EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

Issue n.3/2020

In this issue:

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

Foreword

Reported by Harjit Pal Bhattoa, Editor EuroLabNews

The release of this present issue during an unforeseen COVID-19 pandemic illustrates the determination of the EFLM to reach out to all its Members and National Societies. The EFLM is committed to forward its mission and meet challenges even during these trying times. As a regular column, our Hot Topic is on the importance of Communication between the Clinical Laboratory and the Clinicians. Avi Peretz, the President of the Israel Society for Clinical Laboratory Sciences emphasises the topic as a key for proper medical care. The EFLM Executive Board and Communication Committee summarizes its activities and creativity to keep up with its day to day running and meet ends with the most innovative means. Christa Cobbaert, the EFLM observer in the IVD Working Group, reports postponement of the EU Medical Device Regulation to May of the coming year. Recent key publications of the EFLM Working Group on Biological Variation (EuBIVAS) are summarized using infographics by Lejla Alic, Aleksei Tikhonov, and Adina Hutana, all are dedicated members of the EFLM WG-PP. Although the Coronavirus is keeping us from travelling, the EFLM WG for eLearning and Distance Education is committed to keep us abreast with the latest know-how using the extraordinarily compiled EFLM Academy webinars, the next on Urinalysis will be presented by Dr Jose A.T. Poloni, and is scheduled for the 30th of June at 18:00 CET, don't forget to mark your calendar. If you have missed out on your favourite topics, past webinars are also just a click away.

To be continued on page 2

HOT TOPIC IN LABORATORY MEDICINE

The Importance of Communication between the Clinical Laboratory and the Clinician: The Key for Proper Medical Care

Reported by Avi Peretz, President of the Israel Society for Clinical Laboratory Sciences (ISCLS)

Over the recent decades, the field of clinical laboratory sciences has undergone significant changes, mainly due to technological development on the one hand and economic constraints on the other. We are witnessing rapid technological development and implementation of full automation in laboratories, integration of accurate and fast instrumentation, and increase in the use of point-of-care testing. In addition, there is a growing trend of transition from therapeutic to preventive and personalized medicine, which significantly increases the number of laboratory tests and requires the laboratory to provide knowledge and not just data. Many countries implement an advanced logistic system for the transportation of samples, which allows merging many laboratories into mega labs, thus reducing the activity of small laboratories. As a result of these trends, **the laboratory has been distanced and disconnected from the clinical context**, and the laboratory tests have also been treated

To be continued on page 2

The Spanish Society of Laboratory Medicine report their latest activities. Our regular IFCC corner is highlighted by the announcement of the new IFCC President. Congratulations Prof. Khosrow Adeli. Although with a remark on uncertainty of events in the near future, the Calendar of Events lists all upcoming events in our field. The EFLM Newsletter team wishes all our readers good health!

as a commodity that is evaluated by its cost only [1-3].
This requires us to take action and to strengthen the relationship between the clinicians and the medical laboratory, leading to strong cooperation, **and ensuring that the lab personnel will be a source of knowledge and authority as an integral part of therapeutic decision-making process**. This is highly important for institutions where laboratory managers or senior laboratory staff members are not physicians, but rather workers with academic background in life sciences or basic medical sciences. The reason is that in many cases the doctors, unlike laboratory workers, are seen as the authorized decision-makers, and lab staff is left behind the scenes and becomes transparent. This is despite the fact that laboratory tests, on contrary to common belief, are intended not only to diagnose medical conditions, but also to monitor treatment success, for prognosis, for estimation of risk factors, and tailoring patient-specific care according to their genetic profile. For this purpose, information that can assist in decision-making regarding lab tests should be continuously delivered to the laboratories by the medical staff, and vice versa. The following are several highlights for improvement and practical suggestions.

Provision of specific information about the patient in each test order

The information supplied to clinical laboratory about each patient may have a critical impact on work processes and decision-making. In many cases the test order form supplied to the laboratory includes only minimal details about the patient, usually only demographic data. It is highly important to provide the lab with comprehensive information about the patient! The order should include details of patient's chronic conditions, especially those related to immunosuppression, medications the patient receives, and sometimes personal information such as the patient's occupation or recent visits to countries with specific morbidities. Many examples of this can be seen in diagnosis of infections carried out in the microbiology laboratory. Information provided to the laboratory may have a critical impact on the selection of growth media, sample incubation time, and adjusting different incubation conditions according to the suspected pathogen. One way to get comprehensive information about the patient is switching to computerized laboratory test order form. Such form will help to prevent errors related to unclear marking of the requested type of test or illegible handwriting. It will also include mandatory fields that must be completed by the ordering clinician before sending. Of course, a different format of computerized order form can be created for each laboratory according to the required information.

Incorrect sampling and transportation to the laboratory

Incorrect sampling and transportation in inappropriate conditions for the specific test may lead to a false-positive or false-negative result. Besides critical implications on patient care, this may have financial implications and cause unnecessary burden on the laboratory, associated with repeated testing. Incorrect sampling and improper transportation conditions are some of the main reasons for rejection of samples, and they cause a significant percentage of all errors related to laboratory testing. At this point it should be noted that most errors occur in the pre-analytic phase and not in the analytic phase, as many believe [4]. The solution of this problem requires investment in training and education of medical personnel. Unfortunately, the educational program of many of the health and medical students does not include specific training in the field of clinical laboratory, and most staff members in medical institutions have never visited in a lab. Therefore, the clinical laboratory should be made accessible to these teams, including visits to the laboratory and face-to-face meetings with new staff members who start working at the medical institution as part of the admission process. Another option is to develop educational software that each medical staff member is required to complete, similarly to safety software used in many institutions, including periodic refreshers, subject to changes related to laboratory work processes. In addition, a dedicated course should be developed in medical faculties that will provide knowledge in the field of the clinical lab with all its aspects.

Increase in the volume of laboratory tests

In recent years there has been an increase in the amount of laboratory tests. According to studies, this does not necessarily improve the diagnosis and treatment of the patient. Physician-related factors, such as his seniority, workload, gender, and area of expertise affect the amount of tests he or she orders. It was also found that the distance from the laboratory and the availability of tests also have effect. High number of laboratory tests involves high costs, unnecessary load on the lab, and increases the chance of getting a false-positive result that may cause unnecessary anxiety and unnecessary testing. In one of the studies doctors were asked to order laboratory tests in various simulated situations. The results demonstrated that female doctors order more tests than male doctors, senior physicians order more tests than interns, and doctors who were previously involved in cases of misdiagnosis ordered more tests as well. Additional studies which revealed to doctors the costs of lab tests, demonstrated that the more expensive the test was, the less tests were ordered. In addition, when doctors were required to get approval and justify the reason for lab tests ordering, there was a significant reduction in the amount of tests ordered by the doctor. Therefore it is very important to: 1) Implement administrative measures to identify unnecessary or duplicate tests and cancel them; 2) To characterize and identify doctors who order laboratory tests at significantly higher than average rates,

and implement an intervention program focused on these doctors, and 3) To identify particularly expensive laboratory tests and think about a different and tailored intervention program for these tests. Additional option is using built-in algorithms: Follow-up tests may be added automatically by the testing device, also known as Reflex testing, or manually by the lab worker of manager, also known as Reflective testing. The use of this method in many cases reduces the time needed to reach the diagnosis, optimizes the use of laboratory tests and prevents unnecessary ordering of tests [5-8].

Strengthening the status of the clinical laboratory as a research body

Unfortunately, the high workload in the clinical laboratory draws attention from the fact that the clinical lab workers have scientific education and research skills. It is therefore important for the research to be part of the laboratory work routine. Furthermore, the research work in the clinical laboratory has the potential to connect the laboratory to clinical practice and lead to collaborations with many clinicians. The type of research that can be done in the clinical laboratory has enormous importance for basic and clinical research, since data collected from the laboratory work is a very important knowledge base for future research. Studies have found that clinical laboratories staff members that engage in research are more motivated, more satisfied with their work, and more proficient in the relevant literature.

Summary: Laboratory tests play an important role in the patient's diagnostic and treatment process. The relationship between the clinician and the laboratory must be solid and based on familiarity with laboratory work processes and the needs of the clinicians. There is a need to develop local programs and a national plan to improve the existing situation and strengthen the relationships between laboratories and medical teams.

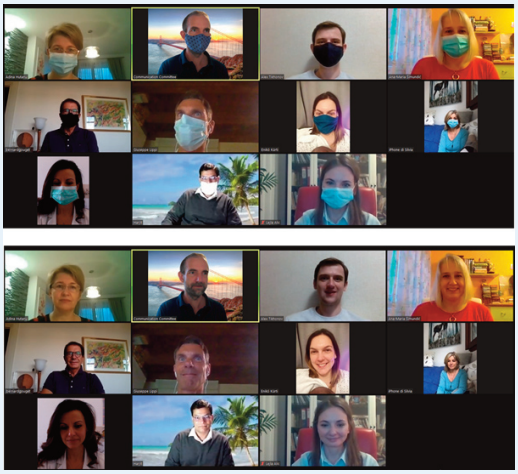
References

1. Kothari, Tarush, et al. "Skills in Data Science and Analytics: The Next Frontier for the Medical Laboratory Scientist?." *Critical Values* 11.1 (2018): e22-e27.
2. Collinson, Paul. "Laboratory medicine is faced with the evolution of medical practice." *Journal of Medical Biochemistry* 36.3 (2017): 211-215.
3. Dolci, Alberto, et al. "Total laboratory automation: do stat tests still matter?." *Clinical biochemistry* 50.10-11 (2017): 605-611.
4. Plebani, Mario. "Errors in clinical laboratories or errors in laboratory medicine?." *Clinical Chemistry and Laboratory Medicine* (CCLM) 44.6 (2006): 750-759.
5. Martins, Carlos Manuel Silva, et al. "The effect of a test ordering software intervention on the prescription of unnecessary laboratory tests-a randomized controlled trial." *BMC medical informatics and decision making* 17.1 (2017): 20.
6. Watson, Jessica, et al. "What do tests do for doctors? A qualitative study of blood testing in UK primary care." *Family practice* 34.6 (2017): 735-739.
7. Sadowski, Brett W., et al. "High-value, cost-conscious care: iterative systems-based interventions to reduce unnecessary laboratory testing." *The American journal of medicine* 130.9 (2017): 1112-e1.

EFLM EXECUTIVE BOARD INFORMS

EFLM in Corona

Reported by EFLM Executive Board and Communication Committee



Communication in EFLM during the Coronavirus pandemia

Coronavirus Disease (COVID-19) pandemic has had disastrous consequences on global public health and has challenged the most stable healthcare systems worldwide. It has affected numerous aspects of human activities and caused the need for reorganization and adjustment of methods of functioning. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), the major professional association in Europe, has accepted great responsibility for acting with prompt initiatives. As one of the members of the Biomedical Alliance in Europe, EFLM has supported the initiatives towards decision-makers in Europe to support the uninterrupted functioning of all medical and research societies throughout Europe. Consequently, this pandemic has had numerous impacts on ELFM's activities, and it has undoubtedly caused rearrangements in its internal activities and events that have been previously planned. As being socially responsible and by prioritizing the health of our members and colleagues in the first place, EFLM has cancelled all face-to-face meetings of its functional units (i.e. working groups, committees), at least those planned for the second half of 2020 and the beginning of 2021. One significant meeting has been cancelled: the 3rd Strategic conference on Demand management that has been scheduled for November 2020 in Zagreb. All EFLM Postgraduate short courses have been cancelled as well. Additionally, the Executive Board has announced the cancellation of all visits of EB members to the meetings of the EFLM National Societies. Despite these mandatory measures, we are able to maintain the continuity of communication with our members, healthcare and research professionals and within EFLM functional units. Videoconferences and applications for remote collaboration are now an indispensable part of our daily routine. To efficiently disseminate clinically relevant information in these demanding times, ELFM has been investing great efforts in organizing webinars and e-learning programs through EFLM's e-Learning platform (www.elearning.eflm.eu). That being said, it is our great pleasure to remind you on two recent very interesting webinars organized by EFLM: Communication Between Laboratory and Clinician: Key for Proper Medical Care held by Prof. Avi Peretz and Updates on COVID-19 biology and diagnostics held by Prof. Giuseppe Lippi. Moreover, we would like to kindly invite you to one upcoming webinar on urinalysis by Prof. Jose Poloni which is planned for June 30 2020, 18.00 CET which might be of great interest not only to laboratory medicine professionals but to professionals of other specialties as well (more information available here). Along with that, we put one of our focuses on social media interactions, spreading information about bi-monthly published EFLM Newsletter, highlighting recent papers on hot laboratory medicine topics, and interacting with the community in different ways, quizzes are one of them. It is reassuring to observe the exponential growth of the EFLM social network community during the crisis, which allows us to reach more healthcare professionals and potentially general public with recent educational, research and professional information. EFLM thanks to all our members and colleagues for support, understanding and patience with hopes that everyone stays healthy and safe. We hope that with our conjoined efforts, we will be able to resume all our planned activities and in-person meetings as soon as possible in 2021.

NEWS FROM EFLM FUNCTIONAL UNITS

Postponement of the EU Medical Device Regulation to 26 May 2021

Reported by Christa Cobbaert, EFLM observer in the IVD Working Group under the MDCG of the EC

Amid all COVID-19 headline news, the European Parliament recently voted decisively in favour of a proposal to delay by one year the implementation of the European Union's Medical Device Regulation 2017/745 (MDR). The proposal was crafted by the European Commission (EC) and was moved forward by the Council of the European Union (EU) in order to permit the medical device industry to prioritize its coronavirus response efforts. The approval -with 693 votes in favour, 1 against, and 2 abstentions- clears a key barrier to the enactment of the delay, but the proposal now has to be approved by the European member states and published in the Official Journal before taking effect. According to Parliament, those actions are expected at the latest by 26 May 2020, MDR's original enforcement date. In a press release following the vote it was stated that a delay would ***"allow authorities and manufacturers alike to prioritise the fight against the coronavirus pandemic by continuing under current procedures."*** Hence, this MDR postponement serves primarily to ensure the supply of critical medical devices and is intended in particular to relieve the EU and its member states during the current Corona pandemic.

Recall that the MDR describes the legal framework and governance for bringing medical devices (among them are high risk implantable devices) to the European market originally per May 2020. In the new MDR more stringent requirements are laid down as compared to the current Medical Device Directive (MDD), such as classification of medical devices, conformity assessment procedures, technical documentation, clinical evaluation/investigation, responsible persons, market surveillance, reporting obligations, quality management and transparency. Key for improved transparency on the safety and clinical effectiveness of medical devices is the database EUDAMED database which should be open to competitors, notified bodies and the public. Appendix VI of the MDR explains in detail what information economic operators need to enter in this database. EUDAMED also includes the UDI database (unique device identification). Hence, every medical device is clearly labelled, and it is possible to trace back the supply chain (traceability).

Position Statements

Both **Medtech Europe** - the European trade association for the medical technology industry including diagnostics, medical devices and digital health - and **BioMed Alliance in Europe** - the latter being a non-profit organization representing 33 research and medical societies - welcomed in press releases the postponement by the European Commission of the date of application of the Medical Devices Regulation (MDR) by one year to 26 May 2021. Both organizations considered it is as essential to ensure a smooth transition from the Medical Device Directive to the new regulatory framework, to guarantee that patients will continue to benefit from a timely access to safe and high-quality devices.

Both organizations urgently call upon all stakeholders, authorities and policy makers to continue preparations for the MDR and IVDR to the maximum extent that the current crisis situation allows. Insufficient progress had been made already in the pre-Corona period, whereas for proper implementation of the MDR, the following elements are essential: 1. The new regulatory system can only operate properly with a functioning EUDAMED portal. Therefore, the European Commission should operationalise the system by May 2021, and not postpone its implementation until the date of application of the IVDR in 2022 (as was previously announced). 2. For healthcare professionals and patients, transparency throughout the new system should be a top priority. Public access to clinical information (e.g. Summaries of Safety and Clinical Performance shared through EUDAMED) will help clinicians to select optimal treatments. The implementation of the clinical aspects of the EUDAMED portal should be implemented ahead of the new application date. 3. The delayed application date allows more time to ensure that the Expert Panels have the necessary support to carry out their important new role for high risk medical devices within the regulatory system. The members of the Expert Panels should receive sufficient education and training. In addition, the system should be tested to ensure that all aspects can run smoothly. 4. The number of notified bodies available to take MDR work and do conformity assessments, as listed in the European Commission's database, only stands at twelve.

MDR postponement: are all problems ironed out?

Anyone who has so far assumed, based on the headlines, that MDR in its entirety will now be postponed by one year is mistaken. Strictly speaking, **the period of entry into force with all its details will only be shortened by one year** - and that at the beginning. As a result, all those who would have to undergo a conformity assessment according to MDR in the period from 26 May 2020 to 26 May 2021, but who are not ready for it yet, can take a deep breath. However, not all transition periods and expiry dates will be postponed by one year, but will remain with the known dates. Individual aspects, such as the introduction of the UDI, are only postponed by one year for the most part. **In the worst case, this means that even more manufacturers will have to obtain certification in even less time.** Manufacturers must nevertheless have shifted to an MDR certificate by May 2024 when their MDD/AIMD certificates expire.

Implications for the IVDR 2017/746 and IVD-stakeholders?

Notwithstanding the MDR postponement, it is important to realize that the In Vitro Diagnostic Regulation 2017/746 (IVDR), slated to take effect in May 2022, remains unaffected. Note that in essence the framework and governance of the IVDR is mimicking that of the MDR. However, for the IVD-sector the IVDR implementation is completely new and much more impactful than the MDR implementation. I.e., 85% of the medical tests have to undergo certification in order to get European market access and CE-labelling under the IVDR, as compared to only 15% under the current IVD Directive (IVDD) regimen. Being far in the second half of the transition period from IVDD

to IVDR, the time is there that medical and laboratory societies should consider the lack of progress on the preparations for IVDR implementation caused by the COVID 19 crisis, which even brought all MDR preparations to a standstill and led to postponement of the MDR application. Other challenges are the limited number of notified bodies qualified for medical test conformity assessments (yet sufficient capacity for assessing 85% of 40 000 IVD-products is needed), the nearly non-availability of guidance documents on this process (https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en; https://ec.europa.eu/docsroom/ documents/41182), the fact that so far none of the experts for evaluating high risk medical tests has been appointed, the postponement of the EUDAMED database until May 2022 etc. These challenges should make us realize that the timelines for careful implementation of the impactful IVDR regulation are no longer realistic. The fact that the European Commission is still fully occupied with handling the huge effects of the COVID 19 crisis and slides forward the MDR implementation to May 2021, should alarm us about the non-feasibility of thoughtful IVDR implementation per May 2022. The IVDR implementation is the last domino in this domino game and it seems unrealistic to chase that application date if neither the governance nor the infrastructure and guidance documents are in place. Therefore, laboratory specialists and (inter)national laboratory medicine societies, task forces, commissions and working groups: be aware of this force field, let us take position and start the dialogue with the EC in order to make a mutually agreed plan with EU-wide realistic goals and deadlines, for the sake of better and safer patient care.

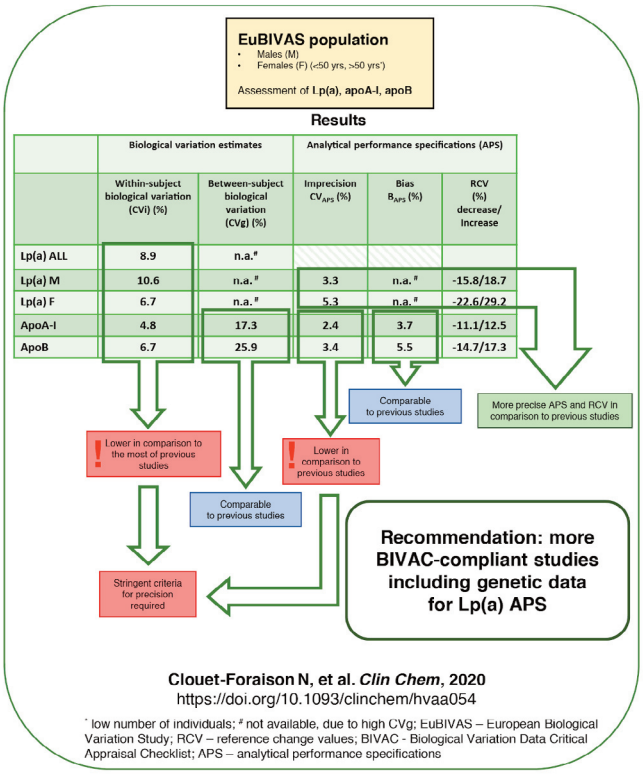
UPDATES ON EFLM PUBLICATIONS

Analytical Performance Specifications for Lipoprotein(a), Apolipoprotein B-100, and Apolipoprotein A-I Using the Biological Variation Model in the EuBIVAS Population

Clouet-Foraison N, Marcovina SM, Guerra E, Aarsand AK, Coşkun A, Díaz-Garzón J, Fernandez-Calle P, Sandberg S, Ceriotti F, Carobene A. on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation

Clin Chem 2020; Available from:
https://doi.org/10.1093/clinchem/hvaa054

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



The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Biological Variation (WG-BV) reports the biological variation estimates (BVE) of important biomarkers for cardiovascular disease (CVD) risk assessment, namely lipoprotein (a) (Lp(a)), apolipoprotein A-I (apoA-I) and apolipoprotein B-100 (apoB). This study has been conducted among the European Biological Variation Study population.
As expected, Lp(a) concentrations showed high variability between individuals and the within-subject BVE (CVi) for Lp(a) was higher in men when compared to women. Moreover, CVi for apoA-I and apoB showed no differences between men and women. CVi was lower for Lp(a), apoA-I and apoB when compared to the most of other studies, suggesting that precision criteria for these parameters should be revised. The between-subject BVE (CVg) for apoA-I and apoB were comparable to previous studies. Although this study offers more precise analytical performance specifications (APS) and reference change value for Lp(a), authors suggest that it is important to conduct more controlled studies with genetic data included in order to revise the APS criteria for Lp(a) measurements and to enable accurate CVD risk assessment.

European Biological Variation Study (EuBIVAS): within- and between-subject biological variation estimates of β-isomerized C-terminal telopeptide of type I collagen (β-CTX), N-terminal propeptide of type I collagen (PINP), osteocalcin, intact fibroblast growth factor 23 and uncarboxylated-unphosphorylated matrix-Gla protein—a cooperation between the EFLM Working Group on Biological Variation and the International Osteoporosis Foundation-International Federation of Clinical Chemistry Committee on Bone Metabolism.

Cavalier E, Lukas P, Bottani M, Aarsand A.K., Ceriotti F., Coşkun A, Díaz-Garzón J, Fernàndez-Calle P, Guerra E, Locatelli M, Sandberg S, Carobene A on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation and IOF-IFCC Committee on Bone Metabolism

Osteoporos Int 2020; Available from: https://link.springer.com/article/10.1007/s00198-020-05362-8

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

Biomarkers of bone formation and bone resorption are frequently used for monitoring patients' responses to therapies and compliance. The reference change values (RCV) serves as an important tool used to correctly interpret the biological significance of a change observed between two consecutive biomarker measurements.

In the present study, a cooperation between the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Biological Variation (WG-BV), the International Osteoporosis Foundation and the International Federation of Clinical Chemistry (IFCC) Committee on Bone Metabolism (C-BM) established updated biological variations (BV) estimates for five different biomarkers implicated in bone metabolism and vascular calcification, namely OC, PINP, β-CTX, iFGF23, and uCuP-MGP within the European Biological Variation Study (EuBIVAS). The BV estimates of these analytes will be included in the EFLM Biological Variation Database at https://biologicalvariation.eu/.

European Biological Variation Study (EuBIVAS)

- EDTA plasma samples from 91 healthy volunteers
- Collected weekly for ten consecutive weeks on a set day at the same hour from the same phlebotomist
- 6 European laboratories
- Stored for 3 years at − 80 °C before analysis

→ Estimates of **biological variation (BV)** for five different bone metabolism and vascular calcification biomarkers

1738 results totally

- Samples from the same individual were measured in duplicate within the same instrument run for a single day
- All the analyses were performed by the same technician within 2 months

Biomarkers	Mean value (95% CI)	Within-subject BV CV_I % (95% CI)	Reference change values RCV (%) decrease; increase
β-isomerized C-terminal telopeptide of type I collagen **(β-CTX), ng/L**	514.3 (499.5–529.1)	15.1 (14.4–16.0)	− 30.8; 44.5
N-terminal propeptide of type I collagen **(PINP), µg/L**	63.7 (62.3–65.0)	8.8 (8.4–9.3)	− 19.9; 24.8
osteocalcin **(OC), µg/L**	22.5 (22.1–23.0)	8.9 (8.5–9.4)	− 19.2; 23.8
intact fibroblast growth factor 23 **(iFGF-23), ng/L**	35.3 (34.7–35.9)	13.9 (13.2–14.7)	− 28.7; 40.2
uncarboxylated-unphosphorylated Matrix-Gla Protein **(uCuP-MGP), pmol/L**	397 (393–401)	6.9 (6.1–7.3)	− 20.3; 25.4

Cavalier E, et al. *Osteoporos Int*, 2020
https://doi.org/10.1007/s00198-020-05362-8

The European Biological Variation Study (EuBIVAS): weekly biological variation of cardiac Troponin I estimated by the use of two different high-sensitivity cardiac Troponin I assays

Ceriotti F, Díaz-Garzón Marco J, Fernández-Calle P, Maregnani A, Aarsand A, Coskun A, Jonker N, Sandberg S, Carobene A.

Clin Chem Lab Med 2020; Available from: https://doi.org/10.1515/cclm-2019-1182

Reported by Adina Huțanu, corresponding member of EFLM WG-Promotion & Publications

Laboratory Medicine (EFLM) Working Group on Biological Variation (WG-BV) and The European Federation of Clinical Chemistry report the weekly biological variation (BV) of cTnI, using two different hs cTnI assays and specimens from healthy individuals recruited from EuBIVAS study. As hs cTnI is a specific marker for cardiac damage, in acute coronary syndrome, the knowledge of BV is important to define analytical performance specification (APS) and also reference change values (RCV), an important tool in the correct interpretation of the clinical significance of the difference between two consecutive measurements. The study estimates the weekly BV within- and between- subjects for cTnI, according to EFLM recommendation, with two recently released methods targeting different epitopes, thus allowing the definition of APS based on BV and RCV based on biology. The study identifies the difference for detection and quantification of the cTnI molecules by the two analytical systems evaluated (Atellica, Siemens and Singulex Clarity), derived rather from different sensitivity levels than from different epitopes design, however, the influence of different sample matrix used for analyses could not be excluded.

The European Biological Variation Study (EuBIVAS): weekly biological variation of cardiac Troponin I estimated by the use of two different high-sensitivity cardiac Troponin I assays

Serum/plasma from 91 healthy Caucasian volunteers
(53 F / 38 M)
(EuBIVAS participants)
(the same drawing protocol for all samples for 10 consecutive weeks, specimens stored for 3 years at -80°C before analysis)

Siemens Atellica
66 samples plasma EDTA
(23 samples excluded due to non-measurable values, higher LoD for Atellica)
1135 total results

Duplicate measurements with the same reagent lot, same subject measured in a single analytical run

Singulex Clarity
89 serum samples
1667 total results

	Biological variation estimates			Reference Change Values RCV % (95%CI) decrease/ Increase	Index of individuality
	Mean value ng/L (95% CI)	Within-subject biological variation CVi % (95%CI)	Between-subject biological variation CVg % (95%CI)		
Men	3.06 (2.96-3.16)	14.7 (13.1-16.3)	36.5 (29.7-52.4)	-33.4/50.1	0.40
Women <50	2.76 (2.59-2.94)	14.6 (12.5-16.7)	36.3 (26.9-54.2)		0.40
Women >50	2.93 (2.79-3.08)	12.8 (9.7-16.2)	28.8 (19.8-68.7)		

	Biological variation estimates			Reference Change Values RCV % (95%CI) decrease/ Increase	Index of individuality
	Mean value (95% CI)	Within-subject biological variation CVi % (95% CI)	Between-subject biological variation CVg % (95%CI)		
Men	1.06 (1.00-1.13)	15.0 (13.7-16.6)	65.3 (51.1-90.0)	-37.4/59.7	0.23
Women <50	0.47 (0.44-0.50)	17.8 (16.0-19.5)	40.3 (33.5-55.0)		0.44
Women >50	0.91 (0.86-0.99)	16.7 (14.3-19.9)	36.8 (24.5-73.0)		

Ceriotti F, et al. *Clin Chem Lab Med*, 2020
https://doi.org/10.1515/cclm-2019-1182

UPCOMING EFLM EVENTS

EFLM Webinar: Urinalysis

All EFLM webinars are organized by the EFLM Education & Training Committee, Working Group for eLearning and Distance Education (WG-DE)

On **30th June 2020 at 18.00 CET**, Dr. **José A.T. Poloni** (BR) will talk about urinalysis that is one of the most common tests performed in Clinical Analysis laboratories worldwide. Despite the simplicity of the method this test can furnish a wide range of information specially to help in the diagnosis of diseases from the kidneys and the urinary tract. The proper knowledge on the recognition of urinary particles and in the comprehension of the urine sediment profiles are mandatory to develop a work in urinalysis on the highest level possible. This webinar will focus on the different analytical phases of the test specially explaining about the urinary findings observed in the different profiles of diseases that can be identified in urine samples.

For registration, go to the EFLM e-learning platform (EFLM Academy members only).

PAST EFLM EVENTS

Communication Between Laboratory and Clinician: Key for Proper Medical Care

EFLM Webinar

On 19th May 2020, prof. **Avi Peretz** (IL) presented a webinar about communication between laboratory and clinician. With a moderator, Dganit Itzhaky (IL), they created a very interesting session that was highly appreciated by attendees. The topic is broadly discussed in the Hot topics section above.

Recorded webinar and certificates for EFLM Academy participants that will pass a short quiz can be found here.

Updates on COVID-19 biology and diagnostics

EFLM Webinar

On 28th May 2020, prof. **Giuseppe Lippi** held a webinar with the title: "Updates on COVID-19 biology and diagnostics". Webinar was organized via EFLM e-learning platform and was moderated by Prof. Ana-Maria Šimundić. This webinar has attracted much interest, as shown by the large number of participants that took part in it. Prof. Lippi presented recent data on the epidemiology of coronavirus disease 19 (COVID-19) and focused specifically on the advancements of detection approaches for acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Additionally, Prof. Lippi addressed the emergence of serological tests for SARS-CoV-2, with a special focus on commercially available assays and criteria required for their mass usage and epidemiologic surveillance. EFLM would like to thank Prof. Lippi for this interesting and comprehensive webinar and for his tireless efforts in providing timely information and data to all our members and colleagues.

Recorded webinar and certificates for EFLM Academy participants that will pass a short quiz can be found here.

NEWS FROM EFLM NATIONAL SOCIETIES

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

Reported by Josefina Mora Brugues, Executive Secretary of SEQC^{ML} Board

SEMI and SEQC^{ML} sign agreement to launch projects in the field of patient care, training, and research

- **The agreement has been signed by the president of SEMI, Dr. Ricardo Gómez, and the president of SEQC^{ML}, Dr. Imma Caballé**
- **It will promote mutual cooperation between the two entities, and facilitate the exchange of scientific knowledge and professional training**

Madrid, February 13, 2020 - The Spanish Society of Internal Medicine (SEMI) has signed a collaboration framework agreement with the Spanish Society of Laboratory Medicine (SEQC^{ML}) through which both entities will collaborate in the implementation of projects and actions in the areas of healthcare, training, and research.

The agreement was signed today by the president of SEMI, Dr. Ricardo Gómez, and by the president of SEQC^{ML}, Dr. Imma Caballé, and involves the creation of a strategic alliance through which both entities will undertake to facilitate the exchange of scientific information, organize work sessions, and cooperate in the continuing education of professionals.

This framework agreement will also serve to promote the dissemination of medical knowledge about the specializations of both organizations. It will also serve to promote research, as well as joint collaboration initiatives of various kinds between professionals of the two societies.

In the words of SEMI president Dr. Ricardo Gómez, this alliance represents "a decisive step in establishing synergies of collaboration that will allow for the establishment of stable and permanent cooperation links between both organizations, and will contribute to launching initiatives of interest to the partners of both organizations in the field of healthcare, training, and research."

For the president of the SEQC^{ML}, Dr. Imma Caballé, "this agreement is a way to bring laboratory medicine closer to internal medicine specialists, one of the groups with greatest importance in the activity of the laboratory. This collaboration will be seen in the healthcare area with the publication of joint documents, and in the informative field in conferences, presentations, congresses, etc."

The signing of the agreement took place today in Madrid, at the headquarters of the SEMI, in which Dr. Gómez and Dr. Caballé held a work meeting that led to the signing of this agreement, which will be automatically renewed annually.

For the coordination and follow-up of activities, a Joint Monitoring Commission will be established, which will include members of the two societies, and which will meet at least once a year.

Snapshots of the SEMI and SEQC ML agreement signature

More information about the Spanish Society of Internal Medicine (SEMI) can be found at www.fesemi.org.

More information about the Spanish Society of Laboratory Medicine (SEQC ML) can be found at www.seqc.es.

The Spanish Society of Laboratory Medicine (SEQC ML) collaborates in the Ditunga Project. Spanish Laboratory Medicine collaborates in setting up a Clinical Laboratory in the Democratic Republic of the Congo.

- **The Spanish Society for Laboratory Medicine (SEQC ML) is participating in this solidarity initiative by providing a grant for a visit by a Clinical Analysis specialist**
- **With the collaboration of a Spanish professional and member of the Society, a clinical laboratory has been launched in the new Hospital Nuestra Señora de Guadalupe**
- **The initiative is part of the CSR objectives of the SEQC ML that seek to improve the quality of life in disadvantaged communities**

Madrid, May 11, 2020 - The Spanish Society for Laboratory Medicine (SEQC ML), through the José Luis Castaño Foundation-SEQC, has collaborated in an ambitious solidarity project in the Democratic Republic of the Congo that seeks to improve health conditions in the area through the launch of a new hospital. This initiative is part of the Ditunga Project, which has launched a new medical center, the Nuestra Señora de Guadalupe Hospital, and which is the most modern in the region in many ways, especially in regard to the equipment it has.

The Ditunga project is taking place in the Ngandanjika territory, in the province of Kasay Oriental, one of the most isolated in this African country, plagued by various armed conflicts in recent decades and with many development needs. As explained by Dr. Antonio Moreno, member of the SEQC ML Board of Directors, this initiative had the necessary characteristics to justify the Society's involvement. This participation takes the form of the financial grant so that one of the SEQC ML members, Belén Fernández Puntero, a doctor in pharmacy and specialist in Clinical Analysis, could travel to and work in the area for two weeks. The objective was for this professional to participate in the start-up of a Clinical Laboratory in the new hospital.

"In this first mission we proceeded to establish the bases of the laboratory, adaptation of spaces, and start-up of equipment, but various actions are still pending", explains Dr. Moreno, who details that, among other aspects, it is still necessary to reinforce the training of personnel in various areas, increase the portfolio of services, and improve the management of both documentation and the clinical laboratory itself.

Belén Fernández Puntero explains that the experience of launching the hospital was "very intense". "We found the building and little else. It was necessary to set up stretchers, operating room tables, an ultrasound machine, the blood bank refrigerator, the hospital pharmacy, the water distiller, sterilizers and, of course, the entire laboratory, which had walls, a laboratory worktable and little more. In fact, it was necessary to extend the worktable, electrical outlets, and finish the water connection".

The Clinical Analysis specialist explains that shortly after arriving in Ngandanjika, the operating room started operations and was able to collaborate with the rest of the health professionals. At the same time, and while the laboratory was being completed, Dr. Fernández Puntero provided analytical guidance for some of the patients undergoing surgery or those who came for consultations.

"At a clinical level, you learn a lot, because there you can see live and in person the pathologies that we have studied in books; but also at a technical level it is a very enriching experience, because with the means available you have to be able to offer support to the clinicians with whatever laboratory medicine that you have available in the circumstances," explains Dr. Fernández Puntero.

"Participating in these initiatives is a personal option, it is a way of contributing and giving back something that we have received. I have had the immense good luck of being born in a developed country, with advanced healthcare and sanitary conditions ... that is why I feel obliged to give back some of all this, and my way of doing so is to teach what little I know. In addition, I must thank the great effort made by the José Luis Castaño-SEQC Foundation and SEQC ML itself to improve the training of its members and enhance the specialty of Laboratory Medicine", concluded this specialist.

In the same vein, Dr. Moreno points out that in Spanish laboratories professionals are used to having technical and personnel resources that cannot be extrapolated to situations such as those seen in the Democratic Republic of the Congo. However, he indicates, "the needs of the population that we must attend to are the same from the healthcare point of view, so our Clinical Laboratory specialists must also learn to cope in these situations".

Corporate social responsibility

As indicated by Dr. Moreno, the purpose of the SEQC ML is to actively contribute, through its corporate social responsibility (CSR), in social, economic, and environmental areas, focusing particularly on communities in underdeveloped or developing countries. "Our objective in this project is to contribute to improving the quality of life in disadvantaged communities. We do not seek external recognition, but obviously, we project the

importance and the high level of Spanish Laboratory Medicine", said the doctor.
Along these lines, Dr. Moreno highlighted that the SEQC^{ML} participates in other initiatives, with special mention of the collaboration with the Latin American Confederation of Clinical Biochemistry (COLABIOCLI) through the José Luis Castaño-SEQC Foundation for the development of Laboratory Medicine, issuing financial grants so that members of Latin American countries associated with COLABIOCLI can carry out training stays in Spanish Clinical Laboratories.

You can find out more about the Hospital Nuestra Señora de Guadalupe, in Ngandanjika, in this video: https://youtu.be/qgHoaSvB4wg

Snapshot of the Ditunga Project in Ngandanjika (Democratic Republic of the Congo)

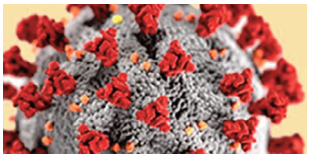
IFCC NEWS Reported by Katharina Psara, IFCC eNews editor

Dear colleagues,
It seems that better times are coming as the summer approaches. People will have the chance to meet each other again, some tones of normalcy may return. Laboratorians play an important role all over the world in the management of this new disease. A lot of knowledge is built up, a lot of it is already published: read the IFCC Information Guide on COVID-19. Keep up-to-date about IFCC and read the eNews.

The IFCC is pleased to announce the new IFCC President: Prof. Khosrow Adeli

Prof Adeli has commenced his term on May 15th, 2020. IFCC congratulates the new President and wishes him a fruitful and successful term of work for the promotion of Clinical Chemistry and Laboratory Medicine worldwide. Prof Adeli is currently the Head of Clinical Biochemistry at the Hospital for Sick Children and the Vice-Chair of Laboratory Medicine & Pathology at the University of Toronto in Toronto, Canada. He is also a senior scientist in Molecular Medicine at the Research Institute, the Hospital for Sick Children. He is very well known for his extensive national and international contributions to clinical laboratory service, research, and education. Click here to know better Prof. Adeli and his vision for the future of IFCC.

IFCC Information Guide on COVID-19 – weekly updates with News Webinars!

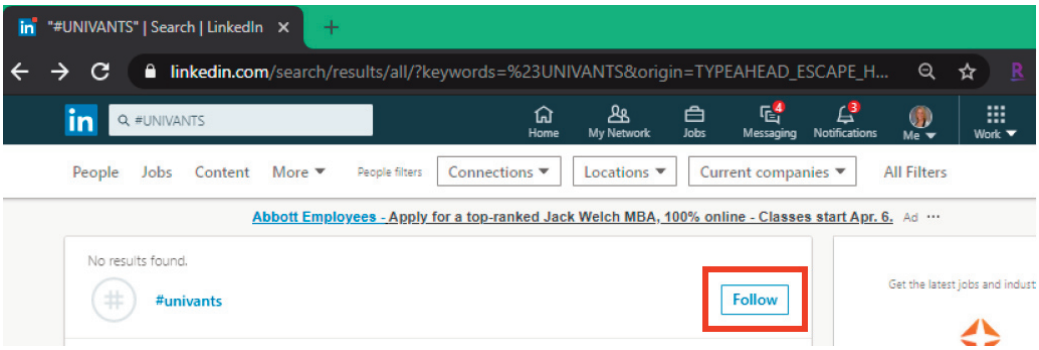


The IFCC is pleased to publish an online resource providing key information on laboratory guidelines, biosafety, and other important resources to assist member societies around the world and their clinical laboratories as they face the challenges posed by the COVID-19 outbreak. Visit the IFCC website to get the most updated information on COVID-19.

Join Us in Celebrating Healthcare Excellence on LinkedIn

Healthcare evolves rapidly. Transforming the delivery of healthcare requires agility, novel thinking, innovation, and teamwork. Opportunities to network and stay up-to-date on key events and best practices associated with the UNIVANTS of Healthcare Excellence Award Program (www.univantshce.com) are possible on LinkedIn. Explore and learn more about award-recognized best practices of integrated care projects that have achieved measurably better healthcare for patients, clinicians, payors and health administrations. Be inspired to emulate similar care projects, improve upon your programs, and/or find new ways to inspire healthcare professionals on the frontlines of enhancing care.

Follow these easy steps to join other like-minded individuals who are passionate about healthcare excellence and the UNIVANTS HCE Award Program using LinkedIn:
Go to the LinkedIn.com
On the welcome page, find the search feature on the top left corner search bar.
Type in #UNIVANTS and select "see all results for #UNIVANTS"
You will be prompted on the next screen to "Follow" the hashtag. Select the "Follow" button.



You will be prompted on the next screen to "Follow" the hashtag. Select the "Follow" button.

Upon following #UNIVANTS, you will join a global community, and have opportunities to explore articles and integrated best practices for patient care. We invite you to also share relevant articles of healthcare excellence across communities by tagging #UNIVANTS for enhanced team engagement. Success stories can inspire new teams and new projects for measurably better healthcare.

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here.
Due to COVID-19 alert throughout the world, some upcoming events could be cancelled or postponed, please direct check with the organizers if the date is confirmed.
Apply for EFLM auspices! For more information visit here or email eflm@eflm.eu

23-25 September 2020
XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Belgrade Symposium for Balkan Region
Belgrade (SRB) Click here for information

28 September - 1 October 2020
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

8-11 October 2020
46th ISOBM Congress
Bled (SL) Click here for information

11-13 October 2020
XIV Congress of Slovak Society of Clinical Biochemistry
High Tatras (SK) Click here for information

15-16 October 2020
17th DGKL e. V. Annual Meeting
Mannheim (DE) Click here for information

23 October 2020
International Conference on Laboratory Medicine "Pathology and Laboratory Medicine: the promise, the hope, the peril"
Padova (IT) Click here for information

16-18 November 2020
Vårmöte, Klinisk Kemi 2020
Umea (SW) Click here for information

30 November 2020
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

4-5 December 2020
54th days of Practical Biology
Paris (FR) 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

25-26 March 2021
6th EFLM Conference on Preanalytical Phase - Biannual Conference organized by the EFLM Working Group on "Preanalyical Phase" in collaboration with BD
Zagreb (HR) Click here for information

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

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