



Communications and Publications Division (CPD) of the IFCC

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International Federation of Clinical Chemistry and Laboratory Medicine



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EDITORIAL

Message from the eNews Editor

by *Katherina Psarra*
eNews Editor

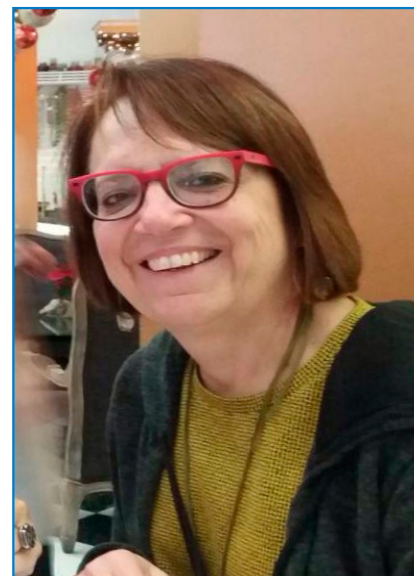
Dear colleagues,

A really interesting issue is ready for you. It has enough information for the two summer months 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... The eNews issues always offer what is best for you (I know you all agree). Think of the countries you come in touch with just by reading.

Our president is promising great innovations in the IFCC structure that will make our organization even stronger and safer. A lot of national societies describe their achievements and the Univants awards are really quite interesting. Some of these projects are so promising.

Let's get ready for face-to-face meetings enjoying the blue seas, the blue skies, the freedom of the summer.

Katherina Psarra



News from the IFCC Website



eJIFCC Vol 32 n°2 (June 2021) is now available!

In this issue: **POCT – making the point**. Guest Editor is **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. A prompt diagnosis is also crucial in the case of contagious diseases allowing rapid isolation of the infected patient and treatment.

The present special issue is, in some way, evidence of our resilience in this very engaging time where Laboratory Medicine has demonstrated again its great value for patient care.

This special issue includes a series of papers reflecting the topics planned for the “POCT: making the point” conference to be held between September 6 and 7, 2021 in Rome, Italy.

The issue is completed with seven other articles, four of them on COVID-19 related topics.

[Read more](#)

THE VOICE OF IFCC

IFCC President's message – July 2021

by Khosrow Adeli
IFCC President



Prof. Khosrow Adeli
PhD, FCACB, DABCC, FAACC

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. There will be brief presentations by the IFCC Executive followed by a panel discussion, aimed at communicating new announcements and addressing any questions or concerns from our members. To ensure that all IFCC members have an opportunity to participate, three (3) townhall sessions will be held annually based on the following regions/time zones: 1) Europe/Africa/Middle East, 2) North/Central/South America, and 3) Asia-Pacific. IFCC Regional

Federation Executives, National Society Presidents as well as all scientists, lab professionals and young scientists in each region will be invited to participate. An additional IFCC Town Hall is also planned for the IFCC corporate members. Official dates will be announced by the IFCC board shortly.

Alongside the Town Hall, we are currently planning the **IFCC General Conference**, which will take place in *Spring or Fall 2022*. As you may know, this meeting is aimed at convening all the IFCC functional units to discuss ongoing activities as well as plan and decide on future actions. The last IFCC General Conference was held in Budapest in 2018 and was scheduled to be held again in 2020 but was unfortunately postponed due to the COVID-19 pandemic. It will be a delight for us to be able to gather in person once again and foster collaboration between our divisions.

In addition to meeting updates, the IFCC is currently working towards strengthening internal procedures and structures, including our **conference guidelines** and **accounting practices**. It was previously mentioned that the IFCC Executive Board was working towards creating new guideline documents for all future conferences to aid in the planning, organization, and execution of these events. These harmonized documents are now being finalized and should be available soon. In terms of accounting, we have been in discussion with an international accounting firm, **KPMG**, which we will be recruiting to provide accounting and related administrative support. IFCC will continue with its internal accounting, but KPMG will support these activities to ensure the best accounting practices are in place. Thereafter, KPMG will support formal controls of documents issued and received, sample

Article continued on next page

checks of recorded entries, monthly reconciliations, and review of financial statements. I anticipate these improvements to IFCC's internal procedures and structures will truly enhance our organization and thus benefit the entire IFCC community.

I look forward to hearing from you and receiving your new ideas or proposals so that we can continue making further improvements to the IFCC organization. Should you have any feedback, questions, or concerns, please feel free to email me at president@ifcc.org.

Till next time 😊
Khosrow

Dogs sniff out COVID-19 infections

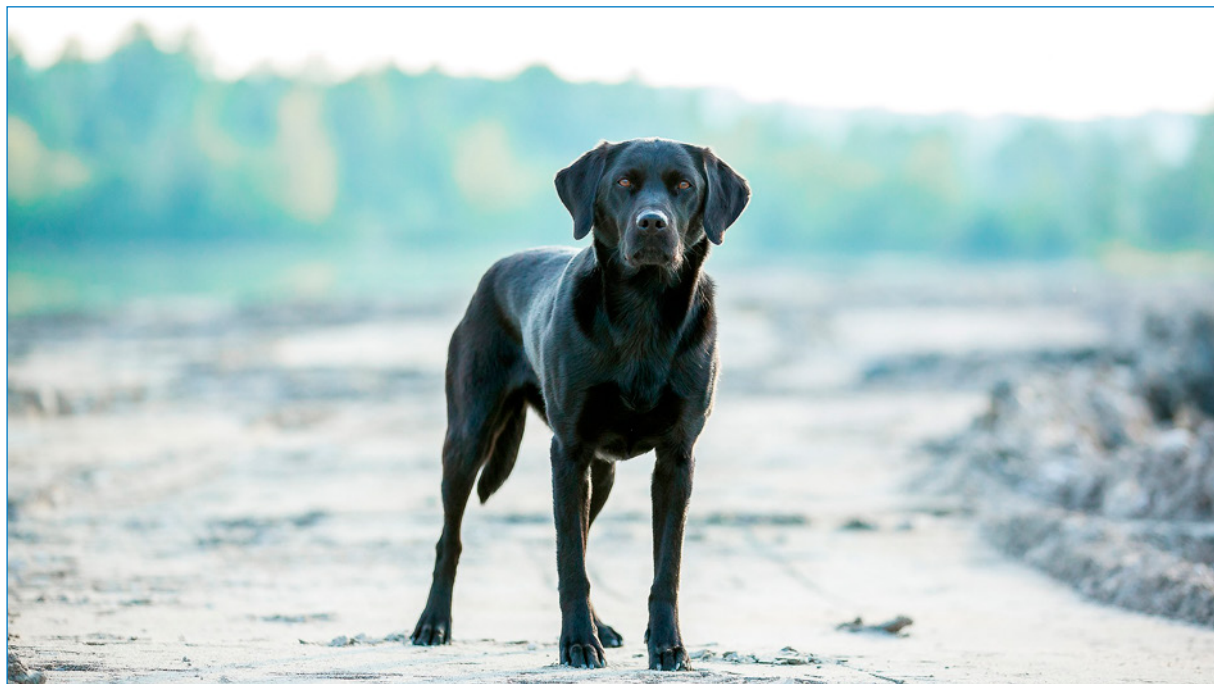
*by Larry J. Kricka
Joe Wienczek
Paolo Fortina*

IFCC Emerging Technologies Division, WG-Vol

A recent, and very newsworthy development has been training of dogs ("sniffer dogs" or "scent dogs") to sniff out COVID-19 infections in real-time. The type of dogs trained for this purpose include Labrador, Golden Retriever, Belgian Malinois, German shepherd, and Cocker Spaniel breeds.

This approach is founded on the considerable success of dogs in detecting disease (e.g., infectious diseases, cancers, diabetes), explosives, drugs and other contraband items (e.g., endangered species).

A dog's nose has 300 million olfactory receptors (vs 6 million for humans) and dogs are attracted to new and interesting odors (neophilia). These factors serve to make a dog a highly sensitive real-time olfactive detector. The WG-Vol has surveyed the literature on this emerging analytical strategy and the survey is published on the WG-Vol webpage: <https://www.ifcc.org/ifcc-emerging-technologies-division/etd-working-groups/wg-vol/>.





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- Evaluate the immune response of vaccine receivers
- Screen convalescent plasma for immunotherapy
- Assist to diagnose COVID-19 infection
- Help to determine patients' infection stage of COVID-19



High correlation with gold standard Virus Neutralization Test (VNT)

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Test results above manifest MAGLUMI® SARS-CoV-2 S-RBD IgG and Neutralizing Antibody kits both have good clinical diagnostic value and can be used for the quantitative determination of the neutralizing antibody concentration.



[1] Padoan A, Plebani M, et al. Analytical and clinical performances of a SARS-CoV-2 S-RBD IgG assay: comparison with neutralization titers[J]. Clinical Chemistry and Laboratory Medicine (CCLM), 2021.

[2] Quoted from the clinical sensitivity study in MAGLUMI® SARS-CoV-2 Neutralizing Antibody IFU.

News from the IFCC Website

Register to the IFCC Live Webinar on 15th July 2021
Point of Care Testing in Resource Limited Settings:
Dotting the “i’s” and crossing the “t’s”



Don't miss the next IFCC webinar on 15th July 2021!

Registration link: <https://www.workcast.com/register?cpak=4908919074925222>

A promotional graphic for an IFCC Live Webinar. It has a blue header with the text 'IFCC Live Webinar on Point of Care Testing'. To the right is a QR code. Below the header are four columns, each with a topic, a speaker's name and location, and a small portrait photo. The topics are: 'Chair/Moderator Committee on Point of Care Testing' (Dr. Adil Khan, USA), 'POCT- coming of age in COVID-19 pandemic' (Dr. Sohini Sengupta, India), 'The Status of Point-of-Care Testing in Vietnam' (Dr. Chi Loan Thuy Nguyen, Vietnam), and 'Formulating and Utilising the 6R tool for effective error prevention at POCT sites in Africa' (Prof Rajiv T Erasmus, South Africa). The IFCC logo is in the bottom right corner.

Dear Colleagues,

Next IFCC webinar on “Point of Care Testing in Resource Limited Settings: Dotting the “i’s” and crossing the “t’s” will be held on July 15, 2021.

Point-of-Care Testing is ideally suited to resource limited settings: it can bring testing to the patient in the field as well as enable reliable laboratory testing in an environment lacking the complicated hospital infrastructure. However, it is vulnerable to the same problems that plague all laboratory tests. The presenters will discuss the particular challenges they faced and some of the resolutions they developed.

News item continued on next page

- Schedule: 20 min per speaker plus 20 min panel discussion
- Time Zones: Live presentations starting at: 10:00AM EDT - 11:00AM Buenos Aires- AR; 4:00PM European Time; 7:30PM India; 10:00PM CST-Beijing
- Important: Please ensure that you carefully determine the time that the presentation will start in your global time zone. [Click here](#) to convert to your time-zone.

Recorded webinar: available on demand

Certificate of Participation: available for all registrants

The IFCC Live Webinar Series is partially sponsored by Siemens and Boston Children's Hospital



News from the IFCC Website



New DIAGNÓSTICO IN VITRO - June 2021 issue

Enjoy the contents of the new DIAGNÓSTICO IN VITRO June issue.

Dr. Girardi, Director de DiV dice: "Estimados colegas de la comunidad Iberoamericana.

Me complace una vez más publicar la edición Nro. 18 de la Revista Científica Diagnóstico in Vitro.

Con el objetivo de difundir y promover las actividades científicas, relacionada con nuestra profesión y modestamente, generar un lugar de reflexión es que se ha trabajado en el número que les presento, no sin antes agradecer la enorme colaboración del Comité de Redacción y especialmente el Consejo Editorial de inestimable eficacia y celeridad que hace de la edición una tarea muy placentera.

En este número encontrarán la descripción de varios eventos científicos y una serie de trabajos de investigación tanto originales solamente publicados en esta revista como aquellos que consideramos de interés para difundir entre la comunidad cedidos gentilmente por los autores y las publicaciones de origen. Concluye la revista un reportaje a la Dra. Ana María Lena Rodríguez para adentrarnos más aun en quien es nuestra Representante Regional de la Confederación Latinoamericana de Bioquímica Clínica (COLABIOCLI) en el Comité Ejecutivo de la International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

Espero disfruten la edición tanto como a mí me provocó armarla."

[Read more](#)

IFCC: THE PEOPLE

IFCC call for nominations



The IFCC invites nominations for the following positions:

New IFCC Task Force on Outcome Studies in Laboratory Medicine (TF-OSLM)

- 5 Members: 1 who will serve as Chair and 4 Members
- Time in office July 2021 - December 2023.

New IFCC Task Force on Global Reference Interval Database (TF-GRID)

- 5 Members: 1 who will serve as Chair and 4 Members.
- Time in office July 2021 - December 2023.

Deadline to receive nominations and supporting documents for above call for nominations is: **July 15th, 2021.**

EDUCATION AND MANAGEMENT DIVISION

Committee on Kidney Disease (C-KD)

- One member position
 - Time in office 2021-2023.
 - Deadline to receive nominations and supporting documents: August 20th, 2021
-

For any further information on nominations, please refer to your National or Corporate Representative.

Contacts are available [here](#).

JCTLM Members and Stakeholders biennial meeting and workshop

Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations

A workshop organized by the IFCC Scientific Division, the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) and the Joint Committee for Traceability in Laboratory Medicine (JCTLM)

Dates: 6-10 December 2021

Location: Virtual sessions

Format: Two 2-hour discussion sessions on three separate topics with a final combined session to develop workshop recommendations

Workshop goals:

The workshop will develop and publish recommendations how the laboratory medicine community can address challenges related to reference materials and to country and region specific regulations to more effectively achieve standardized results on a global basis.

Achieving equivalent results in laboratory medicine is reliant in part on development and global availability of commutable certified reference materials. Ensuring such materials are available for more analytes is a key challenge, which when met will allow the application of fit-for-purpose calibration hierarchies to more end-user measuring systems.

Regulations to enable use of IVD devices differ between countries and regions and can be a challenge to implementing international standardization programs. This workshop focuses on the situation when recalibration of existing end-user measuring systems is needed to conform to internationally agreed standardization goals. Developing harmonized and simplified regulations for this situation will enable faster and less costly standardization of results to improve patient care and safety.

Organizing committee: Philippe Gillery, Christa Cobbaert, Greg Miller, Gary Myers, Joe Passarelli, Robert Wielgosz, Ian Young, Elvar Theodorsson

Welcome and thanks to the Chairs

Welcome to the Chairs of the Task Force on Global Lab Quality (TF-GLQ)

The IFCC welcomes Dr. Egon Amann and Dr. Qing Meng, Chairs of the Task Force on Global Lab Quality (TF-GLQ)

WELCOME TO QING H. MENG (US)



Prof. Qing H. Meng

Dr. Qing H. Meng, PhD, DABCC, FAACC, is a Professor and the Section Chief of Clinical Chemistry in the Department of Laboratory Medicine at The University of Texas MD Anderson Cancer Center. He also serves as Director of Clinical Chemistry Postdoctoral Training Program at MD Anderson Cancer Center.

Prof. Meng is active in national and international societies and committees. He served as Chair of the Canadian Academy of Clinical Biochemistry, Chair of AACC Nutrition Division, Chair of Division Management and Membership Taskforce of AACC, Chair of AACC Texas Section and several professional committees such as AACC Science and Practice Core Committee, AACC Education Core Committee, CAP Diagnostic Immunology Resource Committee, CLSI Document Development Committee, and IFCC Committee on Analytical Quality (IFCC-CAQ).

Currently, he is Chair of AACC Tumor Markers and Cancer Diagnostics, AACC Academy Council member, Commissioner on **the Commission on Accreditation in Clinical Chemistry (ComACC), member of AACC Global Lab Quality Initiative (GLQI) Asia Pacific Working Group (APWG)** and Co-Chair of IFCC Task Force on Global Lab Quality.

His research interests focus on tumor biology, tumor biomarkers, liquid biopsy, and cancer diagnostics in addition to his service-related research in general chemistry, laboratory errors and quality improvement. He is an Associate Editor of Clinical Biochemistry and the Editor of Clinical Pathology Section of Annals of Medicine as well as on the Editorial Board of CCLM, CCA, CRCLS, JALM etc.

WELCOME TO EGON AMANN (DE)



Prof. Egon Amann

Egon Amann is Professor Emeritus at the University of Applied Sciences in Hamm-Lippstadt, Germany. He was Dean of Master Studies “Biomedical Management and Marketing”

He taught courses like Quality Assurance and Product Legislation, Quality- and Risk-Management, General-, Synthetic- and Molecular Biology, and Clinical Chemistry. Currently, he is a free-lance Biotechnology and Clinical Chemistry Consultant.

Previously, Egon Amann was Honorary Professor in Molecular Biology and Genetics at Philipps University in Marburg, Germany.

Prof. Egon Amann has long-time experience in the pharmaceutical and diagnostic industries. He was executive employee with Behringwerke AG, Dade Behring Diagnostics, Siemens Healthcare Diagnostics, and Hoechst AG, Germany. He worked for many years in human vaccine and human plasma protein R&D and in diagnostic assay development in Germany, Japan and the US.

He developed diagnostics tests (e.g. tumor markers, serology, infectious diseases) for several instrument lines, including OPUS, BNII and Behring ELISA processors. He held positions with increasing responsibilities (Program Director, Senior Director) in R&D, Business Development, Technology Scouting, Strategic Planning and Quality Management.

His research interests focus on novel diagnostics tests and osteoporosis research (past) and synthetic biology/biotechnology on enzyme expression and optimization in the circular bioeconomy (present).

Egon Amann has 18 granted patents and > 70 peer-reviewed publications and several book chapters in the areas listed above.

Egon Amann was Chair of IFCC committees and task forces, including C-AQ (Committee for Analytical Quality), DQCML (Developing Quality Competence in Medical Laboratories) and is currently Co-Chair of the TF-GLQ (Task Force for Global Lab Quality).

Welcome to the Chairs of the IFCC Task Force on Newborn Screening (TF-NBS)

The IFCC welcomes Dr. Van Leung Pineda and Prof. Jim Bonham, Chairs of the IFCC Task Force on Newborn Screening (TF-NBS)

WELCOME TO VAN LEUNG-PINEDA (US)



Dr. Van Leung-Pineda

Van Leung-Pineda, PhD, DABCC, FAACC has been the Clinical Chemist at Children’s Healthcare of Atlanta since 2017 where he is the Section Director for Clinical Chemistry and Point of Care Testing.

Dr. Pineda received his PhD in Biomedical Sciences from The University of Florida. He was a postdoctoral research associate at Howard Hughes Medical Institute and Washington University in Saint Louis School of Medicine. He then completed a Clinical Chemistry Fellowship in the Department of Pathology and Immunology at Washington University in Saint Louis School of Medicine.

He previously directed the Clinical Chemistry and the Mass Spectrometry laboratories at Cook Children’s in Fort Worth, Texas.

Dr. Pineda is an Adjunct Assistant Professor of Pathology and Laboratory Medicine at Emory University School of Medicine. He has been involved with the Pediatric Maternal Fetal division of AACC previously as its Newsletter Editor and now as a member at Large.

He has professional affiliations with the American Association for Clinical Chemistry and is a Diplomate of the American Board of Clinical Chemistry and a Fellow of the AACC Academy.

He currently co-chairs the IFCC Global Taskforce on Newborn screening and is a member of the Laboratory Standards and Procedures Workgroup for the Advisory Committee on Heritable Disorders in Newborns and Children, as well as a member of the AACC Diversity, Equity and Inclusion Strategy Task Force.

WELCOME TO JIM R. BONHAM (UK)



Prof. Jim R. Bonham

Jim Bonham is currently the National Laboratory Lead for the newborn Screening Blood Spot Programme in the UK on behalf of Public Health England. He is also President of the International Society for Neonatal Screening with more than 500 members in 40 countries.

In 2012, Prof. Bonham led a study to introduce additional inherited metabolic disorders into the national newborn screening programme in the UK. Four of these were incorporated as part of the programme in England and Wales from 2015.

He has interests in the organisation, quality and effectiveness of newborn screening and how this might be optimised and extended to benefit patients and families in the UK and Europe and more recently as part of the Global Taskforce on newborn screening, to low and middle income countries.

Prof. Bonham has played an active role in several national and international professional organisations including the SSIEM, Royal College of Pathologists, UKNSLN, MetBioNet, NEQAS and UKAS.

He helped found the British inherited Metabolic Disease Group and the International EQA provider for Inherited Metabolic Disorders – ERNDIM.

His efforts in these areas were generously recognised by the award of an MBE in 2020.



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GERMANY**



XV ICPLM 
Emerging Technologies in
Pediatric Laboratory Medicine 



www.icplm2021.org

CONTRIBUTE TO THE IFCC eNEWS

CLSI and IFCC partnership promotes global harmonization of clinical laboratory practices



IFCC and CLSI have renewed their longstanding partnership agreement, the goal of which is promoting global harmonization of clinical laboratory practices. The partnership has led to the development of consensus-based standards and guidelines that reflect a global perspective, leading to the improvement of laboratory test result quality, and ultimately improving patient care.

The Clinical and Laboratory Standards Institute (CLSI) is a volunteer-driven, membership-supported, non-profit global laboratory standards development organization dedicated to develop best practices in clinical and laboratory testing and promote their use worldwide. CLSI promotes the development and use of voluntary standards and guidelines through a consensus process that includes stakeholders from the health care professions, government, education, and industry. CLSI connects professionals worldwide with a common purpose and mission.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) is a worldwide, non-political organization for clinical chemistry and laboratory medicine. As such, it has a range of roles that include global standard setting in collaboration with other international organizations, supporting its members through scientific and educational endeavors, and providing a series of congresses, conferences, and focused meetings for laboratory medicine specialists to meet and present original findings and best practices. The IFCC relies very heavily on volunteers to run the

organization and to undertake its range of activities and programs.

The IFCC and CLSI partnership facilitates the inclusion of broad international perspectives in CLSI's standards and guidelines. These standards and guidelines serve the global medical laboratory community by defining medical laboratory practices that improve quality, safety, consistency, and cost-effectiveness. Regulatory agencies and accrediting bodies around the world recognize the value of implementing CLSI standards and guidelines to establish best practices that meet regulatory and accreditation requirements. Finally, the agreement recognizes IFCC and CLSI's mission of improving the quality of laboratory medicine in resource-constrained countries that bear a heavy burden of disease.

Additionally, in cooperation with the US National Institute of Standards and Technology (NIST), CLSI and IFCC cosponsor the Robert Schaffer award, which honors an individual who has made outstanding and unique contributions to the advancement of reference methods and/or reference materials for laboratory medicine. This award is presented at the IFCC International Congresses.

Volunteering with CLSI is a way to join more than 2000 experts from around the world who are actively engaged in developing consensus-based clinical and laboratory standards and guidelines.

Visit clsi.org for more information about membership and to learn more about the more than 200 standards, guidelines, and other products offered by CLSI.

Democratization of education: adaptive learning courses in laboratory medicine are now available without a subscription fee!

by Prof. Nader Rifai

IFCC EMD Chair

Boston Children's Hospital

Department of Laboratory Medicine

Massachusetts, USA

NEJM
Knowledge⁺

AACC
Learning Lab

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.

Clinical leader in Croatia calls upon integrated clinical care teams for healthcare excellence

The importance of laboratory medicine is vital in the field of cardiology. No one knows this better than Dr. Goran Krstacic, MD, Director Institute of Cardiovascular Prevention and Rehabilitation, Zagreb. This clinical key opinion leader is well-known for his patient-centric approach to improve population wellness as co-founder of the Croatian Heart House. With his passion for advancing education and health outcomes, it is not surprising that he is also a recognized champion of the UNIVANTS of Healthcare Excellence program.

The UNIVANTS of Healthcare Excellence awards celebrate integrated clinical care teams who have achieved measurably better healthcare performance. Now in its third year, cardiovascular disease has been a leading focus of integrated care. In this interview with Dr. Goran Krstacic we explored why and took a closer look at some excellent examples and opportunities underway in Croatia.



Prof. Goran Krstacic, MD, PhD, FESC, FEHRA
Director, Institute of Cardiovascular Prevention and Rehabilitation, Zagreb
Professor of cardiology, Faculty for Dental Medicine and Health and
School of Medicine, University J.J. Strossmayer in Osijek, Croatia

How can healthcare professionals better apply laboratory insights to prevent cardiovascular diseases?

Dr. Krstacic: Opportunities for best practices that utilize the power of laboratory insights in cardiovascular disease are vast and range from application of existing biomarkers in novel settings or in novel ways, to implementation of new biomarkers and/or panels into clinical care for screening and prevention.

A great example may involve strategic implementation of multiple biomarkers to calculate a risk score for cumulative cardiovascular events in order to reliably predict survival (independent of age, sex, or contractile function). While many biomarkers are associated with outcomes in observational studies of the general population, strategic investigation into their clinical applicability in the context of clinical trials remains an open area of investigation.

Similarly, biomarkers that are simple to measure, such as troponin, may help clinicians identify and treat pre-clinical heart disease more effectively. Subclinical cardiac dysfunction precedes the development of heart failure and other cardiovascular diseases but often goes undiagnosed due to lack of screening programs and available testing strategies. Thus, patients with subclinical cardiac dysfunction will benefit from early diagnosis/recognition of the pathophysiological changes that lead to clinical heart disease if they are provided an opportunity for timely intervention and prevention.

What advice do you have for teams exploring healthcare excellence?

Dr. Krstacic: A key first step is having a well-integrated clinical care team and system. In Croatia, this is referred to as “integrated people-centered health services”. This means putting people and communities, not diseases, at the center of health systems, and empowering people to take charge of their own health rather than being passive recipients of services.

Consequently, health services are managed and delivered in a way that ensures people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services, at the different levels and sites according to their needs. Results of this integrated approach suggest that these health systems and communities are more effective, cost less, improve health literacy and patient engagement, and are better prepared to respond to health crises.

In a similar vein, integrative medicine, medicine that selectively incorporates elements of complementary departments and specialties, including laboratory medicine, for comprehensive treatment plans are increasingly important. Modern clinical medicine is interdisciplinary and transdisciplinary. Without the optimal cooperation of all medical subjects, we cannot expect the optimal effect of diagnosis, treatment and monitoring of patients. Individual diseases and conditions, especially rare diseases, are impossible to diagnose and and monitoring the success of treatment without laboratory professionals is impossible as well.

What best practices currently exist in your region?

Dr. Krstacic: As a board member of the Croatian Heart House I am aware of several best practices in our region. The goals of the Croatian Heart House are to assist in the treatment of cardiovascular diseases, promote cardiovascular health, inform and educate citizens about prevention of cardiovascular disease and the active role they should play, including early identification, removal and treatment of risk factors.

In recent years we have successfully completed several projects involving many health professionals and citizens/patients such as “Heart Keepers”, “Revive Me” and “Less Salt More Health”. Recently, we launched a 3-year program called “Woman and Heart”. This program aims to identify women >45 years of age at high-risk for cardiovascular disease through early screening and prevention.

This program utilizes laboratory analysis of biomarkers of cardiovascular diseases, primarily high sensitivity troponin as a possible identifier of low, medium or high-risk CVD, highly sensitive CRP, HbA1c and complete lipid analysis. All participants identified as high-risk are subsequently referred for additional investigations and treatment. Thus far, 650 women have been involved in the program and we look forward to continuing this great work.

Recognized best practices for the UNIVANTS of Healthcare Excellence program can be found on the program website at (www.univantshce.com). Many thanks to the leaders and innovators in this field, new and pioneering best practices emerge, with opportunities for global recognition.

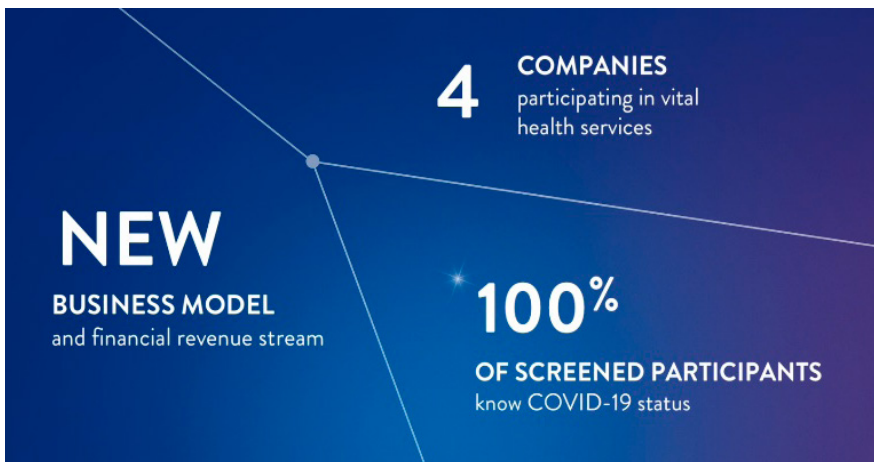




Laboratory-led company-wide screening programs for safe back to work strategies during COVID-19 pandemic

The uncertainty of the COVID-19 pandemic has left us all with more questions than answers; what is safe vs not? Can I see friends and family? Is it safe to go into work? And although we still have many questions, insights, data and some answers are coming to light, in part due to work done by laboratorians and the subsequent strategic implementation of testing to enable us to 'get back to normal'.

The economic impact shutting down businesses during the initial phases of the pandemic cannot be understated. Thus an multidisciplinary team at Dr. Suliman Al Habib Medical Group (HMG) involving infection control, hospital leadership, industrial business owners, and the clinical laboratory saw an opportunity to utilize insights and services from the clinical laboratory to help forward-thinking, health-focused companies seeking safe go-back-to-work strategies for their business and employees. Their focus was on risk mitigation through activation of employee wide screening programs using polymerase chain reaction (PCR) and antibody testing. Their goals were to maximize productivity and employee safety while minimizing virus transmission and loss of work due to new infection and quarantines.



The services were offered to diverse companies, institutions, and sports centers and has enabled safe reopening, avoided lost labor and paid sick leave, with 79% of employees not infected nor in need of quarantine. Collective PCR and antibody testing ensured known viral status for 100% of employees, mandating strategic quarantine measures/procedures for infected individuals, while allowing safe return-to-work for all individuals without active infection.

For their forward-thinking efforts this integrated clinical care team from Dr. Suliman Al Habib Medical Group received the 2020 UNIVANTS of Healthcare Excellence award recognition of Achievement. Congratulations to Faisal Abdullah Al-Owaidi, *Laboratory Director*, Tarif Bizrah, *Business Development Manager*, Nasser Al-Huqbani, *Chief Executive Officer*, Abdullah Nasser Al-Jurayyan, *Consultant Immunologist, Infection Control*.

KEY TAKEAWAYS:

1. Laboratory insights are increasingly important during the COVID-19 pandemic
2. Implementation of strategic testing strategies outside traditional testing, such as within companies, are key to ensure safe back to work efforts
3. Integration across traditional and non-traditional clinical care teams enables pandemic innovation

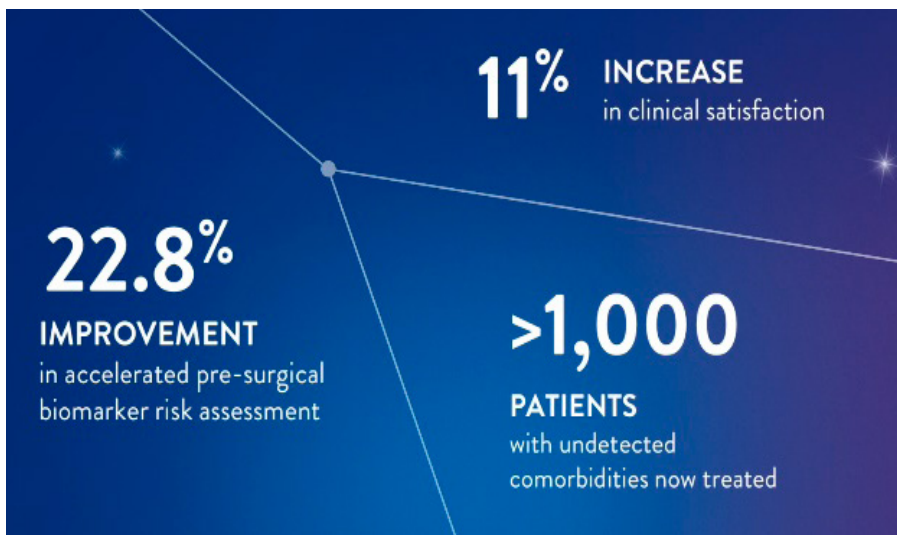


Improving patient experiences via reliable pre-surgical biomarker risk assessments in patients undergoing eye surgery

The prevalence of ophthalmic disease is extremely high in those 50 years of age or older, with almost 82% having some degree of ophthalmic disease. Ophthalmic diseases, including glaucoma, cataracts, macular degeneration and diabetic retinopathy are extremely debilitating and as such often require surgical intervention.

At City Hospital No 2, the largest ophthalmic treatment center in Saint Petersburg, Russia presurgical health checks using biomarker for patients with planned eye surgery is a routine part of patient care. This testing was done in the outpatient setting (policlinic), where often the quantity and/or quality of insights were not always reliable due to missing lab results, the need for retesting and/or the need for further investigations due to decompensating disease. The need for additional testing created inefficiencies within the health system, including the need to delay surgeries. This in turn negatively impacts hospital resources, patient length of stay (LOS), health system reimbursement, and patient satisfaction. Importantly, many of the impacted patients were elderly making travel a true burden, thus, every delay and/or need for additional visits created additional difficulties for them.

To mitigate the need for additional testing, reduce delayed procedures and improve overall experience, an integrated clinical care team involving ophthalmology, department of quality control, laboratory medicine and information technology sought to establish a new process to optimize presurgical biomarker check-ups. This involved a standardized list of biomarkers for comprehensive screening assessments in the outpatient department of the hospital, rather than through polyclinic, thus ensuring standardization and high-quality testing with all biomarker results consolidated and led through the core laboratory.



This new process resulted in a 22.8% reduction in the percentage of patients with incomplete pre-surgical health check-ups (from 28% to 5.2%), reduced the average length of stay from 3.5 to 3.3 days due in part to the increased identification and treatment of comorbidities before eye surgery. Impressively, this helped improve the ranking for the St. Petersburg City Hospital No 2 from 10th place (2015) to 5th place (2019) for service quality across all hospitals in St. Petersburg, Russia.

For their patient-centric care and important outcomes this integrated clinical care team received the 2020 UNIVANTS of Healthcare Excellence Award Recognition of Achievement. Congratulations to Timur Akhmedov, *Head of Laboratories Department*, Alexey Lebedev, *Head of Medical Equipment Department*, Vadim Nikolaenko, *Deputy Chief Physician by Ophthalmology*, Alexandr Pushkin, *Head of Laboratory, Quality Control System*.

KEY TAKEAWAYS

1. Quality and reliability of laboratory testing is a key enabler of patient-centric care
2. An integrated clinical care approach is an important step in ensuring process changes are implemented with success
3. Consolidation and standardization of pre-surgical screening assessments can substantially improve patient outcomes, patient experiences and enhance resource utilization



Improving care and overall experience for patients who present to a Tanzania clinic with suspected cardiovascular diseases

Africa is home to more than 1 billion people and like much of the world, is significantly burdened by the growing cardiovascular disease (CVD) epidemic. In sub-Saharan Africa, CVDs are responsible for approximately 13% of all deaths, and can be partially attributed to lacking or insufficient healthcare systems and infrastructure to identify and manage CVDs. For example, delays in testing can substantially delay patient care and affect patient outcomes. This used to be the case when patients presented to Faith Medical Tanzania Clinics, a local clinic in Tanzania. The facility was capable of basic triage and testing; however, patients requiring additional and urgent follow-up needed to be transported to a larger healthcare facility for additional testing. Given the scarcity of resources and high demand for specialized investigations, identification and treatment could be substantially delayed.



Pictured (L to R): Dr Felician Kibacha, Rev Dr. Yusufu Ngaleni and Joyce B Mung'ong'o

Recognizing that any opportunity to streamline testing could markedly impact treatment and outcomes, an integrated clinical care at Faith Medical Tanzania Clinics collaborated to implement high-sensitivity troponin testing into routine clinical practice for patients with suspected CVD. Thus, when patients were transferred to another facility, troponin results would be immediately available, enabling expedited care.

With integration of this new triage method, patient wait times for additional testing were greatly reduced. Additionally, and due largely in part to in-house troponin testing, there has been a 40% reduction in the number of patients requiring referrals to other hospitals. Consequently, healthcare costs related to transportation and investigations have gone down, while increasing the overall confidence of clinicians providing this greatly needed care.

For their pioneering efforts in improving patient experience and outcomes in Tanzania, this integrated clinical care team from Faith Medical Tanzania Clinics Joyce Mung'ong'o Mazuma, *Laboratory Medicine and Managing Director, Faith Medical Tanzania Clinics*, Felician Kibacha, MD at Muhimbili Hospital, Pendo Kibona, MD at *faith Medical Tanzania Clinics* and Saum Seif, MD, *Medical Officer at Faith Medical Tanzania Clinics* was recognized for achievement with the 2020 UNIVANTS of Healthcare Excellence awards.

To learn more about this integrated clinical care team and more, visit www.univantshce.com.

KEY TAKEAWAYS

1. Cardiovascular disease affects millions worldwide and strategic efforts to reduce this burden can have substantial impact on health and wellness of the population.
2. Streamlining provision of care in emerging markets through expedited triage is an important opportunity to improve outcomes.
3. Improving triage of patients with suspected cardiovascular disease can improve patient experience, increase clinician confidence and reduce overall healthcare costs.



Increased detection of acute myocardial infarction in women using sex-specific upper reference limits

Cardiovascular disease is a leading cause of morbidity and mortality worldwide. Consequently, improving outcomes through integrated clinical care approaches are becoming more important and more common. At Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute (KDAH) the Biochemistry and Immunology Department sought to implement sex-specific cut-offs for high-sensitivity troponin I (hs-cTnI) in order to help mitigate the fact that women are often underrecognized and under-diagnosed for acute myocardial infarction (AMI). Their goal was to not only mitigate the delay in diagnosis of AMI in women, but also to more appropriately treated men for AMI.

To accomplish this, laboratory medicine teamed up with Cardiology, Emergency Medicine and hospital leadership to move from overall upper reference limits (URLs) of high-sensitivity troponin I (hs-cTnI) towards sex-specific URLs.

Implementation of sex-specific upper reference limits identified an additional 14% of at-risk women with potential acute myocardial infarction (female patients with acute cardiac events using overall cut-off was 68% versus 82% using sex-specific cut-off). This in turn decreased the number of men being diagnosed by 3%. Success of this new chest pain pathway was in part due to strong cross-disciplinary collaboration and site-wide education leading to increased clinical adherence to the new protocol from 7% to 93%.

With such strong outcomes and important changes to patient care, this integrated clinical care team has received media recognition in two leading local newspapers recognizing this site's leadership in implementing a novel clinical pathway for patients with suspected acute coronary syndrome.

It takes many to achieve a measurable difference but a special congratulations goes to the program leaders for the recent recognition with the 2020 UNIVANTS of Healthcare Excellence award program, site of Achievement: Dr. Barnali Das, *Consultant, Laboratory Medicine; IFCC Scientific Division Executive Committee Member and Chair, AACC India Section*, Dr. Jamshed Dalal, *Director of Cardiology*, Dr. Sanjay Sm Mehta, *Director of Accident and Emergency*, Dr. Prashant Nair, *Consultant, Cardiology*, Dr. Santosh S Shetty, *Executive Director and Chief Executive Officer*.

KEY TAKEAWAYS:

1. High-sensitivity cardiac troponin (hs-cTn) assays enable accurate detection of low levels of circulating troponin, including the ability to distinguish differences between men and women
2. Application of sex-specific upper reference limits based on the 99th percentile of seemingly healthy individuals can improve patient diagnosis and improved outcomes
3. Education across disciplines is crucial for systemwide implementation of new clinical pathways



Pictured: Dr. Barnali Das, Ms. Bhavya Darod, Ms. Poonam Mandavkar, Mr. Sachin Patil, Ms. Reshma Morajkar, Ms. Urja Parekh, Ms. Poornima Shetty, Ms. Snehal Rajee, Ms. Rasika Shinde, Ms. Akanksha Desai

NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



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

Importance of neonatal screening for spinal muscular atrophy

SEQC^{ML}

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 Malaga, 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

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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, as highlighted by Dr. Calvo.

HETEROGENEOUS IMPLEMENTATION OF SCREENING

The experiences in the implementation of neonatal screening for spinal muscular atrophy vary, 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.

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

The Spanish Society of Laboratory Medicine (SEQC^{ML}) —founded in 1976— is an active member of the international and European Federations of Clinical Laboratory, IFCC and EFLM. It currently encompasses almost 3,000 professionals and its main objective is to bring together all interested scientists in the Clinical Laboratory field, promote the dissemination of scientific and technical publications, organize national and international meetings, courses and congresses, and cooperate with other scientific societies. Likewise, the Society wishes to contribute to studying and recommending standardized methods and establishing guidelines and recommendations for training in the field of Laboratory Medicine.

More information at: www.seqc.es



[@SEQC_ML](https://twitter.com/SEQC_ML)

[Residentes del Laboratorio Clínico - SEQC](https://www.facebook.com/ResidentesdelLaboratorioClinico-SEQC)

[SEQC-ML](https://www.linkedin.com/company/SEQC-ML)

[segresidentes](https://www.instagram.com/segresidentes)



News from the Pakistan Society of Chemical Pathologists

Report of a 3 day virtual course in flipped style

by Dr. Sibtain Ahmed

*Assistant Professor & Consultant Clinical Chemistry
AKU Karachi, Pakistan*

“3rd Course on Fundamentals of Quality Control to Improve Patient Safety” - Report of a 3 day virtual course in flipped style

The section of Clinical Chemistry, department of Pathology and Laboratory Medicine, AKU has been organizing the Fundamentals of Quality Control (QC) in clinical laboratories as a regularly scheduled activity, annually, over the past few years under the auspices of IFCC and Pakistan society of Chemical Pathologists

(PSCP). This course is intended to provide education and training in QC practices encompassing both internal and external QC to a broad audience of healthcare practitioners associated with central laboratories, clinic or outpatient laboratories, and point-of-care settings. The course was attended by a blend of 21 participants from Pakistan, USA, Saudi Arabia, and Kuwait. Three faculty members including Dr. Lena Jafri (Assistant Professor and Section Head Clinical Chemistry, AKU) as the course director and Dr. Sibtain Ahmed (Assistant

Article continued on next page

Professor Clinical Chemistry, AKU) and Dr. Hafsa Majid (Assistant Professor Clinical Chemistry, AKU) as co-directors, designed the course content and coordinated the delivery of the program.

Keeping in view the COVID-19 safety measures, this year the 3rd course was offered exclusively virtually for the first time using the ZOOM platform spread over a period of three days, three hours of face-to-face online interaction daily. 12 CME credit hours were awarded. Flipped material was circulated based on *Calibration Verification of Pipette by Gravimetric Method*, instructions were provided in Microsoft word format and a short 2-minute video clip on demonstration of the procedure was also shared for easy comprehension. To keep the course faculty and participants connected a WhatsApp group was created and information was disseminated with real time interaction and queries were responded by experts.

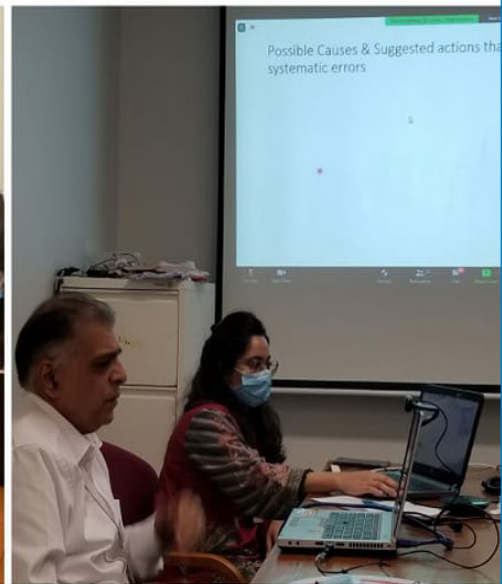
The emphasis is on statistical QC procedures, because this is the backbone of any good laboratory QC program, with hands on practice on individual exercises, faculty facilitated break out rooms' group activity and take-home assignments. Statistical QC is an extensively applicable technique and a powerful tool for detecting problems in test performance and for validating proficiency of analysts and operators, ensuring that the QC data is properly interpreted.

Day 1, began with the introduction and ice breaking session, followed by a quiz to assess the knowledge mix of the audience via Kahoot. Prof Dr. Adnan Mustafa Zubairi (director clinical laboratories – outreach, Indus hospital & health network Pk) delivered the first lecture on quality management, with emphasis on process development and implementation. It was followed by a session on basic statistics in internal QC by Dr. Hafsa Majid, data was shared on the WhatsApp group and the participants responded to the hands-on calculation exercises given. Prof Dr. Aysha Habib Khan (Consultant Clinical Chemistry AKU) shed light on novel insights in QC practices and recent developments and shared her experience of QC monitoring using patient data. In the next session the flipped assignment results were discussed by Dr. Siraj Muneer (Resident Clinical Chemistry, AKU) and participants also shared their working. Subsequently, a take home

assignment was shared based on lab internal QC data for statistical calculation and the Levey-Jennings (LJ) control chart construction to call the day off.

Day 2, began with a review of concepts taught on Day 1 and Dr. Sibtain Ahmed along with Dr. Sahar Iqbal (Associate Professor, DUHS, Karachi) discussed the application of Westgard rules and multi rule QC procedure. It was followed by a case-based discussion and different LJ charts were shared and participants were made to identify the Westgard rule violated. The next session was facilitated by Prof Dr. Imran Siddiqui (Consultant Clinical Chemistry, AKU), it covered real time case studies with interactive discussion encompassing compression of trend and shift in internal QC, type of errors, their causes, trouble shooting and corrective action plan. It was followed by a group activity via break out rooms, where participants were given out of control LJ chart and were asked to identify the discrepancies and develop their root cause analysis and corrective action plan and discussion with their assigned faculty.

The last day was focused on external QC and proficiency testing. The proceedings began with a much-awaited talk by Dr. Farooq Ghani (Director CAP, AKU) focused on College of American Pathologists (CAP) accreditation, encompassing the requirements and road map. Dr. Lena Jafri conducted the next session on evaluation of proficiency testing surveys and basis statistics. Interpretation of graphical content on proficiency testing reports and troubleshooting was discussed by Dr. Sibtain Ahmed, with further hands-on practice on real time reports. A group activity was also conducted and the entire process from proficiency testing reports evaluation, statistical analysis, graphs review troubleshooting and corrective action plan was formulated by each group with their assigned faculty. The session was concluded with a quiz via Kahoot to assess the performance of the group in comparison to the pre course quiz. Prof Dr. Imran Siddiqui delivered the speech of thanks and conclusion remarks and praised the organizers for putting up this much needed course virtually in times of the pandemic and reinforced the participants to apply the skills learnt in daily practice to ensure patient safety and achieve the highest standards of quality.



Glimpses from the course

**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**

*by Christa Cobbaert &
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!

News from the IFCC Website

IFCC Handbook 2021-2023

The IFCC is happy to present its Handbook 2021-2023.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) is a worldwide, non-political organisation for clinical chemistry and laboratory medicine.

As such, it has a range of roles that include (1) global standard setting in collaboration with other international organisations, (2) supporting its members through scientific and educational endeavours, and (3) providing a series of congresses, conferences, and focused meetings for laboratory medicine specialists to meet and present original findings and best practice.

The IFCC relies very heavily on volunteers to run the organisation and to undertake its range of activities and programmes. Those volunteers are constantly changing and so a reference document is required to assist people who want to learn more about the IFCC and its operation. That reference document is this IFCC Handbook. The production of the IFCC Handbook occurs once every three years to coincide with the term of each Executive Board. However, IFCC is a dynamic organisation that evolves constantly. The most up to date information about the IFCC is always available from the IFCC website (www.ifcc.org).

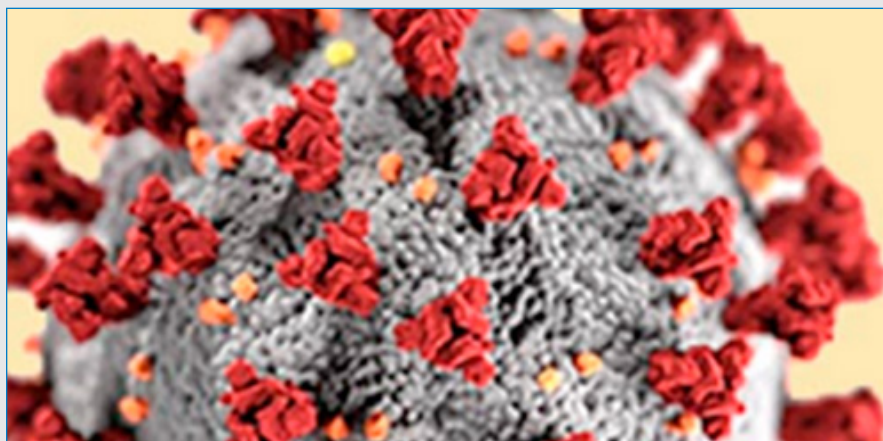
The Handbook puts in one place all the information about the function and operation of the IFCC. This includes the organisation of the FCC and its aims and strategic objectives over the three-year life of the Executive Board. Also, it includes details of IFCC programmes and projects. The Handbook lists, in logical order, IFCC Regional Organisations, Divisions, Committees and Working Groups. The Full Members, Corporate Members and Affiliate Members are also included. Contact names and addresses are included for the many people who work with and for the IFCC. Finally, the necessary Statutes and Rules of the IFCC are published in the Handbook. We thank the many individuals responsible for preparing this useful document. In particular we thank Dr Graham Beastall, an IFCC Past President, whose long experience and deep knowledge of IFCC was fundamental for the revision and completion of this publication.

Khosrow Adeli
President

David Kinniburgh
Secretary

[Read more](#)

News from the IFCC Website



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.

The page is constantly updated with the most recent information on a biweekly basis.

IFCC Information Guide on COVID-19 – NEW updates available

Coronavirus disease 2019, abbreviated to COVID-19, is an emerging global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As the number of individuals infected with COVID-19 continues to rise globally and healthcare systems become increasingly stressed, it is clear that the clinical laboratory will play an essential role in this crisis, contributing to patient screening, diagnosis, monitoring/treatment, as well as epidemiologic recovery/surveillance.

This guide aims to organize relevant available information on laboratory screening, testing protocols, diagnosis, and other general information on COVID-19 for laboratory professionals, including links to helpful resources and interim guidelines. It is continually updated as new guidelines and literature become available.

IMPORTANT INFORMATION: a new IFCC Guideline has been published: “IFCC interim guidelines on rapid point-of-care antigen testing for SARS-CoV-2 detection in asymptomatic and symptomatic individuals”: visit the page clicking [here](#).

Further to the VACCINATION section, the latest update includes various recent publications that have been published in the past weeks in: • Antigen Testing • Serology Testing, Pediatrics.

IFCC WELCOMES A NEW MEMBER

Libyan Association of Clinical Pathology (LACP)



Libyan Association of Clinical Pathology (LACP) is a recently founded association facing multiple and different hurdles along with political instability. It strives to enhance the scientific level of professionals and the quality of medical laboratory diagnostic services in the current difficult situation. LACP members are clinical chemists, laboratory scientists, and laboratory physicians, specialized in Clinical Chemistry, Clinical hematology, Clinical microbiology and parasitology, Clinical immunology, Clinical genetics, and Blood banks.

LACP builds on the commitment of its members to raise awareness about the importance of diagnostic laboratories in good health provision. This will be followed by highlighting the primordial role of the clinical pathologist in bridging the gap between clinical services and the medical laboratories. LACP is working with the scientific council of laboratory medicine in the medical specialty council to graduate clinical pathologists and to ensure the availability of state of art training and education through connection with national and international bodies, societies, universities, and experts, and the provision of financial support.

by Dr. Aisha Nasef

*LACP National Representative
President of Scientific Council of Laboratory Medicine
Medical Specialty Council
Tripoli, Libya*

LACP participated in setting medical laboratory national plan for Covid-19 management in collaboration with the ministry of health, the center of disease control and biotechnology research center, and participated in a seminar for the establishment of national bone marrow transplantation center by providing a talk on the role of Flow cytometry in the diagnosis of hematological malignancy.

LACP members are working with national centers for quality and accreditation. LACP works with the center of accreditation of health establishments in Libya, for the establishment of national quality standards in medical laboratories and blood banks, and it works with the Libyan accreditation center for the preparation of the necessary documents, manuals, and checklists needed for licensing, safety, and accreditation. LACP members presented the role of medical laboratories in good health as a third SDGs on world accreditation day and attended a seminar organized by WHO on quality in Fragile post conflict countries.

LACP will serve as an advocate to develop this specialty in Libya, and to start a nonexistent specialty such as clinical genetics. Columbia University and Pasteur Institute in Tunis kindly invited an LACP member as a panelist for monthly experts talk on genetics in North Africa and Middle East. LACP will work to support Libyan scientific researches in the field. LACP members attended the WHO universal health coverage workshop, about the use of research outcome in policy-making, and participated in qualitative studies conducted by international experts for health reform.

Article continued on next page



Presentation by Aisha NASEF on 09 June 2012 on World accreditation day (WAD), Role of medical laboratories on achieving the good health as a third SDGs



Meeting for setting a standard licensing requirements



Notes on the discussion during the meeting







Meeting with director of Libyan accreditation center and director of center of accreditation of health establishments

IFCC'S CALENDAR OF CONGRESSES, CONFERENCES & EVENTS

We advise readers to keep up-to-date about the evolving situation and possible rescheduled dates.
Contact organizing secretariats for updates on upcoming events.

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses

Jul 15, 2021		<i>IFCC Live webinar on: Point of Care Testing in Resource Limited Settings: Dotting the "i's" and crossing the "t's"</i>	IFCC Live Webinar
Sep 23 - 25, 2021		<i>AFCC Congress 2021</i>	Lusaka, ZM
Oct 18 - 22, 2021		<i>IFCC WG-FC Autumn School of Cell Analysis in Immunology</i>	Geneva, CH
Nov 26 - 28, 2021		<i>International Congress of Pediatric Laboratory Medicine</i>	Munich, DE
Nov 28 - Dec 2, 2021		<i>XXIV IFCC - EFLM EuroMedLab Munich 2021</i>	Munich, DE

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Dec 6 - 10, 2021		<i>IFCC-ICHCLR Workshop on overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations</i>	Paris, FR
Mar 30 - Apr 2, 2022		<i>XXV COLABIOCLI Congress</i>	Leon, MX
June 26 - 30, 2022		<i>XXIV IFCC WorldLab Seoul 2022 XVI APFCB Congress Seoul 2022</i>	Seoul, KR
May 21 - 25, 2023		<i>XXV IFCC - EFLM WorldLab EuroMedLab - Rome 2023</i>	Rome, IT
<i>New date TBA</i>		<i>IFCC Forum for Young Scientists</i>	TBA



Other events with IFCC auspices

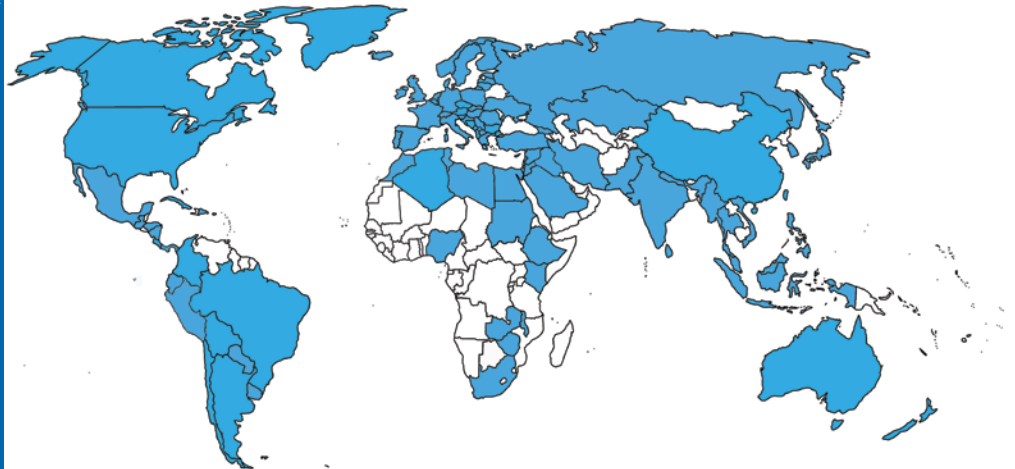
We advise readers to keep up-to-date about the evolving situation and possible rescheduled dates. Contact organizing secretariats for updates on upcoming events.

Mar 3 - Dec 3, 2021	<i>Virtual Diploma in Clinical Biochemistry program</i>	Mexico Online event
Apr 26 - Jul 12, 2021	<i>Course on Neonatal Screening</i>	Uruguay Online event
Jul 12, 2021	<i>MASTERCLASS (POCT) Quality in the Spotlight</i>	Online event
Aug 18 - 21, 2021	<i>XXVII International Congress of the Latin American Cooperative Group of Haemostasis and Thrombosis</i>	Colombia Online event
Sep 1 - Nov 3, 2021	<i>1st EFLM online Postgraduate course: Biostatistics in Laboratory Medicine</i>	Online course
Sep 6 - 7, 2021	<i>POCT: Making the point</i>	Rome, IT
Sep 7 - 9, 2021	<i>International Congress of Metrology 2021</i>	Lyon, FR Hybrid even
Sep 8 - 11, 2021	<i>XXVIII Balkan Clinical Laboratory Federation Meeting and XIII National Conference of Clinical Laboratory</i>	Sofia, BG
Sep 13 - 23, 2021	<i>2nd EFLM online Postgraduate course on Leadership Skills</i>	Online course
Sep 22 - 25, 2021	<i>5th ACTC meeting "Liquid Biopsy in its best"</i>	Kalamata, GR
Sep 23, 2021	<i>International Conference on Laboratory Medicine: "The Ethics of Quality and Artificial Intelligence in Laboratory Medicine"</i>	Padova, IT

Sep 28, 2021	<i>The Global Creation and Monitoring of the Traceability of Test Results in the Medical Laboratory</i>	The Netherlands, Online and on site event
Oct 5 - 10, 2021	<i>FEBS Advanced Course: 360-degree Lysosome; from structure to genomics, from function to disease-update</i>	Izmir, TR
Oct 6 - 8, 2021	<i>4èmes Journées Francophone de Biologie Médicale</i>	Rennes, FR
Oct 7 - 10, 2021	<i>46th ISOBM Congress</i>	Bled, SI
Oct 28 - 30, 2021	<i>II National Meeting Conquilab and Technological</i>	Mazatlan, MX
Nov 19 - 20, 2021	<i>54 èmes Journées de Biologie Praticienne - JBP</i>	Paris, FR
Nov 19, 2021	<i>Annual Meeting of the Royal Belgian Society of Laboratory Medicine</i>	Brussels, BE Hybrid event
Dec 6 - 7, 2021	<i>X Molecular Cytopathology</i>	Naples, IT Hybrid event
Feb 10 - 11, 2022	<i>International Congress on Quality in Laboratory Medicine</i>	Helsinki, FI
May 23 - 26, 2022	<i>10th Santorini Conference "Systems medicine and personalized health and therapy" – "The odyssey from hope to practice: Patient first – Keeps Ithaca always in your mind"</i>	Santorini, GR
New date TBA	<i>XXII Serbian Congress of Medical Biochemistry and Laboratory Medicine and 16th Symposium for Balkan Region</i>	Belgrade, SRB

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	Zimbabwe (ZW)

Regional Federations

Arab Federation of Clinical Biology (AFCB)
 African Federation of Clinical Chemistry (AFCC)
 Asia-Pacific Federation for Clinical Biochemistry
 and Laboratory Medicine (APFCB)
 European Federation of Clinical Chemistry
 and Laboratory Medicine (EFLM)
 Latin America Confederation
 of Clinical Biochemistry (COLABIOCLI)
 North American Federation of Clinical Chemistry
 and Laboratory Medicine (NAFCC)

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 India: Association of Medical Biochemists of India (AMBI)
 Iran: Iranian Association of Clinical Laboratory Doctors (IACLD)
 Jordan: Society for Medical Technology & Laboratories (SMTL)
 Kazakhstan: Public Association - Federation of Laboratory Medicine (FLM)
 Mexico: Federación Nacional de Químicos Clínicos (CONAQUIC A.C.)
 Nepal: Nepalese Association for Clinical Chemistry (NACC)
 Philippines: Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)
 Romania: Order of the Biochemists, Biologists, Chemists in Romanian Health System (OBBCSSR)
 Serbia: Serbian Society for Clinical Laboratory Medicine and Science (SCLM)
 Spain: Andalusian Society for Clinical Analysis and Laboratory Medicine (SANAC)
 Asociación Española de Farmacéuticos Analistas (AEFA)
 Sri Lanka: College of Chemical Pathologists of Sri Lanka (CCPSL)
 Turkey: Society of Clinical Biochemistry Specialists (KBUD)
 Ukraine: Association for Quality Assurance of Laboratory Medicine (AQALM)

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N° 7/8 – July/August: *by mid June*

N° 9 – September: *by mid August*

N° 10 – October: *by mid September*

N° 11 – November: *by mid October*

N° 12 – December: *by mid November*

If you want to submit an article or advertisement to be published in the eNews, send it to:
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