EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

Issue n. 6/2020

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Happy Holiday Season

Season's Greetings from the President of the EFLM

Dear colleagues and friends of Laboratory Medicine, unfortunately, this year has been unexpectedly challenging for all of us, both professionally and personally. The COVID-19 pandemic has impacted all aspects of activities around the world. It has been overwhelmingly demanding for healthcare systems in general and has put Laboratory Medicine on the first line of the fight against the pandemic. Besides many repercussions, the pandemic has accelerated the digitalization processes and has caused that most of the events have moved to on-line platforms or have been cancelled or postponed, waiting for better times. It was not different in EFLM. The EFLM Executive Board (EB) has decided to cancel the 3rd EFLM Strategic Conference 2020 and all EFLM short postgraduate courses planned for 2020, as well as all visits of the Executive Board members to National society meetings. The 6th EFLM Conference on Preanalytical Phase has been postponed to 2022 and EuroMedLab Congress has also been postponed from May 2021 to November 2021. Despite many difficulties we have faced, I dare to say that 2020 was fruitful for EFLM. We have undoubtedly expanded, improved and promoted many of our activities. Maybe the most important EFLM project in 2020 was a launch of the EFLM Academy in January 2020. Today, along EFLM National Societies' members, Academy is open to all individuals (even non-European) interested in Laboratory Medicine, as well as to representatives from In Vitro Diagnostic (IVD) companies.

To be continued on page 2

Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews

The EFLM President Ana-Maria Simundic inaugurates this year's final EuroLabNews issue with her Season's Greetings and recaps this quite eventful years happenings. Christa Cobbaert and Michael Neumaier, co-chairs EFLM Task Force European Regulatory Affairs, are the authors of this issue's Hot Topic column, present the challenges implicated in the In Vitro Diagnostic Medical Devices Regulation. Giuseppe Lippi, EFLM Executive Board Secretary, informs the readers about the postponement of the EuroMedLab 2021 congress. Aasne Karine Aarsand, Chair of the EFLM WG "Biological Variation" and Sverre Sandberg, Chair of the EFLM TG "Biological Variation Database" remember Thomas Roraas who passed away unexpectedly as a pioneer of various indispensible mathematic models. Alexander von Meyer, Chair EFLM Working Group "Preanalytical Phase" reports on preanalytic errors in the Emergency Departments with an invitation to participate in a survery. Eser Sozmen, Chair EFLM Working Group "Congresses and Postgraduate Education" introduces the EFLM Speakers' Bureau, please take their survey to help improve their mission. Silvia Cattaneo, EFLM office reports on the latest vacancy in the EFLM. As a regular column in the EuroLabNews, dedicated members of the EFLM WG Promotions and Publications present recent state of the art EFLM publications with ingenious infographics. The Croatian Society of Medical Biochemistry and Laboratory Medicine, and the Spanish Society of Laboratory Medicine report their latest activities.

To be continued on page 2

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To send your news or advertisement for publication on the newsletter write to: news@eflm.eu

Continued from Foreword

The IFCC corner presents the IFCC Presidents' Message along with a number of vacancies at the IFCC. The Calendar of Events lists all major happenings in our field but please a close eye on the dates. Despite the odds, the dedicated EFLM Newsletter team has tried its best to keep the readership informed on all important events in the EFLM, and we all wish our readers good health, a peaceful festive season and a Happy and Prosperous New Year.

Continued from Season's Greetings from the President of the EFLM

The Academy has so far gained an impressive number of more than 4350 members, and besides other benefits has offered five successful and highly attended webinars, organized via EFLM e-learning platform. EFLM webinars have been a great opportunity for our colleagues to learn about COVID-19 biology and diagnostics, communication, leadership, management, POCT and Urinalysis. For 2021, EFLM continues with this form of education and here I wish to announce three exciting upcoming webinars which will cover very important topics for our everyday work: the verification of quantitative and qualitative methods as well as verification of the indirect methods reference intervals.

With pleasure I also wish to note that one new full member (The Laboratory Medicine Association of Georgia) and three new affiliate members (The Academy of Clinical Science and Lab Medicine, Ireland, Serbian Society for Clinical Laboratory Medicine, Serbia and The Order of Biochemists, Biologists and Chemists in the Romanian Health System, Romania) have joined EFLM in 2020. Welcome on board!

The numerous EFLM's working groups and task forces have been very successful in publishing the results of their studies (14 publications in high impact journals). Furthermore, EFLM has been increasingly active in virtual space and social networks, gaining an exponentially growing number of followers and members.

Collaboration with other biomedical societies and organizations has been set as one of the main goals of EFLM. EFLM has been accepted to the Biomedical Alliance in Europe, an organization representing 33 leading biomedical societies in Europe and more than 400,000 researchers and health professionals. As its member, EFLM has taken part in a critical initiative initiated during the peak phase of spring COVID-19 pandemic with the aim to persuade the decision-makers in Europe to support the uninterrupted functioning of all medical and research societies throughout Europe. Furthermore, EFLM focuses on taking an active role in regulation- and policy-making in Europe. Therefore, we have founded a new Task Force on European Regulatory Affairs, which will have an important role during meetings and consultations of the European Commission (EC) regarding interpretation and operationalization of the IVD Regulations.

To encourage and expand the professional and scientific development and exchanges of our colleagues from EFLM National Societies coming from lower income countries, according to UN and World bank classification criteria, the EB has decided to launch an EFLM bursary programme. The new bursary programme is dedicated to the memory of the first president of EFLM prof. Vic Blaton. Although the programme is designed with a wide range of opportunities for our colleagues, due to COVID-19-related uncertainty we are at the moment able to offer only the EFLM Academy memberships. One of the key aims of EFLM is to attract young colleagues, who definitely are the future of EFLM. We hope they will be encouraged by these exciting opportunities to join the EFLM and get involved in many of its activities.

I would like to share my appreciation and gratitude for witnessing the optimism and devotion of all our committees' and working groups' members and colleagues from national societies. They have shown the will and readiness to adjust and overcome challenges and obstacles set before all of us in these difficult times. I take the opportunity to also welcome a number of new enthusiastic colleagues who have recently joined various Committees, Working groups and Task forces in EFLM. Thanks to all of you, EFLM is rapidly moving forward! I wish to express my sincere thanks and appreciation to all of them. Thank you all very much!

Finally, with hopes that we will overcome this ongoing crisis together, I send you my best wishes for forthcoming holidays and a happy and successful start in 2021. Please keep yourself and your loved ones safe and healthy.

Ana-Maria Šimundić, EFLM President

HOT TOPICS IN LABORATORY MEDICINE

First encounter with the EFLM Task Force on European Regulatory Affairs

Reported by Christa Cobbaert and Michael Neumaier, co-chairs
EFLM Task Force European Regulatory Affairs

New and far-reaching EU legislation has to be implemented in all EU Member States by May 2022: the In Vitro Diagnostic Medical Devices Regulation (IVDR). Succinctly, the IVDR will increase the requirements for clinical evidence aiming to ensure clinical benefit and safety of IVDs, including post-market vigilance. The IVDR will substantially increase the involvement of Notified Bodies, which are independent conformity assessment institutions nominated by the national competent authorities of European member states. Assessments and audits by Notified Bodies will be required under the IVDR for the vast majority of diagnostic tests (class B, C and D tests). Furthermore, this will be complemented via European Commission-nominated EU Reference Laboratories (EURLs) tasked to validate specific high-risk tests (class D tests, i.e. infectious agents and blood group testing). Laboratory Developed Tests (LDTs) are exempted from the full impact of IVDR, but are only justified in healthcare institutions, if no other equivalent tests with similar performance are on the market. Non-existence of such marketed tests has to be shown. The impact of the IVDR on commercial labs with high numbers of LDTs will be substantial as these labs will be required to CE-mark their LDTs. The implementation of the IVDR is managed by the European Commission (DG SANTE) and the National Competent Authorities, who steer several working groups under the umbrella of the Medical Device Coordination Group (MDCG). The IVDR represents both **opportunities and**

threats for the medical laboratory and the diagnostic industry, with variable implications for private, public and commercial labs or healthcare institutions. In any case, laboratories will face strong increases of bureaucratic and administrative work generating additional workload.

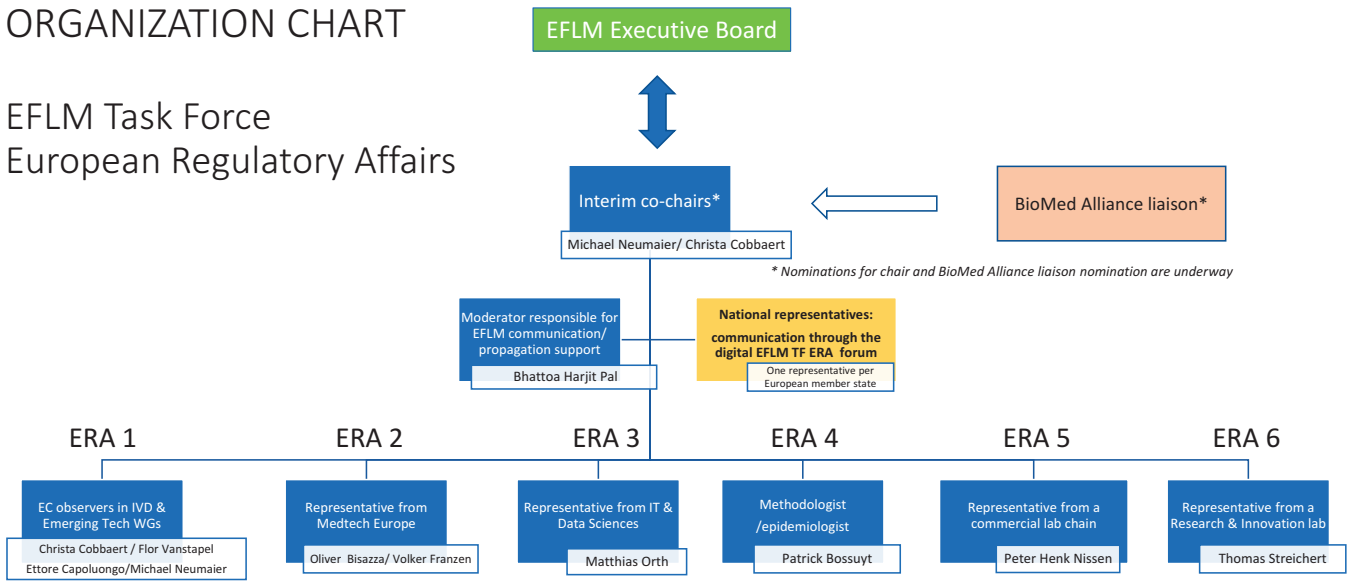
Because of the huge IVDR implications for all IVD-stakeholders and patients, the EFLM Executive Board has established a Task Force on European Regulatory Affairs (TF-ERA). In this newsletter, we want to explain the organigram of TF-ERA and the tasks of the Task Force members nominated by their national societies as well as the tasks of the associated National Representatives nominated by the different European member states (Figure 1). The Task Force ERA consists of ~13 members: next to the chair and a moderator tasked with communication and moderation, there are two observers and two back-ups representing EFLM as a stakeholder in "the IVD-group" and "the Emerging Technology working group" within the MDCG of the European Commission (ERA1). Two members from MedTech Europe with expertise in regulatory affairs represent the affiliated IVD-manufacturers (ERA2). Four nominated members who cover different aspects and perspectives of IVDR such as IT & data Sciences (ERA3), methodology (clinical evidence requirements) (ERA4), the commercial lab chain perspective (ERA5) and research & innovation (ERA6). Very recently, EFLM became a regular member of the BioMed Alliance featuring numerous European clinical and scientific societies (see below). TF-ERA will install a member as liaison to BioMed Alliance to report to the chair. The EFLM TF ERA chair reports directly to the EFLM President and EFLM Executive Board. The nominated TF-ERA members and national representatives are displayed at https://www.eflm.eu/site/page/a/1653. The terms of reference of the EFLM TF ERA are specified at https://www.eflm.eu/site/page/a/1650. It is important to realize that the interaction with the EU authorities and Working Groups is extensive, multi-facetted and demands short response times and actions, thereby requiring an appropriate structure within TF-ERA.

Below, we want to give some specific insights into the major tasks: the TF-ERA observers to the MDCG working groups of the European Commission (EC) are, according to their role, "at the table" during meetings and consultations of the European Commission regarding interpretation and operationalization of the IVDR. The chair (currently 2 co-chairs) is (are) responsible for organizing the monthly virtual meetings and for setting the agenda. The moderator is responsible for drafting minutes during the EFLM TF-ERA virtual meetings and for posting relevant updates and documentation in the TF-ERA forum library, including rapid dissemination of EC guidance documents that demand consultation and input for the national representatives. The moderator also gathers the digital responses and questions from National Representatives from the forum and structures and shares these with the chair (co-chairs), at least 10 days ahead of the next virtual meeting. The other TF-ERA members and the MedTech Europe representatives will provide input on relevant aspects of the IVDR transitioning, in their roles and from the perspective they are expected to cover. All TF-ERA members bring in relevant guidance documents and summarize them effectively to enhance the efficiency of the virtual meetings. The national societies are informed monthly through their national representatives.

The EFLM TF-ERA intends to take a proactive role in the transitioning to IVDR implementation per May 2022 through its functional governance and communication structure, which aims to consult with the political implementation process of the European Commission where needed. Providing such guidance must be done through the national competent authorities of all European members states in order to guarantee a smooth and justifiable IVDR implementation. Because the medical laboratory´s work in patient care will experience a major impact by the IVDR implementation, it needs to assure to be "heard in the EC" during the implementation period. EFLM recently became a member of Biomed Alliance, a non-profit organization representing over 30 leading European research and medical societies involved in both diagnostic and therapeutic care of all EU citizens. BioMed Alliance has a long-standing and acknowledged expertise in regulatory aspects of Medical Devices. With TF-ERA, EFLM contributes an important expertise to the IVD arm of medicine within the EU regulatory frameworks. Indeed, EFLM is geared up to contribute expertise through several WGs, TFs sand TFGs.

Specifically, TF-ERA reaches out to existing EFLM working groups and committees working on related content, among them the EFLM Working group on Test Evaluation (WG-TE), the EFLM Quality and Regulations committee (C-QR) and the TF for Disruptive Technologies (TF-DT). In essence, TF-ERA will share regular updates on the availability of essential infrastructure that is needed for proper IVDR implementation (such as Notified bodies, European Reference Laboratories, Expert Panels and a contingency plan) as well as guidance documents from the European Commission that have to be commented upon at short notice. To reach out quickly to all European National Societies through the nominated national representatives, the digital TF-ERA forum has been set up (https://www.eflm.eu/site/page/a/1650) and is now operational. Access to the TF-ERA forum is restricted to TF-ERA members. National representatives provide a direct conduit to their respective National Societies and are expected to take responsibility for the communication with their professional societies or national competent authorities. The ultimate goal of the EFLM TF-ERA activities is to guarantee EU-wide uninterrupted access to clinically effective, affordable and safe medical tests.

With 18 months to go until the application date of the IVDR, the clock is ticking for its implementation, and there are numerous important issues still to be addressed. So far, the European Commission did not officially react on the Calls for Action from



BioMed Alliance and MedTech Europe. Both organizations recently called on the European Commission to address their concerns about various delays related to the implementation of the IVDR (EU 2017/746). If the European Commission has insufficient capacity to meet the concerns of the diagnostic health sector, then the date of application of the IVDR should be postponed. Other calls for specific actions by the European Commission relate to the necessity of having EU-wide derogations for medical testing in case of crisis management - such as the COVID-19 outbreak, and to have assurance about appropriate implementation of the IVDR for LDTs.

Last week a long-awaited guidance document from the MDCG of the EC on the risk-based Classification of Medical Tests has appeared and is now available. I.e. MDCG 2020-16, entitled: Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746 November 2020. The full guidance document can be approached at https://ec.europa.eu/health_/sites/health/files_/md_sector/docs/md_mdcg_2020_guidance_classification_ivd-md_en.pdf. The deadline for sending comments is 30 November 2020.
In conclusion, TF-ERA is a multi-national Working Group interconnecting with diagnostic and clinical societies to assist in smooth transition of laboratory tests during the implementation phase of the EU IVDR. We believe that it is essential to warrant adequate laboratory testing and diagnosis in the interest of patient safety and improved patient outcome under an active EU-wide IVD regulation.

EFLM EXECUTIVE BOARD INFORMS

EuroMedLab 2021's postponement to November 2021

Reported by Giuseppe Lippi, EFLM Executive Board Secretary

EUROMEDLAB 2021 MUNICH

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

EFLM European Federation of Clinical Chemistry and Laboratory Medicine

DGKL Deutsche Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V.

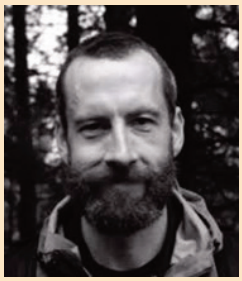
http://www.euromedlab2021munich.org/

The IFCC and EFLM Executive Boards, in consultation with the German Society for Clinical Chemistry and Laboratory Medicine e.V. (DGKL) and MZ Organising Secretariat, have arrived at the difficult and undesired decision to reschedule the upcoming EUROMEDLAB Congress from May 2021 to November 2021.
This choice has been determined by the uncertainties due to COVID-19 in the coming months, including major international travel restrictions.
The 24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine along with the National Congress of the German Society of Clinical Chemistry and Laboratory Medicine will now be held on **28 November - 2 December 2021.**
The venue remains the same: the ICM Internationales Congress Center München - Germany.
Please mark this new date in your calendar!
We apologise for any inconvenience caused and look forward to seeing you in November

NEWS FROM EFLM FUNCTIONAL UNITS

In memory of Thomas Røraas

Reported by Aasne Karine Aarsand, Chair of the EFLM WG "Biological Variation" and Sverre Sandberg, Chair of the EFLM TG "Biological Variation Database"



With great sorrow, we inform the EFLM community about the unexpected and premature death of Thomas Røraas. Thomas was a mathematician who developed many of the new models used to calculate biological variation components. He also designed the meta-analysis that delivers global biological variation estimates in the EFLM Biological Variation Database.

Thomas was Expert/Consultant in both the EFLM Working Group "Biological Variation" and the EFLM Task Group "Biological Variation Database" and essential to this work. He was a humble and kind soul with a great sense of humor and was very knowledgeable both in his field as well as in other aspects of life. His work will remain an important contribution to the area of biological variation and to the establishment of the EFLM Biological Variation Database. He will be greatly missed.

From TG-BVD and WG-BV meeting in Barcelona, 2017

Preanalytical errors in Emergency Departments

Reported by Alexander von Meyer, Chair EFLM Working Group "Preanalytical Phase"

EFLM is collaborating with the European Society for Emergency Medicine (EUSEM) and the European Society of Emergency Nursing (EuSEN) on a project concerning preanalytical errors in Emergency Departments which are currently facing serious challenges. Preanalytical errors affect the performance of Emergency Departments negatively and compromise the quality of care.
The aim of this collaboration is to have a deep understanding of the problems in the preanalytical phase affecting the performance indicators, like the total time in the Emergency Department. To do that, a survey on blood sampling has been assembled with the following objectives:
General:

- To have a deep understanding of the Preanalytical Phase Process (PPP) in the Emergency Department
- To identify the use of key performance indicators (KPI) in the PPP

Specifically:

- To evaluate the use of the KPI
- To estimate the rate of rejections

We will appreciate your participation, especially considering the actual COVID-19 pandemic. This survey takes approximately 10 minutes to finish. The results of this survey will give us a clear understanding of the preanalytical phase in the emergency department. **The survey will remain accessible till December 7, 2020**. Please feel free to invite other laboratories to take part in this survey and thanks in advance for your collaboration.

CLICK HERE TO ACCESS THE SURVEY
The survey has 29 multiple-choice questions for an easy compiling

Click here to preview the questions of the survey

The EFLM Speakers' Bureau: how do you want it?

Reported by Eser Sozmen, Chair EFLM Working Group "Congresses and Postgraduate Education"

The EFLM Speakers' Bureau is a list of outstanding speakers, selected among current and former EFLM officers, indicating the specific expertise for each of them. This list aims to represent a tool for EFLM National Societies when searching for a speaker on a specific topic for National and local scientific events.
The current EFLM Speakers's Bureau was assembled many years ago and therefore the EFLM WG on Congresses and Postgraduate Education has prepared a survey with the aim to collect expectations from EFLM National Societies before preparing the new version, in order to offer the most beneficial tool tailored on the needs and suggestions received. Please take part in the survey because "we are working for you" to offer a tool tailored on your needs! **The access to the survey will remain open till 31 December 2020**. Thanks for your collaboration!

CLICK HERE TO ACCESS THE SURVEY
Do not hesitate to take part, the survey takes only 5' of your time!

VACANCIES IN THE EFLM FUNCTIONAL UNITS

Vacancy in the EFLM Working Group "Postanalytical Phase"

Reported by Silvia Cattaneo, EFLM Office

Starting from January 1, 2020 there will be a vacancy in the EFLM WG "Postanalytical Phase" (WG-POST) and EFLM invites its National Societies to send nominations for a position as Full Member. **The deadline to send nominations is 20 December 2020.**

Clinical knowledge and skills combined with laboratory expertise are needed for optimal interpretation of laboratory results in the setting of the individual patient. Increasing number of studies emphasise the need for improving the clinical utilisation of laboratory tests and that laboratory professionals should play a more prominent role in this optimization process. A spectrum of activities has been identified to assist clinicians in translating specific laboratory results to diagnostic information but too few is known about how these activities are practiced in laboratories and the aim of this WG, currently chaired by Ann-Helen Kristoffersen (Norway) is focused on that.

Here below the Terms of Reference of the WG-POST:

- to promote the importance of those activities that can improve clinical utilisation of laboratory tests in the postanalytical (PA) and post-postanalytical (PPA) phases including assisted test requesting (AR);
- to support laboratories in taking an active, prominent role in the above activities when they assist clinicians in finding the appropriate laboratory tests to meet their clinical needs and in translating the laboratory results to diagnostic information;
- to develop and organise surveys and external quality assurance (EQA) programmes focusing on laboratory and/or clinical aspects of the above activities in European laboratories;
- to provide a scientific paper and a feedback report summarising the main findings of each survey and updating the recent literature of the investigated practice on each project.

The term of office will be for 2 years (1 Jan 2021 - 31 Dec 2022). 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 (COVID-19 permitting).

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 must 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 must 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.

Platelia SARS-CoV-2 Total Ab Assay

Detection of IgM, IgA, & IgG In One Test

High Specificity. No Cross-Reactivity. High Sensitivity.

This Total Antibody assay is designed for the detection of total anti-nucleocapsid antibodies (IgM, IgA, IgG) to SARS-CoV-2 all in one test. Granted FDA EUA for testing in the U.S. and CE-IVD authorization, this microplate assay is recommended for use on Bio-Rad EVOLIS instruments and stand-alone instruments.

Bio-Rad is your partner in COVID-19 testing.

Learn more about this Total Antibody serology assay and our other solutions at bio-rad.bz/EFLM

BIO-RAD

FDA Emergency Use Authorization
This test has been authorized by the FDA under an EUA for use by authorized laboratories. The test has not been FDA cleared or approved. The test has been authorized only for the presence of total antibodies against SARS-CoV-2, not for any other viruses or pathogens. The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

European Biological Variation Study (EuBIVAS): within- and between-subject biological variation estimates for serum biointact parathyroid hormone based on weekly samplings from 91 healthy participants

Bottani M, Banfi G, Guerra E, Locatelli M, Aarsand AK, Coşkun A, Díaz-Garzón J, Fernandez-Calle P, Sandberg S, Ceriotti F, González-Lao E, Simon M, Carobene A, and on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Ann Transl Med 2020; Available from: https://doi.org/10.21037/atm-19-4498

Reported by Aleksei Tikhonov, member-young scientist of EFLM WG-Promotion & Publications

The European Biological Variation Study (EuBIVAS) was created by the EFLM Working Group on Biological Variation to establish high-quality biological variation (BV) estimates for clinically important measurands. In this study, the aim was to deliver reliable BV estimates for the biointact parathyroid hormone (PTH 1-84).

The within-subject BV [CV_I (95% CI)] estimates were significantly different between men and women [13.0% (12.1–14.2%) and 15.2% (14.3–16.3%), respectively], while the between-subject estimates [CV_G (95% CI)] were similar (men: 26.8% (21.4–35.1%), pre-menopausal women: 27.8% (22.7–36.1%)], allowing for delivery of updated analytical performance specifications and reference change values.

The EuBIVAS CVI estimates were lower than those delivered by previously published papers on biointact PTH, possibly related to different statistical approaches and to the strict control of the fasting status. These EuBIVAS BV estimates, together with a suitable interpretation of the PTH 1-84 concentration changes, represent a key tool in medical practice for a correct diagnosis and monitoring of bone turnover and parathyroid glands pathologies, for patient management, for creating standardized protocols for the pre-analytical, analytical, and post-analytical stages of PTH evaluation, and for giving information about the analytical quality of the method used for PTH 1-84 evaluation.

European Biological Variation Study (EuBIVAS):
within- and between-subject biological variation estimates for serum biointact parathyroid hormone based on weekly samplings from 91 healthy participants

- Serum samples from 91 healthy individuals
- Phlebotomy for ten consecutive weeks
- 5 European countries
- Stored at − 80°C before analysis

→ Estimates of **biological variation (BV)** and the associated **analytical performance specifications (APS)** and **reference change value (RCV)** for serum PTH in its biointact form

- All samples from each individual were analysed in duplicate within a single run
- Analysis was performed at the coordinating centre on the Roche Cobas e801

Parathyroid hormone (PTH) is a key biomarker for diagnosing of parathyroid glands' pathologies, calcium-phosphate metabolism disorders and for monitoring chronic kidney disease mineral and bone disorder. PTH 1-84 - form of biointact PTH, which is a peptide composed by 84 amino acids.

	Number of individuals	Total number of results	Mean number of samples/individuals	Mean number of replicates/samples	Mean value, ng/L (95% CI)	Analytical variation, CV_A % (95% CI)	Within-subject BV, CV_I % (95% CI)	Between-subject BV, CV_G % (95% CI)	APS for imprecision, CV_{APS} %; CV_{APS} = ½ CV_I;	APS for bias, B_{APS} %; B_{APS} = 0.25* $(CV_I^2 + CV_G^2)^{0.5}$	RCV %, decrease; increase
All subjects	91	**1,721**	9.51	1.98	**37.9 (37.2–38.6)**	**3.3 (3.1–3.4)**	14.7 (14.0–15.5)		**6.5**	**7.5**	**–26.7; 36.5**
Men	38	716	9.45	1.99	39.3 (38.3–40.3)		**13.0 (12.1–14.2)**	**26.8 (21.4–35.1)**			
Women	53	993	9.43	1.97	36.7 (35.8–37.6)		**15.2 (14.3–16.3)**				
<50 years	43	802	9.33	2.00	35.5 (34.6–36.4)		15.5 (14.4–16.7)	**27.8 (22.7–36.1)**			
>50 years	10	191	9.90	1.87	41.7 (39.4–43.9)		14.2 (12.3–16.6)	30.8 (21.3–62.3)			

Infographic by Aleksei Tikhonov (EFLM CC)

Bottani M., et al. *Ann Transl Med 2020;8(14):855*

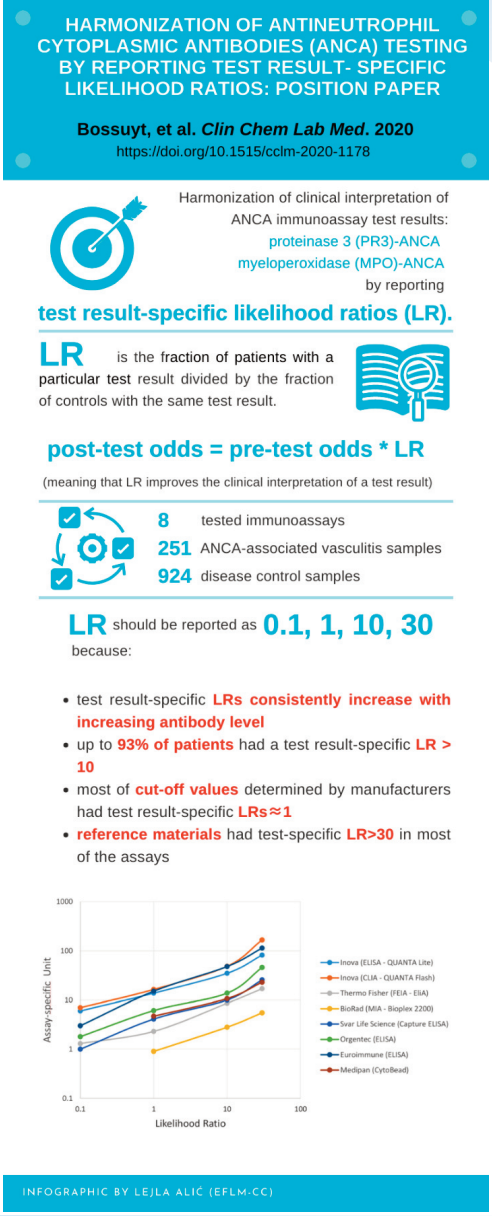
Harmonization of antineutrophil cytoplasmic antibodies (ANCA) testing by reporting test result-specific likelihood ratios: position paper

Bossuyt X, Damoiseaux J, Rasmussen N, van Paassen P, Hellmich B, Baslund B, Blockmans D, Vermeersch P, Lopez-Hoyos M, Vercammen M, Barret E, Hammar F, Leinfelder U, Mahler M, Olschowka N, Roggenbuck D, Schlumberger W, Walker R, Rönnelid J, Cohen Tervaert J-W, Csernok E, Fierz W for (i) the European Federation of Laboratory Medicine (EFLM) Task and Finish Group "Autoimmunity Testing," (ii) the European Autoimmune Standardization Initiative (EASI) and the (iii) European Consensus Finding Study Group on autoantibodies (ECFSG)

Clin Chem Lab Med 2020; Available from: https://doi.org/10.1515/cclm-2020-1178

Reported by Lejla Alić, member of the EFLM WG-Promotion & Publications

Recently, many high-quality immunoassays for proteinase-3 and myeloperoxidase antineutrophil cytoplasmic antibodies (ANCA) have come up. Although reference materials and standards are available for these measurements, studies have shown that the harmonization of ANCA test results reporting is an open question. In this position paper authors propose harmonization of reporting test results of ANCA immunoassays using test-results specific likelihood ratios (LR). Eight different immunoassays were tested using samples of 924 disease controls (suspected for ANCA-associated vasculitis) and 251 diagnostic samples (confirmed ANCA-associated vasculitis, AAV). The test results-specific LRs were estimated using derivative of the receiver operating characteristics (ROC) curve and by Bezier curves. Authors propose reporting of the test results as LR of 0.1, 1, 10, and 30. This is based on the fact that test-results specific LRs consistently incresed with increasing antibody levels, up to 93% AAV patients have LR > 10, cut-off values of most of the assays had a test-specific LR of around 1 and reference materials' test-specific LRs were > 30.



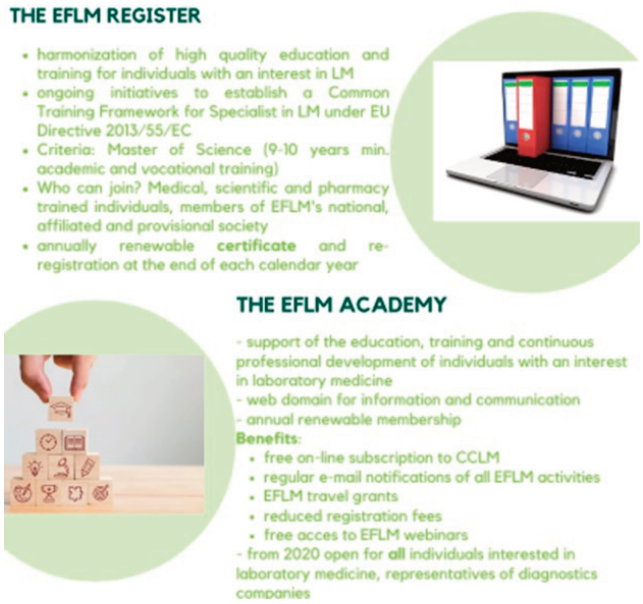
The Academy of the European Federation of Clinical Chemistry and Laboratory Medicine and the European Register of Specialist in Laboratory Medicine: guide to the Academy and the Register, version 4 - 2020

Wieringa G, Jassam N, Homsak E, Rako I, Racek J

Clin Chem Lab Med 2020; Available from: https://doi.org/10.1515/cclm-2020-1507

Reported by Tara Rolić, member of the EFLM WG-Promotion & Publications

The 4th version of the guide to the Register for European Specialist in Laboratory Medicine (EuSpLM) describes the transfer of the register to the EFLM in 2016, the extension in 2018 and transfer under the umbrella of the EFLM Academy in 2019 when the Academy was founded. Furthermore, it elaborates the benefits of membership, including reduced registration rates at selected conferences and a free subscription to Clinical Chemistry and Laboratory Medcine (CCLM). With effect from 2020, eligibility was extended to anyone with interest in laboratory medicine. The updated guide describes the processes for individual membership and block enrolment and the steppingstones to recognition as an EuSpLM within the Academy. Additionally, the guide explains the new ways of working for the EFLM Register and introduces the EFLM Academy. It includes an update for establishing the criteria for joining the Register and the Academy, the value to the individual and the profession in achieving recognition as a EuSpLM. In this guide, a process of individual or block registration and enrolment mediated by societies/organizations is described. In updated criteria, new expectations across Europe in education, training, professional regulation, and qualifications are reflected. All this reflects EFLM's leadership role in harmonizing high-quality laboratory medicine practice.



NEWS FROM EFLM NATIONAL SOCIETIES

News from the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM)

Reported by Anamarija Rade and Željka Kelava, Medical Biochemistry Laboratory, General Hospital Varaždin, Varaždin, Croatia

31st Symposium of the Croatian Society of Medical Biochemistry and Laboratory Medicine

Over three decades, the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) has been organizing an annual symposium covering new and interesting topics in clinical chemistry. This year in October, we held the first ever virtual Symposium organized by the Northwestern branch of CSMBLM. The main topic of this year's Symposium was "Hemodialysis - clinical and diagnostic challenges".

The Symposium consisted of 6 lectures which were presented by MDs and specialists in laboratory medicine. After an introductory lecture held by Igor Zabic, MD, on methods of substituting kidney function and pathophysiological basis of laboratory parameter changes, Tihana Herceg Brlek emphasized pre- and postanalytical problems in the analysis of hemodialysis patients' samples. Alen Androvic, MD, discussed mineral metabolism monitoring in secondary hyperparathyroidism with a very interesting case report. Hematological parameters in samples of dialysis patients were presented by the President of the Scientific Committee, Irena Kocijan, MS, while Ana Matisa and Sonja Podolar explained the value of biomarkers of cardiovascular changes. The Symposium concluded with a presentation on monitoring the nutritional status of patients undergoing chronic dialysis held by Valentina Kutnjak Flac. The abstracts of the lectures were published in the October issue of Biochemia Medica journal.

The Symposium was attended by 166 participants from Croatia and neighboring countries. Virtual education impressions and experience were rated as very good in on-line polls.

Lecturers of the 31th Symposium of the CSMBLM

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

Reported by Josefina Mora, Executive Secretary of SEQCML Board

Preparation of the document - a pioneering project in the clinical laboratory field in our country – will be preceded by a survey of sector professionals

The Spanish Society of Laboratory Medicine is preparing a White Book to provide information on the current situation and the challenges of the clinical laboratory

- **The SEQC^{ML} hopes to be able to offer proposals for improvement for laboratories and their professionals.**
- **This initiative is part of the Strategic Plan of the Society and represents a commitment made by the Board of Directors at the Conference on the Future of Laboratory Medicine held in Zaragoza.**

The Spanish Society of Laboratory Medicine (SEQC^{ML}) has begun work on the preparation of a White Book on Laboratory Medicine in Spain, a document that seeks to summarize the situation of public and private laboratories and their professionals. This is the first time that an initiative of this kind has been carried out in the clinical laboratory field in our country.

As the first phase in the preparation of this White Book, the Society is carrying out a comprehensive national survey among various Clinical Laboratory professionals so as to have all the necessary information.

The survey will gather information on issues such as the organizational model, resources available, the number of tests that must be done, their resolution capacity, the accreditation and training plans carried out, as well as the teaching and research activity, quality control, and challenges for the future.

As stated by the president of the SEQC^{ML}, Dr. Imma Caballé, "full knowledge of the current state of the specialty of Laboratory Medicine requires gathering basic information about the current situation. But also, through this initiative, we will not only obtain a picture of the number of laboratories, professionals, activity, etc. of our specialty, but also trends and future projects will be revealed".

"The final objective of the survey is to facilitate decision-making based on objective information," indicated Dr. Antonio Buño, vice president of SEQC^{ML}. For this reason –he adds-, once finished and analyzed, the SEQC^{ML} will

To be continued on page 11

proceed to the publication of the final report, in such a way that it is accessible not only to members, but also to political leaders, managers, professionals, and other agents involved".

The White Book is one of the major projects of the Society. In fact, it is part of its Strategic Plan, explains its president, who points out that "it is also a commitment on the part of the Board of Directors that we made at the Conference on the Future of Laboratory Medicine held in Zaragoza".

Detailed information on the operation of clinical laboratories

The purpose of the survey is to know the operation of the clinical laboratories in our country in more detail, to later be summarized in the White Book. In this sense, the study is interested in aspects such as the origin of requests received by laboratories (Primary Care, Emergency, hospitals, specialists, etc.), or if there is an organic dependence on a service or a model of continuing care.

Likewise, both qualitative and quantitative data (number of employees, for example) on laboratory operations are being requested. There is also interest in other activities related to the management carried out by laboratory professionals, such as attendance at clinical commissions, the acquisition of equipment and reagents, and participation in the laboratory's business strategy.

Challenges for the future

Regarding future challenges, the survey asks that clinical laboratory specialists assess the importance of the main challenges they face, including the integration and consolidation of their own center, the emergence of new specialties, patient response times, the attraction and retention of talent, the temporal characteristics of personnel, the capacity for carrying out research and clinical trials, certification and accreditation, teaching, innovation, and big data.

The White Book seeks to establish a series of guidelines so that laboratories can face the changes that are expected in coming years. In this respect, respondents are also asked about their continuous improvement programs and their environmental and waste management programs.

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

The Spanish Society of Laboratory Medicine (SEQC^{ML}) -founded in 1976- is an active member of IFCC and EFLM. SEQC^{ML} currently includes almost 3,000 professionals, and its main objectives are to bring together all scientists interested in the field of Laboratory Medicine, promote the dissemination of scientific and technical publications, organize meetings, courses and congresses of national and international character, cooperate with other Scientific Societies, and defend and promote the specialties of the field of Laboratory Medicine as well as those of its members. Likewise, the Society wishes to contribute to studying and recommending methods and guides, and to establishing guidelines and recommendations for training in the field of Laboratory Medicine.

More information at: www.seqc.es.

HEMCHECK™

Hemolysis free blood sampling.

Point of care detection of hemolyzed blood samples can increase patient safety and create major time and cost savings for healthcare

Hemolysis – the most common pre-analytical error

Hemolysis is well documented as the globally most common pre-analytical error in laboratory medicine. The incidence of hemolyzed blood samples varies and is normally most common in emergency departments often having a hemolysis rate of 5-12%.

Hemolyzed blood samples in vacuum tubes are usually detected in central laboratories, often resulting in a delay of 60-120 minutes in acute situations for correct test results, as the blood samples must be recollected. This can lead to increased waiting times and costs and a patient's condition not being treated in time, which might have severely negative consequences for patient safety in individual cases.

Although it is proven that hemolysis is common in blood gas samples and that several analyzes performed are significantly affected by hemolysis, there is no built-in hemolysis control in any blood gas instruments on the market. Healthcare staff will therefore regularly risk basing clinical decisions on incorrect test results or repeating analyzes or sending supplementary samples to the laboratory, which increases lead times and costs and reduces the value of the blood gas analysis.

Unique POC-concept for hemolysis detection

Hemcheck has developed a CE-marked solution for fast detection of hemolysis in whole blood samples in vacuum tubes (v-Test) and blood gas syringes (s-Test).
Learn more about the concept

The user-friendly system is small, robust and portable and can be used anywhere, but is especially valuable for units having a high rate of hemolyzed blood samples and where the clinical impact and cost of each hemolyzed sample is high.

The v-Test enables hemolysis detection and direct sample retake in connection with blood collection and aims to improve the flows of samples and patients, reduce turnaround time, waiting times and patient length of stay, decrease staff workload, increase patient safety and save costs. The s-Test enables hemolysis detection either in connection with blood-sampling or blood gas analysis, and aims to contribute to more informed, reliable and timely clinical decisions and thereby improved patient safety.

Cost/benefit analysis shows substantial time and cost savings

Clinical studies show that the tests can effectively identify hemolyzed blood samples and, in case of vacuum tubes, greatly reduce the number of hemolyzed blood samples that reach the laboratory. The total cost for a rejected blood sample has been estimated in scientific articles to be above EUR 100 per sample and implies that Hemcheck's products are cost-effective even at lower levels of hemolysis. The positive effects of the concept in terms of reduced patient length of stay and cost savings, can be evaluated using the interactive, customized cost/benefit model.
Perform your own cost/benefit analysis

High user satisfaction and several new and ongoing customers

A user survey targeting all nurses enrolled in a clinical study at Capio S:t Göran hospital in Stockholm showed 100% user satisfaction with the products. The products are implemented in clinical practice at for example Tartu University Hospital in Estonia for usage at the oncology and hematology clinic and SYNLAB Sweden in primary care. Hemcheck is looking for other interesting projects and collaborations and offers healthcare providers the possibility to test the concept free of charge.

For further details, please contact:
peter.andersson@hemcheck.com

Facts about Hemcheck

- Hemcheck produces and commercializes a unique concept for point of care detection of hemolysis in venous and arterial blood samples, contributing to more efficient and patient-safe care.
- The products are CE-marked and developed in Sweden together with healthcare staff.
- The technology has patent protection in Europe and the USA.
- The company is listed on Nasdaq First North Growth Market since 2017.

www.hemcheck.com

The IFCC President's message

Firstly, I would like to say that I hope you, your family and your friends are safe and well during these tough times. The IFCC Executive Board is aware of the many challenges faced by laboratory professional across the globe and has been activity supporting the membership. Despite the pandemic, the IFCC organization has been very busy developing new programs to ensure continued progress on a number of fronts, including development of guidelines on laboratory management of COVID-19, a new live webinar series to provide e-learning opportunities to members and non-members around the world, as well as new programs in Global Newborn Screening and Global Laboratory Quality. An important new development is the new **IFCC Global Conference on COVID-19 Diagnostic Testing on February 15-17, 2021.** The conference will bring together scientific and industry leaders from around the world to present on the latest advances in COVID-19 diagnostics as well as public health authorities and medical experts to present on rapidly growing list of therapeutics and vaccines. The second announcement is already available and the online sites for registration and abstract submission are open. I would like to invite you all to consider registering for this conference and participating in this important virtual congress. We have kept the cost very low for all regular attendees from academia or industry and have arranged for free registration for all young scientists and trainees under 40 years of age read more:

Open positions within IFCC

The following calls for nominations are currently open for the time in office 2021-2023

Education and Management Division

- Executive Committee: one member
- Committee on Point of Care Testing: one corporate member
- Committee on Clinical Laboratory Management: one member
- Committee on Clinical Molecular Biology Curriculum: one member

Scientific Division

- Executive Committee: Secretary
- Nomenclature, Properties and Units (C-NPU) in collaboration with IUPAC: one member

For further information on the open Calls for Nominations, please visit the IFCC Call for Nominations page.

Twenty-four teams receive global recognition for Healthcare Excellence in 2020

The UNIVANTS of Healthcare Excellence Award Program announced its 2020 winners. Foundational principles across all winning teams include "UNIFYING" across the care continuum for the development and implementation of "AVANT-GARDE" processes with measurable differences to clinical care. The 2020 submissions included hospitals, commercial laboratories, reference laboratories, clinics and rural community care. Applications included best practices across key areas of unmet needs with representation from every region of the world, spanning both emerging and established markets. Comprehensive judge review revealed 3 top winners, 9 teams of distinction, and 12 teams of achievement.

More details about the UNIVANTS of Healthcare Excellence program or 2020 best practices can be found on the program website at www.univantshce.com or on social media, by including #UNIVANTS on LinkedIn. The success stories are especially meaningful in 2020 during unprecedented times for patients, communities and healthcare professionals. It is with great honour that we congratulate all participating teams while celebrating strategic activation and insights from clinical and laboratory medicine to achieve measurably better outcomes for patients, payors, clinicians and health systems.

Calendar of EFLM events and events under EFLM auspices

Due to COVID-19 alert throughout the world, some upcoming events could have been cancelled or postponed, please direct check with the organizers if the date is confirmed.

8-11 December 2020
Journées de l'innovation en biologie (JIB 2020)
online Click here for information

18-20 December 2020
31st National Biochemistry Congress of the Turkish Biochemical Society
on-line Click here for information

4-5 March 2021
XVIII Meeting of the SEQC-ML Scientific Committee
Madrid (SP) Click here for information

15-16 March 2021
POCT: making the point
Rome (IT) Click here for information

14-16 April 2021
XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Belgrade Symposium for Balkan Region
Belgrade (SRB) Click here for information

20 November 2020 (and accessible till 20 May 2021)
2020 Annual Meeting of the Royal Belgian Society of Laboratory Medicine (RSBLM)
on-line Click here for information

24-27 May 2021
The 10th Santorini Conference "Systems medicine and personalised health & therapy" - The odyssey from hope to practice: Patient first - Keeps Ithaca always in your mind
Santorini (GR) Click here for information

10-11 June 2021
8th International Symposium on Critical Care Testing and Blood Gases
Biarritz (FR) Click here for information

7-10 October 2021
46th ISOBM Congress
Bled (SL) Click here for information

10-12 October 2021
XIV Congress of Slovak Society of Clinical Biochemistry
High Tatras (SK) Click here for information

EuroMedLab 2021 NEW DATE!!!!
28 November - 2 December 2021
24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Munich (DE) Click here for information

November 2021
14th CIRME International Scientific Meeting "Implementation of metrological traceability in laboratory medicine: where we are and what is missing"
Milan (IT) Click here for information

10-11 February 2022
International Congress on Quality in Laboratory Medicine 2021
Helsinki (F) Click here for information

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE