The Newsletter of the Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine for circulation among APFCB and IFCC members only

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APFCB News 2020 Issue 2

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Submissions

The APFCB News welcomes suitable contributions for publication. These should be sent electronically to the Chief Editor. Statements of opinions are those of the contributors and are not to be construed as official statements, evaluations or endorsements by the APFCB or its official bodies.

Cover page: Pleasure of Life in a Farming Community Contributed by Tan It Koon Founding and Past President APFCB

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From the desk of Chief Editor

Dear Friends and Colleagues,

Greetings from Kuala Lumpur!

Despite these challenging times, I am pleased to bring you the second issue of the APFCB News 2020.

Many countries around the world have been affected by the Covid-19 pandemic. It has caused a global healthcare crisis and brought much sorrow. As of 18th October 2020, the World Health Organization (WHO) reported 39,596,858 confirmed cases of COVID-19 including 1,107,374 deaths.

The COVID-19 pandemic has drawn attention to and shown the importance of clinical laboratory testing to the overall treatment outcome of the patient like never before. Many among us are directly or indirectly involved and have contributed to the COVID-19 crisis, ranging from establishing diagnosis, prognosis, disease staging, therapeutic drug monitoring and epidemiologic surveillance studies. Although clinical laboratory professionals provide the crucial data to doctors, they are often "forgotten warriors" in the fight to save a patient's life. In this issue of the APFCB News, Mr. Joseph Lopez, past President of the APFCB has contributed a lovely poem as a tribute to all Covid-19 fighters in healthcare and especially to those working in the laboratory. I take this opportunity to thank the IFCC for sharing the information on the various initiatives undertaken by the IFCC Global Taskforce on COVID-19. The work of this task force has been invaluable in supporting clinical laboratories around the world in the fight against COVID-19.

I am happy to report that we have also received articles from a number of national societies. To add value to the content, the C-CP is working on including scientific articles, opinion papers and scientific reviews to the APFCB News. This issue features four scientific articles that are contributed by our corporate members. These articles provide useful information that can serve as a reference. I wish to thank all contributors of this issue and look forward to getting continuing support from all member societies and corporate members. Any feedback, comments or views for further improvements to the APFCB News is most welcome. My heartfelt thanks to the C-CP team for all their help in ensuring the successful publication of this newsletter. Continuing with tradition, the cover-page of this issue of the APFCB News features the image of a painting graciously provided by Dr. Tan It Koon, founder and past President of APFCB. We are grateful to Dr. Tan It Koon for his unfailing support to the APFCB and for sharing with us his beautiful blue painting, to view and enjoy in these difficult and troubling times.

To all, take care and stay safe! Best wishes,

Rajelina

Dr. Raja Elina Chief Editor, APFCB News





Message from APFCB President

Dear friends and colleagues, greetings and my best wishes to everyone in the APFCB family.

This has been a stressful period for many of us because of the Covid-19 pandemic and many APFCB laboratory staff is playing an essential role in the fight against this deadly virus in your respective countries. My sincere appreciation to everyone.

I take this opportunity to share that the laboratory community around the globe has been able to demonstrate our value contribution towards healthcare because of the pandemic. Hospital leadership and frontline workers constantly worked with laboratory professionals for results in order to diagnose, isolate and treat positive cases. Many of us were involved in a frenzy of activities as we validated the emerging assays and streamlined the process of timely reporting of results. This was a challenge the laboratory communities around the world took up and successfully proved to everyone, truly how valuable we are to our community. I stand proud to be part of our laboratory community. I do not enjoy making comparisons, but with the current Covid pandemic, the Asia Pacific can stand particularly tall. Many of our countries have handled the situation very well. Do continue to keep up the good work.

I would like to thank the APFCB Newsletter and editorial team working with the Chief Editor, Dr. Raja Elina from Malaysia, for their determination and hard work. It is not easy to dedicate oneself to such activity in these busy and difficult times. I trust you will learn and you will enjoy reading this issue as it contains a wide variety of articles.

My best wishes to you and your families. Stay safe everyone!

SK Sethi

Associate Prof. Sunil Sethi President, APFCB







Challenges and Opportunities for Clinical Laboratories During the COVID-19 Pandemic

Shannon Steele, Mary Kathryn Bohn, and Khosrow Adeli Pediatric Laboratory Medicine, Hospital for Sick Children, University of Toronto and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

The coronavirus disease 2019 (COVID-19) pandemic has highlighted the importance of laboratory medicine in healthcare, resulting in unparalleled visibility and also unprecedented challenge. The challenges encountered by clinical laboratories worldwide during this pandemic encompass both diagnostic testing and patient monitoring, as well as biosafety and operational procedures. To assist clinical laboratories in navigating these challenges, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established a Global Taskforce on COVID-19, which has been instrumental in summarizing and disseminating the latest evidence-based information. At the onset of the pandemic, the Taskforce published the IFCC Information Guide on COVID-19 to share key information and resources with laboratory professionals worldwide. Since then, this information guide has been regularly updated as new literature and guidelines become available. In addition to publishing an evaluation of the latest evidence in the early period of the COVID-19 pandemic (CCLM 2020; 58:1037-52), the Taskforce has now published interim guidelines that provide practical recommendations to laboratories on several topics, including a new series on clinical laboratory testing (CCLM 2020). This recently published three-part series includes interim guidance on: 1) molecular testing of SARS-CoV-2 infection, 2) serological testing for antibodies against SARS-CoV-2, and 3) biochemical and hematological monitoring of COVID-19 patients based on available evidence. All articles are also published on the IFCC website (www.IFCC.org).

These interim guidance documents by the IFCC Global Taskforce on COVID-19 could not be more timely. In the past several months, hundreds of laboratory tests have been rapidly produced by manufacturers and released for clinical use through emergency use authorization by various regulatory bodies. Clinical laboratories have been tasked with selecting, evaluating, implementing, and performing these tests, including molecular assays for the detection of SARS-CoV-2 RNA as well as serological assays for the identification of antibodies against SARS-CoV-2, at an exceptional rate with minimal associated evidence. This unprecedented urgency has resulted in a wide reaching debate regarding the appropriate clinical applications of molecular and serological testing as well as their respective clinical performance in specific patient populations.

Several questions have also been posed regarding appropriate pre-analytical and analytical practices, including timing of sample collection, considerations in assay selection and verification of assay performance.



In addition, the questions surrounding molecular and serological testing, laboratories have also supported the prognostication of patients with severe COVID-19 through routine biochemical and hematological testing (e.g. markers of inflammation, multisystem organ damage, etc.). While some laboratory tests have demonstrated excellent prognostic potential, there is still debate regarding what biochemical and hematological tests should be ordered and when. The aforementioned published interim guidance documents were developed by the Taskforce to address these questions through an extensive review by a panel of expert laboratory professionals, including virologists, clinical chemists, and industry representatives. The international authorship of these documents underscores their global applicability, with special consideration for low-resource settings. We encourage all IFCC member societies, as well as independent laboratories, to refer to these guidelines for evidence-based recommendations and practical advice during the COVID-19 pandemic.

In addition to providing practical guidance on clinical laboratory testing related to COVID-19, an important objective of the IFCC Global Taskforce on COVID-19 is to identify the current status of operational and bio safety measures in place in laboratories worldwide. Undoubtedly, the large volumes of specimens submitted for molecular or serological testing has placed immense pressure on clinical laboratories during the COVID-19 pandemic, necessitating significant changes to operational procedures. A survey created and distributed by the Taskforce revealed challenges in the following areas: limited availability of supplies and testing resources, particularly personal protective equipment as well as equipment, reagents, consumables, and materials; inadequate staff and difficulty managing staff morale; difficulty ensuring a safe working environment; and difficulty managing changes in testing demand (CCLM 2020;58:1441-9). Another survey by the Taskforce was circulated globally to understand how laboratories were managing biohazard risks during the COVID-19 pandemic (CCLM 2020;58:1433-40). This survey identified variable practices and procedures. To better standardize these practices worldwide, the Taskforce also published recommendations on bio safety in clinical laboratories during the pandemic, based on available evidence.

Clearly, the clinical laboratory has faced unique challenges in the face of the COVID-19 pandemic. Despite this, clinical laboratories worldwide have developed strategies to manage the unprecedented demand, emerging as vital contributors to the global COVID-19 response. In doing so, the role of the clinical laboratory has become much more visible in the realm of healthcare. The IFCC Global Taskforce on COVID-19 will continue to support clinical laboratories around the world, by continuing to update its recommendations based on the latest scientific evidence.





APFCB Scientific Committee Report 2020

Dr. Samuel Vasikaran Chair APFCB Scientific Committee

The APFCB Scientific Committee currently has the following active Working Groups.

 The Mass Spectrometry Harmonisation WG which is Chaired by Dr Ronda Greaves is undertaking a multicentre study of the influence of internal standard on the analysis of 17-hydroxyprogesterone by LCMSMS, in association with RCPAQAP - AACB and IFCC Emerging Technologies Division Paediatric Hormonics Working Group. The following publication is a recent offering from this group.

Influence of isotopically labeled internal standards on quantification of serum/plasma 17α -hydroxyprogesterone (17OHP) by liquid chromatography mass spectrometry. Loh TP, Ho CS, Hartmann MF, Zakaria R, Lo CWS, van den Berg S, de Rijke YB, Cooke BR, Hoad K, Graham P, Davies SR, Mackay LG, Wudy SA, Greaves RF. *Clin Chem Lab Med* 2020;58(10):1731–9.

- 2. APFCB / WASPaLM Task Force on Chronic Kidney Disease which is chaired by Dr. Pavai Sthaneswar is undertaking a survey of testing and reporting practices for CKD related laboratory indices in the region in order to ascertain concordance of reporting practices with current guidelines and industry standards. It is hoped that the results of the survey would help harmonize practice according to current recommendations throughout the region.
- 3. The Diabetes Testing Harmonisation WG chaired by Dr. Mithu Banerjee is similarly conducting surveys of diabetes testing and reporting practices in the region. Results of surveys conducted in the Philippines and India have been presented at the PAMET conference in 2018 and the APFCB Congress in 2019 respectively. The results of the Indian survey have been written up and accepted for publication in the upcoming issue of *e/IFCC*. Surveys are currently under way in Sri Lanka and Singapore. It is clear that whilst most laboratories follow recommended practices, there is some lag in laboratory practices in some areas which could benefit from activities to harmonize and update practice. Ideally, this would be locally driven, led by each national professional body, but APFCB would certainly support these activities going forward.



- 4. The Harmonization of Reference Intervals WG chaired by Dr Tze Ping Loh plans to derive and compare indirect reference intervals from paediatric to geriatric subjects from laboratories within the Asia–Pacific region. To achieve this, they are calling on interested laboratories that are serving primary care (Non–hospital) patients to contribute de–identified laboratory results for derivation of indirect reference intervals study. The output of this study will be returned to the participating laboratories to help inform their practices. It is hoped that the results of this study may contribute towards regionally relevant paediatric to geriatric reference intervals for patient care, as well as provide insights into biological variation within the region. Those interested should contact Dr. Tze Ping Loh (tploh@hotmail.com)
- 5. Dr. Mohamed Saleem is chairing a WG to Analyse Laboratory Data for Improving Diagnostics. Results of benchmarking surveys in the region will be used to support healthcare goals for improved disease management. The support of Roche Diagnostics for this activity is acknowledged.
- 6. Interpretative commenting on Clinical Chemistry reports. Webinars to discuss and analyse interpretative comments and to educate laboratory professionals on the addition of interpretative commenting are in progress. Two Webinars on thyroid function tests have been concluded with wide participation from the region. The resource material and the recordings of these webinars are available on the APFCB website under the heading of Webinars: https://www.apfcb.org/webinars.html

Future webinars are planned on a number of topics including endocrine testing, dynamic function tests and reproductive hormone tests. I would like to acknowledge the support of Siemens Diagnostics for this activity.

I am grateful for the support of many APFCB colleagues, and the corporate sector coordinated by Dr Alex Wong, for their help and support for the activities for the Scientific Committee.

If you have any ideas for future scientific activities in the APFCB region or would like to participate in our current activities, please feel free to contact me: samuel.vasikaran@health.wa.gov.au



APFCB Task force on CKD

Associate Prof Dr. Pavai Sthaneswar, Chair, APFCB / WASPaLM Task Force on Chronic Kidney Disease

Chronic kidney disease (CKD) is a common but silent and often under-recognised condition. The worldwide prevalence of CKD stages 1-5 is estimated to be up to 13.4%.¹ It has emerged as a global public health problem because of the increasing number of patients with CKD who have an increased risk of progression to kidney failure.

The Kidney Disease: Improving Global Outcomes (KDIGO) CKD Working Group released new updated KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.² Laboratory medicine plays an important role in the diagnosis and management of CKD. The diagnosis and staging of CKD are based on estimated glomerular filtration rate (eGFR) and albuminuria. The recommended formula for reporting eGFR in this guideline is the Chronic Kidney Disease Epidemiology Collaborative (CKD-EPI) equation. The requirement for reporting eGFR by CKD-EPI is the measurement of serum creatinine by using standardised assays traceable to isotope-dilution mass spectrometry (IDMS). Regarding evaluation of albuminuria, the KDIGO guideline recommends the following measurements for initial testing (in descending order of preference, in all cases an early morning urine sample is preferred): 1) urine albumin-to-creatinine ratio (ACR); 2) urine protein-to-creatinine ratio (PCR); 3) reagent strip urinalysis for total protein with automated reading; 4) reagent strip urinalysis for total protein with manual reading. They recommended that the term microalbuminuria should no longer be used by laboratories.

The major problem hampering efforts in estimating CKD is the inadequate standardisation in sampling and measurement methods. Significant inter–laboratory variations in serum creatinine measurement exist internationally.³ Small analytic changes in serum creatinine create major shifts in the distributions of eGFR, which can cause large differences in the classification of patients.⁴ Automatic laboratory reporting of eGFR calculated from serum creatinine measurements would help to identify asymptomatic kidney dysfunction at an earlier stage. eGFR estimated by CKD–EPI equation allowed better staging of renal function compared to Modification of Diet in Renal Disease (MDRD) formula.⁵ With a limited resource for the healthcare system, guidelines may improve the efficiency of health care. The initial step to create a guideline is to explore the current status of CKD testing in a national environment.

Objectives

- 1. Assess the current practice in CKD testing.
- 2. Obtain information on the current state of testing for CKD.
- 3. Identify laboratory-related issues in the diagnosis and/or management of CKD.
- 4. If required, provide assistance for member organisations and others in planning and implementing CKD guidelines.



5. Assess the current status of laboratory in the diagnosis of acute kidney injury (AKI).

The APFCB CKD Task Force as a committee, have created a questionnaire to assess the practices and current policies regarding CKD and AKI. A simple questionnaire has been designed seeking information about the methods used, reagent manufacturers for measuring creatinine, equations used for calculating eGFR, as well as reporting of eGFR. Regarding urine albumin, information on the types of samples used for measuring, units of measurement, reference interval and the terminology used are sought. The task force also framed questions to know the current practice about AKI in the laboratory.

The link for the questionnaire is

https://docs.google.com/forms/d/1kiLDjJAtBSbWA82_1kPNTACrAnI5nEYgG5fFRLPm slw/edit

To start with APFCB CKD task force will be conducting the survey in South East Asian counties.

References

- 1. Hill NR, Fatoba ST, Oke JL, et al. Global prevalence of chronic kidney disease a systematic review and meta-analysis. PLoS ONE. 2016; 11: e0158765
- Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group KDIGO clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney Int Suppl 2013; 3:1–150
- 3. Delanghe J, Cobbaert C, Galteau MM, et al. Trueness verification of the current creatinine assays demonstrates a disappointing variability which insufficiently meets changing clinical needs. Clin Chem Lab Med. 2007; 45: S59.
- 4. Klee GG, Schryver PG, Saenger AK, Larson TS. Effects of analytic variations in creatinine measurements on the classification of renal disease using estimated glomerular filtration rate (eGFR). Clin Chem Lab Med. 2007; 45:737-41.
- Matsushita K, Tonelli M, Lloyd A, Levey AS, Coresh J, Hemmelgarn BR; Alberta Kidney Disease Network. Clinical risk implications of the CKD Epidemiology Collaboration (CKD-EPI) equation compared with the Modification of Diet in Renal Disease (MDRD) Study equation for estimated GFR. Am J Kidney Dis. 2012; 60:241-9





APFCB Communication and Publications Committee Report 2020

Dr. Raja Elina Raja Aziddin, Chair, APFCB Communications and Publications Committee

The APFCB Communications and Publications Committee(C-CP) is responsible for disseminating information, news and activities of the APFCB and its member societies. It does this through the APFCB official website, the publication of the APFCB Newsletter and social media.

The Covid-19 pandemic has had serious worldwide impact on the planned physical scientific meetings for 2020. Conferences, seminars, training courses etc. had to be cancelled or postponed until such a time when the situation improves. When this will be is still uncertain. The limitation to physical contact has limited the opportunities for meetings and scientific discussions between medical laboratory professionals not only in Asia-Pacific but all around the world. This situation has given rise to the need for alternative platforms to ensure continual communication and active scientific discussions among the medical laboratory scientific community.

Realising the importance of active communication between APFCB and its member societies, the APFCB Communications and Publications Committee has taken the initiative since April 2020, to actively update the APFCB website with the latest information on scientific and educational activities of the APFCB and its member societies. In addition to this, scientific publications, guidelines, recorded and live webinars on COVID-19 and other topics of interest are now also available on the APFCB website. Since 20 September 2020, APFCB is officially available on social media platforms such as Facebook, Twitter, LinkedIn, Instagram and YouTube. I wish to thank all members of the C-CP for all the hard word.

The Communications and Publications Committee would like to encourage all APFCB member societies to keep to date with the APFCB announcements and educational activities through the available virtual platforms.





APFCB is now on Social Media

Dr. Rojeet Shrestha, MS, PhD, FAACC Social Media Coordinator and Member Committee for Communication and Publication, APFCB

In this age of digitalization, the social media has changed the way we communicate. Social media has become a powerful platform to communicate and disseminate news and information. As an effort for effective communication and distribution of news and updates of APFCB's activities among the national societies and clinical laboratory professionals, the Committee on Communication and Publication of APFCB has since August 2020, started to actively use this powerful tool.

APFCB is now officially available on Facebook, Twitter, LinkedIn, Instagram and YouTube. We will be using these social media platforms to feed news and updates of APFCB's recent activities, publications, congress and events, nominations and awards, and various eLearning materials produced by APFCB.

Links to our social media pages are as follows – Facebook Page: <u>https://www.facebook.com/APFCB/</u> Twitter: <u>https://twitter.com/APFCB_LM</u> Instagram: <u>https://www.instagram.com/apfcb_Im/</u>



LinkedIn: https://www.linkedin.com/company/apfcb/

YouTube: https://www.youtube.com/channel/UCoiicTsnVX-COjklgZHQ54Q

Please follow and subscribe to our channel, share our social media pages with your colleagues and let's stay connected!





APFCB Congress & Conference Committee Report 2020

Prof Praveen Sharma Chair, APFCB, Congress and Conferences Committee

The Executive Board (EB) of the APFCB appointed Professor Praveen Sharma, the former Chair of Communications and Publications Committee as the new Chair of Congresses and Conferences Committee (C-CC) on February 3rd2020. Later, a full committee was constituted by the EB comprising of three full members: Prof Woei Horng Fang (Taiwan), Dr. Ronaldo Puno (Philippines) and Dr. Prasenjit Mitra (India) and two corporate members: Will Greene (Roche) and Ai Tin Lim (Siemens).

The mandate of the committee was to streamline the process of granting APFCB auspices to various scientific events like conferences, congresses, events organised by regional society members and corporate member events. With the COVID-19 situation affecting the global scientific community, there were no applications for physical conferences. Rather, there was a surge in the events based on virtual platform. The committee received a number of applications for grant of APFCB auspices. Till October, 2020, the committee members evaluated and recommended five scientific events for the grant of APFCB auspices. These events were:

- 1. Serological markers in Treatment and Management of COVID-19 (Webinar organised by Snibe).
- 2. The power of Laboratory Medicine to Achieve Measurable Better Healthcare (Webinar organised by Malaysian Association of Clinical Biochemists (MACB)).
- Vietnam Chemical Pathology Course (Organised by Roche along with Vietnam Association of Clinical Biochemists, Ho Chi Minh City Association of Clinical Biochemists, Ho Chi Minh City Medical Association, Ho Chi Minh Association of Medical Laboratory Technologists).
- Clinical Application of Access High Sensitivity Troponin I in the Emergency Department (Webinar organised by Beckman Coulter).
- 5. Roche Experience Days (RED) 2020 Virtual Event (a virtual event by Roche).

The committee is also working on updating the Congresses and Conferences webpage of APFCB to include the details of all the scientific events, which have been granted APFCB auspices.





APFCB Education And Laboratory Management Committee Report 2020

Dr. Tony Badrick Chair APFCB, Education and Laboratory Management Committee

APFCB virtual workshop on Complete Guide on Laboratory Testing of COVID-19 Rojeet Shrestha and Tony Badrick

With the beginning of this devastating COVID-19 crisis, the importance of clinical laboratory and laboratory professionals has risen more than ever. Lab professionals around the globe are working around in clock performing diagnostic tests to fight in this pandemic against the virus. Hundreds of millions of tests have been performed to identify the infections so that appropriate healthcare management can be done efficiently. Therefore, laboratory medicine plays a central role in this fight against the COVID-19 crisis.

As the information of laboratory diagnosis and monitoring of COVID-19 in rapidly evolving with new information arising in daily basis, laboratory professional need a constant update on the developments. Furthermore, many developing countries are struggling to meet requirement of appropriate testing not only because of lack of resources but also due to lack well-trained laboratory professionals on the molecular assays. As the number of molecular diagnostic laboratory is increasing in the developing countries, many laboratory professionals are struggling to get fundamental knowledge and advice from experts. To ameliorate the gap in information, APFCB committee for Education and Laboratory Management is working for a virtual workshop that contains a series of lectures from experts as a complete guide on Laboratory Testing of COVID-19. The workshop in its final stage of preparation and will be available free for all laboratory professionals through our website. The complete detail of the workshop is as follow:

Lecture 1: General introduction to COVID-19

Speaker: Ranjit Sah, Assistant Professor, Institute of Medicine, TU Teaching Hospital, Nepal

Learning objective: Basic information on a brief history, viral structure, epidemiology and mode of transmission, pathogenesis, signs and symptoms, preventive measures, contact tracing, general management, and future challenges

Lecture 2: General aspect of Laboratory diagnosis of COVID-19

Speaker: Tjan Sian Hwa, Head of Clinical Laboratory Department Premier Jatinegara Hospital, Jakarta, Indonesia

Learning objective: Introduction to various laboratory tests available for diagnosis, who to test, specimen collection and preanalytical issues



Lecture 3: Basic on molecular assays for the detection of SARS-CoV-2.

Speaker: Rojeet Shrestha, Assistant Professor, Faculty of Health Sciences, Hokkaido University, Japan

Learning Objective: Principle NAAT assay, RNA extraction and purification, qPCR, the technical guide on NAAT, reporting and interpretation

Lecture 4: Technical guide to establishing a molecular diagnostics laboratory

Speaker: July Kumalawati, lecturer, Clinical Pathology Department, Medical Faculty, Universities Indonesia

Learning objective: Steps for planning and building a molecular laboratory, Physical and equipment requirements and Designs

Lecture 5: Method evaluation, validation and Quality control for NAAT of COVID-19

Speaker: Miswar Fattah, Indonesia

Learning objective: how to evaluate method and validate the result of NAAT testing for SARS-CoV-2

Lecture 6: Molecular POCT for COVID-19

Speaker: Donal Huda Nasril, National Public Health Laboratory, Malaysia Learning objective: Introduction and role of Molecular POCT, Challenges and Way forward

Lecture 7: Serological testing for COVID-19

Speaker: July Kumalawati, lecturer, Clinical Pathology Department, Medical Faculty, Universitas Indonesia

Learning objective: Serocon version of SARS CoV-2 infection and possibilities of anti-SARS CoV-2 and SARS CoV-2 antigen detection usage

Lecture 8: Biochemical monitoring of severe covid-19 and laboratory biosafety

Speaker: Kay Weng Choy, Chemical pathologist, Northern Pathology Victoria, Australia

Learning objective: Summarise what comorbidities are predictors of COVID-19 severity, how routine tests can support the management of patients with COVID-19 and how general biochemistry laboratories manage the pre-analytical, analytical and post-analytical processes to mitigate biohazard risks

Lecture 9: Biosafety practices and operational challenges with COVID-19

Speaker: Tze Ping Loh

Learning objective: various issues in biosafety and best practices in the laboratory

Lecture 10: IFCC Guidelines on Molecular & Serological Testing of SARS-CoV-2 and Biochemical Monitoring of COVID-19 Patients

Speaker: Khosrow Adeli, President IFCC

Learning objective: Summarize recent IFCC guideline on molecular and serological Testing of SARS-CoV-2



APFCB TRAVELLING LECTURER

The APFCB Travelling Lecturer for 20/21 will be Helen Martin. Because of the constraints of COVID-19, any lectures will be delivered virtually. However, the Travelling Lecturer is a key resource that member Associations should utilize.

Speaker Bio



Helen Martin,

Helen Martin is a Consultant Clinical Scientist at SA Pathology in Adelaide Australia. She is the current Secretary of the Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine and the immediate Past-President of the Australasian Association of Clinical Biochemists (AACB). Helen holds the Membership and Fellowship qualifications of the AACB and is an Associate of the Royal College of Pathologists of Australasia. She is passionate about medical science education and is the immediate past Chief Examiner of the AACB as well as the longest serving member of that examination board. Helen was awarded the AACB's outstanding service medallion in 2011 and the prestigious Roman Lectureship in 2012. She has almost 40 years' experience in Clinical Biochemistry, gained in both public hospital and private pathology laboratories. Helen serves on a number of advisory groups including the Australian National Pathology Accreditation Advisory Council (NPAAC), the Patient Report Comments and Toxicology Advisory Groups for the Royal College of Pathologists of Australasia, Quality Assurance Programs (RCPAQAP) and the Emerging Technologies Division and Conference and Congress Committees of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

Proposed Lecture Topics

- Laboratory Indicators of Pre-Analytical Processes
- Critical Risk Result Reporting
- Adding Value by Targeted Patient Report Commenting
- The Importance of Standardization and Traceability
- Recommendations for Reporting Electrophoresis
- Vitamin D No Bones About It: Non-skeletal Roles for Vitamin D
- Vitamin D It's Role in Bone Health
- Iron, Why Too Little or Too Much is Bad for You Albumin Matters
- The Best Test to Assess Proteinuria?

For further information, please contact Tony Badrick at tony.badrick@rcpaqap.com.au





AUSTRALASIAN ASSOCIATION FOR CLINICAL BIOCHEMISTRY AND LABORATORY MEDICINE

In January 2020, the Australasian Association of Clinical Biochemists adopted a revised constitution and a new name: Australasian Association for Clinical Biochemistry and Laboratory Medicine. The change reflects the changing nature of pathology and the opportunities to extend our education and professional development opportunities to all clinical laboratory staff.

Like many societies around the world, the AACB has had to change the focus of our operations because of the COVID-19 pandemic.

Our Annual Scientific Meeting for 2020, scheduled to take place in Brisbane in October, has been postponed until 2021. However, we are holding our first ever Virtual Annual Scientific Meeting "Get your head in the cloud" on 27–28 October. Moving to an online platform brings new opportunities and we look forward to a successful event.

Our major educational activity for 2020, the AACB/RCPA Chemical Pathology Course was able to take place in February in Perth WA and was well received with around 150 attendees. At the Perth course Fr Ronda Greaves was awarded the Geoffrey Kellerman Award in recognition of her outstanding contribution to the education and training of clinical laboratory scientists in the region.



Ronda Greaves receives her award from Geoffrey Kellerman at the 2020 Chemical Pathology Course.



The 2021 course was due to be held in Christchurch New Zealand. Events over the last few months on both sides of the Tasman have meant freedom to travel by February 2021 is far from guaranteed and so the Christchurch course will now be held in 2022 and the 2021 CPC will also go virtual.

Face to face branch events have also been largely put on hold and instead we have increased our webinar activities. Although online educational activities have their challenges the AACB membership have embraced the concept and to the end of August we have seen almost 1,200 registrations for our webinars and branch events with over 650 attending "live" and a further 500+ viewing recordings.

Planning for the 2022 APFCB Congress in Sydney is continuing with the website now operational: https://apfcbcongress2022.org/. We look forward to welcoming colleagues from around the region in 2022.





Chinese Society of Laboratory Medicine

On September 24th-26th, 2020, the 16th National Conference of Laboratory Medicine (NCLM2020), organized by the Chinese Medical Association and Chinese Society of Laboratory Medicine, at Qingdao Cosmopolitan Exposition International Conference Center, ended successfully. The NCLM is an annual and the biggest academic exchange event on laboratory medicine of China in 2020. The conference covers the latest research results and development trends in various fields of clinical laboratory and laboratory management. During the three-day thoughtprovoking discussion, doctors and scientists shared their perspectives regarding the challenges faced by and the prospective development of laboratory medicine. This conference has built a platform to promote the wisdom exchange and cooperation for experts and scholars, and promote the sustained and healthy development of our country's medical laboratory industry.

Professor Wang Chuanxin, The President elect of the Chinese Society of Laboratory Medicine, summarized the conference: This year, NCLM received 5140 submissions, set up 9 conference reports, 128 special presentations, 9 case discussions, 37 oral presentations, and 4823 written reports. After expert review, 16 English speeches and 272 poster exchanges were arranged. The conference officially registered 2,540 delegates, of which 32 were from western region and grassroots units, and 188 companies. The conference has a main venue, 15 branch venues, 25 forums, 59 academic units, and 41 corporate seminars.



The President of CSLM, Dr. Chengbin Wang made a speech at the opening ceremony





Part of the experts at the closing ceremony of NCLM 2020

Finally, experts took a group photo together to mark the perfect conclusion of this academic feast. So far, NCLM2020 has come to a successful conclusion, let's meet again next year!





Chinese Association for Clinical Biochemistry (CACB-Taiwan)

CACB held its Executive Board meeting on September 14th, 2020 and planned for the upcoming annual General Meeting and scientific symposium. Due to COVID19 pandemic, the 35th Joint Annual Conference of Biomedical Science (JACBS) was postponed to 2021; thus, CACB rescheduled its 2020 annual meeting. In conjunction with Taiwan Society of Laboratory Medicine, CACB will hold the annual General Meeting and scientific symposium at the 2020 Annual Meeting of Taiwan Society of Laboratory Medicine which will be held at the National Taiwan University Hospital International Convention Center on 7 November 2020.

The CACB symposium will discuss the role of laboratory medicine in immunotherapy. Three speakers will present the progress on identifying novel biomarkers and therapeutic targets for immunotherapy. Dr. Mi-Hua Tao, Research Fellow of Academia Sinica, will give a keynote lecture on "Current status of cancer immunotherapies and future aspects". Dr. Shuen-Iu Hung, Professor of Cancer Vaccine & Immune Cell Therapy Core Lab, at Chang Gung Memorial Hospital, will present "Precision immune cell therapy for cancers: targeting neoantigens". Dr. Huang-Yu Yang, Associate Professor of Nephrology, Chang Gung Memorial Hospital will share his findings on "MiRNAs as biomarkers and clinical therapeutic targets".

Meanwhile, CACB is also planning for its 2021 annual meeting in conjunction with the 35th JACBS, which has been rescheduled to March 27–28, 2021. CACB will hold a symposium on "Laboratory Developed Tests (LDTs) and discuss about the current status of LDTs in Taiwan.



CACB president Ms. Hsiao-Chen Ning (center in the front) and Board members at the Executive Board meeting on September 14th, 2020.

Upcoming events for 2020:

7 November 2020 - CACB Annual General Meeting and scientific symposium, National Taiwan University Hospital International Convention Center.





Iranian Association of Clinical Laboratory Doctors (IACLD)

The functions and activities of the Iranian Association of Clinical Laboratory Doctors (IACLD) are as listed below:

- Establishment and cooperation of committees of education, research, tariffs and insurance, IVD, professional ethics, legal affairs, taxation, public affairs and welfare, and information technology
- Establishment and cooperation of the working group for continuing Ph.D. program in laboratory science
- Membership and close collaboration with The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
- Informing IACLD members of the webinars and invitations of IFCC, AFPCB, etc.
- Presenting scientific articles, educational files, community news and introducing the scientific works of colleagues through the website of www.iacld.com
- Extensive collaboration of IACLD public relations office in propagating various programs including video clips and educational podcasts, etc.
- Laboratory accreditation and membership in Asia Pacific Accreditation Cooperation (APAC)
- Delivering 36 courses of External Quality Assessment Programs (EQAP) for more than 2000 laboratories in the country
- Publishing 48 volumes of Journal of Laboratory and Diagnosis
- Holding 17 educational webinars with the latest findings in diagnosis of COVID-19 pandemic, and quality management in biochemistry
- Establishment of the scientific department for IACLD
- Cooperation of legal advice office to facilitate the legal affairs of premium and affiliate members
- Holding 17 national congresses and 12 international congresses on Quality Improvement of Clinical Laboratories in Iran before the outbreak of COVID-19
- Setting up a big data permanent secretariat, planning to hold scientific panels and specialized workshops, inviting prominent figures worldwide, holding the Hakim Jorjani Festival and selecting the best blood bank, and establishing student festivals before the outbreak of COVID-19
- Holding meetings of the national assembly of laboratory science associations with the presence of representatives of associations in laboratory science, pathology and DCLS
- Cooperation and interaction with associations of laboratory science technologists and the national clinical laboratory community
- Evaluation of the draft regulations on delegation of authority for sampling
- Amendment of the regulations for the establishment of laboratory management in cooperation with the assembly of laboratory science associations
- Signing MoU to provide training related to improving the knowledge and skills of laboratory personnel



- Pursuit of payment of laboratory claims by insurance organizations
- Observing the laboratory service tariffs and laboratory tax rates
- Providing solutions to solve problems and issues of the laboratory science community
- Evaluation of the comprehensive checklists for laboratory assessment and monitoring
- Forming joint committees with other laboratory associations
- Check the comprehensive health assessment document for permitting the pharmacies to do the medical tests
- Evaluating the advertising regulations for clinical and medical diagnostic laboratories
- Signing MoU to provide supplementary insurance, technical liability, accidents, COVID19, and employer -employee insurance
- Categorizing health services and laboratory levels
- Establishment of the accreditation committee for triple assembly of associations
- Cooperation with associations, universities, organizations and scientific and specialized institutes
- Preparation and compilation of bulletins, articles and promotional videos to raise awareness in facing with COVID-19
- Licensing and formation of provincial branches of IACLD
- Purchasing or pledging the office of association for establishing the provisional branches
- Holding meetings with provincial representatives of IACLD
- Providing tourism and travel-related services and hotel reservation
- Cooperation with travel agencies to offer best travel tours
- Purchasing laboratory equipment to help flood victims in Sistan and Baluchestan province
- Holding meetings with the following organizations:
 - 1. Institute of Standards & Industrial Research of Iran
 - 2. National Medical Device Directorate
 - 3. Ministry of Health and Medical Education
 - 4. Health Reference Laboratory
 - 5. Medical Council of the Islamic Republic of Iran
 - 6. Tarbiat Modares University
 - 7. The Parliament of Iran
 - 8. Iranian Blood Transfusion Organization
 - 9. Supreme Insurance Council
 - 10. Insurance organizations (Social Security Organization, Armed Forces Social Security Organization, Iran Health Insurance Organization)
 - 11. Imam Khomeini Relief Foundation
 - 12. Technical and Vocational Training Center
 - 13. Iranian Medical Association
 - 14. Food and Drug Administration of Iran
 - 15. Iran Chamber of Commerce, Industries, Mines, and Agriculture
 - 16. Center for Progress and Development of Iran
 - 17. Center for Strategic Studies
 - 18. Milad Tower International Conference Center



Japan Society of Clinical Chemistry

The JSCC has about 1,700 members which includes MDs and PhDs. Its annual meetings are held regularly once a year while the regional meetings are held once a year in different regions. At these meetings interesting symposiums and special lectures are planned by the chairman of the meeting. Last year JSCC held the 59th annual meeting in Sendai on Sep 27–29, 2019, chaired by Prof. Nariyasu Mano. The program included a chairman's lecture, 2 plenary lectures, 3 educational lectures, 22 symposia and workshops, 12 luncheon seminars, 1 evening seminar, 1 satellite seminar and 108 poster presentations. In all the annual meetings of JSCC and the regional meetings in Japan, educational lectures on various clinical chemistry related subjects, such as standardization, analytical methods, and laboratory related trouble shootings are delivered by specialists in clinical chemistry. In addition, clinical chemistry related companies plan various symposiums and educational meetings all over Japan all the year round. Clinical Chemistry Academy and Educational Lecture for Certified Clinical Chemistry and Immunochemistry Quality Assurance Medical Technologists and Professions are held at the annual meetings.



Editorial board symposium in 2019 summer



Prof. Mano's chairman's opening address at the 59th annual meeting in 2019





Award ceremony at the 59th annual meeting in 2019



Speakers for JSCC sponsored symposium at the 15th A PFCB Congress 2019 in Jaipur

In APFCB Congress in Jaipur, JSCC sponsored a symposium entitled "Novel biomarkers and their possibility from Japan" with 4 topics that were delivered by 4 speakers.

This year JSCC will host the 60th annual meeting from Oct 30 to Nov 1. The meeting was supposed to be in Tokyo, but the meeting style was changed to live streaming on the web because of the COVID-19 epidemic. We hope we will be able to get together at the 61th annual meeting in Fukuoka in 2021.





Korean Society of Clinical Chemistry (KSCC)

KSCC Fall Meeting, October 22, 2020

KSCC held a fall meeting as a Webinar on October 22 (Thursday), 2020, although 2020 KSCC Spring Meeting had been cancelled due to COVID-19 pandemic. A total of 393 people, attended the event, including 257 clinical pathologists, 41 resident doctors, 32 certified laboratory technologies, and 63 in vitro diagnostic companies participated in the exhibition. The number of attendees was increased compared with that of previous fall meeting in 2019 (272 attendees) probably due to increased accessibility of the Webinar. We have provided information on the latest laboratory tests and instruments in the field of clinical chemistry including COVID-19 and deep learning. The meeting included four symposia and two review courses. The details of the academic programs were as follows. The symposia were broadcast live. In addition, all the review courses and workshop were recorded and will be available for a month.

⊘ Symposium

Time	Description		Speaker
	Registration / Opening Address / Congratulatory Address / Awards Recognition Ceremony		
09:00~09:10	Opening address	Jeong-Ho (President, KSCC)	Kim , Korean Society of Clinical Chemistry –
	Congratulatory address	Gye Cheol Kwon (CEO, Korean Society for Laboratory Medicine – KSLM) Won-Ki Min (President, The Korean Association of External Quality Assessment Service – KEQAS)	
	Awards announcement (best papers) and Recognition of Appreciation		
	Session 1 [Current State Updates in Clinical Chem	of Laborato iistry]	ry Quality Management V, Guideline
	Current State of Laboratory Quality Management V		
09:10~11:50	Metrological traceability and uncertainty		Woochang Lee (University of Ulsan College of Medicine, Asan Medical Center)
	Commutability issues encountered in the laboratory		Soo Young Moon (Pusan National University Hospital)
	How to use biological variation in clinical laboratory		Chul Min Park (Dongnam Institute of Radiological and Medical Sciences)
Q&A			

Guideline Updates in Clinical Chemistry Chair: Won-Ki Min (University of Ulsan, College of Medicine and Asan Medical			
Chair. WO		or orsan, co	Center)
Vancomycin T	DM 2020: Use of	Hyun-Ki K	im
AUC/MIC		, (Ulsan Univ	versity Hospital)
Diabetes ADA 2020: Summarv		Kyunghoo	n Lee
Update		(Seoul Nat	ional University Bundang Hospital)
Dyslipidemias	ESC/EAS 2019:	Sang-Guk Lee	
Summary Upd	ate	(Yonsei Un	iiversity, Severance Hospital)
Q&A			
11:50~12:50		Lunch	
		Session 2	Operation of Clinical Chemistry
12:50~15:30		Laboratory	in the Age of Infectious Diseases,
		Toward a V	World of Deep Learning]
		Operation	of Clinical Chemistry Laboratory in
		the Age of	Infectious Diseases
		Chair: Jeor	ng–Ho Kim (Yonsei University,
	1	Yongin Sev	verance Hospital)
	Laboratory diagnos	sis and	Kyoung Ho Roh
	quarantine for the	COVID-19	(National Health Insurance Service
	pandemic		Ilsan Hospital)
	Guidance and prac	tice on	Jae-Woo Chung
	sample handling		(Dongguk University IIsan Hospital)
	Analysis of clinical	chemistry	Hyunwoong Park
	test results of COV	'ID-19	(Seoul National University
	patients		Hospital,Boramae Medical Center)
	Q&A Toward a World of Deep Learning		
			ing achon University, Gil Medical Center)
	Chairt HW		Dohvoung Rim
	What is Deep Learn	ning?	(D-Field)
			Namshin Kim
	Deep Learning in the Medical Field How to start a deep learning study		(Korea Research Institute of
			Bioscience and Biotechnology)
			Kyu Tae Choi
			(Chungnam National University,
			Sejong Hospital)
	Q&A		
15:30~15:50	Closing Address ar	nd General A	ssembly

© Review Course

Session	Description	Speaker	
	Laboratory Management I		
RC1	Planning of Laboratory Services	Sun Min Lee (Pusan National University, Yangsan Hospital)	
	Financial Management of Laboratory	Sang Gon Lee (Green Cross Laboratories)	
	Laboratory Test Utilization Management	Jooyoung Cho (Yonsei University, Wonju Severance Christian Hospital)	
	Quality Management System I		
RC2	Risk Management in the Clinical Laboratory	Sollip Kim (Inje University, Ilsan Paik Hospital)	
	Laboratory Safety Management	Sung-Eun Cho (Lab Genomics)	
	Analytical Methods in Clinical Chemistry		
RC3	Analytical techniques in clinical chemistry	Suekyeung Kim (Green Cross Laboratories)	
	Liquid chromatography-tandem mass spectrometry	Seungman Park (Seegene Medical Foundation)	
	Laboratory Tests for Digestive System		
RC4	Liver function testing	Seung Gyu Yun (Korea University Anam Hospital)	
	Hormone, Bone Markers, and Pregnancy Complication-related Tests		
RC5	Adrenal and sex hormones	Sun Young Cho (Kyung Hee University Hospital)	
	Bone turnover markers	Jinsook Lim (Chungnam National University Hospital)	
	Evaluation for pregnancy complications	Misuk Ji (VHS medical center)	

◎ Clinical Mass Spectrometry Research Committee Workshops

Session	Description	Speaker
	Accreditation, Validation & Quality Assurance for LC-MS/MS	
Revi Accr	Review of Checklist for LC-MS/MS Accreditation	Yong-Wha Lee (Soonchunghyang University Hospital Bucheon)
RCT	LC-MS/MS method validation Quality Assurance for LC-MS/MS testing	Hyun Jung Choi (Chonnam National University Hospital)
		Serim Kim (Green Cross Laboratories)



Professor Jeong-Ho Kim delivering opening address



Live broadcasting of four symposia



Group photo: Organizing Committee and attendees of 2020 KSCC Fall Meeting





Malaysian Association Of Clinical Biochemists (MACB) 2020

Just like many countries around the world, Malaysia is not spared from the Covid-19 pandemic. On 18thMarch 2020, the Malaysian government declared a nationwide movement control order to control the increasing number of Covid-19 positive cases in the country. Restrictions to mass gatherings impacted many of the planned activities of the MACB for 2020. Training programs and conferences had to be cancelled or postponed. However, in July 2020, MACB made a decision to continue its activities by going virtual.

1. MACB Meetings

• <u>Council Meetings</u>

The MACB has held two of its council meetings via video conferencing. The first meeting was on 25th July 2020 and the second meeting was on 12th October 2020.



MACB Council meeting

2. 17th APFCB Congress 2020 Organising Committee Meeting

As the MACB had won the bid to host the 17th APFCB Congress 2024 in Kuala Lumpur at the APFCB Council Meeting in Jaipur, the MACB held the first APFCB Congress Organising Committee meeting on 11thJuly 2020 via ZOOM video conferencing.



At this meeting, Dr. Raja Elina was appointed as Chair of the Congress Organising Committee with Dr. Munirah Mohd Mansor as the co-chair, while Dr. Leslie Lai was appointed as chair of the Scientific Committee. Secretary, Treasurer and Chairs of other committees were also appointed.

3. MACB Webinars

In line with its main objective, the MACB launched a series of webinars to ensure continuous education and learning of clinical laboratory professionals during the Covid-19 pandemic.

<u>Role of the Laboratory in the Battle Against Covid-19 Report</u>

The MACB organized its first live webinar on 26th Aug 2020 on the topic of Laboratory Role in the Battle Against Covid-19.This webinar focused on experiences of Malaysian laboratories involved in the testing of Covid-19 patients during the current Covid-19 pandemic with the hope that the sharing of experiences will be of benefit to all laboratories during these difficult times.

This webinar was supported by our corporate partner Roche Diagnostics (M) Sdn. Bhd. Lectures were delivered by 4 local speakers: Dr. Tuan Suhaila on the topic of Molecular Testing of Covid-19: Sungai Buloh Experience, Dr.Donul Huda on Serology Testing for Covid-19, Dr. Sharifah Khairul Atikahdan Dr. Firdaus on The Importance of Supporting Tests in the Management of Covid-19 Patients.

The 206 participants who registered for this webinar were mainly from Malaysia while others were from Indonesia–15, Nepal–2 and Japan–1. Despite some hiccups and technical problems during the live session, the recorded version was quickly uploaded on the MACB website and can be viewed on the MACB website (www.webinar.macb.org.my). Overall, the webinar received a positive feedback from participants.

<u>The Power of Laboratory Medicine to Achieve Measurable Better Healthcare</u>

The second MACB webinar was held on 4th September 2020 on the title of *The Power of Laboratory Medicine to Achieve Measurable Better Healthcare.* The webinar was organised with the objective of creating awareness for the UNIVANTS of Healthcare Excellence Award and to promote collaboration across disciplines. The MACB hopes that the webinar will be able to inspire member countries in the Asia Pacific region to push beyond convention and transform care delivery through teamwork, novel thinking and insights associated with laboratory medicine that will have positive effects on clinicians and patients.

This webinar received the auspices of the APFCB and was supported by Abbott Diagnostics.

Lectures in this webinar were delivered by 3 speakers. The first lecture on the topic of Unifying for Something Greater: The Univants of Healthcare Excellence Program was delivered by Tricia Ravalico. The second lecture was delivered by Dr. Eleanor Dow on the topic of Intelligent Liver Function Testing (ILFT): A Cost-Effective Way to Increase Early Diagnosis of Liver Disease while the third lecture was delivered by Dr. Marthias Orth on the topic of Avoiding Insufficient Therapies and Overdosing with Co-Reporting e-GFRs for Personalized Drug Therapy and Improved Outcomes.



This webinar had 123 participants; 58% were from Malaysia - 74, 23% from Singapore- 27 and the rest were from China- 1, Germany- 2, South Korea- 1 Thailand- 5, India- 4, Indonesia- 5, Sri Lanka- 1, United State- 2 and Vietnam- 1.

Myocardial Injury in the Era of High Sensitivity Troponin

The latest generation of high-sensitivity cardiac troponins support rapid diagnostic protocols aiding in the earlier discharge of a significant percentage of non-AMI patients, as well as aid a faster admission. The webinar, held on 9th September 2020 discusses the latest updates in the guidelines related to high sensitivity troponins and their clinical utility within Asia Pacific.



Dr. Pearline Teo and the organising team for the Myocardial Injury webinar

This third webinar organized by the MACB was delivered by Dr. Pearline Teo and was supported by Siemens Healthineers.

Tube Verification and Validation Webinar Series

The Tube Verification and Validation webinar series is a 3-part webinar, organised to shed light to important questions such as: the regulatory guidelines for blood collection tube selection and validation, how to design a validation protocol and the variables that should be considered during verification to ensure adequate performance in clinical use. This webinar is supported by Becton Dickinson.



The first part of the webinar was held on 18th September 2020 on the topic of The Science Behind Blood Collection Tube and Tube Validation. The lecture was delivered by Dr. Puneeta Bhatia. This webinar received an overwhelming response where a total of 962 people registered. Of this number, 402 were live viewers of the webinar (37%) where Malaysians accounted for 126 participants, Philippines – 102, Indonesia – 82, Singapore – 49 and others (Australia, India, UAE, etc.) – 43.

This second part of this webinar series was held on 16thOctober 2020. Mr. Brian Smith delivered the lecture on the topic of *Tube Verification Protocol Design*. A total of 673 people registered. There were 279 live viewers of the webinar (41.5%; an increase of 4.5% from the first webinar) of which Malaysians accounted for 116 participants, Philippines – 77, Indonesia – 61, Singapore – 20 and other (Australia, India, UAE, etc.) – 5.

4. E-learning Program

In addition to webinars, the MACB launched a pilot e-learning project in September 2020. The online learning module, the PEP connect is designed to give easy access to educational material on important topics in laboratory medicine. This collaborative effort between the MACB and Siemens Healthineers is to drive educational initiatives during the COVID19 pandemic. The MACB received a 90-day trial subscription license which allows participants to follow selected modules and print certificates upon completion.

5. MACB Elections

As 2020 is the year for re-elections of the MACB council, the MACB carried out a survey among its members on electronic voting (e-Voting). All respondents agreed that election of the new council members will be carried out through e-Voting. Nomination for council positions were received from 6 ordinary members. The nominations received names of one new member and 8 existing members. No position was contested. Dr. Raja Elina was re-elected as president for the term 2020–2022.

6. Upcoming MACB Events

MACB will be organizing part 3 of the Tube Verification and Validation webinar sometime in November 2020. The MACB will also be organizing the MACB Virtual Conference on 26th-28th November 2020 (https://conference.macb.org.my/). Further details of MACB events are available on the MACB website (https://macb.org.my).





Nepalese Association for Clinical Chemistry (NACC)

Ram Vinod Mahato, General Secretary, (NACC)

Nepalese Association of Clinical Chemistry (NACC) is a national society working in the field of clinical chemistry and laboratory medicine in Nepal. It is established in 2014 and members include MD, MSc, PhD students, faculties and researchers in the field of clinical Biochemistry. The association is currently working on the welfare of laboratory professionals and on improving the quality of laboratory reports.



2nd Congress of NACC at Kathmandu University, Dhulikhel Hospital, Kavre



Meeting of NACC members @Pokhara Chapter





New Associate Members of NACC, MSc Medical Biochemistry (MMB) Students at Pokhara University during guest lecture by General Secretary.

Clinical Biochemistry and Laboratory Medicine Professionals: Nepalese scenario

In Nepal, there are professionals with MD and MSc as well as PhD in clinical/Medical Biochemistry while others have MSc MLT in clinical/ Medical Biochemistry. The basic education for MD is MBBS while the basic education for the MSc and PhD is Bachelor in biological science or BSc MLT.

MBBS, MD clinical Biochemistry professionals are registered in Nepal Medical Council (NMC) whereas MSc, MLT, PhD Clinical Biochemistry Professionals are registered in Nepal Health Professional Council (NHPC). Both councils are government bodies for the recognition of these professionals.



Pictures: GOOGLE meet of executive board (EB)



The Nepal Medical council Executive Board has made a resolution that the number of MD to MSc, PhD professionals will be employed in the ratio of (3:1) in medical colleges as teaching faculty. This means that a smaller number of MSc, PhD personnel will get the opportunity to work as faculty in Nepal. In addition, professionals with MSc, PhD are getting less than 50% salary in comparison to MD faculties. This discrimination has resulted in specialized human resource migrating abroad. NACC executive board had meeting on 19th September 2020. At the meeting, discussion was concentrated on how to reduce the gap between these two groups of Biochemistry professionals. We have decided to discuss this issue with the National Medical Education Council (NMEC), Nepal Medical Council (NMC), Ministry of Health and population (MOHP) and Ministry of Education (MOE)



Philippine Association of Medical Technologists (PAMET)

PAMET's "Caring for the Carers": Serving Filipino Medical Technologists and Front liners in the Midst of Pandemic By: Ronaldo E. Puno, RMT, MBA-H National President PAMET

Now that the whole world is fighting against the pandemic brought about by COVID-19, the Philippine Association of Medical Technologists (PAMET), with its local chapters nationwide, are called upon to do our share, in our own little way, to show how we care for everyone. And we are proud that PAMET is at the forefront.

In response, the professional organization was at the helm in initiating several activities directed towards advocacy, health promotion, and members' assistance and benefits since the early stage of the crisis.

As early as February, PAMET started its activities with Health and Wellness Campaign on February 25, in one community in Manila. Focus of the activity was the importance of hand washing to break the chain of infection. Targeted participants were parents and school children in the area.

As the number of COVID-19 cases progressed and increased, problems also emerged particularly on the provision of Personal Protective Equipment (PPE), Biosafety and Biosecurity. Other concerns like discrimination and unsafe workplace practices were also highlighted.

This prompted PAMET to launch the "Caring for the Carers" Campaign on March 14, 2020.

PAMET "Caring for the Carers" is part of the associations corporate social responsibility program known as "PAMET Para Sa Kapwa" (PAMET for Fellowmen). which started in 2017.

Primarily, it aims to extend support and assistance to various medical front liners handling the different cases in various hospitals.

To date, the project already covered 140 hospitals and laboratories in Metro Manila covering 16 cities and 1 municipality. It also extended its help to selected military groups and barangays. Through the different PAMET chapters, over 200 hospitals were reached in close to 50 provinces in Luzon, Visayas and Mindanao. More than 10,000 front liners were served.

Since the start of its operation, the project was able to distribute more than 30,000 items composed of hygiene kits (soaps, sanitizers, hand wash, alcohol), personal protective equipment (PPEs), masks, gloves, face masks and food packs. Currently, the project is on-going and still receiving several requests both in NCR and provinces.



Since current statistics show increasing number of COVID-19 positive Medical Technologists, PAMET took a step forward by providing financial assistance to its affected members by approving an "Interim Guidelines on Members' Benefits in Relation to Positive COVID-19 Cases". Survey on the details of affected members is now on-going.



Pictures 1–4: Turnover of PAMET assistance to different health institutions, that include PPEs, health and hygiene kits, food packs and financial aids. (Only 1 photo selected for newsletter)



Picture 5: PAMET staff and volunteers packing the different items for distribution



Pictures 6–7: Advocacy on the importance of proper hand washing in fighting against COVID–19



Picture 8: Appreciation post of Medical Technologists who received assistance from PAMET

With the current situation, PAMET was compelled to move towards:

1. Development of Biosafety Guidance on COVID-19 Testing for Laboratorian, in partnership with Biorisk Association of the Philippines.

2. Curriculum Enhancement to strengthen the knowledge and skills related to Molecular Diagnostics, in collaboration with CHED Technical Committee for Medical Technology Education.

3. Transmitting a Letter to the Office of the President (Malacanang) and to different legislators to highlight the concerns of Medical Technologists.

4. Drafting a new version of Medical Technology Bill to upgrade the practice of Medical Technology.

5. Capacity-building through trainings and online webinar related to COVID-19.

We are hoping to continue this advocacy by appreciating, inspiring and thanking the noble deeds of our front liners and encouraging them, through the expression of heartfelt support, which were made possible through the generosity of our partners and donors.



Vietnam Association Clinical Biochemists

The chairman of Viet nam Association Clinical Biochemists (VACB) Hoang ThiBich Ngoc and the General secretary is Pham Thien Ngoc. There are 3 vice presidents: TrầnHoài Nam, PhạmTrungHà, Lê Thu Hà, as the association is made up of 3 member associations:

- 1. The Medical Biochemistry Association of Hanoi and the northern provinces includes about 300 members;
- 2. The Biochemistry Association of Ho Chi Minh City about 200 members.
- 3. The Medical Biochemistry Association of the central region of Vietnam about 100 members.

Since the beginning of 2020 up to now, there have been 2 epidemics of SARS.CoV.2 occurring in February and July in several provinces in our country; Although the prevention and control of the SARS.CoV.2 epidemic in Vietnam has been very good, activities with large numbers of participants are limited including VACB's activities. Some major activities of VACB from the beginning of 2020 up to now are as follows.

- 1. VACB's Executive Board online meetings every 2 months.
- 2. Notice of Advocacy for members to participate in the IFCC survey on "Perception and improvements of the laboratory in SARS prevention. CoV.2 "
- 3. Collaborated with ROCHE to provide members with links to online seminars international and regional webinars on VIRUS CORONAR.
- 4. Collaborated with Erba Mannheim Company to organize an online learning session on the topic "Tests in the diagnosis and treatment of SARS pneumonia. CoV.2"on the May 28th- 2020 and "Usage of blood tests in diagnosis and monitoring for patients with cytokine storm syndrome" on the July 31, 2020.

The course organized had test questions to certify class attendance.

The association also collaborated with the company SNIBE to organize an online seminar on the October 2th 2020 on the topic "Improving the quality of laboratories (Managing Nonconforming Events NCE) and applied tests in diagnosis and monitoring of thyroid disease."This course organized had test questions to certify class attendance.

From now till the end of 2020, the VACB will have 2 main events as follows.

- In collaboration with the Hanoi Biochemistry Branch Association and the Northern provinces, the VACB will hold the 24th National Scientific Conference and the Congress of Hanoi Biochemistry Branch and the Northern provinces on November 26–27th 2020 at Quang Binh province. This conference is expected to get about 700 participants. The event will showcase about 30 scientific reports on different fields of clinical biochemistry and will focus on research related to the Covid epidemic.
- The VACB will be collaborating with the Clinical Biochemistry of the Ho Chi Minh City to hold its Scientific Conference on the December 4th 2020 at the Riverside Palace 3900 Ben Van Don in Ho Chi Minh city.

HoàngThị Bích Ngoc VACB president

Assay Interference by Therapeutic Agents: Mechanisms and Solutions

By H. Roma Levy, MS

Introduction

Immunoassay results inconsistent with clinical presentation are often associated with interference caused by a variety of sources, such as heterophilic antibodies (e.g., rheumatoid factor, human-anti-animal antibodies), haemolysis, icterus, lipemia, cross-reactive analyte metabolites, and various other factors. These familiar interferents are not the only molecules that are problematic. Over the past decade or so, new classes of therapeutic agents bearing two-dimensional molecular similarity to a variety of target analytes have entered the market, and case reports of interference by some of these agents have surfaced. In addition, interference by at least two popular over-the-counter (OTC) supplements has been reported in both expected and unexpected ways. Chemistry-based tests are not immune to interference, with laboratories now reporting interference by drugs acting as hydrogen peroxide (H2O2) reducing agents that can impact assays reliant on Trinder and Trinder-like reactions. This paper explores a few of these compounds and the mechanisms by which they are either known or presumed to interfere.

Potential interference by biological mimics

Drugs that share molecular or conformational similarity to biological molecules can function in a variety of ways. For example, a drug might have an effect by blocking a specific receptor and preventing the action caused by the natural agonist (i.e., a molecule that stimulates a response) or antagonist (a molecule that impedes or down regulates a response). Conversely, other types of therapeutic analogs might stimulate a receptor in the absence of, or in addition to, its natural agonist. Regardless of the mode of action, testing in the presence of physiologically analogous drugs can yield erroneously high or low results for the analyte which investigated, can potentially lead to misdiagnosis or patient mismanagement.1,2

FASLODEX (fulvestrant: AstraZeneca Pharmaceuticals LP, Wilmington DE) is an estrogen receptor (ER) antagonist used to treat women with hormone receptor-positive (HR+) or HR+/human epidermal growth factor receptor² (HER2)-negative breast cancer (advanced or metastatic) who meet the prescribing criteria.³ As an estradiol (E2) analog, fulvestrant diminishes tumour cell reproduction by binding to the ER and blocking the action of endogenous E2. Because fulvestrant does not stimulate the ER, growth of estrogen-sensitive cancer cells is impeded. Additionally, fulvestrant increases the rate of ER degradation.⁴

Recently, some labs have reported falsely-elevated E2 using commercial estradiol immunoassays when testing blood from women receiving fulvestrant, however published reports of fulvestrant interference are uncommon.^{1,5,6} As explained by both Krasowski et al. and Bender et al., interference likely arises because of the high similarity between the two-dimensional structures of E2 and fulvestrant, rather than because of three-dimensional conformational similarity (Figure 1).^{2,7}Because two-dimensional structural similarity is, in fact, computationally predictive of cross-reactivity between similar compounds (e.g., steroid hormones), fulvestrant can potentially interfere with any E2 assay, regardless of the manufacturer.⁷⁻⁹ Other factors such as immunoassay design or antibody selection have the potential to contribute to, mitigate, or negate possible fulvestrant interference. For this reason, it is not possible to predict if fulvestrant will actually interfere with an assay until specific testing has been conducted.

Berger et al. emphasize that clinicians should be informed of the potential for fulvestrant interference with E2 immunoassays, and AstraZeneca's package insert warns that fulvestrant can interfere with E2 assays.^{1,3} Siemens Healthineers concurs with this assessment and recommends that doctors inform the laboratory when a patient referred for E2 testing is receiving fulvestrant therapy. At least one and rostenedione analog (exemestane) used for aromatase inhibition in hormone receptor-positive breast cancer has also been reported to intefere with E2 immunoassays, presumably because of structural similarities between E2, and rostenedione, and exemestane (Figure 1).¹⁰ For these patients, testing should be conducted using a mass spectrophotometric method such as Liquid Chromatography-Mass Spectrometry (LC–MS), which can distinguish between E2 and potentially interfering analogs on the basis of elution time and spectral profile. Clinicians should also consider whether or not E2 testing is necessary or appropriate for women receiving fulvestrant.

No medical association has published guidelines for monitoring E2 in women who are taking fulvestrant for HR+ breast cancer. Examples of monitoring guidance can be found in the manufacturer's package insert, a monograph the manufacturer released in 2017, and formulary information from Cancer Care Ontario (CCO). All of these sources recommend assessing liver (AstraZeneca and CCO) and kidney function (CCO) at using commercial monitoring E2.3,11,12



Figure 1. Molecular similarity between and rostenedione and exemestane, and E2 and fulvestrant.



Potential interference by endogenous hormone supplementation

Because they are all synthesized from cholesterol, steroid hormones share highly similar two-dimensional structures. For this reason, capture and/or detection antibodies are typically selected to minimize or negate cross-reactivity. Despite this, interference by therapeutically applied steroid hormones has been reported and erroneous test results can affect treatment decisions. For example, DHEA alone and in combination with other drugs is used in some in vitro fertilization (IVF) protocols to stimulate an ovarian response in women with reduced ovarian reserve.^{13,14} However, much of ingested DHEA is rapidly converted to the more stable DHEA-SO4 (DHEAS). Supraphysiological DHEAS has been reported to interfere with some progesterone assays.^{15–17} As with fulvestrant, this is likely a result of structural similarity between DHEAS and progesterone (Figure 2).15,17,18 Because elevated progesterone levels at oocyte harvest are associated with poor embryo viability, some IVF protocols call for monitoring progesterone to determine the timing of oocyte maturation trigger injection that will result in the highest likelihood of implantation success. In such cases, falsely elevated progesterone could impact clinical decision making and lead to additional treatment costs.^{17,19-21} For this reason, IVF clinic laboratories should determine the extent of DHEAS interference with their progesterone assay. It has also been suggested that clinicians should consider suspending DHEA treatment before progesterone testing.¹⁸ Unfortunately, timing of discontinuation has not yet been established.

Many other steroid analogs are used in the treatment of endocrine or other disorders. Although reports of immunoassay interference by pharmaceutical androgen and gestagenanalogs are scant, if assay results are discordant with the clinical presentation, interference should be investigated and non-immunometric testing should be considered.



Figure 2. Structural similarity between DHEA, DHEAS, and progesterone.

Potential interference by fusion drugs (chimeric molecules)

Recently, a new class of therapeutic biological agents has entered the market. "Fusion" drugs use recombinant technology to create novel chimeric molecules by splicing together portions of two or more genes. One recent example of this is the drug Elonva (corifollitropin alfa, MSD Ltd, Hertfordshire, UK), which is composed of two subunits: an α -subunit identical to native follicle stimulating hormone (FSH) α subunit, and a β -subunit that combines the complete human FSH β -subunit with the carboxy-terminal peptide (CTP) of the β -subunit of hCG.²² The drug is used during controlled ovarian stimulation in some IVF protocols because it has a long half-life: only a single injection is needed to sustain follicle stimulation for 7 days as compared to daily injections of recombinant FSH.^{22,23} However, because the CTP is biologically identical to native hCG-CTP (although physiologically inactive), concerns have been raised over the potential for Elonva to cause false elevations in hCG assay results. This could happen if CTP is an epitope for at least one of the assay's capture or detection antibodies (Figure 3).

As in the case of fulvestrant, it is necessary to consider whether or not it is reasonable to test hCG levels during follicle stimulation. MSD Ltd. does not suggest conducting hCG testing concurrent to Elonva use. In practice, hCG testing is not conducted to assess fertilization success until approximately 14 days after embryo transfer, which would occur not less than 23 days after injection of Elonva.^{22,24-26}



Figure 3. Potential for interference of hCG assays by the ElonvahCG-CTP.

Potential interference by dietary supplements: biotin and maca

Assay interference is not limited to prescription medications. OTC use of biotin (vitamin B7) has increased significantly in recent years because it is marketed as beneficial to hair, skin, and nail quality. So-called nutraceutical dosages range from 0.5 to 10 mg/day—levels far in excess of the U.S. dietary reference intake of ~30 μ g/day for (nonlactating) adults.^{27,28} Biotin can also be found as a component of many multivitamins and prenatal vitamins recommended for preventing biotin deficiency during pregnancy. Additionally, high dose biotin therapy is used to treat multiple sclerosis, certain in–born errors of metabolism, and mitochondrial diseases.^{29–31}

In such cases, biotin intake can exceed 10–15 mg/kg/day (up to 300 mg/day for an adult). $^{32-35}$



Studies have revealed that biotin supplementation in both OTC and therapeutic dosages can interfere with assays based on streptavidin-biotin linkage of the capture/analyte complex with the solid substrate, yielding false-negative or false-positive results, depending on assay design (Figure 4). Several published articles have reported on the impact biotin interference has on some thyroid function tests, and how this has caused some euthyroid individuals to be incorrectly diagnosed with Graves' Disease and, in some cases, treated incorrectly.^{33,36-39}

a. Normal reaction, sandwich assay



b. Biotin interference, sandwich assay



c. Normal reaction, competitive assay





flash 🚆

Analyte concentratio

Streptavidin-biotin-antibody complexes bind either analyte + tracer or competing analyte in sample

d. Biotin interference, competitive assay

capture antibody-

biotin complex

bound to

solid substrate





Figure 4. How biotin interferes with sandwich and competitive assays.

coupled to analyte

The nutritional supplement maca (made from the root of the Andean plant Lepidium meyenii) has become a popular alternative to hormone replacement therapy for alleviating menopausal symptoms and improving libido in women, and for improving sperm production in men. This product has been implicated in falsely elevated testosterone assay results in at least one woman.^{40,41}Although supplementation does not appear to have a direct impact on testosterone levels either in men or women, the author speculates that at least one as yet unidentified component of the root is molecularly analogous to testosterone and is responsible for the interference.⁴¹

Potential interference of Trinder-based assays by H2O2 reducing agents

Interference is not unique to immunoassays. Several chemistry assays rely on a Trinder or Trinder–like reaction to produce a colorimetric change. In this reaction, peroxide generated by one or several precursor reactions is used in conjunction with peroxidase to catalyze the formation a colored product (quinoneimine dye complex) by oxidation of phenol and 4–aminoantipyrine (4–aminophenazone, Figure 5). However, many sulfur–containing compounds can reduce H2O2 to H2O and free-radical oxygen, which disrupts the Trinder reaction and results in a decreased or absent colorimetric response.^{42,43} Two sulfur–containing drugs that are now known to interfere with Trinder reactions are N–acetylcysteine (NAC) and metamizole. These drugs have been found to interfere with assays from many manufacturers.^{43–46} NAC is an essential hepato–protective drug for treating acetaminophen (paracetamol) overdose and is also used to treat a variety of other neuropsychiatric and mucogenic disorders, such as cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD). Metamizole is a non–opioid analgesic used in some countries outside of the U.S.





a. Trinder reaction using glucose oxidase as the example analyte

b. One mechanism that can explain interference of the glucose oxidase assay by NAC (direct assay)

Figure 5. Trinder reaction and interference.



Depending on the Trinder reaction assay format (direct vs. competitive), clinically significant falsely elevated or decreased results can occur if NAC or metamizole are present at therapeutic levels.^{43,46} Because they are rapidly metabolized, interference is most problematic if blood is drawn shortly after administration. For this reason, Siemens Healthineers and other manufacturers recommend that blood for assays affected by these agents be drawn before they are administered. As can be seen by the list of affected Siemens Healthineers assays, not all Trinder reaction assays are affected by both drugs (Table 1).

Table1. Examples of Trinder-based assays subject to NAC and metamizoleinterference.

Interference by:	Assay affected:
NAC and metmizole	Cholesterol
	Enzymatic Creatinine
	Glucose Oxidase
	Triglycerides
	Uric Acid
	Fructosamine
Metamizole only	LDL Cholesterol
	HDL Cholesterol
NAC only	Lactate

Conclusion

Many drugs and over-the-counter supplements could potentially interfere with immunoassays and chemistry-based assays. In some cases, the mechanism of interference might be predictable or at least understandable on the basis of two-dimensional structural similarities between interferents and the target analyte, but the mode of interference may be less predictable or obvious for others. Regardless, awareness by—and communication between—laboratorians and clinicians of the potential for newly-introduced analyte analog drugs and OTC nutritional supplements to cause erroneous results can facilitate identification of assay interference. Regardless of the mechanism, assay results that are not consistent with the clinical presentation warrant further investigation for possible interference, which often can only be determined empirically.

When assay design is at the root of interference and cannot be resolved by common methods such as dilution or pre-treatment for heterophilic antibodies, consideration must be given to the use of alternative testing methods or timing of blood draw in relation to drug administration.



References

1. Berger D, Waheed S, Fattout Y, Kazlauskaite R, Usha L. False Increase of Estradiol Levels in a 36-Year-Old Postmenopausal Patient With Estrogen Receptor-Positive Breast Cancer Treated With Fulvestrant. Clin Breast Cancer 2016; 16: e11-3.

2. Klee GG. Interferences in hormone immunoassays. Clin Lab Med 2004; 24:1-18.

3. AstraZeneca Pharmaceuticals L. FASLODEX (fulvestrant) injection package insert. Wimington, DE, U.S.A.: AstraZeneca Pharaceuticals LP; 2012:1–7.

4. Robertson JF. Fulvestrant (Faslodex) – how to make a good drug better. Oncologist 2007;12:774-84.

5. Roche Diagnostics. Urgent Field Safety Notice: Cross reactivity of Elecsys Estradiol assays with fulvestrant. Roche Diagnostics. West Sussex, UK2016.

6. Chiang C, Faulkner D, Doery J, et al. Falsely Elevated Estradiol Levels in Postmenopausal Women with Metastatic ER+ Breast Cancer. The Clinical Biochemist Reviews 2012;33:S1-S53.

7. Krasowski MD, Drees D, Morris CS, Maakestad J, Blau JL, Ekins S. Cross-reactivity of steroid hormone immunoassays: clinical significance and two-dimensional molecular similarity prediction. BMC Clin Pathol 2014; 14:33.

8. Bender A, Glen RC. Molecular similarity: a key technique in molecular informatics. Org Biomol Chem 2004; 2:3204-18.

9. Krasowski MD, Siam MG, Iyer M, Ekins S. Molecular similarity methods for predicting cross-reactivity with therapeutic drug monitoring immunoassays. Ther Drug Monit 2009; 31:337-44.

10. Mandic, S, Kratzch J, Mandic D, et al. Falseley elevated serum oestradiol due to exemestane therapy. Ann Clin Biochem. 2017;54(3):402–5.10. Fulvestrant Drug Monograph. at https://www.cancercare.on.ca/toolbox/drugformulary/.)

11.FulvestrantDrugMonograph.athttps://www.cancercare.on.ca/toolbox/drugformulary/.

12. AstraZeneca Pharmaceuticals Ltd. FASLODEX product monograph. AstraZeneca Canada Inc. Ontario, Canada: AstraZeneca; 2017.

13. Depalo R, Jayakrishan K, Garruti G, et al. GnRH agonist versus GnRH antagonist in in vitro fertilization and embryo transfer (IVF/ET). Reprod Biol Endocrinol 2012; 10:26.

14. Zhang H, Chu Y, Zhou P, et al. Dehydroepiandrosterone plus climen supplementation shows better effects than dehydroepiandrosterone alone on infertility patients with diminished ovarian reserve of low-FSH level undergoing invitro fertilization cycles: a randomized controlled trial. Reprod Biol Endocrinol 2016; 14:9.



15. Forman EJ, Franasiak JM, Scott RT, Jr. Elevated progesterone levels in women on DHEA supplementation likely represent assay interference. J Assist Reprod Genet 2015;32:661.

16. Siemens Healthineers. Urgent Medical Device Correction, CC 17-06.A.US: Elevated Results in Patient Samples Due to Cross Reactivity of DHEA-S with Progesterone Assays. Tarrytown, NY. 2017.

17. Franasiak JM, Thomas S, Ng S, et al. Dehydroepiandrosterone (DHEA) supplementation results in supraphysiologic DHEA-S serum levels and progesterone assay interference that may impact clinical management in IVF. J Assist Reprod Genet 2016;33:387-91.

18. Maninger N, Wolkowitz OM, Reus VI, Epel ES, Mellon SH. Neurobiological and neuropsychiatric effects of dehydroepiandrosterone (DHEA) and DHEA sulfate (DHEAS). Front Neuroendocrinol 2009;30:65-91.

19. Huang Y, Wang EY, Du QY, et al. Progesterone elevation on the day of human chorionic gonadotropin administration adversely affects the outcome of IVF with transferred embryos at different developmental stages. Reprod Biol Endocrinol 2015;13:82.

20. Huang B, Ren X, Wu L, et al. Elevated Progesterone Levels on the Day of Oocyte Maturation May Affect Top Quality Embryo IVF Cycles. PLoS One 2016;11: e0145895.

21. Bosch E, Labarta E, Crespo J, et al. Circulating progesterone levels and ongoing pregnancy rates in controlled ovarian stimulation cycles for in vitro fertilization: analysis of over 4000 cycles. Hum Reprod 2010;25:2092–100.

22. Elonva New Zealand Data Sheet. 2012. Accessed April 7, 2017, at http://www.medsafe.govt.nz/profs/Datasheet/e/elonvainj.pdf.

23. Mannaerts B. Innovative Drug Development for Infertility Therapy Utrecth, The Netherlands: Utrecht University Repository in NARCIS; 2013.

24. Tobler KJ, Zhao Y, Weissman A, Majumdar A, Leong M, Shoham Z. Worldwide survey of IVF practices: trigger, retrieval and embryo transfer techniques. Arch Gynecol Obstet 2014;290:561-8.

25. Cookingham LM, Goossen RP, Sparks AE, Van Voorhis BJ, Duran EH. Successful treatment algorithm for evaluation of early pregnancy after in vitro fertilization. Fertil Steril 2015;104:932-7.e1.

26. IVF Treatment Series - Part One. Accessed March 5, 2018, at https://www.shadygrovefertility.com/blog/treatments-and-success/ivf-treatment-series-part-one/.



27. Paxton A. Beauty fad's ugly downside: test interference. CAP Today 2016 Sep.

28. Biotin Fact Sheet for Consumers. 2017. Accessed February 26, 2018, at https://ods.od.nih.gov/factsheets/Biotin-Consumer/.

29. Sedel F, Bernard D, Mock DM, Tourbah A. Targeting demyelination and virtual hypoxia with high-dose biotin as a treatment for progressive multiple sclerosis. Neuropharmacology 2015;Sep 5. pii: S0028-3908(15)30073-3.

30. Slavin TP, Zaidi SJ, Neal C, Nishikawa B, Seaver LH. Clinical Presentation and Positive Outcome of Two Siblings with Holocarboxylase Synthetase Deficiency Caused by a Homozygous L216R Mutation. JIMD Rep 2014;12:109–14.

31. Zempleni J, Hassan YI, Wijeratne SS. Biotin and biotinidase deficiency. Expert Rev Endocrinol Metab 2008;3:715-24.

32. Henry JG, Sobki S, Arafat N. Interference by biotin therapy on measurement of TSH and FT4 by enzyme immunoassay on Boehringer Mannheim ES700 analyser. Ann Clin Biochem 1996;33 (Pt 2):162-3.

33. Kwok JS, Chan IH, Chan MH. Biotin interference on TSH and free thyroid hormone measurement. Pathology 2012;44:278-80.

34. Sehgal S, Du Toit S, Yarndley T, Conaglen J, Elston M. Biotin Interference in TSH, T4, and B12 Immunoassays. ENDO Annual Meeting. Boston, MA2016.

35. Wijeratne NG, Doery JC, Lu ZX. Positive and negative interference in immunoassays following biotin ingestion: a pharmacokinetic study. Pathology 2012;44:674-5.

36. Kummer S, Hermsen D, Distelmaier F. Biotin Treatment Mimicking Graves' Disease. New England Journal of Medicine 2016;375:704-6.

37. Li D, Radulescu A, Shrestha R, et al. Association of Biotin Ingestion With Performance of Hormone and Nonhormone Assays in Healthy Adults. Journal of the American Medical Association 2017;318:1150-60.

38. Peyro Saint Paul L, Debruyne D, Bernard D, Mock DM, Defer GL. Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol 2016;12:327-44.

39. Piketty ML, Polak M, Flechtner I, Gonzales-Briceno L, Souberbielle JC. False biochemical diagnosis of hyperthyroidism in streptavidin-biotin-based immunoassays: the problem of biotin intake and related interferences. Clin Chem Lab Med 2017;55:780-8.

40. Melnikovova I, Fait T, Kolarova M, Fernandez EC, Milella L. Effect of Lepidium meyenii Walp. on Semen Parameters and Serum Hormone Levels in Healthy Adult Men: A Double-Blind, Randomized, Placebo-Controlled Pilot Study. Evid Based Complement Alternat Med 2015;2015:324369.



41. Srikugan L, Sankaralingam A, McGowan B. First case report of testosterone assayinterference in a female taking maca (Lepidium meyenii). BMJ Case Rep 2011;2011.

42. Aruoma OI, Halliwell B, Hoey BM, Butler J. The antioxidant action of N-acetylcysteine: its reaction with hydrogen peroxide, hydroxyl radical, superoxide, and hypochlorous acid. Free Radic Biol Med 1989;6:593-7.

43. Genzen JR, Hunsaker JJ, Nelson LS, Faine BA, Krasowski MD. N-acetylcysteine interference of Trinder-based assays. Clin Biochem 2016;49:100-4.

44. Roche Diagnostics. Field Safety Notice FSN-RPD-2014-008: Drug Interference in tests based on Trinder Reaction. Singapore. 2015.

45. Siemens AG. Urgent Medical Device Correction CHC 16-)1.A.US. ADVIA® Chemistry systems. N- Acetylcysteine (NAC) and Metamizole Interference with Trinder and Trinder-like reaction Assays. Tarrytown, NY. 2016.

46. Wang Y, Clapps S, Horne B, Chamion-Lyons E, Zhu Y. N-acetyl Cysteine Interferes with the Trinder Reaction Based Assays and Beyond, Abstract A-265. 2016 AACC Clinical Laboratory Expo. Philadelphia, PA.



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IL-6 shows promise for COVID-19 management in Asia Pacific

Based on interviews with **Tobias Weinberger**, Senior Physician, Ludwig Maximilian University Hospital, Germany; **Conrad Liles**, Professor and Associate Chair, Medicine, University of Washington Department of Global Health, United States

In the ongoing fight against the COVID-19 pandemic, many healthcare systems are adding interleukin-6 (IL-6) to their diagnostic toolkit. An early predictor of severe COVID-19, IL-6 is an ideal prognostic biomarker because it can be detected from an easily accessible biological source (serum or plasma) and via well-characterised, rapid assay systems. A growing body of evidence highlights its potential in becoming an integral part of critical COVID-19 management [1].

In a recent webinar hosted by Roche Diagnostics, Dr Conrad Liles, Associate Chair and Professor at University of Washington Medical Center, and Dr Tobias Weinberger, Senior Physician at *Ludwig Maximilian University Hospital*, discussed the role of IL-6 as a biomarker in COVID-19 management. The webinar focused on clinical research and case sharing from the United States and Germany, but it offers insights that have relevance for many healthcare systems in Asia Pacific—particularly those facing high caseloads of severe and critically ill patients.

An early predictor of respiratory failure

IL-6 is a pleiotropic inflammatory cytokine and a major component of the cytokine storm in patients with severe COVID-19. Increased serum or plasma IL-6 is the most reported cytokine abnormality in patients with COVID-19 ^[2]. Several studies in Chinese populations have also found that elevated IL-6 is associated with poorer outcomes and higher fatality ^[3-5].As lung macrophages express a higher level of IL-6 compared with blood monocytes, Dr Weinberger noted that "IL-6 may represent a window into the lung and could be a good diagnostic tool to address disease severity".

A prospective cohort study by Dr Weinberger's research group found that elevated IL-6 was highly predictive of the need for mechanical ventilation in 89 hospitalised COVID-19 patients at *Ludwig Maximilian University Hospital* ^[6]. Maximal IL-6 level before intubation at a cut-off point of 80pg/ml showed the strongest association with positive and negative predictive values of 74% and 83%, respectively. In the combined cohort, IL-6 predicted the need for intubation up to 23.2 hours before the patient received it.

Despite the predictive value of maximal IL-6 in the study, Dr Weinberger generally recommends IL-6 testing at initial assessment as they also found that IL-6 retained high sensitivity in detecting patients at risk of respiratory failure at a low cut-off threshold of 35pg/ml.



At the University of Washington Medical Center, IL-6 is measured in hospitalised patients who show signs of clinical deterioration such as hypoxia but are not intubated or in ICU. "Our approach is to treat the individuals to mitigate the need for mechanical ventilation and stop progression of lung disease...to prevent acute lung injury in individuals who have acute hypoxemic respiratory failure due to COVID prior to intubation," Dr. Liles shared.

Dr. Weinberger emphasised the difficulty in assessing the prognosis of COVID-19 patients due to a broad spectrum of disease courses and silent hypoxia. He presented two patient cases with similar symptoms, one of whom experienced rapid clinical deterioration within two days and required eventual intubation (Figure 1). Here, he reiterated that a laboratory parameter such as IL-6 is useful to identify the need for ventilatory support in patients with silent hypoxia.



Figure 1: Clinical cases of COVID–19 presented by Dr Weinberger

Growing interest in IL-6 in Asia Pacific

In the Asia Pacific region, the utility of IL-6 as a biomarker for COVID-19 management is being actively explored in China, where it is specifically mentioned in the Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis (7th edition) as an indicator of severe and critical cases in adults ^[7]. Clinical stakeholders in India and other countries are also taking interest.

As an early predictor of respiratory failure compared with other inflammatory biomarkers such as ferritin and C-reactive protein, IL-6 can help identify critical patients in a more timely and effective manner so that physicians can organise intensive care or intensify treatment as appropriate. In this respect, assessment of IL-6 may be of particular benefit in Asian countries which are experiencing high ICU bed occupancy and mortality rates such as Indonesia ^[8].



References

1. Del Valle DM, Kim-Schulze S, Huang H-H, et al. An inflammatory cytokine signature predicts COVID-19 severity and survival. *Nat Med.* Published online August 24, 2020:1-8.

2. Ragab D, Salah Eldin H, Taeimah M, Khattab R, Salem R. The COVID-19 Cytokine Storm; What We Know So Far. *Front Immunol.* 2020;11.

3. Liu Z, Li J, Chen D, et al. Dynamic Interleukin-6 Level Changes as a Prognostic Indicator in Patients With COVID-19. *Front Pharmacol.* 2020;11.

4. Chen X, Zhao B, Qu Y, et al. Detectable Serum Severe Acute Respiratory Syndrome Coronavirus 2 Viral Load (RNAemia) Is Closely Correlated With Drastically Elevated Interleukin 6 Level in Critically III Patients With Coronavirus Disease 2019. *Clin Infect Dis*.

5. Ruan Q, Yang K, Wang W, Jiang L, Song J. Clinical predictors of mortality due to COVID-19 based on an analysis of data of 150 patients from Wuhan, China. *Intensive Care Med.* 2020;46(5):846-848.

6. Herold T, Jurinovic V, Arnreich C, et al. Elevated levels of IL-6 and CRP predict the need for mechanical ventilation in COVID-19. *J Allergy Clin Immunol.* 2020;146(1):128-136.e4.

7.Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment (7th edition) 抗击新冠肺炎. Accessed August 10, 2020. http://kjfy.meetingchina.org/msite/news/show/cn/3337.html

8.Jakarta's Covid-19 Response Team. Jakarta's Covid-19 Response Team. Accessed August 25, 2020. https://corona.jakarta.go.id/en





Point-of-Care Testing Pandemic management an interview with Dr Gerald Kost

As Director of the Point-of-Care Testing Center for Teaching and Research (POCT·CTR) and Professor Emeritus of Pathology and Laboratory Medicine at the University of California Davis School of Medicine, **Dr Gerald Kost** is one of the world's leading experts in point-of-care testing (POCT). He is also a Fulbright Scholar 2020-21 in ASEAN. In this Q&A, he shares insights for evaluating new POCT for COVID-19 management, implementing these tests in clinical practice, and developing policies to fuel diagnostic innovation and help prevent future outbreaks of highly infectious diseases.

What are some key considerations to effectively deploying POCT in the current pandemic?

An important consideration for evaluating a new COVID-19 test is the elimination of false negative test results. To do that, tests need to have high sensitivity, defined by the ratio of true positive results (TP) to the sum of true positive and false negative (FN) results [TP/(TP + FN)], whether the test is performed at the point of care or elsewhere.

Mathematical models of test performance are extremely important for setting testing strategy. The chart below looks at three different "tiers" of testing quality, showing the false positive to the true positive ratio (FP/TP), predictive value (PPV), negative predictive value (NPV), and the false omission rate (RFO) as a function of prevalence (from reference 1).

At a low prevalence of 2–5%, Tier 3 tests with very high sensitivity (100%) and specificity (\geq 99%) are needed. Most communities are experiencing low prevalence. In ERs, clinicians are seeing more infected patients, so the pre-test probability of COVID-19 increases, and as a result, the effective prevalence increases as well. Hence, prevalence depends on the setting.





What are some promising tests that authorities can consider for COVID-19 POCT?

Any test with objective confirmation of high performance in Tier 3 is very promising for full implementation in management of the current pandemic, as well as new outbreaks. This includes molecular diagnostic tests for primary detection of SARS-CoV-2 or antibody tests for assessment of the immune response following infection or immunisation.

Tests authorised by the Food and Drug Administration in the USA under Emergency Use Authorization rules can be found under reference 10. A word of caution is that many tests on the market do not perform well. POCT should not be an excuse for inaccuracy. A healthcare practitioner should evaluate the performance of POCT before implementing it for COVID-19.

How can clinical lab professionals contribute to POC deployment for COVID-19 management?

The dozen recommendations listed below show how laboratory professionals can deploy POCT to control the pandemic, help acutely infected patients, and expedite decision-making, therapy and recovery.



- Collecting specimens, screening and evaluating peoplesafely in driveup/in/throughs, walk-bys and pop-ups to prevent the spread
- Assuring high test performance with excellent positive predictive value [TP/(TP + FP)] and negative predictive value [TN/(TN + FN)]
- Relieving hospital infrastructure by limiting emergency room burden, unnecessary hospitalisation and readmission of low-risk patients
- Differentiating common Influenza A/B from COVID-19
- Discovering stealth COVID-19 transmission through widespread access to testing andself-testing
- Accelerating molecular diagnosis, triage, isolation and decision making for patients infected with SARS-CoV-2
- Assisting public health tracing of contacts of infected persons
- Monitoring "happy hypoxaemia" (pulmonary compromise) using fingertip pulse oximetry(oxygen saturation monitoring)
- Diagnosing bloodstream pathogens, determining antimicrobial resistance and speeding targeted therapy for co-infections and sepsis
- Staging patients with pulmonary infections, and those critically ill with ARDS
- Measuring arterial blood gases and with inspired FiO₂, determining the severity of ARDS using the P/F ratio (PaO₂/FiO₂): >200, mild; 100-200, moderate; and <100, severe
- Assessing viral loads during pharmacological treatment, IgG and IgM immunity during remission and antibody titers following vaccination

How can governments and policymakers support the use of POCT for COVID-19?

Governments and policymakers should fund research and development of POCT to detect disease, assess the immune response and develop strategies to couple diagnostics with therapeutic regimens. They should offer funding mechanisms and promote business models to help start-ups to invent new POCT for SARS-CoV-2. They should create national guidelines for testing and provide free access to testing for the general public. Importantly, they should launch public health campaigns to ensure the general public understands the purpose of POCT for disease surveillance, contact tracing and management.

What can we learn from past pandemics to inform the role of POC strategies in the COVID-19 response?

The Ebola epidemic in West Africa taught us crucial lessons in preparing for the COVID-19 crisis, but advice, strategies and technological development—especially in POCT—were mostly ignored. We must take action so this does not happen again.

For additional information, please refer to Global Point of Care—Strategies for Disasters, Emergencies and Public Health Resiliency, as well as references 7 & 8 below. Dr. Mark Shephard's A Practical Guide to Global Point-of-Care Testing also provides valuable material.



What can education institutions do to support training in POCT technologies and practices?

Schools of public health must modernise curricula to include training in POCT. TheCOVID-19 pandemic has shown unequivocally that POCT strategies are needed for detection of infection, contact tracing and documentation of immune response when people want to return to work. As POCT has not been emphasised in public health education, we are inadequately prepared in implementing POCT in the midst of the largest public health crisis of the century. For more discussion of POCT curricula and accreditation for public health, please see the references 5 & 6 below.

How can POCT systems be used to anticipate the next pandemic?

Nations are not ready for the next pandemic. The world has changed, and the POC profession must change with it. One way to implement change is through "point-of-careology," a novel and also common sense concept for the future. Developed in China by a team led by Professor Xiguang Liu in Wuhan, point-of-careology is an emerging medical discipline that focuses on the role of POCT to quickly produce test results, accelerate therapeutic decision-making and reduce the economic burden of healthcare. Rapid, accurate and safe POCT would allow nations to contain the next infectious disease outbreak early before it spreads worldwide.



References

1. Kost GJ. Designing and interpreting COVID-19 diagnostics: Mathematics, visual logistics, and low prevalence. *Archives of Pathology and Laboratory Medicine*. 2020. *[open access]*

2. Kost GJ. Geospatial spread of antimicrobial resistance, bacterial and fungal threats to COVID-19 survival, and point-of-care solutions. *Archives of Pathology and Laboratory Medicine*. 2020. *[Open access]*



3. Kost GJ. Geospatial hotspots need point-of-care strategies to help stop highly infectious outbreaks: Ebola and Coronavirus-19. Archives of Pathology and Laboratory Medicine. 2020. [open access]

4. Liu X, Zhu X, Kost GJ et al. The creation of point-of-careology. Point of Care. 2019;18(3):77-84. [open access]

5. Kost GJ. Geospatial science and point-of-care testing: Creating solutions for population access, emergencies, outbreaks, and disasters. Frontiers in Public Health. 2019;7:329. [open access]

6. Kost GJ, et al. POCT curriculum and accreditation for public health: Enabling preparedness, response, and higher standards of care at points of need. Frontiers in Public Health. 2019;6:385. [Open access]

7. Kost GJ. Molecular and point-of-care diagnostics for Ebola and new threats: National POCT policy and guidelines will stop epidemics. Expert Review of Molecular Diagnostics. 2018; 18(7):657-673.

8. Kost GJ et al. Molecular detection and point-of-care testing in Ebola virus disease and other threats: a new global public health framework to stop outbreaks. Expert Review of Molecular Diagnostics. 2015;15(10):1245-1259.

9. Kost GJ, Curtis CM, Eds. Global Point of Care — Strategies for Disasters, Emergencies, and Public Health Resiliency. Washington DC: AACC Press-Elsevier, 2015. [Contributed book, 701 pp.]

10. Food and Drug Administration, United States. In vitro diagnostics EUAs. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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Rapid diagnosis of acute myocardial infarction: the critical role of clinical labs

Based on interviews with **Krongwong Musikatavorn**, Head of Emergency Medicine Department, King Chulalongkorn Memorial Hospital, Thailand; **Wacin Buddhari**, Director, Cardiac Catheterisation Laboratory, King Chulalongkorn Memorial Hospital, Thailand; **Chintana Chirathaworn**, Associate Professor, Department of Microbiology, Chulalongkorn University, King Chulalongkorn Memorial Hospital, Thailand.

Rapid and safe diagnosis of acute myocardial infarction (AMI) is of major medical and economic importance because it facilitates the timely treatment of chest pain and possible early discharge for outpatient management.

The recent clinical introduction of high-sensitivity cardiac troponin T (hs-cTnT) testing using the European Society of Cardiology (ESC) 0-hour/1-hour (0h/1h) algorithm means that suspected AMI cases in the emergency department can now be diagnosed in as fast as 1 hour, which translates into improved clinical outcomes and reduced costs for healthcare systems. Successful implementation of the algorithm in the hospital setting requires the concerted efforts of multi-disciplinary teams including clinical lab professionals, emergency department (ED) physicians, cardiologists and nurses. This article provides a brief introduction to the 0h/1h algorithm, the role of the lab in making it possible, and its benefits for patients, clinicians and providers.

The 0h/1h Algorithm Principle

The 0h/1h algorithm is a widely validated protocol recommended by the ESC to provide rapid disposition of patients into 'rule-in' or 'rule-out' AMI in 1 hour when hs-cTnT is available. A low baseline troponin concentration of less than 12ng/L at 0h and concentration change of <3ng/L within 1 hour qualifies for 'rule-out'; a high baseline troponin that is greater than or equal to 52ng/L at 0h and concentration change of $\geq 5ng/L$ within 1 hour qualifies for 'rule-in'. Patients who do not fulfill either criteria are placed into the 'observe' zone (see Figure 1 below).





Figure 2: 0h/1h algorithm using hs-cTnT as recommended by the ESC

In a recent series of interviews with Roche Diagnostics Asia Pacific, cardiologists and ED physicians from King Chulalongkorn Memorial Hospital in Thailand and Juntendo University Nerima Hospital in Japan—two hospitals in the Asia Pacific region that have successfully adopted the 0h/1h algorithm for AMI diagnosis—shared their experience with the implementation and the positive impact on patient care and outcomes.

The Critical Role of Clinical Labs

In patients with suspected AMI, labs must ensure rapid turnaround time (TAT) of the hs-cTnT to enable the accurate interpretation of the change in cardiac troponin over 1 hour.

"Nowadays, lab tests are not just simply about quality and accuracy," said Dr. Chintana Chirathaworn, Associate Professor at the Department of Microbiology at Chulalongkorn University in Thailand. "Today, we need to focus more on speed and fast turnaround time so that clinicians can diagnose and assess patients quickly."

Some of the key factors that are driving lab efficiency to make the 0h/1h algorithm possible include pre-analytical units for rapid sample processing, automated detection systems that produce test results within minutes, information systems that send results directly to clinicians, and auto-validation systems for quality control and delta checks. Active participation of the lab members in discussions with the involved physicians is also important to ensure accuracy of the test results and adherence to the required protocols. "We need to know what kind of tests the doctors want, and how they want it to properly diagnose the patients," Dr Chirathaworn added.

Steps to Ensure Rapid TAT for the 0h/1h Algorithm

"When we first used the 1-hour algorithm, we sometimes could not get the results back within 1 hour," said Dr. Wacin Buddhari, who directs the Cardiac Catheterisation Laboratory at King Chulalongkorn Memorial Hospital. "Therefore, we had to adjust a few things to be able to receive test results within 1 hour, from the process of sending the blood sample, the test procedure, and the reporting of results."

Dr. Chirathaworn described '4Rs' that the clinical lab at King Chulalongkorn Memorial Hospital considers important to ensure fast TAT and successful implementation of the 0h/1h algorithm (see Figure 2 below).





Figure 3: Dr. Chirathaworn's '4Rs' for clinical labs to implement the 0h/1h algorithm

For patients, the 0h/1h algorithm can improve safety and clinical outcomes. Rapid exclusion of AMI can significantly reduce the waiting time and anxiety of patients and their family members in the ED. The high negative predictive value of the 0h/1h algorithm also ensures more precise diagnosis, which increases confidence in clinical assessments, particularly 'rule-out' cases where physicians can safely send patients back home.

"In caring for patients with acute chest pain from myocardial infarction, we often hear the term 'time is muscle', indicating that the earlier we can detect and initiate treatment, the more myocardium can be saved," said Dr Krongwong Musikatavorn, Assistant Professor and Head of Emergency Medicine Department at King Chulalongkorn Memorial Hospital.

Benefits for Clinicians and Providers

Clinicians also benefit from implementation of the 0h/1h algorithm. Since the algorithm provides an objective and absolute index, it enables non-cardiologists and young or night shift doctors to make critical decisions when assistance may be unavailable. At Juntendo University Nerima Hospital, ED physicians are also sometimes hesitant to seek consultation from cardiologists without a solid basis for assessment.

For providers, fast and accurate triage of patients can reduce overcrowding in the ED and non-essential hospitalisation, freeing up resources including bed spaces and physicians for other critical patients. Reduced emergency cardiac catheterisation exams may also vacate bed spaces and spare patients from the risk of associated complications.

Rapid TAT and reliable processes in the clinical lab make all these benefits possible. By supporting implementation of the 0h/1h algorithm, hospital labs can play a central role in improving patient care while simultaneously demonstrating clear value to all their key stakeholders.



Pleasure of Life in a Farming Community



Dr. Tan It Koon "Founding and Past President of SACB and APFCB, IFCC Executive Board Member (First Asian Board Member), WHO Expert Committee Member"

The following provides a description of the poem, its background as well as my painting. The Chinese ink and colour artwork was done after my participation in a special art exhibition where I displayed some of my paintings and calligraphy works at the Museum of the City of Luoyang 洛阳. The event was held in conjunction with the International Peony Flower Festival. Luoyang served as the capital of 7 dynasties from 1 st to 6th centuries in China. It is the largest capital city in ancient China and is well known as the home of the Peony Flower which symbolises nobility, honour, and prosperity. Special handmade paper newly acquired during the trip was used for the painting. It is based on the rustic scene as described in a poem entitled (Pleasure of Farm Life», written by famous Tang Dynasty poet, musician, painter, calligrapher, and politician, Wang Wei \pm (692 – 761). The full text of the poem in 4 sentences of 6 words each is given below in Chinese:



桃红復合宿雨,柳绿更带朝煙,花落家童未掃,莺啼山客猶眠。

It may be translated into English as follows:

On the red petals of the peach blossoms, drops of rainwater from the previous night still remain visible; The green willow trees are shrouded in early morning mist; Withered flowers that have fallen to the ground have not yet been swept away by the teenage domestic helper; Yellow orioles are already singing their routine morning songs, but the inhabitants in the mountain village are still enjoying their sweet slumber!

«Pleasure of Farm Life» is one of a series of seven set of poems that Wang wrote. It is his later period literary work. This poem portrays springtime vividly through the characteristic symbols of the season so well described by him: peach blossoms, willow trees, Orioles. It expresses the joy and tranquillity of living in a rural villa close to nature after leaving his employment.

Wang was one of the most famous men of art and letters of his time. More than 400 of his poems are preserved until today. He was promoted to high position of chief minister in the imperial court. But he found the political situation of the time too corrupt and unpredictable. Working life became increasingly oppressive and stressful. These negative circumstances prompted him to aspire to the tranquil life of a hermit in a mountain abode. When he eventually ceased

"Working as a government official, he became a vegetarian and found happiness spending his retired life as a devout Buddhist in the quiet and serene environment of a farming community at the mountains".

Tribute for all Covid-19 fighters in healthcare



By Joseph Lopez Kuala Lumpur, Malaysia

"As flies to wanton boys are we to the' gods, They kill us for their sport." Shakespeare - from King Lear, Act 4 Scene 1

For all Covid-19 fighters in healthcare and especially those who work in the in the lab, people often unseen and unheard from.

TRIBUTE

The enemy, lethal, unforgiving and merciless, Savaging a ravaged planet, Soldiers, in flimsy fatigues of blue and green, Charging fearlessly like warriors of yore.

Ministering silently, valiantly, among the sick, Shielded with amour of little more than apron, glove and mask, Facing not planes, bullets, bombs, take your pick, To engage in mortal combat is their noble task.

Haunted looks, hooded eyes, the creased visage, Exhausted beyond measure, yet never surrendering, Tears freely flowing, sometimes for fallen comrades, Stoic looks, care beyond the ken dispensing.

She emptying the bins, he mopping the floor, Those, whose toil we oft take for granted, The pharmacist, the medtech, the guard at the door. Those, whose praises have seldom been chanted.

And within the forest, the oft forgotten kin, But now remembered, indeed, earnestly sought, Miners of gold dust, the results desperately needed to win, Responding to plaintive cries of Test! Test! Test! is their lot.

> I see kindness in all corners, Compassion given without rest, "Unsung heroes" they've been called, I've seen humankind at its very best.

(The poem was first published in the May 2020 issue of the eIFCC Newsletter)