

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

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



HOT TOPIC IN LABORATORY MEDICINE

Vitamin D Myths and Facts

Reported by Ali Unlu, Head of Medical Biochemistry Department at the Medical School in Selçuk University, Konya, Turkey

The effect of vitamin D on bone health, calcium and phosphate metabolism has been known for years. However, with the demonstration that 1 alpha hydroxylase enzyme and vitamin D receptor are found not only in tissues such as bones, kidneys and small intestine, but also in almost the whole body, its relation with almost every disease has begun to be investigated. As a result, the relationship between vitamin D and health or disease has become very popular not only in the scientific area but also in the media. Since the promising data obtained in laboratory studies on the relationship of vitamin D with extraskeletal diseases cannot be supported by clinical studies, vitamin D cannot find a place for itself in the upper steps of the evidence-based medicine pyramid such as in meta-analysis and clinical treatment guidelines. Although serious promising results have been published in molecular studies in cancer, the results of epidemiological studies do not support basic laboratory studies of vitamin D and cancer. Approximately 3% of the human genome is regulated by vitamin D-vitamin D receptor interaction. At least 8 cancer-related signaling pathways affected by vitamin D at supraphysiological concentrations affect cell cycle (G0 / G1 phase), decreased CDK1 activity. Antitumor efficacy in mice treated with vitamin D, colon hyperplasia developed in VDR gene-knockout mice. Vitamin D treatment results with increased tumor suppressor genes activity and TGF β and TGF β receptor, GDF-15, bone morphogenic protein levels. Vitamin D treatment decreases MAPK activity (IGF1 activity), decreases CDK1, Cyclin A, B, F, -myc, jun, c-fos, EGF receptor levels.

To be continued on page 2

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Foreword

Reported by Harjit Pal Bhattoa, Editor EuroLabNews



The current summer issue of the EuroLabNews commences with the Hot Topic column where Ali Unlu presents the Myths and Facts about Vitamin D. Ana-Maria Šimundić, EFLM President and Chair of the Task Group EFLM Syllabus Course announces the EFLM Syllabus Course. The AACC Learning Lab is a promising platform for all in the field of Laboratory Medicine. The EFLM Office informs the readership the benefits of the EFLM Academy and announces the formation of the EFLM Young Scientist Task Group. News from the EFLM Functional Units highlights the activities of the EFLM Task Force on European Regulatory Affairs (TF-ERA) presented by Christa Cobbaert and Michael Neumaier. Quite a few new EFLM publications are listed. Mark your calendars for the upcoming EFLM events. Silvia Cattaneo from the EFLM Office reports change of guard in the Danish, Greek, Netherlands and Swedish National Societies. The Spanish Society of Laboratory Medicine report their latest activities. Under its regular column, the IFCC corner presents global perspectives in Laboratory Medicine. The Calendar of Events lists all major happenings with its usual and unfortunate COVID-19 alert. Have a Safe and Rejuvenating Summer!





Clinical epidemiological studies do not support results from laboratory studies. International agency for research on cancer concluded that the relationship between food and vitamin D intake and cancer is not reliable, colon cancer data are limited, prostate and breast cancer results are negative. Plasma level of vitamin D may have some protection to the colon but no effect on the development of breast and prostate cancer. Vitamin D supplement has similar incidence in randomized clinical trials. Not only common cancers, rare cancers such gastric, renal, endometrial, over and lymphomas have also displayed no relation with vitamin d levels. In contrast, high vitamin D levels (>100 nmol/l) were found to be associated with a high odd ratio risk to develop pancreas carcinoma. The United States Preventive Service Task Force (USPSTF) stated that, due to insufficient evidence, it was unable to assess the balance of benefits and harms of supplemental vitamin D to prevent cancer (1).

Vitamin D and cardiovascular disease; VDR and 1 α Hydroxylase gene knockout mice develop cardiac hypertrophy and heart failure. VDR and 1 α Hydroxylase SNP are associated with left ventricular hypertrophy, heart failure, and coronary calcification. Application of vitamin d to these animals has some benefits with the regression of these pathologies. Similar to cancer research clinical trials found no benefit of vitamin D supplementation although some observational studies displayed some degree of association with cardiovascular disease incidence and mortality. American Heart Association concluded vitamin D and CVD relation U shape, high risk at low and high levels of plasma vitamin D (2, Figure 1).

The Cochrane database also displayed that vitamin D and pneumonia and diarrhea relations are uncertain. Supplementation did not give any beneficial effect on depression. Vitamin D supplementation has no benefit regarding Multiple Sclerosis risk (3), frequency of relapse development, prognosis. Similar conclusions are also mentioned in other autoimmune diseases such as psoriasis (4) and asthma (5). None of the autoimmune disease treatment guidelines do not contain Vitamin D treatment. Vitamin D has no effect on chronic pain and still needs more studies. There is no clear beneficial effect of vitamin D on pregnancy. Vitamin D has been found to reduce fall of seniors but this relation seems to be U shape, high risk at low and high level.

Institute of Medicine from Pennsylvania State University concluded that extraskelatal outcomes, including cancer, cardiovascular disease, diabetes, and autoimmune disorders, the evidence was inconsistent, inconclusive as to causality, and insufficient to inform nutritional requirements (6). Randomized clinical trial evidence for extraskelatal outcomes was limited and generally uninformative. The relationship between vitamin D and vascular health by type U and splayed N type relationship with cancer, and splayed U type relationship on total mortality have been published by WHO.

Vitamin D-Covid 19

Since 2020 is a pandemia year, vitamin D and COVID-19 relation has also been studied widely since vitamin D has some immunomodulatory role. Vitamin D deficiency increases proinflammatory cytokines such as NF-KB, IL-6, TNF-alpha, interferons and CRP.

Vitamin D suppresses T cell proliferation and T cell activity. However, lymphopenia is one of the worst signs of severity of COVID-19 disease. Studies demonstrated T helper 1 suppression by vitamin D results with decrease in proinflammatory cytokines while T helper 2 stimulation results in increase of anti-inflammatory cytokines. Vitamin D increases tight junction stabilisation, and may block virus entrance into tissues. Vitamin D treatment results in vasodilation which is an important part of inflammation. Animal studies have shown D vitamin supplementation increases Ace-2 receptor levels in lung tissue. All molecular mechanisms affected by vitamin D in terms of COVID infection are still questionable whether treatment may be helpful.

In a most comprehensive clinical study related to vitamin D has been performed in the UK and it concludes no relation with D vitamin levels to hospitalization, morbidity, mortality rate (7). Randomised clinical trials are still ongoing and looking for their results. NIH concludes that there is insufficient data to recommend either for or against the use of vitamin D for the prevention or treatment of COVID-19. Only immunomodulatory agent recommended by NIH is dexamethasone in COVID-19 treatment guidelines (8).

Vitamin D and Clinical Laboratory Data

The reference ranges of vitamin D were determined to be a "normal" circulating 25(OH)D range related to health and disease rather than the values obtained in the Gaussian distribution of a random population. In order to define "health" or "disease" condition, optimal vitamin D levels criteria should have maximal suppression of parathormone, adequate intestinal calcium absorption and fracture prevention. Optimal levels of vitamin D are accepted as 20-40 ng/ml (50-100 nmol/l) by US Preventive Service Task Force, NIH and Australian Royal College of Pathologies. Individuals less than 12 ng/ml are suggested to take supplements. In Europe 13% of the population has less than 12 ng/ml (30 nmol/l), 40.4 % have less than 20 ng/ml (50 nmol/l) vitamin D levels. 15 ng/ml 25 (OH) D is enough to have sufficient amounts of 1, 25 (OH) $_2$ D. Recent literature considers vitamin deficiency if it is less than 10 ng/ml. In a comprehensive data mining study in Turkey, 20 % of the population have less than 12 ng/ml 25 OHD. However, it was observed that 25 (OH) D values lower than 10 ng/ml were accompanied by elevated PTH. In addition to that, although elderly population uses supplements, they still have high PTH levels compared to the young and middle age population. USPSTF does not recommend screen or use supplements in asymptomatic adults. Of course, the highly risky population needs extra care.

Vitamin D Analysis

Vitamin D has more than 50 metabolites (figure) and its analysis has always been on the agenda since its discovery. 25(OH) D $_{total}$ accepted as biomarker of vitamin D status. While vitamin D $_2$ can be taken from plant-based foods and D $_3$ can be synthesized in the body and taken with animal origin foods. Vitamin D $_2$ and D $_3$ have similar potency although D $_2$ has one more double bond and methyl group than D $_3$. D $_3$ is formed as a result of breaking of the B ring of 7 dehydrocholesterol in the skin with the effect of UVB light and the resulting D $_3$ undergoes hydroxylation from its 25 th carbon in the liver. 25 OHD $_3$ or $_2$ is converted to either highly active 1, 25 (OH) $_2$ D or inactive 24, 25 (OH) $_2$ D in the kidney. 1 alpha hydroxylase and 24 hydroxylase activities are strictly regulated by PTH, ionised calcium and phosphate

Commonly used to measure 25 (OH)D methods are:

- o Competitive protein binding assay
- o RIA (125 I radiolabelled 25 OH D $_3$)
- o Liquid/liquid extraction, HPLC
- o Liquid/liquid extraction LC-MS/MS
- o ELISA
- o ELFA (Biomérieux)
- o Chemiluminescence, CLIA, (Roche, Siemens, Beckman Coulter, Abbott, Fujirebio)
- o ITA (Diazyme)

Mass spectrometric method is accepted as the gold standard to measure 25(OH) D_{total} level. Since it has the most accurate results with NIST SRM, declared by NIST, Ghent University and CDC. Triple quadrupole mass spectrometers are the mainstay in mass analysis. Since most of the LC-MS/MS methods developed in-house, MS methods using NIST material and certified by DEQAS are accepted as standardized analysis. Commercial kits are available from Waters, Sciex, Thermo, SEM etc.

CLIA analysis is the most commonly used method in the laboratory world since it is easy to use in daily practice. Immunoassays have over estimation when compared to LC-MS/MS because of 24,25 (OH)₂ D cross reactivity. This imprecision increases at low levels. 1, 25 (OH)₂ D₃ levels are low pg/ml in circulation (30-70 pg/ml, nearly 1/100 to 25 OH D) and its free form at femtomolar level. It is highly lipophilic and relatively unstable. LC-MS/MS is the most common method to measure the active metabolite and there are 2 CLIA (Diasorin, IDS-ISYS) and 1 RIA (IDS) methods also available. 24, 25 (OH)₂ D is the second most abundant metabolite after 25 (OH) D (2,7-34 ng/ml UK, 2-8 ng/ml in other studies) and its level is positively correlated with 25OHD. LC-MS/MS is the only method to measure its level. Authors suggest 25 OH D/24, 25 (OH)₂ D₃ ratio rather than using its alone level. DEQAS shows high variability for these 2 metabolites between labs since most of the mass spectrometric methods developed are "in-house". Both active and inactive metabolite levels are suggested to use only in disease-focused patients, such as vit D resistant rickets, 1 α hydroxylase deficiency, undefined hypo/hypercalcemia and hypophosphatemia. Their measurements are not recommended for a healthy population. There are some standardization programs such as DEQAS (D Vitamin External Quality Assurance Program), VDSP (Vitamin D Standardisation Program), VITDQAP (Vitamin D Metabolites Quality Assurance Program, after 2107 NIST Health Assessment Measurements Quality Assurance Program), German Reference Institute for Bioanalytics and some other national programs. DEQAS is one of the most comprehensive programs and contains 1200 participants from 54 countries. DEQAS have programmes for 25OHD, 1, 25 (OH)₂ D and 24, 25 (OH)₂ D analysis. VDSP recommended assay performance limits, for "routine" laboratory assays should have CVs ≤ 10% and biases ≤ 5%. Either NIST material or patient sample displayed LC-MS/MS achieved CV ≤ 10% and mean bias ≤ 5%. 50% of immunoassays met the criterion for a ≤ 10% CV, only 3 of 8 immunoassays achieved the ≤ 5% bias in VDSP Interlaboratory Comparison Study I (10). VDSP published an intra-laboratory data in 2021, 13 assay (CLIA, ELFA, ELISA, ITA, EIA, LCMSMS) met the criterion for a ≤10% CV, only 9 assay (CLIA, ELFA, ITA, LCMSMS) met ≤ 5% bias. VDSP Interlaboratory comparison study still has not been published. The effect of vitamin D on bone health and calcium phosphate metabolism is clear. Its benefits other than bone health are full of question marks and therefore cannot be included in treatment

algorithms. Many reports on vitamin D indicate that level screening in the general population and supplementation in those without bone disease are unnecessary.

However, with the popularity of vitamin D, the number of vitamin D analyzes requested from laboratories has increased considerably, making it difficult to use mass spectrophotometric methods. With this increasing demand, there has been an increase in available immunoassay commercial kits, first generation kits followed by second generation kits. It is observed that the new generation products give more accurate results according to the standardization program reports. The fact that the 25 OH D level at the level of 15 ng/ml creates sufficient active metabolites and at higher levels the metabolic pathway shifts to inactive metabolite production in the kidney, causing a decrease in the attention to the relation of general health and many non-bone diseases with vitamin D. It seems that the vitamin D story has evolved into "The More Vitamin D You Get, the best, better, may be, may not be.....?" for general health.

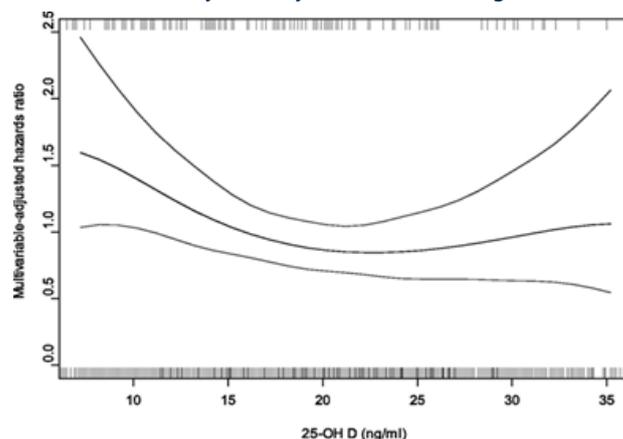


Figure 1: Baseline vitamin D status and incidence of cardiovascular events (2).

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EFLM EXECUTIVE BOARD INFORMS

Announcement of the EFLM Syllabus Course

Reported by Ana-Maria Šimundić, EFLM President and Chair of the Task Group EFLM Syllabus Course



EFLM SYLLABUS COURSE



THE MOST COMPREHENSIVE ONLINE COURSE IN LABORATORY MEDICINE

AVAILABLE FROM JANUARY 2022

FREE FOR EFLM ACADEMY MEMBERS

In January 2021, EFLM established a new task group – Task Group for EFLM Syllabus Course, with the aim to initiate and maintain EFLM Syllabus Course in Laboratory Medicine. From that point on, great efforts and enthusiasm have been invested in assembling the first program of the Course. Only a few months later, we are proud and happy to announce the launch of the EFLM Syllabus Course in January 2022. The program of the Course can be explored and accessed [here](#).

EFLM Syllabus Course is the most comprehensive online course in Laboratory Medicine and Clinical Chemistry, which comprises more than 40 modules and more than 300 speakers - esteemed experts in their fields from all over the world. Importantly, all lectures will be available on-demand on the EFLM Syllabus Course designated website.

The idea behind this fundamental project was to offer a convenient and attractive educational resource that will enable trainees and residents in Laboratory Medicine and Clinical Chemistry to increase or review their knowledge and confidence. Moreover, we believe that it will be exciting and valuable to all who are interested in Laboratory Medicine. The Course is in accordance with the European Syllabus (document available [here](#)) and covers all fields of laboratory medicine, including general topics such as laboratory management, quality control and statistics to more specific fields such as biochemistry and diagnostics of different organ systems and related diseases, body fluids, inflammation, tumor markers, etc.



Additionally, EFLM Syllabus Course is an important response to needs and requests expressed by the EFLM members and has been set as one of the priority goals in the EFLM Action Plan for 2021 (document available [here](#)). It is important to note that EFLM educational resources and activities are the most appreciated by the EFLM members, as our survey has shown; thus, we are proud that with this project, we could sustain our significant task and mission in providing education and training in Laboratory Medicine in Europe.

Importantly, EFLM Syllabus Course will be free for all EFLM Academy members. It is included in the new set of benefits and assets of the EFLM Academy membership that have been recently expanded (benefits of the EFLM Academy can be explored [here](#)).

Democratization of Education: Adaptive Learning Courses in Laboratory Medicine Are Now Available without A Subscription Fee!

Reported by Nader Rifai, Co-Editor-in-Chief of NEJM Knowledge+/AACC Learning Lab for Laboratory Medicine

In order to increase utility and eliminate financial barriers, AACC Learning Lab for Laboratory Medicine on NEJM Knowledge+ program is now available without a subscription fee for individual users (previously \$89/year). This cloud-based program consists of over 100 courses, covering topics span across all disciplines of laboratory medicine (<https://area9lyceum.com/laboratorymedicine/course/>). The courses are based on the concept of adaptive learning, the closest to personalized education.

Adaptive learning is an ingenious way to communicate information. Through sophisticated computer algorithms, the platform interacts with the learner and identifies the areas in which they are not proficient. It then provides targeted learning materials to remedy the deficiency, thus enabling efficient learning in small blocks of time. The program can be accessed via mobile devices for added flexibility.

Over 125 leading clinical laboratory scientists and physicians from the United States, United Kingdom, Canada, Australia, Iceland, Denmark, Norway, Croatia, Italy, South Africa, Hong Kong, Turkey, and Singapore have built these courses. Each course consists of ~100 granular learning objectives; every learning objective is coupled with one to two probes and a learning resource. The probes are the actual questions and can be presented in one of nine different formats that meant to be engaging and interesting to the learner. Each course goes through a rigorous internal and external review process followed by a beta testing evaluation. Over 250 laboratory medicine professionals have participated in reviewing and performing the beta testing evaluation of these courses.

This program has been designed for laboratory medicine professionals in hospital laboratories, commercial laboratories and the in vitro diagnostics industry to help them to assess their knowledge, remain abreast with current knowledge, and prepare for certification exams.

This ambitious program is a collaborative effort between NEJM Group, the publisher of the New England Journal of Medicine, AACC, the publisher of Clinical Chemistry, and Area9 Lyceum, a global leader in education technology. We sincerely hope that laboratory medicine professionals worldwide, regardless of their financial abilities, can now take advantage of this opportunity and join the other thousands of users of this program.

EFLM OFFICE INFORMS

EFLM Academy benefits

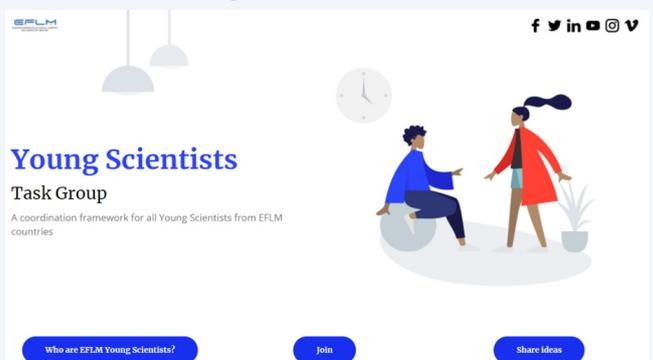


To illustrate in detail the benefits offered by the EFLM Academy to its Members and the modalities of joining the Academy, a dedicated brochure has been developed by the EFLM Communication Committee upon request of the EFLM President.

[Click here to access the brochure.](#)

[At this link](#) you can find also the presentation of the EFLM Academy made by the EFLM Executive Board and the EFLM Profession Committee on occasion of individual meetings with EFLM National Societies.

EFLM Young Scientist Task Group



EFLM established a coordination framework for all Young Scientists from EFLM countries: the Young Scientists Task Group.

Young scientists, residents, IVD companies representatives, all young professionals in Laboratory Medicine and related disciplines from all EFLM functional units and EFLM countries can join. The main activities of Task Groupe is raising awareness of young scientists in laboratory medicine, building a communication network of young scientists and laboratory professionals in Europe, facilitating professional and scientific

exchange of young scientists, creative contributions promoting EFLM activities, laboratory medicine and laboratory specialists using innovative ways and formats, organizing virtual and face to face social, scientific and educational meetings to share experience and foster collaboration among young scientists, actively participating on events organized by EFLM, inspiring EFLM functional units with topics relevant for young scientists and more.

All activities will be done in close cooperation with EFLM mother functional units and home countries and are coordinated with Communication Committee. For joining this Task Group and more information please [click here](#).

A new issue of CCLM is available online!

A new issue of CCLM, the scientific Journal of EFLM, is available on-line. [Click here](#) to access CCLM Vol 59, Issue 8.

Do you wish to freely access all articles in CCLM? Become an EFLM Academy Member! [Click here](#) to know more. We remind EFLM Academy Members that to free access papers in CCLM is only possible through the personal area in the EFLM Academy where some other interesting opportunities await for you such as for example the access to some other international journals, the EFLM webinars and the access to CLSI documents* (*this latter opportunity is reserved only to EFLM Academy members en-bloc registered by National So-cieties). To know more, contact: eflm@eflm.eu

The CEN and CENELEC Annual Reports 2020 are available

CEN and CENELEC Annual Reports for 2020 have been [published](#) and are now available.

The Annual Reports consist of three parts: the joint CEN and CENELEC activities and one each individual report for CEN and CENELEC. The document provides an overview of the relevant and diverse standardization activities that the CEN and CENELEC community implemented over the course of 2020, a challenging but successful year. To learn more about CEN and CENELEC's activities in 2020, read and download the full version of the CEN and CENELEC Annual Reports.

NEWS FROM EFLM FUNCTIONAL UNITS

[EFLM Task Force on European Regulatory Affairs \(TF-ERA\)](#)

The new EU Regulation for In Vitro Diagnostic Medical Devices: a first breakthrough to mitigate the risks related to the unpreparedness of the EU Regulatory System

Reported by Christa Cobbaert and Michael Neumaier, EFLM TF-ERA



The new European In Vitro Diagnostic Regulation (IVDR) EU/2017/746, published in the Official Journal of the European Union on May 5, 2017, entered into force on May 25, 2017. The official transition period for full implementation is five years. The IVDR is planned to be implemented in all EU Member States by May 2022. The biggest changes are the scope enlargement and the introduction of a risk-based approach to classification of medical tests in combination with increased Notified Body (NB) oversight, also for existing tests. The IVD companies need to (re-)register their entire IVD portfolio under the new regulation by the end of this five-year transition period in order to stay in business and to get market access in the European Union. Medical Laboratories that are running in-house tests -the so-called Lab-Developed-Tests or LDTs- are considered to be manufacturers in their healthcare institution; these tests should conform to the Art 5.5 requirements in the IVDR. With only ~10 months left before the Date of Application of this stringent regulation, it is important that both IVD-manufacturers and medical laboratories are prepared.

What is the current situation regarding preparedness of the diagnostic sector?

Firstly, the EU Regulatory infrastructure for certifying and allowing market access of conventional medical tests under the IVDR is not in place, which means that the continuity and availability of conventional medical tests is seriously endangered. Till April 2021, only 7 certifications passed, whereas ~19,000 medical tests need CE-approval under the IVDR.

A statement entitled "[Implementation of the new EU Regulation for In Vitro Diagnostic Medical Devices: a ticking time bomb for the diagnostic sector](#)" (and related Table) was prepared by BioMed Alliance in collaboration with EFLM Task Force on European Regulatory Affairs (TF-ERA) and the European Hematology Association (EHA) to clarify the **hard stop** that the diagnostic sector will face for commercial CE-IVDs if we do not collectively stand up now. At the latest (closed) EPSCO meeting, held on 14-15 June 2021, thanks to the awareness campaign of BioMed Alliance and the EFLM National Societies & National Representatives, about 15 National Ministers of Health spoke up about the urgent need to find solutions for the looming unavailability of many commercial CE-IVDs. These Member State contributions overwhelmingly called for legislative actions to address the IVDR transition challenges. The fact that so many ministers of health have taken the floor gives the European Commission a clear mandate for legislative action. In the coming weeks the ministers of health should reach alignment on what particular actions are needed, e.g. enlarged grace period, postponement, a combination of measures or something else. Apparently all solutions are equally on the table and the discussion to find a way out for commercial medical tests is ongoing. So for the IVD-manufacturers and the commercial tests that medical labs purchase, a solution will come for the supply issues.

Secondly, irrespective of the trajectory for the commercial CE-IVDs the diagnostic labs that run LDTs in their institutions are still expected to be compliant with the requirements of Art 5.5 per May 2022. Depending on the type of laboratory (e.g. core laboratory versus specialty laboratory), the number of LDTs that have to fulfill the new requirements can be substantial. So resources to accomplish this are key. On top, the EU guidance document on LDTs is not yet available but will be later this year. Nevertheless, it is important that lab professionals anticipate now on what is feasible and take a common standpoint regarding the time frame needed to make this happen. Note that asking for delaying the implementation of the LDT part of the IVDR will be a hard nut to crack for the European Commission and strong arguments will be needed. In order to get an idea of the issues that medical labs encounter and the degree of preparedness for LDT-compliance to the new requirements, BioMed Alliance will send out a survey during the summer season among all diagnostic disciplines to inventory the LDT-situation. We count on your willingness to contribute to this survey!



THE EUROPEAN BIOLOGICAL VARIATION STUDY (EUBIVAS): A SUMMARY REPORT

Carobene, et al. Clin Chem Lab Med. 2021
<https://doi.org/10.1515/cclm-2021-0370>



DESIGN

HIGHLIGHTS

 <p>Six laboratories: Milan (Italy), Bergen (Norway), Madrid (Spain), Padua (Italy), Assen (The Netherlands)</p>	study is powered to enable subgroup analyses (e.g. men vs. women)
 <p>91 healthy individuals (58 men, 43 women, 10 women in postmenopausal age)</p>	BIVAC grade A (all 14 BIVAC quality items satisfied)
 <p>sampling for 10 consecutive weeks (serum, EDTA- and citrated-plasma)</p>	BV estimates for the first time for some measurands (e.g. non-HDL, NSE, free, conjugated and %free PSA)
 <p>BIVAC-compliant study</p>	confirmation for some of the previously published BV studies (e.g. albumin, creatinine, urea, etc.)
 <p>Estimates: within-subject BV (CV_I) between-subject BV (CV_G) analytical variation (CV_A)</p>	EuBIVAS is the only BIVAC grade A study for enzymes
 <p>80 different measurands</p>	study offers stricter APS, smaller RCVs
 <p>pre-analytical and analytical phases controlled</p>	reveals gender differences for some measurands - need for revision of reference intervals (e.g. triglycerides and urea)

BV - biological variation, BIVAC - biological variation data critical appraisal checklist, APS - analytical performance specifications, RCV - reference change values

INFOGRAPHIC BY LEJLA ALIĆ (EFLM C-C)

UPDATES ON EFLM PUBLICATIONS

The European Biological Variation Study (EuBIVAS): a summary report

Carobene A, Aarsand AK, Bartlett WA, Coskun A, Diaz-Garzon J, Fernandez-Calle P, Guerra E, Jonker N, Locatelli M, Plebani M, Sandberg S and Ceriotti F

Clin Chem Lab Med 2021; Available from:
<https://doi.org/10.1515/cclm-2021-0370>

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

A recent study by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) summarizes the European Biological Variation Study (EuBIVAS). The authors shortly describe the historical background and arguments for initiation of the study, followed by the overview of the design, including sample collection, study population, analytical methods, and data analysis. The study evaluated impressive 80 measurands in 91 healthy individuals and their biological variation (BV) estimates: within-subject BV (CV_I), between-subject BV (CV_G) and analytical variation (CV_A). It is important to note that the EuBIVAS is compliant with all 14 Biological Variation Data Critical Appraisal Checklist (BIVAC) quality items and therefore is designated as BIVAC grade A study. Interestingly, the study reveals significant differences in some of the measurands between men and women, suggesting the need to revise traditional reference intervals. Additionally, for some measurands prone to seasonal or other variations (e.g., inflammation markers, vitamin D), the authors discuss potential solutions for assessing their BV. This fundamental study offers high-quality BV data for a wide range of measurands and represents a basis for implementing further studies on issues that the EuBIVAS has uncovered.

Other recent EFLM publications:

Systematic review and meta-analysis of within-subject and between-subject biological variation estimates of serum Zinc, Copper and Selenium

Coskun A, Aarsand AK, Braga F, Carobene A, Díaz-Garzón J, Fernandez-Calle P, Jonker N, Gonzalez Lao E, Marques-Garcia F and Sandberg S, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation and Task Group for the Biological Variation Database
Clin Chem Lab Med 2021 <https://doi.org/10.1515/cclm-2021-0723>

Within- and between-subject biological variation data for tumor markers based on the European Biological Variation Study

Abdurrahman Coşkun A, Aarsand AK, Sandberg S, Guerra E, Locatelli M, Díaz-Garzón J, Fernandez-Calle P, Ceriotti F, Jonker N, Bartlett WA, Carobene A, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Biological Variation
Clin Chem Lab Med 2021 <https://doi.org/10.1515/cclm-2021-0283>

Presentation and formatting of laboratory results: a narrative review on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group "postanalytical phase" (WG-POST)

Cadamuro J, Hillarp A, Unger A, von Meyer A, Miquel Bauçà J, Plekhanova O, Linko-Parvinen A, Watine J, Leichtle A, Buchta C, Haschke-Becher E, Eisl C, Winzer J, Kristoffersen AH
Crit Rev Clin Lab Sci 2021 <https://doi.org/10.1080/10408363.2020.1867051>

Quality benchmarking of smartphone laboratory medicine applications: comparison of laboratory medicine specialists' and non-laboratory medicine professionals' evaluation

Jovičić S, Siodmiak J, Duque Alcorta M, Kittel M, Oosterhuis W, Moberg Aakre K, Jørgensen P, Palicka V, Kutt M, Anttonen M, Velizarova MG and Marc J, European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Patient-Focused Laboratory Medicine
Clin Chem Lab Med 2021 <https://doi.org/10.1515/cclm-2020-0869>

UPCOMING EFLM EVENTS

EFLM postgraduate courses

EFLM Working Group on Congresses and Postgraduate Education (WG-CPE) organizes two online EFLM Postgraduate Courses. The aim of the courses is to focus on attractive topics for young trainees and specialists.



Under the auspices of
IFCC
International Federation of Clinical Chemistry and Laboratory Medicine

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

AN ON-LINE COURSE DEVELOPED BY THE EFLM WORKING GROUP ON CONGRESSES AND POSTGRADUATE EDUCATION

1st EFLM online Postgraduate course
BIostatistics IN LABORATORY MEDICINE
1 September - 3 November 2021

Statistics plays a crucial role in many areas of Laboratory Medicine. The knowledge and the correct use of the statistical methods allows us to deal with data variation, to organize and summarize information, to make inference and communicate meaningful experimental results. Moreover, specific statistical methods are frequently applied to routine results and experimental data from validation study designs or verification protocols. In this virtual course, basic statistical concepts, including descriptive and inferential statistics, will be reviewed and applied to real scenarios using a statistical software. Recorded sessions for self-paced learning (theory and practice) will be followed by interactive live sessions with open discussion and case simulation.

Outcome of the Course
To learn basic methods of descriptive and inferential statistics and apply them to real scenarios. The knowledge and the correct use of the statistical methods will allow you to deal with data variation, to organise and summarise information, to make inference and communicate meaningful experimental results.

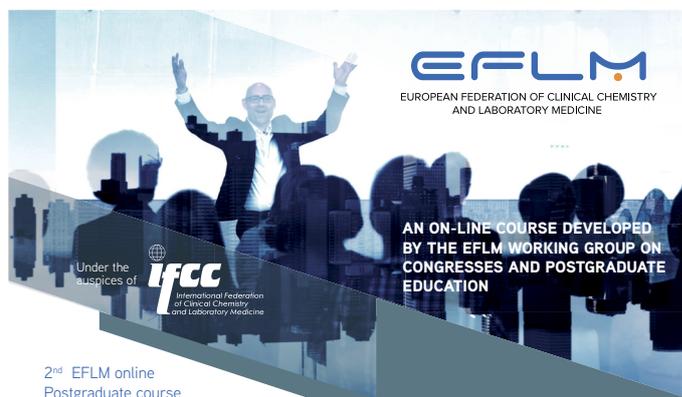
Target Audience
Specialists/trainees, Residency students, PhD students, Specialist of LM, Lab. Directors

Course Organizing Committee
Eser Sozmen, Zsuzsa Bagoly, Daria Pašalić, Silvia Cattaneo

Course Scientific Committee
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International Federation of Clinical Chemistry and Laboratory Medicine

EFLM
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AN ON-LINE COURSE DEVELOPED BY THE EFLM WORKING GROUP ON CONGRESSES AND POSTGRADUATE EDUCATION

2nd EFLM online Postgraduate course
LEADERSHIP SKILLS
13-23 September 2021

The ability to lead effectively a group of people relies on a number of key skills which varies in styles but with a common feature: the flexibility and ability to adapt to circumstances. Leadership skills are highly important to motivate, enthuse and build trust and respect in the work place. Nine experts from different professional fields (including the Presidents of EFLM and IFCC) will be delighted to illustrate the key aspects to be a good leader. In this virtual course, participants will have the opportunity to learn about identification and definition of the of leadership skills such as: rethinking education to shape the future, basic communication skills, how to understand and manage conflicts, change management and insight into different leadership styles. This course will also introduce to the TEST values which provide organizational harmony: Trust, Empathy, Sustainability and Transparency. The original, scientific theory of emotional intelligence will close the course. The course is structured on nine live sessions of one hour each scheduled on 9 days at h. 17.00 CET

Outcome of the Course
To improve leadership skills by discussing the characteristics of charismatic leaders and the qualities required to be effective leader. During the course, strategic leadership in organizations, challenges and problem-solved skills, key points to motivate, mobilize team members to get positive results will be presented.

Target Audience
Specialists/trainees, Residency students, PhD students, Specialist of LM, Lab. Directors

Course Organizing Committee
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PAST EFLM EVENTS

Myths and facts about vitamin D

EFLM Academy webinar



EFLM Academy webinar
MYTHS AND FACTS ABOUT VITAMIN D

Speaker
DR. ALI UNLU (TR)

On June 15th, 2021, at 18:00 CET Dr. Ali Unlu (TR) presented to the EFLM Academy members always interesting topic in laboratory medicine: vitamin D. Moderator of the webinar was Dr. Sedat Abusoglu (TR) while webinar manager was Dr. Oguzhan Zengi (TR). Importance of vitamin D in health was highlighted, as well the role of these vitamin in calcium-phosphate metabolism. The association of vitamin D with many diseases caused a serious increase in scientific articles as well as an increase in number of analysis in routine laboratory practice. Vitamin D analysis, which is increasingly emphasized with both, scientific and media approaches, seriously occupies routine biochemistry laboratories. The efficacy of vitamin D in various diseases is observed in the lower steps of the evidence-based medicine pyramid such as animal and laboratory studies. However, vitamin D cannot find a place for itself in cohort studies, meta-analyses, and clinical practice treatment guidelines, which are the higher steps of the pyramid. This presentation was about myths and facts about vitamin D from the perspective of evidence-based medicine. This webinar presented vitamin D from a laboratory point of view, such as reference intervals, analytical techniques and more.

More information can be found in [EFLM eLearning platform](#) (accessible for EFLM Academy members only).



Young Scientist task group kick-off

On June 18th 2021, online kick-off meeting of the EFLM Young Scientist Task Group was held. Young scientists, residents, and young professionals in Laboratory Medicine from all EFLM functional units and EFLM countries discussed ideas and future steps of this newly formed task group. Participants presented ideas for better communication and networking and for expanding the educational and scientific collaboration between young scientists.

EFLM proudly announces

ONLINE KICK-OFF MEETING OF

THE EFLM YOUNG SCIENTISTS TASK GROUP

Kick-off meeting will gather young scientists, residents, and all young professionals in Laboratory Medicine from all EFLM functional units and EFLM countries

JUNE 18, 2021 | 2.00 - 3.00 PM CET

ZOOM

REGISTER HERE

SAVE THE DATE

Participants in the Zoom meeting grid include: Ana-Maria, Tara Rolic, Hikmet Can Çu..., Communication C..., Aika Tashba, Mirjam van der..., Giulia Sanchezar..., Hayley Foy-Sto..., Jan Van Elstanc, Lejla Alic, Temiza Özben, Jorge Diaz-Gar..., James Harte, Santiago, Nade Daniel Fa..., Nicoara Mariana, Anamarija Rade, Zin Mar Aung, Carmen Minea, José Manuel Go..., Kay Weng Choy, Fevziye Akman, Adel Gouri, Inga Bikulciene, Daniel.

CHANGING OF THE GUARD IN EFLM NATIONAL

Changing of the guard in EFLM national

Reported by Silvia Cattaneo, EFLM Office

A warm welcome to the new incoming National Society officers and a great thank you to the outgoing EFLM National Representatives and National Society Presidents for the support to EFLM activities during their terms of office.

Danish Society of Clinical Chemistry

Prof. Mads Nybo (Dept Clinical Biochemistry, Odense University Hospital) is the new President of the Danish Society of Clinical Chemistry replacing Dr. Lise Bathum.

Greek Society of Clinical Chemistry and Clinical Biochemistry

Prof. Christos Tsatsanis (Lab of Clinical Chemistry, Dept of Laboratory Medicine, Univ. of Crete Medical School) is the new EFLM National Representative for the Greek Society of Clinical Chemistry and Clinical Biochemistry replacing Prof. Christos Kroupis.

Netherlands Society for Clinical Chemistry and Laboratory Medicine

Dr. Merel van Wijnen (Dept of Clinical Chemistry, Meander Medisch Centrum, Amersfoort) is the new President of the Netherlands Society for Clinical Chemistry and Laboratory Medicine replacing Dr. Marc Elisen, who now covers the position as new EFLM National Representative replacing Dr. Claudia J. Pronk-Admiraal.

Swedish Society for Clinical Chemistry

Dr. Mats Ohlson (Dept of Clinical Chemistry, Sahlgrenska University Hospital, Gothenburg) is the new President of the Swedish Society for Clinical Chemistry replacing Dr. Ivar Tjernberg.

Importance of neonatal screening for spinal muscular atrophy

SEQC^{ML}

Sociedad Española de Medicina de Laboratorio

Spinal muscular atrophy (SMA) is a rare and progressive genetic neuromuscular disease characterized by irreversible degeneration of motor neurons, which causes symmetric

proximal weakness and progressive muscular atrophy of muscle groups, affecting motor functions and, in the most serious forms, breathing and swallowing.

The approximate prevalence is 1 in 10,000 live newborns. In Spain, it is estimated that there are 1,500 families that have or have had patients affected by this disease, which is classified into four groups (I-IV) based on severity, age of onset of symptoms, and clinical evolution. Types I and II are the most serious phenotypes, and at the same time, the most frequent. Type I presents before 6 months of life with hypotonia, flaccidity, symmetrical muscle weakness and absence or decrease of deep tendon reflexes, causing death or the need for permanent assisted ventilation in the first two years of life in more than 90% of cases if no treatment is received.

In recent years, the development of new molecular-based therapies has opened possibilities for the treatment of some genetic diseases, including SMA. The effectiveness of these SMA-modifying therapies is significantly higher when treatment is started in the presymptomatic phase, as recent clinical trials have shown. The time from birth to the onset of symptoms is a window of opportunity to detect the disease early and prevent damage to motor neurons. This is why the detection of this disease is being incorporated into neonatal screening programs.

For this reason, on April 8 the [Spanish Society of Laboratory Medicine \(SEQC^{ML}\)](#), with the sponsorship of Novartis, analyzed the **'Advances in neonatal screening: a new horizon for those born with spinal muscular atrophy'**, within the framework of its virtual training project **SEQC^{ML} ACADEMY**, launched recently.

Neonatal screening is of vital importance, since early intervention can stop the progression of the disease in children born with spinal muscular atrophy and save lives, according to the moderators of the course, Doctors Raquel Yahyaoui, of the Metabolopathies Laboratory of the Regional University Hospital (HRU) of Málaga, and Hugo Rocha, of the Neonatal Screening, Metabolism, and Genetics Unit of the Department of Human Genetics of the National Institute of Health- Doctor Ricardo Jorge of Oporto, Portugal.

In the same vein, Dr. Rocío Calvo Medina, neuropediatrician and researcher in Rare Diseases for 12 years at HRU Málaga and participating speaker in the seminar, stressed that if for almost all diseases early diagnosis is important for avoiding unnecessary tests and saving time and suffering for families, in SMA it is even more so, since the available treatments can completely modify the progression of the disease. This can allow for preservation and even improvement of the motor situation of these children.

As this expert explained, in the studies that have been carried out with these treatments, it has been seen that the early initiation of disease-modifying therapy after diagnosis is correlated with a much more favorable motor and vital prognosis. For this reason, pediatricians, neurologists, and other specialists are currently being activated and trained to quickly identify potential symptoms of concern, and neonatal screening studies are being launched to be able to diagnose patients before the development of symptoms. Professionals who have lived through the stage prior to the development of these therapies, she assured, know what it is like to see the disease progress without hope. The effectiveness of the treatments is evident in symptomatic patients, in whom hope, quality and vital functionality improve. But in presymptomatic patients, the results are spectacular, preserving a motor function close to normal in the studies carried out, and a future life expectancy that we could not imagine a few years ago.

These therapies pave the way for future treatment possibilities in many genetically based diseases. In all of them, early diagnosis will allow more efficient results, so developing presymptomatic diagnosis techniques should be an objective within the approach to the global care of all these pathologies. Multidisciplinary collaboration at all levels of care (diagnosis, treatment, social integration, and support for families) is essential for all these patients, highlighted Dr. Calvo.

Heterogeneous implementation of screening

The experiences in the implementation of neonatal screening for spinal muscular atrophy are varied, according to the session moderators. In 2018, for example, it was recommended in the US and is currently being carried out in 34 American states, which represents a coverage of 69% of newborns. In Europe, the process of introducing this screening is a little slower and more heterogeneous, they noted. The first European pilot study was carried out in southern Belgium between 2018 and 2020 and obtained good results, so in 2021 screening has been officially incorporated in this region. Some countries such as Germany, the Netherlands, Poland, Slovenia, Norway, and Serbia have already approved its implementation, and there are active pilot studies in regions of Italy and Russia.

Recently, a committee of experts that includes Dr. Raquel Yahyaoui, a SEQC^{ML} member, published a white paper to promote neonatal screening for SMA in Europe. This initiative, promoted by the European Alliance for Newborn Screening in Spinal Muscular Atrophy (an organization that includes patient associations, scientific societies and institutions, academic networks, and pharmaceutical and health technology companies), aims to ensure that neonatal screening for SMA is established throughout Europe by 2025. Although as of yet the Spanish Ministry of Health, Consumption and Social Welfare has not evaluated the inclusion of SMA in neonatal screening programs at the national level, Drs. Yahyaoui and Rocha believe that the development of methodologies that allow for simultaneous screening for SMA and for severe combined immunodeficiency (SCID) will accelerate its evaluation in Spain, since favorable reports have already been published for SCID that support the clinical effectiveness and cost effectiveness of neonatal screening. The start of pilot studies of neonatal screening for SMA in Andalusia and the Valencian Community is planned for 2021, and in the coming years it is very possible that other Autonomous Communities in Spain will join this effort. These experts stressed that their hope is that the results obtained from these pilot studies will help to promote its implementation in Spain.

Advances in neonatal screening

Currently, neonatal screening consists of the detection, using molecular biology techniques, of a very prevalent mutation that causes the disease in approximately 95% of cases (of the homozygous deletion of exon 7 of the SMN1 gene). This genetic analysis could be performed on the same dried capillary blood specimen on paper that is currently collected in neonatal screening programs. In the last decade, various methods have been developed to perform neonatal screening for SMA, such as that based on LAMP (loop-mediated isothermal amplification) technology or real-time PCR, the latter being the most commonly used method. These techniques are very reliable as they have a high sensitivity and specificity (95/100%) and can be automated to adapt them to the work needs of neonatal screening laboratories. In addition, some of these methods have the advantage of allowing simultaneous determination of severe combined immunodeficiency (SCID) screening, concluded Drs. Yahyaoui and Rocha.

More information at: <https://www.seqc.es/>



Dear colleagues,

A very interesting issue is ready for you. It has enough information for the summer before the next eNews issue. Perhaps you would like to go through the articles to keep you cool in your lab or to keep you company at the seaside. Click [here](#) to read the full issue of the eNews.

Prof. Adeli, IFCC President's Message

I hope the entire IFCC family is having an enjoyable summer season and feeling optimistic about a return to normalcy as the COVID-19 pandemic continues to ease. I am hopeful that we will soon be able to hold our IFCC scientific events in person or in hybrid format and many of the travel restrictions will be lifted by this fall. Taking advantage of the power of virtual communication tools, I am excited to announce a new strategy to significantly enhance internal communication within the IFCC organization, the IFCC **Annual Town Halls**. Starting this fall, these will be international virtual forums (2-3 hours) that will allow the IFCC Executive, IFCC Board Members, and Chairs of IFCC Divisions to meet with the IFCC community in different IFCC regions. Click [here](#) to read the full message.



eJIFCC Vol 32 n°2 (June 2021) is available! In this issue: POCT – making the point. Guest Editor: Prof. Sergio Bernardini. Point of care testing (POCT) represents an important step forward in the clinical management of patients. POC assays are easy to use and do not require skilled personnel, thus they are particularly useful in low-resource settings (where diagnostics laboratories equipped with complex instruments and well-trained technicians are not available), as well as in the Proximity Medicine networks working in synergy with central laboratories. Furthermore, results are delivered in real-time, accelerating the decisional process behind the clinical decision as in the Emergency setting.

IFCC Webinars

Live Series 2021

International Federation
of Clinical Chemistry
and Laboratory Medicine

www.ifcc.org

IFCC free Live Webinars on Tumor Liquid Biopsy

Aug 10, 2021, 7:00 AM (Eastern Standard), 1:00 PM (Central Europe), 7:00 PM (Beijing)

The Webinar will be chaired by Prof. Chuanxin Wang, President elect of the Chinese Society of Laboratory Medicine.

- Circulating tumor cell characterization of lung cancer brain metastases in the cerebrospinal fluid through single-cell transcriptome analysis: Prof. Ming Guan
- The application of mitochondrial DNA mutation as novel biomarker in cancer detection: Prof. Jinliang Xing
- Using tRNA-derived small RNAs as biomarkers in the screening of gastric cancer: Junming Guo

Registration link soon available on IFCC website. Watch out! A maximum of 5.000 registrants is accepted.

The UNIVANTS of Healthcare Excellence Program is Now Accepting Applications

The UNIVANTS of Healthcare Excellence awards recognizes teams who collaborate across disciplines to achieve measurably better healthcare through use of laboratory insights and new processes. If this sounds like you and your integrated clinical care team and/or you are interested in learning more about this prestigious opportunity, we encourage you to visit www.univantshce.com and apply today. Applications are accepted from August 1st to November 15th, 2021.

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here.

Apply for EFLM auspices! For more information [visit here](#) or email eflm@eflm.eu

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.

<p>1 September - 3 November 2021 1st EFLM online Postgraduate course: Biostatistics in Laboratory Medicine EFLM Course, on-line Click here for information</p>	<p>13-23 September 2nd EFLM online Postgraduate course: Leadership skills in Laboratory Medicine alliance" EFLM Course, on-line Click here for information</p>
<p>8-11 September 2021 XXVIII Balkan Clinical Laboratory Federation Meeting and XIII National Conference of Clinical Laboratory Sofia (BU) Click here for information</p>	<p>22-25 September 2021 5th ACTC meeting "Liquid Biopsy in its best" Kalamata (GR) Click here for information</p>



23 September 2021

International Conference on Laboratory Medicine "The ethics of quality and artificial intelligence in laboratory medicine"
Padova (IT)

[Click here for information](#)

EuroMedLab 2021

28 November - 2 December 2021

24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine"

Munich (DE)

[Click here for information](#)



5-10 October 2021

FEBS Advanced Course: 360-degree Lysosome; from structure to genomics, from function to disease-update

Izmir (TR)

[Click here for information](#)

1-2 December 2021

Journées de l'innovation en biologie (JIB 2021)

Paris

[Click here for information](#)

7-10 October 2021

46th ISOBM Congress

Bled (SL)

[Click here for information](#)

Date to be defined

XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Belgrade Symposium for Balkan Region

Belgrade (SRB)

[Click here for information](#)

10-12 October 2021

XIV Congress of Slovak Society of Clinical Biochemistry

High Tatras (SK)

[Click here for information](#)

10-11 February 2022

International Congress on Quality in Laboratory Medicine 2021

Helsinki (F)

[Click here for information](#)

19 November 2021

Annual Meeting of the Royal Belgian Society of Laboratory Medicine (RBSLM) - Hybrid event

Bruxelles (BE)

[Click here for information](#)

March 2022

6th EFLM Conference on Preanalytical Phase Biannual Conference organized by the EFLM Working Group on "Preanalytical Phase"

on-line

[Click here for information](#)



19-20 November 2021

JBP 2021 - Journees de Biologie Praticienne

Paris

[Click here for information](#)

23-26 May 2022

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](#)

26-28 November 2021

XVth International Congress of Paediatric Laboratory Medicine

Munich (DE)

[Click here for information](#)

November 2022 - Date to be defined

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](#)

Boost your brand and increase your company's visibility through the EFLM Newsletter!

EuroLabNews is the digital bi-monthly newsletter of EFLM targeting more than 8,500 laboratory medicine professionals and is also published on the EFLM website.

The EFLM IVD partners are offered the possibility to advertise on EuroLabNews.

Those interested in this opportunity can contact the EFLM Office at silvia.cattaneo@eflm.eu