedicine2018/>

18 May 2019

**VII International Symposium Laboratory Medicine and Quality.
Satellite Meeting EuroMedLab 2019**

Barcelona, Spain

www.seqc.es

13 November 2018

Workshop on Alzheimer's Disease "Making the point"

For more information: pragueworkshop2018@cbttravel.cz

Prague, Czech Rep.

19-23 May 2019

EuroMedLab 2019

**23rd IFCC-EFLM European Congress of Clinical Chemistry and
Laboratory Medicine**

Barcelona, Spain

<http://www.euromedlab2019barcelona.org>



27 November 2018

Preanalytical mysteries

EFLM webinar

on-line

<https://elearning.eflm.eu>



29 November 2018

**12th International Scientific CIRME Meeting "Standardization
in Laboratory Medicine and Patient Safety"**

Milan (IT)

<http://users.unimi.it/cirme/home/>

19 May 2019

**International Symposium: Standardization
and Recommendations in the Laboratory of Haematology.
Satellite Meeting EuroMedLab 2019**

Barcelona, Spain

www.seqc.es

29 November 2018

**Place and role of the medical biology and lab medicine in the
Health System Transformation Strategy**

Paris, France

[Click here for information](#)

9-12 June 2020

XXXVII Nordic Congress in Medical Biochemistry

Trondheim, Norway

www.nfkk2020.no



**MAY 19-23, 2019
CCIB, BARCELONA, SPAIN**



www.euromedlab2019barcelona.org

**23TH IFCC-EFLM EUROPEAN CONGRESS OF CLINICAL CHEMISTRY AND LABORATORY
MEDICINE • NATIONAL CONGRESS OF THE SPANISH SOCIETY OF LABORATORY MEDICINE**

EFLMLabX: Laboratory Exchange Programme

a database of medical laboratories willing to offer practical education/training in different specialties of Laboratory Medicine where Specialists can search for practice

to know more: <https://efmlabx.eflm.eu/en>

EFLMLabX: the experience of an hosting laboratory



by Olga M. Koper, Dept of Clinical Laboratory Diagnostics, Med. Univ. of Białystok Poland

Last week an applicant from Ukraine (Zoryana Lavro, MD from the University of Lviv) attended our training at the Department of Clinical Laboratory Diagnostics in the Medical University of Białystok (Poland).

It was a great opportunity to exchange experiences and to collect even small bits of information about how laboratory diagnostics works in Ukraine.

The language barrier did not stop us from communicating, we talked in three languages: Polish, English and Ukrainian. I think that our offer is especially attractive for our eastern neighbors.

Currently, I am exploring opportunities for free accommodation at our University's dormitory for future applicants, which will make our offer even more encouraging. In my opinion, EFLMLabX is a very good project and we look forward to receiving new applications!

From left: Dr Olga M. Koper, Zoryana Lavro, MD, Dr Joanna Kamińska and Prof Joanna Matowicka-Karna

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