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International Federation of Clinical Chemistry and Laboratory Medicine







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The evolving digital era and ethics

by Bernard Gouget

Chair, IFCC Committee on Mobile Health and Bioengineering
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SFBC-International Committee
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Counselor for Public Health-FHF
Chair-Human Health Care Committee-COFRAC

Any health system today is confronted with new societal and ethical challenges and the growing pace of scientific development. The great increase in chronic diseases as well as technical progress, the emergence of new therapies and the acceleration of the digital revolution will change healthcare needs and approaches to care.

Digital technology is fundamentally positioned at the heart of all health-care systems. Its development is part of an extremely active international context. It is a major and irreversible element for the organization of care and a source of progress for improving quality and efficiency in health. The expected benefits in the field of teaching and research are also considerable. All professionals and citizens are directly concerned with this movement of technological innovation and the democratization of digital technology in health.



Dr. Bernard Gouget

The French National Ethics Advisory Council reported in a recent opinion piece that digital technology also concerns data collection, the development of learning algorithms (AI), and their applications, as well as in-silico modeling of diseases and modeling the action of new drug molecules. Today, the human part in medical practice is constantly being reduced by robotization in the medical technology sectors. The future becomes the present with algorithms already validated by peers. Their developments in medical decision making assistance or prescription assistance software allow diagnoses and therapeutic approaches to be facilitated and refined thanks to computing potential multiplied via big data or international registers collating the data of rare patients. Digital innovations in health have become essential and the quality of care is improved to the benefit of patients through more personalized and predictive management and care is more secure, with better traceability. The gains that can be obtained also concern prevention and screening, care, support and healthcare governance more generally.

The use of digital technology can constitute a source of concern for professionals and users, especially regarding the use of data and associated services. It is therefore essential that the shift to digital technology is done in the context of ethical values and standards in order to structure and set limits for use. Respecting the rights and freedoms of individuals and protecting health data and the extent they are shared to improve clinical and biological quality are imperative. Algorithmic medicine must not deprive patients of their ability to participate in the process of constructing the management of their disease. It is also necessary to be vigilant that the digital revolution does not create new inequalities and does not penalize non-digital citizens, who are fragile populations with significant health needs. The objective of e-health is to reduce the risks of disease, obtain better treatment and care with a patient who is no longer an object of care, but rather an actor in their healthcare.

In this context, ethical reflection on data, algorithms, practices and AI must be undertaken very early in the conception and development of solutions. For this purpose, research into digital ethics should be increased.

The digital transformation is a source of motivation; it is urgent to take action to anticipate changes in jobs and possibilities for new functions and professions in health. The appeal of our profession also depends on training in the necessary skills to respond to the challenges of digital health. Preparing for the future means training future professionals and preparing them to understand the ever-faster progress in medical knowhow. Laboratory medicine is diversifying. Professionals are in demand to work more collectively in a comprehensive approach to care and share the same engagement and professional culture. Dialogue, responsiveness, collective deliberation, and cross-referencing are

all useful to further improve the quality of care in an ethical framework and get the most out of the added value of laboratory medicine. Bioethics and digital technology are increasingly the subject of practical and theoretical training. Ethical considerations at the international level are inseparable from the dissemination of tools. The organizational and cultural heterogeneity of the various national ethics committees with different regulatory or legislative responses leads to the creation of coordinated digital committees to better communicate and understand our cultural differences.

The digital revolution penetrates all healthcare sectors and requires unprecedented ethical reflections driven by scientific advances. Our Federation can doubtlessly be a place for transcultural sharing and reflection to study and debate new ethical problems in laboratory medicine.

IFCC and Global Healthcare Organizations join ABBOTT to launch the UNIVANTS of Healthcare Excellence Award

Global recognition for cross-functional care teams achieving measurably better healthcare Apply Now!

IFCC, together with leading global healthcare organizations, AACC, EHMA, Modern Healthcare, and HIMSS, in partnership with Abbott, is part of the UNIVANTS of Healthcare Excellence Award initiative.

UNIVANTS, which stands for "unity" and "avant-garde" is a unique healthcare industry award that honours integrated multidisciplinary clinical care teams with innovative approaches to achieve measurably better healthcare performance for patients, clinicians, payers and healthcare institutions.

"Through the UNIVANTS of Healthcare Excellence Award program we hope to encourage healthcare system departments to break out of their silos and persuade all areas of the hospital to take advantage of the data from the lab to solve critical needs in the hospital and, above all, improve patient outcomes," said Howard Morris, PhD, President of the IFCC.

"Our partners currently include global organizations dedicated to lab medicine, healthcare management

and healthcare media," said Lisa Rose, divisional vice president, global marketing, Abbott. "Just as there is a need for healthcare providers to reach across the aisle and break down silos, our multi-disciplinary partners also are unifying to find solutions to the evolving state of healthcare together."

The call to action for 2019 nominations for this prestigious award occurred at the 70th AACC Annual Scientific Meeting & Clinical Lab Expo in Chicago and featured healthcare teams that have already achieved success.

By recognizing the integrated clinical care teams who are already achieving measurably better healthcare and leveraging expertise across disciplines, the award is intended to inspire healthcare professionals around the world.

The award partner organizations will be sharing best practices in publications, in roundtable events, and more.

The founding partners invite teams to apply for the inaugural award who demonstrate:

- **Strength in Unity** − teams working across disciplines to break down silos and develop care projects as collective and integrative teams
- → **Avant Garde** implementation of ideas that are at the forefront of change and mobilizing insights from the clinical laboratory to transform healthcare delivery
- **Nurturing and Passion** cultivation of communities, passionate about integrated clinical care and enabling others to do the same

The awards are open to all healthcare professionals and teams regardless of affiliation with Abbott. All partners, excluding Abbott, will evaluate submissions to determine the 2019 winners. Award entries are being accepted through March 2019.

For more information and to enter the 2019 UNIVANTS of Healthcare Excellence Awards, please visit:

UnivantsHCE.com

Award-winning teams for the UNIVANTS of Healthcare Excellence Award will be recognized for their contributions in multiple ways, locally and globally.

For applications, register at:

https://www.diagnostics.abbott/int/en/knowledge-center/healthcare-excellence-program/verification





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IN PARTNERSHIP WITH











AACC Learning Lab for Laboratory Medicine on NEJM Knowledge+

A cloud-based adaptive learning program



by Nader Rifai
Founder of CCTC programme
by Christina Ellervik
Co-editor, AACC Learning Lab

In the past several months, we reported on the *Clinical Chemistry* Trainee Council (www.traineecouncil.org) and its various educational features. Here, we wish to describe another *Clinical Chemistry* initiative, the AACC Learning Lab for Laboratory Medicine on NEJM Knowledge+ (http://www.aacc.org/education-and-career/learning-lab), known as the Learning Lab (Figure 1).

This ambitious programme is a collaborative effort between NEJM Group, the publisher of the *New England*

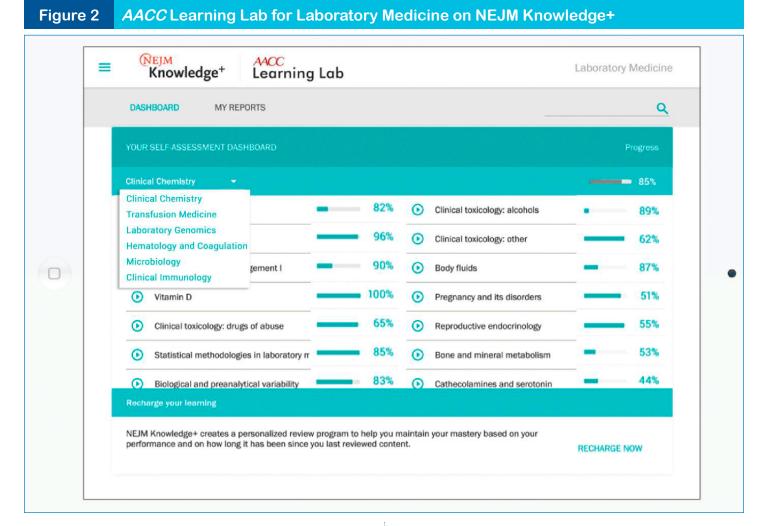
** AACC Learning Lab

**EJM
Knowledge+
AACC Learning Lab

Journal of Medicine, AACC, the publisher of Clinical Chemistry, and Area9 Lyceum, a global leader in education technology.

The Learning Lab is a cloud-based educational programme, which utilizes the concept of adaptive learning, the closest method to personalized education. Through sophisticated computer algorithms, timing of the learner's response, and assessing the learner's confidence in the answers provided, the system identifies the areas in which the learner is deficient and provides the appropriate learning materials to correct the deficiency. Learning Lab can be accessed via mobile devices and enables efficient learning in small blocks of time. When completed, this curriculum-based program will consist of over 120 courses in the six main disciplines of laboratory medicine including clinical chemistry, laboratory genomics, haematology/coagulation, transfusion medicine, microbiology, and clinical immunology (Figure 2); at present, over 40 courses are available.

Over 90 clinical laboratory scientists and physicians from the United States, United Kingdom, Canada, Australia, Iceland, Denmark, Norway, Croatia, Singapore and South Africa have volunteered to build courses for the Learning Lab. A typical course consists of 100-150 granular learning objectives; every learning objective is coupled with two probes and a learning resource. The probes are the actual questions and can be presented in one of nine different formats including multiple choice, fill-in-the-blank, matching and categorizing, and clinical cases. Morphology images, tables, chromatograms, and figures can be used in the probes and the learning resources to enhance the learning experience.



Like all NEJM Knowledge+ products, the Learning Lab courses go through a rigorous internal and external review process followed by a beta testing evaluation. Over 120 laboratory medicine professionals have participated in reviewing and performing the beta testing evaluation of these courses.

Learning Lab has been designed for laboratory medicine professionals in hospital laboratories, commercial laboratories and the *in vitro* diagnostics industry to help them to:

- Remain abreast with current knowledge in the field;
- Maintain certification by obtaining the required credits;
- 3. Assess competency, on personal or institutional level; and
- 4. Prepare for certification exams.

Although the primary audience for this programme is meant to be made up of laboratory medicine professionals at all levels, a secondary audience includes clinicians and other health professionals.

Since courses are built in cellular blocks, specific courses targeting a particular group such as clinical laboratory scientists or certain medical specialty can be easily constructed.

This programme is available commercially, but priced reasonably in order to enable those with limited resources to access it. The hope that in the future, institutions and companies will realize the value of this program to their trainees and employees and make it available to them.

This article is based on an editorial published in *Clinical Chemistry* by N. Rifai. (clinchem.2018.296798, Published October 2018)





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VLP Report: Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)

Manila, Philippines September 24-28, 2018

by Khosrow Adeli Chair, IFCC CPD

Head and Professor, Clinical Biochemistry, Paediatric Laboratory Medicine Senior Scientist, Molecular Medicine, Research Institute The Hospital for Sick Children/University of Toronto - Canada



PCQACL officers with Dr. Godwin Hernaez, Dr. Elizabeth Arcellana Nuqui, and Prof. Khosrow Adeli at the opening ceremony

The Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL) kindly invited me to be their keynote speaker at their 15th annual conference in September 2018. PCQACL is a non-governmental and non-profit organization composed of health professionals' associations, clinical laboratories, both hospital based and free-standing, and industry partners. PCQACL's vision is to be the leader in promoting Quality Services provided by Clinical Laboratories in the Philippines by means of Advocacy, Training, Education, and Research. PC-QACL through its Committee on Continuing Education

and Research conducts annual conventions, symposia, seminars, round table conferences and workshops to equip and enhance the capabilities and competencies of Pathologist, Medical Technologists, and other health professionals.

This year the PCQACL held its 2018 annual convention under the theme of "Sustaining Global Quality Innovations" over three days in Quezon City, Manila. This is the premiere conference on Quality for Clinical Laboratories in the Philippines. The event was extremely well attended with over 1000 participants all of whom

were in attendance throughout the three days of the conference. Participants were medical laboratory professionals including lab scientists/physicians, lab technologist, university faculty, as well as graduate/undergraduate students. There were several presentations including a plenary presentation by another invited speaker, Dr. Raja Elina Raja Aziddin, President of Malaysian Association of Clinical Biochemists (MACB).

As an invited speaker, I gave the Keynote presentation and three plenary/interactive talks (30-45 min each). My Keynote presentation was entitled: *Advancing Laboratory Medicine through Innovation: Predicting the Lab of the Future!* I reviewed innovation in all areas of Lab Medicine & Clinical Laboratory Service as well as exciting new developments *In Vitro* diagnostics, focusing on nanotechnology, microtechnology (lab on a chip), machine learning, artificial intelligence, automation and robotics, smartphone based diagnostics, and medical diagnostics data management.

My first plenary presentation was entitled: **Lipid Guide- lines in Cardiovascular Risk Stratification.** I reviewed

basics of lipid and lipoprotein metabolism and the current guidelines on lipid testing and interpretation. I also reviewed the recommendations made by various international guidelines including the Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult.

Abnormal Routine Lab Results in Cancer Patients. I conducted an interactive session, together with another speaker, on the challenges faced by the laboratory in interpreting laboratory test results in patients diagnosed with cancer. Abnormal biochemical test results in cancer patients can be either factual or factitious. In other words, they might be real high or low results, but they also sometimes represent false elevations or decreases. Thus, abnormal results need to be interpreted with caution and with a thorough understanding of cancer biology, since misinterpretation could lead to inappropriate medical intervention and negative consequences for patients.



Organizing Committee members, PCQACL and EB Officers with Dr. Godwin Hernaez, Dr. Elizabeth Arcellana Nuqui, and Prof. Khosrow Adeli

My third plenary presentation was on Challenges to Lipid Testing: Introduction of the Non-Fasting Lipid Profile. I participated in a second interactive session, together with another speaker, on fasting versus non-fasting lipid testing for cardiovascular risk stratification. I reviewed the advantages of non-fasting lipid measurements including: non-fasting lipids are more representative of the normal state, increase convenience for patients, improve patient compliance, eliminates testing difficulty for patients who have trouble with prolonged fasting (such as children and elderly), and samples can be collected and received in lab throughout the day.

Despite a very busy presentation schedule, I really enjoyed my time in Manila, closely interacting with our Filipino colleagues who were extremely warm and kind hosts, very hospitable and friendly.

I want to personally thank all of the organizers particularly the conference president Dr. Godwin Hernaez as well as other PCQACL board members including Dr. Elizabeth Arcellana Nuqui, Dr. Pauo Belen, and Ms. Erlinda Cua.

Finally, my sincere thanks to IFCC VLP program for their sponsorship of my travel as well as Abbott Diagnostics for funding the VLP program.

NEWS FROM REGIONAL FEDERATIONS AND MEMBER SOCIETIES



News from the Vietnamese Association of Clinical Biochemists (VACB)

2018 National Scientific Conference of VACB

by Hoang Van Son National Representative of the VACB to IFCC

The Vietnamese Association of Clinical Biochemists (VACB) received the IFCC-Abbott Visiting Lectureship for the 2018 National Scientific Conference in the framework of the Jubilee Ceremony of the 55th Anniversary of the Foun-



Prof. Abderrazek Hedhili, (TU), IFCC EB member, during the Conference

dation of the VACB, organized in Da Nang, Vietnam, between 17-18 August 2018.

The visiting lecturer was Prof. Abderrazek Hedhili, IFCC EB member. Two lectures of Prof. Abderrazek Hedhili were highly appreciated by the audience.

A total of 520 members of the VACB attended, from many provinces of Vietnam, including Hanoi, Ho Chi Minh-City, Da Nang, Hue, Hai Phong.

The lectures were:

- "Mycotoxins and human health", and
- "Role of Laboratory in the diagnosis of pesticides intoxications".

The audience found that these lectures were very useful, improving their knowledge especially in the area of toxicology.

These lectures and that of Dr. Raja Elina Raja Aziddin, APFCB traveling lecturer, President of the Malaysian Association of Clinical Biochemists: "Methodologies and Technologies for Therapeutic Drug Monitoring and Drugs of abuse testing" given in this VACB National Scientific Conference greatly contributed to the VACB Programme of development of Therapeutic Drug Monitoring and Toxicology in the Vietnamese Clinical Laboratories.

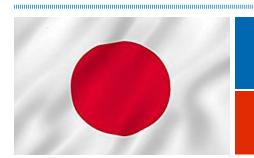
The VACB National Committee and the VACB members in the Conference found the great friendship of

the two colleagues from IFCC and APFCB, from Tunisia and Malaysia very heartwarming.

We express our sincere thanks to you.

On behalf of the Vietnamese Association of Clinical Biochemists, I would like to express our gratitude and thanks to IFCC and APFCB, to Abbott Diagnostics for their generous support, to Prof. Nader Rifai, IFCC-Abbott VLP Chair and the IFCC EMD for generous help in implementing the VLP in Vietnam.

VACB National Committee



News from the Japanese Society of Clinical Chemistry (JSCC)

The JSCC 2018 Article Award

by Hideo Sakamoto International Exchange Committee of JSCC

The Japan Society of Clinical Chemistry (JSCC) has been the leading society in the field of Clinical Chemistry in Japan for more than fifty years.

The JSCC Article Award is given annually to a person or persons having made outstanding academic research in the field of clinical chemistry.

In 2018, Yutaka Suehiro, MD, PhD and Eriko Mori, MS are the winners of the 2018 Article Award.

The award presentation was held at the 58th Annual Meeting of JSCC in Nagoya, Japan, from 24-26 August, 2018. At the presentation, the award recipient was congratulated by Dr. Masato Maekawa, President of JSCC, for their outstanding academic research in clinical chemistry.

In this issue, we would like to introduce two winners work to distribute their outstanding work.

Yutaka Suehiro, MD, PhD (Department of Oncology & Laboratory Medicine, Yamaguchi University Graduate School of Medicine) is the winner of the 2018 Article Award, entitled "Highly sensitive stool DNA testing of Fusobacterium Nucleatum as a marker for detection of colorectal tumours in a Japanese population".

Accumulating evidence shows an overabundance of Fusobacterium nucleatum (Fn) in colorectal tumor tissues. Although stool DNA testing of Fn might be a potential marker for the detection of colorectal tumors, the difficulty in detecting Fn in stool by conventional methods prevented further explorations.



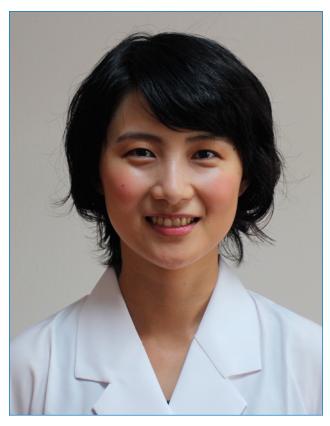
Mr. Yutaka Suehiro, winner of the 2018 JSCC Article Award

Therefore, they developed a droplet digital PCR assay for detecting Fn in stool and investigated its clinical utility in the management of colorectal tumors in a Japanese population.

Faeces were collected from 60 healthy subjects (the control group) and from 11 patients with colorectal non-advanced adenomas (the non-advanced adenoma group), 19 patients with colorectal advanced adenoma/carcinoma in situ (the advanced adenoma/CIS group), and 158 patients with colorectal cancer (CRC) of stages I to IV (CRC group).

Absolute copy numbers of Fn were measured by droplet digital PCR. The median copy number of Fn was 17.5 in the control group, 311 in the non-advanced adenoma group, 122 in the advanced adenoma/CIS group, and 317 in the CRC group. In comparison with that in the control group, the Fn level was significantly higher in the non-advanced adenoma group, the advanced adenoma/CIS group, and the CRC group.

This study illustrates the potential of stool DNA testing of Fn by droplet digital PCR to detect individuals with colorectal tumors in a Japanese population.



Ms. Eriko Mori, winner of the 2018 JSCC Article Award

Eriko Mori, MS (Department of Clinical Laboratory, The University of Tokyo Hospital) is the winner of the 2018 Article Award, entitled "Existence of a squamous cell carcinoma antigen-immunoglobulin complex causes a deviation between squamous cell carcinoma antigen concentrations determined using two different immunoassays: first report of SCCA coupling with immunoglobulin A".

Squamous cell carcinoma antigen (SCCA) is used as a tumor marker for squamous cell carcinoma and is routinely measured, using an immunoassay in clinical laboratories.

Measurements based on an immunoassay, however, have several issues to be solved. One of them is interference with serum proteins and antibodies, such as heterophilic antibodies, which could make the data falsely high or low. Another problem is the difference in the reactivity to antigen among commercially available kits, since each immunoassay uses different specific antibodies.

Ms. Mori and her co-author have experienced three cases in which the SCCA concentrations differed considerably between two different SCCA kits, a chemiluminescent immuno-assay (CLIA method) and a fluorescent enzyme immunoassay (FEIA method).

Moreover, the SCCA concentrations determined with the CLIA method in these cases maintained at unexplainably high levels after successful treatment. Therefore, they aimed to elucidate the mechanism for the deviations in the SCCA concentrations in these three cases.

Ms. Mori and her co-author demonstrated that large molecular weight SCCA complexed with IgG (two cases) and IgG plus IgA (one case) existed in the serum samples collected from these three deviated cases. To our knowledge, this is the first report which demonstrates the coupling of SCCA with IgA.

In conclusion, the mechanism for the deviation observed between the two immunoassays might be the difference in the reactivity to immune complexes of SCCA with its autoantibody.

IFCC's Calendar of Congresses, Conferences & Events

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses

May 19 - 23, 2019	BARCELONA EUROMEDLAB 2018	XXIII IFCC - EFLM EuroMedLab Barcelona 2019	Barcelona, ES
Sep 11 - 13, 2019	COLABIOCLI	COLABIOCLI Regional Congress 2019	Panama, PA
Nov 17 - 20, 2019	15 th APFCB 2019	APFCB Regional Congress 2019	Jaipur, IN
May 24 - 28, 2020	SEOUL 2020 ** Wordful Corpus of Chicar Chevistry of Chicar Chicar Chevistry of Chicar Chevistry of Chicar C	XXIV IFCC WorldLab Seoul 2020	Seoul, KR
May 16 - 20, 2021		XXIV IFCC - EFLM EuroMedLab Munich 2021	Munich, DE
May 21 - 25, 2023		XXV IFCC - EFLM WorldLab EuroMedLab - Rome 2023	Rome, IT

	Calendar of events with IFCC auspices	
Nov 1 - 3, 2018	LMCE 2018 and KSLM 59th Annual Meeting	Seoul, KR
Nov 1 - 4, 2018	2nd International Cell Death Research Congress	Izmir, TR
Nov 9 - 12, 2018	18º Congreso Internacional del Colegio Nacional de Bacteriología	Barranquilla, CO
Nov 13, 2018	Workshop on Alzheimer's disease "Making the point"	Prague, CZ
Nov 14 - 16, 2018	Promoting Research in the area of Vitamin D	Karachi, PK
Nov 15 - 18, 2018	26th AMBICON Annual Conference	New Delhi, IN
Nov 21, 2018	Réunion LABAC	Paris, FR
Nov 26 - 27, 2018	QLAC 2018 - POCT innovation, Connected Health and Beyond: How digital technology is transforming lab medicine health and social care?	Belgrade, SRB
Nov 28 - Dec 1, 2018	II International Conference of the Bolivian Society of Clinical Biochemistry	La Paz, BO
Nov 29, 2018	Place and role of the medical biology and lab medicine in the Health System Transformation Strategy	Paris, FR
Nov 29, 2018	International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME): "Standardization in Laboratory Medicine and Patient Safety"	
Nov 29 - Dec 1, 2018	ec 1, 2018 IV International Conference on Continuous Training in Clinical Biochemistry and Hematology	
Dec 5 - 6, 2018	4th Annual Meeting, Saudi Society for Clinical Chemistry	Riyadh, SA
Dec 7 - 8, 2018	7 - 8, 2018 JBP 2018 - Journées de Biologie Praticienne	
Dec 24 - 27, 2018	Dec 24 - 27, 2018 ICB 2018 - 2nd International Congress on Biomedicine	
Feb 7 - 8, 2019	International Congress on Quality in Laboratory Medicine	Helsinki, Fl
Mar 22 - 23, 2019	19 Sth EFLM European Conference on Preanalytical Phase "Preanalytical Challenges - time for solutions"	
Apr 4 - 5, 2019	10th European Symposium on Clinical Laboratory and In Vitro Diagnostic Industry: 'The Clinical Laboratory in the Pregnancy Monitoring'	Barcelona, ES

Apr 11 - 12, 2019	15th Belgrade Symposium for Balkan Region	Belgrade, SRB
May 18, 2019	VII International Symposium Laboratory Medicine and Quality - Satellite Meeting IFCC-EFLM EUROMEDLAB 2019	Barcelona, ES
May 19, 2019	International Symposium : Breast Cancer and Environment - Satellite Meeting IFCC-EFLM EUROMEDLAB 2019	Barcelona, ES
May 19, 2019	International Symposium: Standardization and Recommendations in the Laboratory of Haematology - Satellite Meeting IFCC-EFLM EUROMEDLAB 2019	Barcelona, ES
Jun 29, 2019	The 23rd International Conference on Laboratory Maedicine and Pathobiology: An expert forum in clinical and laboratory sciences	Chios Island, GR
Sep 11 - 13, 2019	XXIV Congreso Latinoamericano de Bioquímica Clínica (COLABIOCLI) and XIV Congreso Nacional de Laboratoristas Clínicos de Panamá	Panama City, PA
Jun 9 - 12, 2020	XXXVII Nordic Congress in Medical Biochemistry	Trondheim, NO



WORKSHOP ALZHEIMER'S DISEASE "MAKING THE POINT"

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Iran: Iranian Association of Clinical Laboratory Doctors (IACLD) Jordan: Society for Medical Technology & Laboratories (SMTL)

Kazakhstan: Public Association - Federation of Laboratory Medicine (FLM)

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Starting in 2018, the Communications and Publications Division publishes ten editions of the e-News per year, including two double issues.

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