APFCB News

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

2022

Issue 1

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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.
Contact email: afpcbofficial@apfcb.org

Cover page: "Watching Opera Performance on a River at an Ancient Water Village in China"
Contributed by Dr. Tan It Koon
Founding and Past President APFCB

Address

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APFCB, c/o Solid Track Management Pte Ltd. 150 Cecil Street, #10-06, Singapore

Contents

From the desk of Chief Editor

Dear colleagues and friends,

On behalf of the C-CP team I take this opportunity to wish everyone a Happy 2022!

In this issue of the APFCB News we bring exciting news on the coming 16th APFCB Congress 2022 in Seoul Korea. Details are reported under APFCB activities and also under the KSCC report as conference organisers. Also included are reports on the activities of the various chairs of the APFCB Committees, reports of the national societies and corporate members. We thank all contributors and would like to encourage more members to share news on their activities in the newsletter.

We are very grateful to Prof Bernard Gouget and Prof David Kinibrough for their support and for contributing very interesting and informative articles to this newsletter. We hope that these opinion papers as well as the educational articles which are included in this issue will be useful resource for members. The response for educational article submission has been encouraging and we look forward to receiving more articles in the coming issues. Another exciting feature in this issue is a quiz section which is a new feature of the newsletter. Questions in this section are based on the APFCB webinars which were organized in 2020-2021 and which are still available on the APFCB website.

I take this opportunity to thank the editorial committee and reviewers for all their contribution to this publication.

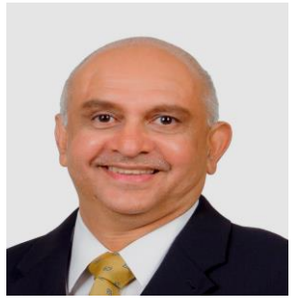
In keeping with tradition, the cover of this issue of the APFCB News is a painting of Dr. Tan It Koon. We would like to thank Dr. Tan for his generous contribution to the APFCB newsletter and for his continuing support to the APFCB.

May 2022 be a successful and good year for all.

Best wishes,
Dr. Raja Elina

Chief Editor, APFCB News

Message from APFCB President



Dear APFCB family,

Greetings and best wishes for 2022!

The Covid-19 pandemic which started in 2019 is still a global concern till this very day. Laboratory medicine which has played a critical role in the diagnosis, monitoring, tracking, tracing and treatment of Covid-19 continues to be in the spotlight. I take this opportunity to commend everyone for their continuous efforts in this battle against Covid-19. I pray that the situation will continue to improve so that we can return to a safer and more stable lifestyle.

In the last two years, professional organisations like the APFCB have suffered in not being able to conduct physical meetings and congresses. We were very optimistic that the joint IFCC 24th International Congress of Clinical Chemistry and Laboratory Medicine and the 16th APFCB Congress of Clinical Biochemistry can be held as a physical conference in Seoul, Korea from 26-30 June 2022. However, the recent emergence of new variants of concern has created new waves across the globe. In these uncertain times, a physical meeting may be challenging. Irrespective of the mode of delivery, the joint IFCC WorldLab – 16TH APFCB Congress will proceed as scheduled. So do keep these dates blocked in your busy schedules and do look out for further announcements. With your support, I am confident this meeting will be a successful event.

Finally, I have great pleasure in acknowledging the work of Dr. Raja Elina and her editorial team in this latest publication of the APFCB Newsletter. Enjoy reading this issue.

My best wishes, always.

SK Sethi

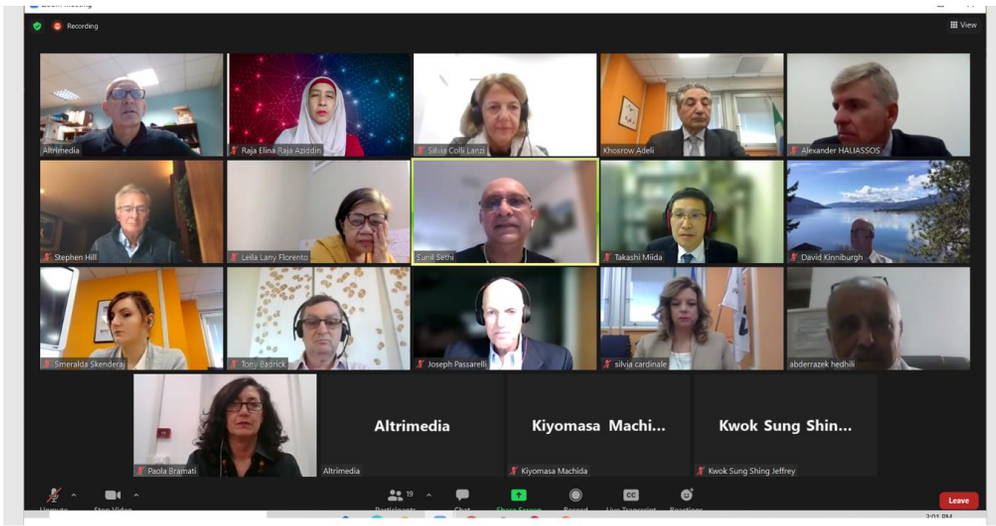
Prof. Sunil Sethi
President, APFCB

Report of APFCB Activities for 2021

1. APFCB participation in IFCC Townhall for APFCB Region

The IFCC Townhalls are a new initiative aimed to significantly enhance internal communications within the IFCC organization and between the IFCC Executive Board and all IFCC member Societies and Regional Federations. On 20th October, 2021, the APFCB attended the IFCC Townhall that was hosted for the APFCB region.

IFCC Town Hall event for the APFCB region.



The APFCB Executive board and chairs of committees at the IFCC Town Hall Event on 20 October, 2021.

In this combined IFCC/APFCB Townhall, the following speakers gave brief presentations to update the membership on current and upcoming IFCC programs and new initiatives globally or in specific regions.

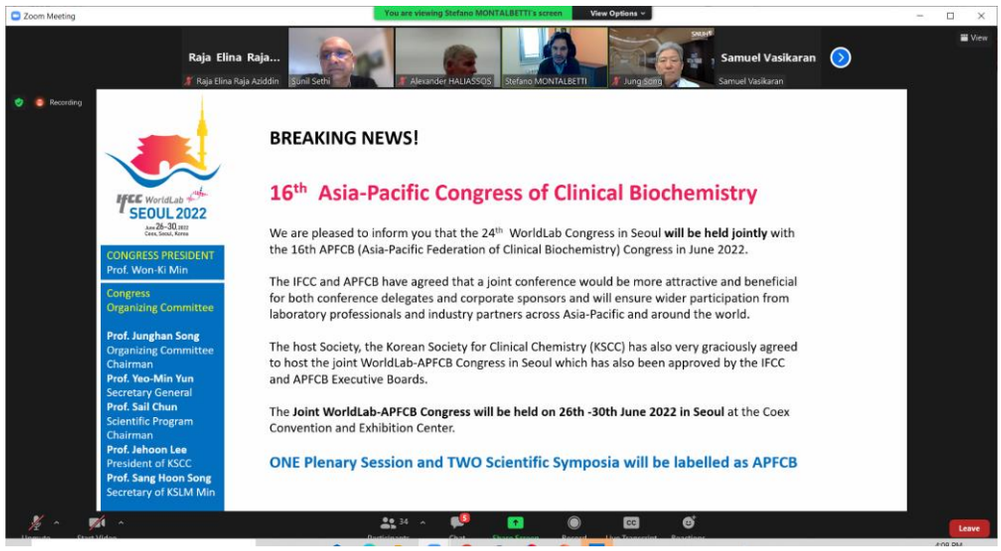
- Prof. Khosrow Adeli – IFCC President.
- Dr. David Kinniburgh – IFCC Secretary.
- Dr. Alexander Haliassos – IFCC Treasurer.
- Mr. Joe Passarelli – IFCC Corporate Representative.
- Dr. Sunil Sethi– APFCB President.

This event provided a unique opportunity to bring everyone together in the APFCB region and allow for exchange of ideas and free communication between the various organizations.

The APFCB look forward to attending the IFCC Townhall event in 2022.

2. 16th Asia-Pacific Congress of Clinical Biochemistry

The pandemic of Covid-19 which started in 2019 has had a profound effect on physical meetings and congresses. The APFCB Congress which was planned for 2022 in Sydney, has been moved to 2024, while the WorldLab which was supposed to be have been held in Seoul in 2020, has now been scheduled to June 2022. Taking this situation into consideration, the IFCC and the APFCB have agreed that at this time, a joint congress would be more beneficial. The 16th Asia-Pacific Congress of Clinical Biochemistry will now be held jointly with the 24th WorldLab Congress from 26-30th June, 2022 in Seoul, Korea.



An exciting program has been put together by the congress organisers and details are available in the KSSCC report. APFCB Young Scientist Award are available where winners will be invited to present their papers at the 16th APFCB Congress in Seoul, South Korea. Details on the award and application process is available under the C-ELM report in this issue.

The APFCB would like to welcome all its members to this congress and look forward to a successful meeting.

The APFCB Council meeting will also be held at this time.

3. Joint Corporate Member Symposia

In 2021 the APFCB worked together with some of the Corporate Members to produce the following webinars.

- MindRay webinar - Laboratory Management and ISO 15189 – 28 Jan 2021.

- ThermoFisher - APAC Webinar series on Pre-Natal Screening.

    - Preeclampsia screening and prevention: tips and considerations -21st May 2021.
    - How to manage preeclampsia more effectively in Covid-19 era? – 18th June. 2021.
    - Improve patient management with first trimester screening – 20th July, 2021.

- ThermoFisher -Toxicology and Clinical Biochemistry webinar series.
    - "Drugs of Abuse Automated Screening vs Manual Testing: What are the benefits?" – 7th July, 2021.
    - "Biochemical Markers in COVID 19" – 22nd July, 2021.
    - "Clinical Application of Measurement Uncertainty" – 28th July, 2021.

- Beckman-Coulter Webinars -Evidence-Based Medicine and Clinical Practice Guidelines in Sepsis Detection – 26 July 2021.

- Roche – Transforming Data into Insights Webinar Series.

    - The power of Patient-Based Real-Time Quality Control in the laboratories – 24th March, 2021.
    - Observability in healthcare: why a holistic view of telemetry data is essential – 16th June, 2021.
    - Leveraging the latest trends in the digital healthcare revolution – 15th September, 2021.

- Roche Experience Days (RED) 2021 – 16th – 17th November, 2021.

4. Other activities of the APFCB

Other activities are reported under the APFCB committee reports.

APFCB Congress and Conference Committee (C-CC) Report of activities for 2021

Chair: Prof Praveen Sharma

APFCB Congress Committee consist of the following:

Praveen Sharma (India)	Chair
Woei Horng Fang (Taiwan)	Member
Ronaldo Puno (Philippines)	Member
Prasenjit Mitra (India)	Member
Will Greene (Roche)	Corporate Member
Ai Tin Lim (Siemens)	Corporate Member

The mandate of the committee is 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 platforms. The committee received a number of applications for APFCB auspices. During 2021, the committee members evaluated and granted APFCB auspices for the scientific events shown in the following two tables:

1. Conferences

Event name	Organised by	Event Start Date	Event End Date
15th IACC Working Conference	IACC	25/06/21	27/06/21
CCPSL AAS 2021	CCPSL	26/07/21	27/07/21
LMCE 2021	KSLM	30/09/21	02/10/21

2. Corporate Member Events/Webinars

Event name	Organised by	Event Date
Roche Experience Days (RED) 2021 Virtual Event.	Roche	16/11/21
Webinar on "Managing the Covid-19 pandemic in 2021: The Henry Ford Experience".	Beckman Coulter	15/06/21
Webinar on "Digital webinar on Observability in healthcare".	Roche	16/06/21
Series of educational webinars focused on the Asia Pacific region related to Prenatal & Pre-eclampsia Screening, Clinical Biochemistry, Toxicology and 3rd party QC.	Thermo Scientific	
Leveraging the latest trends in the digital healthcare revolution.	Lab workflow solutions (Roche Digital Webinar)	15/09/21

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

APFCB Committee for Communications and Publications (C-CP)

Dr. Raja Elina Raja Aziddin, Chair C-CP

The Communications and Publications Committee (C-CP) is made up of the following members Dr. Raja Elina Raja Aziddin (Chair), Dr. Purvi Purohit (Web Editor), Dr. Rojeet Shrestha (Media Coordinator), Dr. Pradeep Dabla, Will Greene (Corporate -Roche) and Lim Ai Tin (Corporate -Siemens). The C-CP is responsible for communicating and promoting the activities of the APFCB to medical laboratory personnel, clinicians and health care policy makers in the Asia Pacific region and the rest of the world.

1. APFCB Website Development and Management

The C-CP is responsible for the APFCB website development and management. The APFCB website is frequently updated with the latest information on webinars, online courses, virtual conferences of the APFCB, its member societies and international professional bodies. Also available are scientific publications, guidelines, recorded and live webinars on various topics of interest. Understanding the need to support more virtual events in future, the C-CP is currently looking into further upgrading the capability of the APFCB website. Discussions are currently underway on the design of the new website.

The C-CP team welcomes suggestions from members and look forward to the support especially from its corporate partners to the successful implementation in 2022.

2. Promotional Activities

The application of the virtual platform for educational and training purposes accelerated with the onset of the Covid-19 pandemic. In 2021, the C-CP team collaborated with other committees and the corporate sector to coordinate these online activities. These events are promoted by sending out announcements to members and are also made available on the homepage of the APFCB website https://www.apfcb.org/index.html.

Also on the homepage is the APFCB virtual workshop on Complete Guide on Laboratory Testing of COVID-19. To date, recordings and slides of the APFCB Masterclass Webinars on Interpretative Commenting have been uploaded on the webinars page of the APFCB website at https://www.apfcb.org/webinars.html.

Also available on the webinars page are the IFCC webinars. Links to past webinars organised by the APFCB corporate members under the auspices of the APFCB are listed under the Congress and Conferences Committee page at https://www.apfcb.org/conferences.html. Links to these events have also been made available on APFCB social media which are listed at the footnote on the APFCB website homepage.

3. Publication of APFCB Newsletter

The C-CP is also responsible for the online publication of APFCB News. Advertisement rates in the APFCB News was revised in 2021 to make it more attractive to corporate members. This year the C-CP team also drew up a Guideline for the submission of reports, articles and advertisements to the APFCB News. This guideline is now available on the APFCB website homepage via this link:

https://www.apfcb.org/Submission%20Guidelines%20APFCB%20News%20050721.pdf

In 2021, the C-CP successfully published two issues of the APFCB News.

APFCB Committee for Education and Laboratory Medicine

Tony Badrick, Chair, C-ELM

The Education and Laboratory Management Committee (C-ELM) is chaired by Dr. Tony Badrick (Australia) with the following members: Dr. Lia Gardenia Partakusuma (Indonesia); Dr. Tze Ping Loh (Singapore); Dr. Ronda Greaves (Australia); Dr. Raja Elina (Malaysia); Dr. July Kumalawati (Indonesia); Dra Endang Hoyaranda (Indonesia); Dr. Jozi Habijanic (Roche Corporate); Dr. Amit Manjure (Siemens Corporate); Dr. Rojeet Shrestha (Japan); Dr. Hong-yew Lim (Roche Corporate). The role of the C-ELM is to provide support for member organisations in education.

This usually involves the organisation of visiting lecturers, seminars, and training activities. However, the impact of the ongoing global pandemic has restricted many of the activities of the C-ELM. Nevertheless, the committee has continued with existing projects as well as some new initiatives.

1. APFCB Travelling Lecturer

The APFCB Visiting Lecturer for 2021/22 is Dr. Helen Martin from Australia. Whilst there are travel restrictions on this key role, virtual lectures will continue. On the 26th November 2020, Dr. Helen was a Plenary Lecturer at the MACB meeting and delivered a lecture entitled 'Adding value with patient report commenting.'

2. APFCB – Roche – 12th Chemical Pathology Course – Vietnam

This is an ongoing annual event organised by Roche in collaboration with Rhonda Greaves from Australia. In 2020, the virtual event attracted approximately 400 participants and consisted of a mixture of invited and local speakers presenting on routine chemical pathology topics.

The course is supported and endorsed by many prestigious local and international medical organisations and associations, such as International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB), Australasian Association of Clinical Biochemists (AACB), Vietnamese Association of Clinical Biochemists (VACB), Ho Chi Minh City Association of Clinical Biochemists (HACB), Ho Chi Minh City Association of Medical Laboratory Technologists (HAMLT), Bach Mai Hospital, Cho Ray Hospital and other medical organizations and Associations.

3. APFCB-AACC Workshops

The APFCB has been collaborating with the AACC with their Global Lab Quality Initiative (GLOI) as part of the Asia-Pacific Working Group (APWG).

It was not possible to run any workshop in 2020. However, it is planned to run the next programme in Mongolia in 2022.

4. Workshop on Laboratory Testing of Covid-19

As the information of laboratory diagnosis and monitoring of COVID-19 was rapidly evolving with new information arising on a daily basis, laboratory professionals needed a constant update on the developments. Furthermore, many developing countries were struggling to meet requirements of appropriate testing not only because of lack of resources but also due to lack of well-trained laboratory professionals on the molecular assays. To help lab professionals with appropriate guide in COVID-19 testing, the APFCB committee for Education and Laboratory Management organised a two-day virtual workshop that contained a series of lectures from experts as a complete guide on Laboratory Testing of COVID-19.

There are two other significant projects which have been put on hold until travel is possible. The APFCB / VACB / Roche Lean Project has been running for five years now and is developing skills with the implementation of Lean laboratories.

The APFCB has also developed a three-year Chemical Pathology Course which was piloted with the assistance of the MACB. We were hopeful of running this course in a new site in 2020 but this was not possible. We hope to offer this course in 2022.

5. The APFCB Young Scientists Award Competition 2022

Objective

The APFCB Young Scientist Award Competition is a scientific paper competition conducted by the APFCB through its Education and Laboratory Management Committee with the following objectives:

1. Foster scientific potential of young scientists within the Asia-Pacific region.
2. As a means of aiding and encouraging young scientists in written and oral communication of their research results.

Eligibility

3. Scientists under the age of 40 on 26 June 2022 (opening of the 16th APFCB Congress in Seoul where the awarding will take place).
4. Researcher must reside in the Asia Pacific region (all Asian countries except Arab region), Australasia, or Pacific islands.

Requirements

The selection process will take place starting March 2022 with the following conditions:

1. Submitted scientific research papers shall be original works of one individual (single author) or as main author in a group research project.
2. Research paper has not been published elsewhere or submitted at the same period/time for another competition or publication.

3. Literary search or reviews are not acceptable.
4. All research areas in laboratory medicine are welcome, but emphasis will be put to novel findings.
5. Language will be English.
6. Each researcher may submit more than one research paper.
7. All papers must include a title page with the following information: title of the paper, name of scientist, affiliation name and address, researcher's email address and name, address and email address of the sponsor who endorses the project.
8. The maximum length of the paper is 1,500 words, not including title page, abstract, references, figures, tables, and appendices. The body of the paper shall begin with the abstract so that it is not on a separate page.
9. Deadline of submission is 1st May 2022.
10. All submissions shall be addressed to: Dr. Tony Badrick, APFCB Education and Laboratory Management Chairperson, email address: Tony.badrick@rcpaqap.com.au.

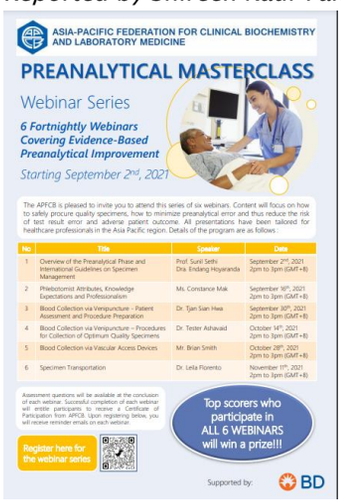
Successful candidates

1. There will be 12 (twelve) winners selected from all submitted papers.
2. The twelve successful candidates will be invited to the 16th APFCB Congress in Seoul, South Korean, on 26-29 June 2022. If they attend in-person, SGD 1,500. This will be to cover travel and hotel expenses.
3. A dedicated symposium during this congress will be allocated for this competition award.
4. A Juror Team chaired by the APFCB Education and Laboratory Management Committee will be in charge for determining the winners of this competition.

The APFCB encourages scientists under the age of 40 to participate in this competition, through which they will have unique opportunities to learn a crucial part of scientific work which is communicating their work to others.

Report on APFCB Preanalytical Masterclass Webinar Series

Reported by Shireen Kaur Pannu, Clinical Marketing Manager, BD



Flyer on the Preanalytical webinars

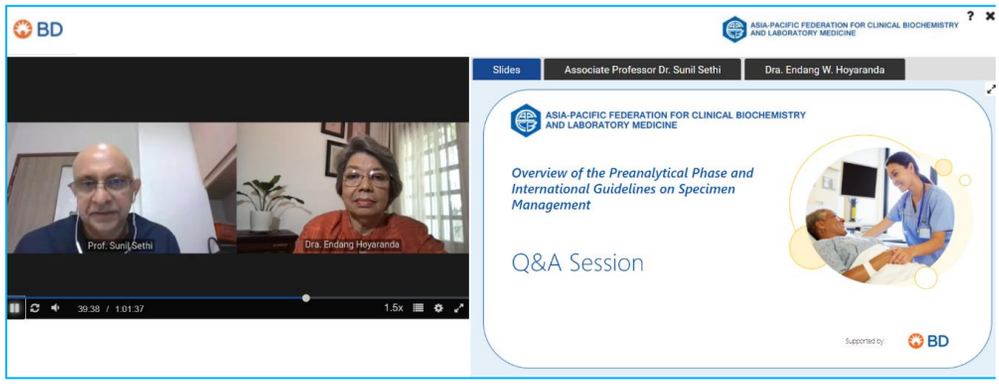
With the COVID 19 pandemic continuing in our region with limited opportunities for face-to-face meetings and conferences, a number of webinars have been facilitated by the APFCB over the past 18 months. The objective has been to maintain the Federation's commitment to continuing education in the challenging circumstances associated with the pandemic. Most recently, a series of webinars was presented on key aspects of the preanalytical phase. The series was titled 'Preanalytical Masterclass' and lead by Dr. Endang Hoyaranda and Dr. Tony Badrick with support from BD Diagnostics. Apart from delivering evidence-based recommendations, an underlying theme was to present material tailored to address specific needs of the Asia Pacific region. The series comprised six parts, delivered from September to November 2021:

Webinar	Title	Speaker
1	Overview of the Preanalytical Phase and International Guidelines on Specimen Management	Prof. Sunil Sethi Dr. Endang Hoyaranda
2	Phlebotomist Attributes, Knowledge Expectations and Professionalism	Ms. Constance Mak
3	Blood Collection via Venipuncture – Patient Assessment and Procedure Preparation	Dr. Tjan Sian Hwa
4	Blood Collection via Venipuncture – Procedures for Collection of Optimum Quality Specimens	Dr. Tester Ashavaid
5	Blood Collection via Vascular Access Devices	Mr. Brian Smith
6	Specimen Transportation	Dr. Leila Florento

Preanalytical Webinar Programme

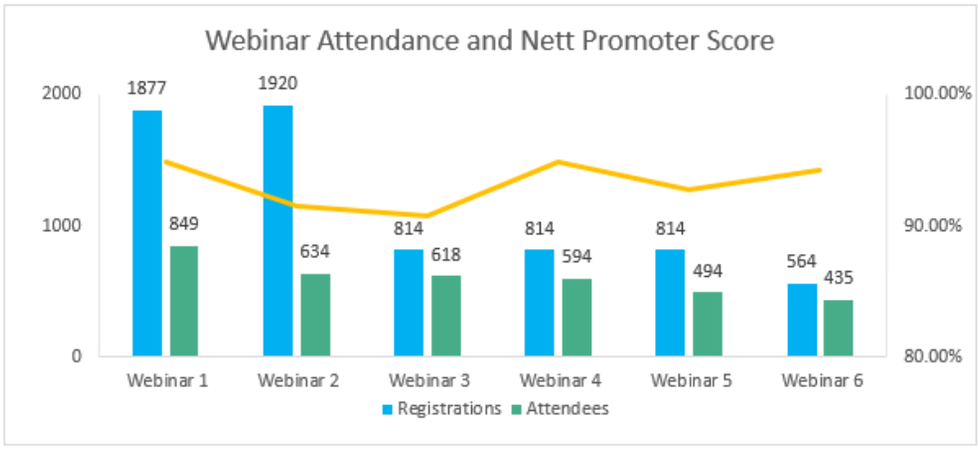
Presentations for each webinar ran for approximately 25 minutes followed by a Q&A session hosted by the speakers.

From the number of questions, it was clear that the topics were very relevant and that participants were highly engaged. Answers to all questions, along with others unable to be taken due to time constraints, were sent to all registrants following each webinar. Separately, assessment questions were sent to all registrants with a Certificate of Participation from APFCB provided for each webinar to those correctly answering the questions. Prizes were awarded to the top 5 responders to assessment questions for all six webinars.



Sunil Sethi and Endang at the Q & A Session of the First Preanalytical Webinar.

We believe this educational program was very successful with large numbers of registrants for each webinar:



Attendance at the Preanalytical Webinar Series.

Participant feedback was overall positive:

Participant Feedback on the Preanalytical Webinars.

Discussion is already underway for another series of webinars, again supported by BD Diagnostics.

APFCB Scientific Committee Report of activities for 2021

Samuel Vasikaran, Chair APFCB Scientific Committee

1. WG on Diabetes Testing Harmonisation in APFCB Region

The Diabetes Testing Harmonisation WG chaired by Dr. Mithu Banerjee has conducted surveys of diabetes testing and reporting practices in four countries in the AP region. Results of the survey conducted in India was presented at the APFCB Congress in 2019 since been published.1 The results of the survey in the Philippines were presented previously at the PAMET conference in 2018. Survey results for Sri Lanka were presented at the Annual Academic Sessions of the College of Chemical Pathologists of Sri Lanka (July 2021). A survey has also been conducted in Singapore.

The survey uncovered some issues that the laboratory profession as a whole and the professional Clinical Chemistry association in each country needs to address. For example, the units for reporting of blood glucose concentration is not uniformly followed in most countries. Even though the recommended standard international units for reporting blood glucose is mmol/L, a significant proportion, infact a majority, of laboratories in the AP region report blood glucose in mg/dL. Hence, this practice can lead to confusion amongst clinicians as well as patients when interpreting blood glucose results and monitoring over time especially when different laboratories are used for serial measurements.

The reporting of HbA1c units is similarly non uniform. The situation with HbA1c, however, is somewhat different in that the traditional % units are used by the vast majority of laboratories, with a significant proportion of laboratories reporting in mmol/mol, the IFCC units also. This is considered a transitional phase, and once clinicians (and patients) become familiar with the IFCC units, the latter would be used exclusively. However, the profession needs to work towards this actively together with educating our customers. The survey identified a need to harmonize the provision of testing for gestational diabetes mellitus. Glucose challenge test is no longer recommended. Oral glucose tolerance test with appropriate cut-offs for the diagnosis of gestational DM is now recommended and should be followed by all laboratories. Urine albumin testing should be performed on spot urine samples collected in the morning and reported as a ratio to creatinine. The use of 24-hour collection or timed collection is not recommended. The variation in reporting units for creatinine was also found to lead to reporting of spot urine albumin as mg/mol creatinine or mg/g creatinine, another potential area of confusion and needing harmonization.

Finally, we also encourage the exclusive use of certified methods in clinical laboratories and participation in proficiency testing programs (external Quality Assurance) for all tests offered.

These results from the region are being written up for publication as a follow up to our previous publication of the survey conducted in India.

Publication

Trends in laboratory testing practice for diabetes mellitus. Banerjee M, Vasikaran S. eJIFCC 2020;31:(3):231-41.

Measures to harmonize practice according to recognized recommendations should be locally driven, led by each national professional body, but APFCB would strongly support national organisations to take forward plans to harmonise testing and reporting practices in every jurisdiction within the AP region.

2. Masterclass in Interpretative Commenting on Clinical Chemistry Reports - Webinars

Since August 2020, the APFCB Scientific Committee has organized a monthly webinar series on Interpretative Commenting. In this series, chemical pathology experts discuss the interpretation of laboratory test results and recommend comments that may be suitable to provide in the laboratory report. The format of the webinars is generally a discussion of case reports for 45 minutes followed by question-and-answer session for about 15 minutes.

Despite some recent gaps due to scheduling difficulties and COVID-19, the series continues to enjoy excellent support from invited experts and the APFCB community.

The list of 2021 webinars and upcoming topics for early 2022 are as follows:

Month	Topic	Speaker
January 2021	Calcium and parathyroid	Dr Sam Vasikaran
February 2021	Endocrine Dynamic Function Tests- Adult	Dr Cherie Chiang
March 2021	Lipid testing	A/Prof. Ken Sikaris
April 2021	Cardiac troponin	A/Prof. Chris Florkowski
May 2021	Diabetes testing	A/Prof. Ken Sikaris
June 2021	Dynamic Function Tests Part 2	Dr. Cherie Chiang
July 2021	Anti-Mullerian Hormone	Dr. Melissa Gillett
August 2021	Serum Protein Electrophoresis (SPEP)	Dr. Nilika Wijeratne
September 2021	Essentials of Porphyrias	A/Prof. Chris Florkowski
December 2021	Tumor Markers	A/Prof. Ken Sikaris
February 2022	Hyperandrogenism in Females	Dr. Melissa Gillett
March 2022	SPEP Part 2 & Free Light Chains	Dr. Nilika Wijeratne

I would like to specially acknowledge the efficient organisational support of Dr Pearline Teo of Siemens Healthcare Pte Ltd for this activity. Recordings and slides of past webinars are available via the APFCB website and youtube channel, while registration links for future webinars are posted on Eventbrite.

https://www.apfcb.org/webinars.html

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

http://APFCB.eventbrite.com

We thank the speakers for volunteering their time and effort to support this educational initiative.

Their depth of knowledge and experience are clearly appreciated by our webinar participants. Participant feedback continue to be overwhelmingly positive: >95% of responders "agree" or "strongly agree" that the session had been useful to them, and that they would recommend it to others.
We thank the participants for their attendance and lively discussion during the Q&A sessions. Many participants are consistent supporters of the series and have provided valuable suggestions and feedback.

We also thank the APFCB Communications team, for their support in publicizing each event, and making the slides and recordings available online.

We invite all interested laboratory professionals to participate in future webinars.

3. APFCB-WASPaLM TF-CKD

APFCB / WASPaLM Task Force on Chronic Kidney Disease which is chaired by Dr. Pavai Sthaneswar has undertaken a survey of testing and reporting practices for CKD related laboratory indices in India in order to ascertain concordance of reporting practices with current guidelines and industry standards as well as the degree of harmonisation of practice between laboratories. It is hoped that the results of the survey would help harmonize practice according to current recommendations in that country and throughout the region.

4. Mass Spectrometry Harmonisation WG

The Mass Spectrometry Harmonisation WG which is Chaired by Dr. Ronda Greaves has undertaken a multicenter 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.

Publication

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.

5. The Harmonization of Reference Intervals

WG chaired by Dr Tze Ping Loh have plans to derive and compare indirect reference intervals from paediatric to geriatric subjects from laboratories within the Asia-Pacific region. The output of this study would 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.

6. 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.

Australasian Association for clinical biochemistry and laboratory medicine (AACB)

Dr. Fernando San Gil MSc PhD MAACB ARCPA
Chief Executive Officer, Australasian Association for clinical biochemistry and laboratory medicine.

Throughout 2021 AACB activities have met the challenges presented by COVID. At the core of the AACB's vision is ongoing professional development for its members and the wider pathology community. To this end, AACB Branch meetings were held almost on a monthly basis, albeit in virtual format quite often. National activities, such as the annual RCPA-AACB Chemical Pathology Course and the AACB 58th Annual Scientific Conference, were also undeterred by COVID obstacles. Both national meetings were highly successful, and aside from the excellent scientific content, showcased that the AACB and its members could adapt and overcome almost any adversity. The "year that was" commenced on a very positive note, with Dr Samuel Vasikaran receiving the highly prized Geoffrey Kellerman Award (for commitment to education in the profession) for 2020.

Toward the end of 2021, AACB invited members to participate in a satisfaction survey. The results showed overwhelmingly that members had adapted to the "new" normal of webinars and virtual meetings. The survey responses also provided the AACB with valuable information on which to plan future activities and disseminate event information to its members. The format for meetings will undoubtedly evolve over the coming year, but webinars and other virtual activities have been readily embraced by members.

The year 2022 has begun optimistically. Sydney is looking forward to the 2024 APFCB Congress later in the year. The AACB looks forward to welcoming colleagues from around the region for a very exciting meeting. Locally, registrations are currently open for the RCPA-AACB Chemical Pathology, to be held virtually in February. This event is a significant learning opportunity for both experienced medical and non-medical professionals and trainees. Planning is also underway for the AACB 59th Annual Scientific Conference to be held in October in Perth, Western Australia (currently being advertised on the AACB website). This is planned to be a face-to-face meeting with the option of virtual participation for those who cannot travel. The theme of the meeting is very appropriately entitled "From disruption to innovation". It's a theme that comprehensively captures our experiences over the last 2 years. As always, this is the premier meeting for the Association each year and brings together many colleagues and friends with an interest in Clinical Biochemistry and laboratory medicine. It's hoped that other popular events, such as the Roman travelling lectureship, workshops etc. can recommence this year.

Chinese Association for Clinical Biochemistry (CACB-Taiwan)

Election for CACB Executive Board 2021-2024 ran smoothly on the election day (Photo 1&2) - On 3rd October 2021, Dr. Huey-Jen Hsu, Chief Technologist and Leader of the Sample Collection Center, Department of Laboratory Medicine, National Taiwan University Hospital, was elected as the CACB President. The immediate past-president Ms. Hsiao-Chen Ning will serve as Executive Director. Dr. Woei-horng Fang continues to serve as Executive Director and National Representative for the same period. Dr. Ching-Ying Kuo was reappointed for a second term as The Secretary General.

Photo 1 CACB newly-elected President Dr. Huey-Jen Hsu (left) and the immediate-past president Ms. Hsiao-Chen Ning (Right).

Photo 2 CACB Executive Board 2021-2024.

CACB Annual General Meeting was held on the same day and Dr. Tjin Shin Jap was invited to give a special lecture on “The impact of COVID19 on laboratory” (Photo 3).

Photo 3 Special lecture from Dr. Tjin Shin Jap.

CACB held its Executive Board meeting and the year-end dinner gathering on December 13th, 2021 and planned for the upcoming 36th Joint Annual Conference of Biomedical Science (JACBS) (Photo 4).

Photo 4 CACB Executive Board Meeting and Year-end dinner gathering.

The 36th JACBS is scheduled on 26-27 March 2022. The Conference venue will be at the National Yangming Jiaotong University, Yangming Campus, Taipei. CACB has planned for a scientific symposium focusing on “Precision Laboratory Medicine and Sustainable Healthcare”. Four speakers have been invited to present the progress on identifying novel biomarkers and therapeutic targets for various diseases. The speakers include Dr. Khosrow Adeli, IFCC President and Professor at The Hospital for Sick Children/University of Toronto; Dr. Wen-Chien Chou, Director of the Department of Laboratory Medicine at National Taiwan University Hospital; Dr. Sui-Yuan Chang, Professor of Clinical Laboratory Sciences and Medical Biotechnology, National Taiwan University and Dr. Wen-Hui Ku, CEO of Taipei Institute of Pathology.

Japan Society of Clinical Chemistry

1. The 61st Annual Meeting of the Japan Society of Clinical Chemistry

The 61st Annual Meeting of the Japan Society of Clinical Chemistry (JSCC), chaired by Professor Dongchon Kang (Kyushu University), was held in Fukuoka from November 5 to 7 in 2021. The theme of the meeting was “Charts for future of Clinical Chemistry”, reflecting the era of great changes in industry, medicine, and academia.

Photo 2: Poster for the 61st Annual Meeting of the Japan Society of Clinical Chemistry.

The meeting was planned in a hybrid fashion amid the 5th wave of COVID-19 infection in Japan. In principle, all participants were anticipated to join the meeting on site. For participants who were not allowed to visit the conference venue, all presentations were on-line-streamed after the all programs were finished in the site. A total 718 of registration were obtained. Despite the hard environment, many participants could enjoy the face-to-face discussion for the first time in two years.

Dr. Takayuki Honda (Professor Emeritus in Shinshu University) talked in the keynote lecture about a history of the Clinical Laboratory of the Shinshu University Hospital, which has been a pioneer providing medical technologists with many research opportunities and environments and then produced many excellent clinical chemical scientists. He finally proposed that future clinical chemist should aggressively make diagnostic comments based on the laboratory data.

Photo1: From left, Ms. Taeko Hotta (Executive director), Dr. Dongchon Kang (Meeting chair) and Dr. Takeshi Uchiumi (Deputy meeting Chair).

In the chair's lecture, Dr. Dongchon Kang presented his long research history on "Mitochondria in common diseases" such as aging, cancer, heart failure, Alzheimer, autoimmune disease etc. He has stressed that a variety of mitochondrial functions play key roles in pathogenesis of many diseases and therefore analysis of mitochondria can be a good target for new disease markers in clinical chemistry.

In addition to many symposia on new technology areas, international Japan-China joint symposium was held with theme of the current COVID-19 situations in Japan, China, and Europe. In the symposium, the treatment, testing, and vaccine in those areas were compared and discussed. The Chinese zero-corona policy in particular was explained by the speakers from China.

The next 62nd meeting is to be held by Dr. Isao Kitajima (Toyama University) in Toyama from September 30 to October 2 in 2022.

Korean Society of Clinical Chemistry (KSCC)

1. IFCC WorldLab Seoul 2022 News

1) Overview

As a member of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), it is with great delight we welcome you to the 24th International Congress of Clinical Chemistry and Laboratory Medicine & 16th Asia-Pacific Congress of Clinical Biochemistry at Coex, Seoul, Korea from June 26 to 30, 2022. Also, we are pleased to announce that this Congress in Seoul will be held jointly with the 16th APFCB (Asia-Pacific Federation of Clinical Biochemistry) Congress in June 2022. The IFCC and APFCB have agreed that a joint conference would be more attractive and beneficial for both conference delegates and corporate sponsors and will ensure wider participation from laboratory professionals and industry partners across Asia-Pacific and around the world.

Now there are only 6 months left, we would like to inform you about the latest updates of the upcoming the 24th IFCC WorldLab & 16th APFCB. The organizing committee is gearing up for an exciting and informative symposium program including plenary lectures, educational workshops, satellite meetings and poster sessions.

Title	24th International Congress of Clinical Chemistry and Laboratory Medicine & 16th Asia-Pacific Congress of Clinical Biochemistry
Date	June 26-30, 2022
Venue	Coex, Seoul, Korea
Hosts	IFCC, APFCB, KSCC
Theme	Value-Based Laboratory Medicine
Website	www.seoul2022.org
Scale	over 4,000 participants
Program	Plenary lectures, Symposia, Education workshops, Satellite meetings, etc.

2) Scientific program highlights

Theme: Value-based Laboratory Medicine

The aim of the scientific program will be to provide attendees with the most up-to-date information on a wide variety of topics related to Laboratory Medicine and its clinical applications. The program will include an Opening Lecture, 4 Plenary Lectures, 33 Symposia (28 organized by the Scientific Program Committee, "SPC" and 5 by IFCC), 42 Education Workshops and 3 Poster Sessions.

Plenary lectures will cover innovative and value-based Laboratory Medicine which will be useful to all attendees.
The 28 symposia coordinated by SPC will cover a wide spectrum of important topics, including the current status of LM, new areas of service, research and development. They will consist of four invited lectures.
A substantial part of the program will be devoted to poster viewing and discussion.
Education workshops will be organized with the active support of the IVD industry, which will be reviewed by the SPC in order to be fully integrated in to the IFCC WorldLab Seoul 2022.
A number of satellite meetings will be organized either before or after the main Congress in collaboration with other related organizations.

3) Weekly agenda

SUNDAY 26 JUNE

17:30-19:30	OPENING CEREMONY
19:30-21:30	WELCOME PARTY

MONDAY 27 JUNE

10:00-17:30 EXHIBITION OPEN

	AUDITORIUM	ROOM 103	ROOM 101	ROOM 102	ROOM 104	ROOM 105
09:00-11:00	SYM1	SYM2	SYM3	SYM4	SYM5	IFCC SYM1
11:00-11:45	BREAK					
11:45-12:30	PL 1					
12:30-13:00	POSTER / LUNCH					
13:00-14:00		LW 1 Roche	LW 2 Binding Site	LW 3	LW4 Siemens	Korean Student Session
14:30-15:30	IFCC SYM 2 (15:00-17:00)	EDUW2 Roche 14.30-15.30	EDUW5 Snibe 14.30-15.30	EDUW8 Green Cross 14.30-15.30	EDUW11 Siemens 14.30-15.30	EDUW13 Beckman Coulter 14.30-15.30
16:00-17:00		EDUW3 Segeene 16.00-17.00	EDUW6	EDUW9 Green Cross 16.00-17.00	EDUW12 Arkray 15.30-16.30	EDUW14 Ortho Clinical D. (15:30-16:30)
17:30-18:30	EDUW1 (17.30-18.30)	EDUW4 (17.30-18.30)	EDUW7 (17.30-18.30)	EDUW10 (17.30-18.30)	SYM6 (16:30-18:30)	SYM7 (16:30-18:30)

TUESDAY 28 JUNE

10:00-17:30 EXHIBITION OPEN

	AUDITORIUM	ROOM 103	ROOM 101	ROOM 102	ROOM 104	ROOM 105
09:00-11:00	SYM8	SYM9	SYM1	SYM11	SYM12	IFCC SYM3
11:00-11:45	BREAK					
11:45-12:30	PL 2					
12:30-13:00	POSTER / LUNCH					
13:00-14:00		LW 6	LW 7 Abbott	LW 8 Green Cross	LW 9 Sysmex	Korean Student Session
14:30-15:30	IFCC SYM 4 (15:00-17:00)	EDUW16 Roche 14.30-15.30	EDUW19 Beckman Coulter 14.30-15.30	EDUW22 Siemens 14.30-15.30	EDUW25 Sebia 14.30-15.30	EDUW27 SCL Lab 14.30-15.30
16:00-17:00		EDUW17 Snibe 16.00-17.00	EDUW20 Bio-Rad 16.00-17.00	EDUW23 Sekisui 16:00-17.00	EDUW26 Thermo Fisher 15:30-16:30	EDUW28 Hanlab 15:30-16:30
17:30-18:30	EDUW15 (17.30-18.30)	EDUW18 17.30-18.30	EDUW21 Handok (17.30-18.30)	EDUW24 (17.30-18.30)	SYM13 (16:30-18:30)	SYM14 (16:30-18:30)

WEDNESDAY 29 JUNE

10:00-17:30 EXHIBITION OPEN

	AUDITORIUM	ROOM 103	ROOM 101	ROOM 102	ROOM 104	ROOM 105
09:00-11:00	SYM15	SYM16	SYM17	SYM18	SYM19	SYM20
11:00-11:45	BREAK					
11:45-12:30	PL 3					
12:30-13:00	POSTER / LUNCH					
13:00-14:00		LW	LW 12 Abbott	LW 13	LW 14 Sysmex	LW 15
14:30-15:30	IFCC SYM 5 (15:00-17:00)	SYM 29 (14.30-16.30)	EDUW33 BD (14.30-15.30)	SYM 31 (14.30-15.30)	SYM 30 (14.30-16.30)	SYM 32 (14.30-16:30)
16:00-17:00			EDUW34 (16.00-17.00)	EDUW37 (16.00-17.00)		
17:30-18:30	EDUW29 (17.30-18.30)	EDUW32 (17.30-18.30)	EDUW35 (17.30-18.30)	EDUW38 (17.30-18.30)	SYM21 (16:30-18:30)	SYM22 (16:30-18:30)

THURSDAY 30 JUNE

	AUDITORIUM	ROOM 103	ROOM 101	ROOM 102	ROOM 104	ROOM 105
09:00-11:00	SYM23	SYM24	SYM25	SYM26	SYM27	SYM28
11:00-11:45	BREAK					
11:45-12:30	PL 4					
12:30-13:00	CLOSING CEREMONY					

4) Abstract Submission

- Submission Closing: January 15, 2022 at 18:30 CET.
- Submission Acceptance Notice: February 28, 2022.
- Register presenter: Presenting Author must register as Full Registration on IFCC2022.

5) Registration

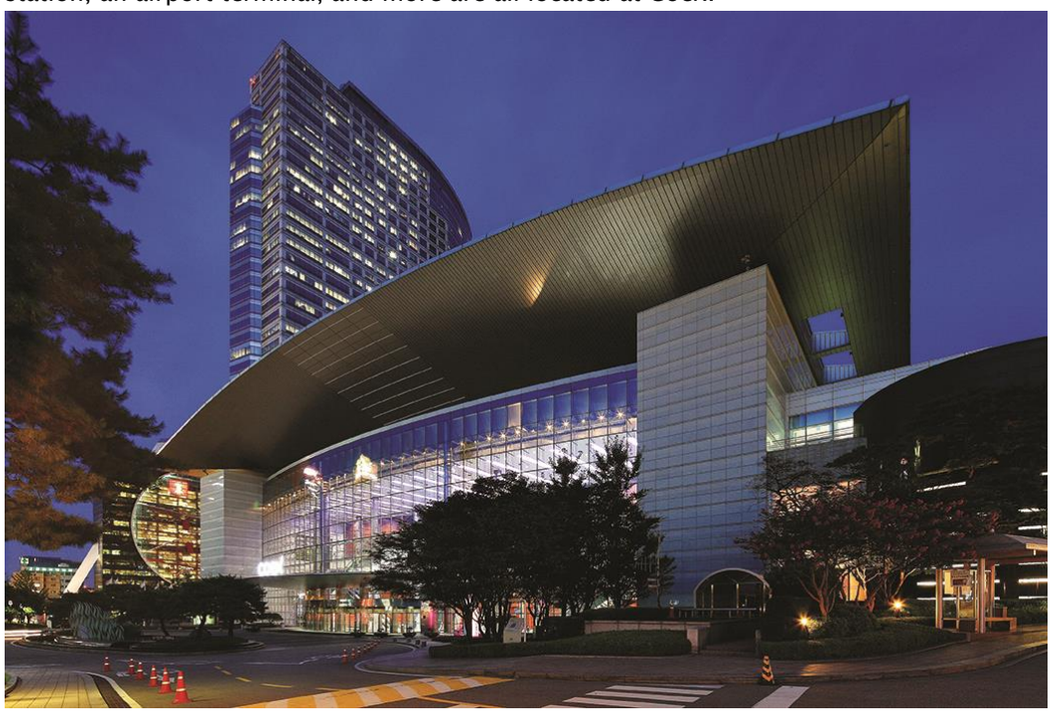
- All delegates must register for the congress. Registration fees (no VAT applied) are as follows:

Table 1 Registration Fees

Registration	Until March 31, 2022	After March 31, 2022	On-site
Full Registration	€ 500	€ 650	€ 750
Young Registration & Technicians (from Korea)	€ 250	€ 325	€ 375
Day Registration	€ 150	€ 200	€ 250

6) Venue

Coex is a business and cultural hub located in the heart of Gangnam, Seoul's business district. It is a popular entertainment destination in Seoul for both domestic and foreign visitors, and welcomes an average of 150,000 people a day. Asia's largest underground mall, three five-star hotels, two premier office towers, a department store, a subway station, an airport terminal, and more are all located at Coex.



Conference venue

The organizing committee are sure that the 24th IFCC WorldLab & 16th APFCB will be a rewarding and unforgettable experience for all participants attending from around the world. We look forward to meeting you at the 24th IFCC WorldLab & 16th APFCB in Korea.

Won-Ki Min M.D., Ph.D.
Congress President,
24th IFCC WorldLab & 16th APFCB

Junghan Song M.D., Ph.D.
Congress Organizing Committee Chair
24th IFCC WorldLab & 16th APFCB

Sail Chun M.D., Ph.D.
Scientific Programme Committee Chair,
24th IFCC WorldLab & 16th APFCB

Jehoon Lee M.D., Ph.D.
President,
Korean Society of Clinical Chemistry

2. 2021 KSCC Biannual Fall Meeting

The Autumn Conference of Korean Society of Clinical Chemistry was held as an online conference on October 21th, 2021. It was the third online conference since last year's autumn conference. The online symposium (2 sessions, 4 major topics, 13 postponements) was held in real-time, and the review course (12 postponements) was provided for 17 days from October 22nd (Fri) to November 7th (Sunday) only for registrants.

The number of registered participants at the conference was 358, including 225 clinical pathologists, 52 resident doctors, 19 certified laboratory technologies, and 62 participants from in vitro diagnostic companies, a slight increase from 350 in the last spring conference. The number of review course registrations was 159.

Scenes at the 2021 KSCC Biannual Fall Meeting.

In the symposium session 1, there were lectures on "Current State of Laboratory Quality Management" and "The Latest Trends in Drug of Abuse Testing." The first half covered the explanation of the concept of total allowable error and how to apply it to practice, practical application of the HIL index provided by automated chemistry analyzers, and how to evaluate and resolve interference impacts in practice. In the second half, lectures were given on the recent trends of drugs of abuse and forensic toxicological analysis, screening of abuse drugs in clinical laboratories, and confirmatory testing of abuse drugs with mass spectrometry.

In the symposium session 2, there were “Education Workshop” and lectures on “The New Biomarkers”. In the Education Workshop, four companies, Abbott, Beckman Coulter, Roche, and Siemens, gave presentations on the clinical usefulness of procalcitonin for sepsis prediction, diagnostic performance of cardiac troponin assays using 99 percentile reference interval, the use of everolimus test in liver transplantation, and clinical utility of free light chain assay, respectively.

The second half covered introductions of new biomarkers, in vitro diagnostic multivariate index assay, and biomarkers for interstitial lung disease such as KL-6, SP-A, and CCL18. The participants could take information on a trend of analyzing new biomarkers such as LuRI, M2BPGi, beta D glucan, and EDN.

The review course of this conference has increased to 12 topics, enriching it more. This is accessible only to members who pay the annual fee.

⊙ Symposium (October 21th, 2021)

Time	Description	Speaker
09:00~09:10	Registration / Opening Address / Congratulatory Address / Awards	
	Opening Address	Jehoon Lee (President, Korean Society of Clinical Chemistry – KSCC)
	Congratulatory Address	Gye Cheol Kwon (CEO, Korean Society for Laboratory Medicine – KSLM) Won-Ki Min (President, Korean Association of External Quality Assessment Service – KEQAS)
	Awards Announcement (Best Papers)	
09:10~11:50	Session 1 [Current State of Laboratory Quality Management VI, The Latest Trends in Drug of Abuse Testing].	
	Current State of Laboratory Quality Management VI.	Chair: Won-Ki Min (University of Ulsan, College of Medicine)
	Practical application of total allowable error.	Jong Do Seo (Konkuk University, School of Medicine)
	Practical application of the HIL index.	Sollip Kim (Inje University, College of Medicine)
	How to investigate and manage interferences.	Kyoung-Jin Park (Sungkyunkwan University, School of Medicine)
	Q&A	
	The Latest Trends in Drug of Abuse Testing.	Chair: Min-Jeong Park (Hallym University, College of Medicine)
	Recent trends of drugs of abuse and forensic toxicological analysis.	Sanggil Choe (National Forensic Service)
	Drugs of abuse screening tests in the clinical laboratory.	Hae In Bang (Soonchunhyang University, College of Medicine)
	Confirmatory test for drugs of abuse.	Youngwon Nam (Seoul National University, College of Medicine)
	Q&A	
11:50~12:50	**Lunch Break**	

12:50~15:30	Session 2 [Education Workshop, The New Biomarkers].	
	Education Workshop	Chair: Jehoon Lee (The Catholic University of Korea, College of Medicine)
	Clinical utility of PCT for possible sepsis.	KyungEun Bae (Abbott)
	Diagnostic performance of cardiac troponin assays using the 99th percentile reference limit in angina, acute myocardial infarction (AMI), and other cardiovascular diseases.	Yeongsic Kim (The Catholic University of Korea, College of Medicine/Beckman Coulter Korea Ltd.)
	Everolimus usage in liver transplantation .	Suk Kyun Hong (Division of HBP surgery, Department of Surgery Seoul National University Hospital/Roche Diagnostics Korea Co., Ltd.)
	Clinical utility of free light chain (FLC) assay.	SungMin Kim (SIEMENS Healthineers)
	Q&A	
	The New Biomarkers	Chair: Pil Whan Park (Gachon University, College of Medicine)
	Novel biomarkers	Jaehoon Choi (EONE Laboratories)
	In Vitro Diagnostic Multivariate Index Assay, IVD-MIA.	Hae-il Park (The Catholic University of Korea, College of Medicine)
	Biomarkers in interstitial lung disease.	Hongseok Yoo (Division of Pulmonary and Critical Care Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine)
	Q&A	
15:30~15:50	Closing Address	

⊙ Review Courses

Session	Description	Speaker
RC1	External quality assessment in clinical chemistry.	Sunhyun Ahn (Seoul Clinical Laboratories)
RC2	Interpretation and corrective action of proficiency test results.	Yong-Wha Lee (Soonchunhyang University, College of Medicine)
RC3	Basic requirements for total laboratory automation.	Hyojin Chae (The Catholic University of Korea, College of Medicine)
RC4	Useful information resources in clinical chemistry.	Hyun-Ki Kim (University of Ulsan, College of Medicine)
RC5	Standardization status of clinical chemistry tests.	Sang-Guk Lee (Yonsei University, College of Medicine)
RC6	Practical methods for evaluating assay performances.	Jooyoung Cho (Yonsei University Wonju College of Medicine)
RC7	Understanding POCT	Hyung-Doo Park (Sungkyunkwan University, School of Medicine)
RC8	Preanalytical variables	Jae-Woo Chung (Dongguk University, College of Medicine)
RC9	Enzymes part I	Chul Min Park (Dongnam Institute of Radiological & Medical Sciences)
RC10	Enzymes part II	So Young Kang (Kyung Hee University, College of Medicine)
RC11	Urine dipstick test and sediment analysis.	Sun Min Lee (Pusan National University, School of Medicine)
RC12	Analysis of body fluids in clinical chemistry.	Eun-Jung Cho (Hallym University, College of Medicine)

Malaysian Association of Clinical Biochemists (MACB)

Dr. Raja Elina Raja Aziddin, President, MACB

1. Membership to the EFLM e-Academy

The EFLM Academy provides a package of professional benefits for individuals working in the field of laboratory medicine. As a service to its members, the MACB made a block enrolment to the EFLM e-Academy for year 2021. A certificate of registration to the Academy and personal credentials to log-in to the website were provided to 47 MACB members who enrolled in the Academy.

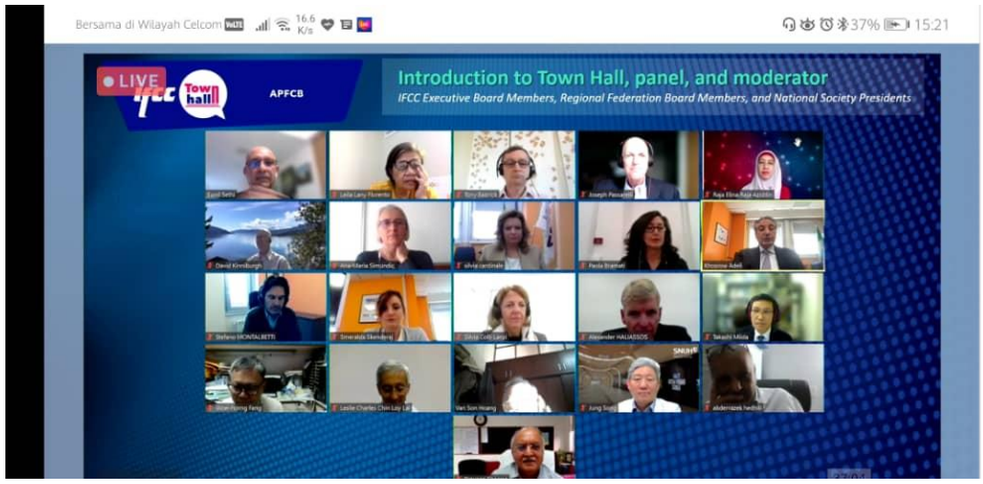
On 3rd June 2021, the president of MACB attended a zoom meeting that was organised by the EFLM for National Societies who are members of the Academy. At the meeting the EFLM President, C-P Chair and Executive Board members, presented new exciting, important benefits of EFLM Academy membership.

MACB President at the meeting organized by EFLM on the EFLM Academy.

MACB members found the Academy a very beneficial resource for learning. On 1st December 2021, the MACB renewed the existing membership to the Academy and also registered additional members to the Academy. In total, 91 MACB members were registered to the EFLM Academy for 2022.

2. Participation in the IFCC Townhall for APFCB Region

The MACB Council participated in the IFCC Townhall that was organized for the APFCB region on 20th October, 2021. The event provided an opportunity for members to interact and ask questions with the IFCC president and Executive board.



MACB participation at the IFCC Townhall organized for the APFCB region.

MACB requested IFCC to continue hosting hybrid meetings and conferences as the Covid-19 travel restrictions are still imposed by the Malaysian government. Hybrid meetings and conferences are also more affordable and therefore will encourage a bigger participation from Malaysian delegates.

3. MACB 31st Annual General Meeting

The 31st Malaysian Association of Clinical Biochemists (MACB) Annual General Meeting (AGM) for 2021 was successfully carried out virtually on Tuesday. 26th. Oct, 2021.

Pre-AGM Scientific Program

Prior to the 31st MACB AGM, a 2-hr scientific program was organised for members. In the first hour, a webinar on the topic of Method Verification for Qualitative Tests for delivered by Associate Professor Dr. Pavai Sthaneswar from University Malaya Medical Centre.

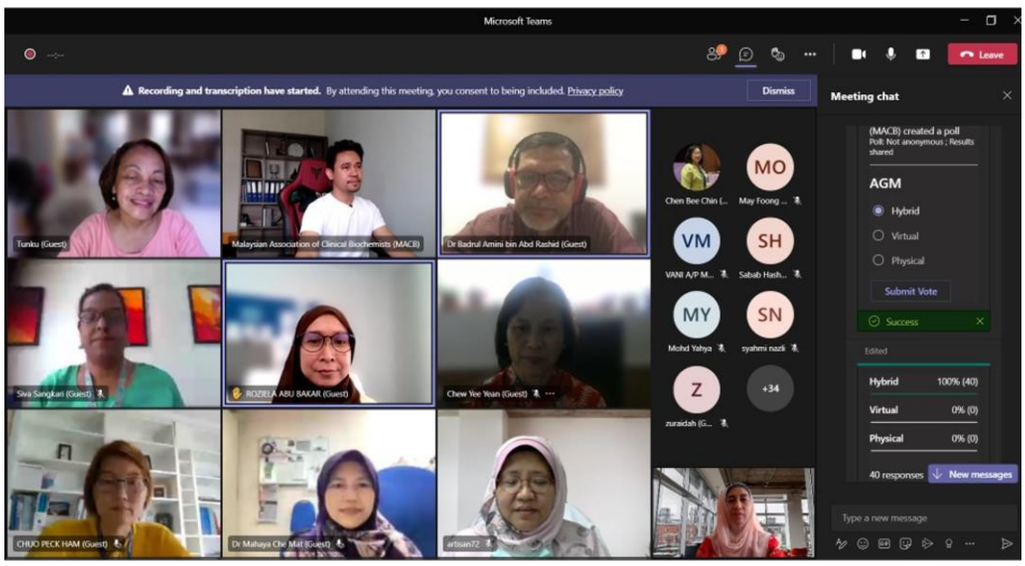
This was followed by a forum on the topic 'A practical approach to lot-to-lot verification'. The 3 panellists for the forum were Dr. Tony Badrick, CEO of RCPAQAP, Dr. Nor'ashikin bt Othman from Hospital Kuala Lumpur and Rozita Abdullah from Hospital Sg Buloh. The forum was moderated by Dr. Raja Elina, President of MACB.

The scientific program received good response and had active participation from members.

Forum on the topic 'A practical approach to Lot-to-lot verification'.

4. Annual General Meeting

The AGM began with the President's address. The president presented MACB's activities and achievements in 2021. She encouraged more members to join the various committees. She also presented the future plans and activities for 2022 which includes webinars, workshops on method verification and a project on Measurably Better Healthcare Performance.



Attendees at the 31st MACB Annual General Meeting.

The Annual report was presented by the MACB secretary and chairs of committees. MACB treasurer presented the financial report. The AGM was attended by 84 MACB members.

5. Project on Method Evaluation for TSH, PCT and HFABP diagnostic kits

The MACB coordinated a research project in 2020 that was completed in 2021. The project was a collaboration between Hospital Canselor Tunku Muhriz UKM (HCTM UKM), Malaysian Association Clinical Biochemist (MACB) and Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE). The project involved method evaluation for Maglumi Thyroid Stimulating Hormone (TSH), Procalcitonin (PCT) and Heart Fatty Acid Binding Protein (HFABP) diagnostic kits on Maglumi 1000 analyzer. The objectives of the study were as follows:

- To verify the performance of Maglumi 1000 analyzer for precision, accuracy, linearity range and Limit of Quantitation (Functional Sensitivity) as compared to manufacturer's claim and analytical quality requirement.
- To evaluate the correlation between Maglumi 1000 VS Architect i2000sr for TSH assay, Maglumi 1000 VS Cobas e411 for PCT assay and Maglumi 1000 VS HUMASIS Hubi-QuanPRO for HFABP assay.
- To provide objective evidence that the new analyzer fulfills the requirements for a specific intended use.

Results of the TSH study was presented in a poster presentation at the 31st MACB Conference on 21-22nd June 2021. A complete report on the study was completed on 12th July 2021 and will be published in a scientific journal in the near future.

6. Project on Measurably Better Healthcare Performance

The MACB launched the project to encourage inter-disciplinary collaboration and to promote a value-based approach in the delivery of laboratory medicine services. The first meeting on the project was held virtually on 9th December 2021. Representatives from leading government and private hospitals and laboratories attended the meeting.

Virtual meeting on the Measurably Better Healthcare Performance project.

The MACB president gave a briefing on the project and Mr Lim Yew Khuay from Abbott presented some examples of projects from winners of the Univants Award program. This project is supported by Abbott Laboratories and is due to start in early 2022.

Philippines Association of Medical Technologists

1. CONVENTION TURN-OUT BREAKS RECORDS

The number of participants in the 57th PAMET Annual Convention broke attendance records for this year reaching a whopping 6,690 virtual participants. There were 1,668 participants from the National Capital Region, 2,132 from Northern Luzon, 1,287 from Southern Luzon, 772 from Visayas, 433 from Northern Mindanao, 366 from Southern Mindanao, and 32 international participants.

2The said event which was provided free and exclusive for PAMET members is the second time that PAMET is hosting a virtual convention and revolved on the theme 'Solidarity Towards International Recognition: PAMET Community in Unity.' *"We are very happy for the turnout of participants and this is in line with the commitment of PAMET to provide learning opportunities for its members. Truly this is one for the books,"* said Ms. Ma. Rita Cristina Sebastian, PAMET National Executive Secretary and Chair of the Committee on Registration.

The event was broadcasted live from Joy Nolstag Hotel & Suites Manila in Ortigas and was streamed via MS Teams to thousands of virtual participants. Special events were likewise live streamed via Facebook in the official social media channels of PAMET.

2. LABEXPO 2021

PAMET launched a virtual exposition of the latest and cutting-edge technology from its diagnostic industry partners dubbed LABEXpo 2021 with 26 companies participating.

We would like to extend our gratitude for all the companies who participated namely: Snibe Diagnostic, Ortho-Clinical Diagnostics, Serodiagnostic Trading, Guille-Bern Corporation, Scientific Biotech Specialties, FIRMED Enterprises, Mindray, BioSystems, Esco Lifesciences Group, FAS Diagnostic Group, Sysmex Philippines, Medical Test Systems, Labmate Pharma, Zafire Distributors, RGL Bioalliance Corporation, Allied Hospital Supply International, Biosite Medical Instruments, BD Philippines, One Mark Engineering Technologies, Grepcor Diamonde, Erba Mannheim, Lifeline Diagnostics, Medical Trends and Technologies, Vitaline Healthcare, Abbott Laboratories and Siemens Healthineers.

3. President's Message

Good day to all!

Thank you for celebrating with us, this 57th Annual Convention. I am pleased to welcome all of you, especially those who have been with us for a long time. Good night to all through good and challenging times, and the new members of our family. Thank you for the continuous trust. Today marks our 57th yearly tradition and the 2nd Virtual Annual Convention. The officers and board of directors of the Philippine Association of Medical Technologists are glad that once again we fulfill our oath to our beloved organization, that is, to strengthen our unity through general assembly despite the challenges in connectivity and technology.

In this regard, I would like to emphasize my earnest appreciation to all of you who made a difference to make this occasion a success: the PAMET officers, board of directors, and staff, various committees, and chapters. We couldn't have done it without you!

In this year's convention, central is on how we can accomplish our organizational goal, the international recognition that PAMET deserves. We are all willing to participate in every activity of our association due to our shared passion for PAMET's vision and mission. Our passion bind us together, and the energy we create permits us to attain not just our personal goals but also the dreams of our organization. With the help of our Almighty God, we will remain united. In the words of the psalmist, let us say to one another virtually, "God is our refuge and strength, an ever-present help in trouble" (Psalm 46:1). In this 3-day conference, we will learn from the experiences of the resource speakers that will further develop both our personal and professional competencies. Likewise, the learnings from this convention are springboards toward the international recognition of PAMET, with fervent hoped that after this gathering, we will go back to our respective institutions with greater skills and reflections.

Again, a warm welcome to the PAMET annual convention, stay safe and healthy, and thank you for your attention.

4. ASCLS President Graces Opening Ceremonies

Dr. Hazzan Aziz, President of the American Society for Clinical Laboratory Sciences, graced the opening of the 57th PAMET Annual Convention as keynote lecturer, 01 December 2021.

His keynote lecture delved on building resilience at work. In his discussion, he mentioned that resilience is the ability to recover from and or adjust readily to adversity or change. He further imparted that resilience is developed over time and is a universal human ability to thrive despite of setbacks. He also discussed how to develop resilience particularly resilient leadership and in closing mentioned that resilience is a psychological strength that can help as adapt and grow despite challenges. Further, it is not fixed state and can be developed and enhanced with strategies and flexible thinking.

5. 2021 MedTech Scholars Recognized by PAMET

The 2021 Batch of PAMET-Safeguard MedTechs ng Kinabukasan Scholarship Program was announced in a virtual awarding ceremony as part of the 57th PAMET Annual Convention, 02 December 2021.

In 1989, Safeguard partnered with PAMET for the first "Handog ng Safeguard: MedTechs ng Kinabukasan" Scholarship Program. Each Year, Safeguard and PAMET support intellectually gifted but financially needy Medical Technology students. To date, they have awarded over 300 scholarships. The PAMET scholarship committee is chaired by the PAMET National Vice President Mr. Ricky Martinez who also chairs the education committee. The awarded scholars were Hannah Develos, Keya Gargar, Jennilie Del Rosario, Angelica Jazmin Gallego, Dagny Dominique Aquino, Ivan Casinillo, Cleofe Dian Galamiton, Verlie Jean Firmeza, Rhea Mae Corros, Rochelle Avendano, Mia Girley Tomboc, Trishia Canlas, Shanly Yanna Granada, Jan Lorden-Gail Codilana and Nicole Angeline Apura. Meanwhile, the Best Essay was awarded to Jennilie Del Rosario.

The scholars will be receiving full support for their academics.

6. Digital System in Data Management for COVID-19 Cases

Dr. Jomar Rajabante of the University of the Philippines gave a glimpse into the number crunching involved in the epidemiological mapping of the COVID-19 pandemic. The number of COVID-19 cases is continuously increasing in different countries including the Philippines.

It is estimated that the basic reproductive number of COVID-19 is around 1.5 to 4. The basic reproductive number characterizes the average number of persons that a primary case can directly infect in a population full of susceptible individuals. However, there can be superspreaders that can infect more than this estimated basic reproductive number. To describe and predict the dynamics of the disease, several preliminary mathematical models are formulated by various international study groups. Here, the insights that can be drawn from these models are discussed, especially as inputs for designing strategies to control the epidemics. Proposed model-based strategies on how to prevent the spread of the disease in local setting, such as during large social gatherings, are also presented. The model shows that the exposure time is a significant factor in spreading the disease.

With a basic reproduction number equal to 2, and 14-day infectious period, an infected person staying more than 9 hours in the event could infect other people. Assuming the exposure time is 18 hours, the model recommends that attendees of the social gathering should have a protection with more than 70 percent effectiveness. In a study, a conceptual mathematical model on the transmission dynamics of COVID-19 between the frontliners and the general public was formulated. It was assumed that the general public has a reproductive number between 1.5 to 4, and frontliners (e.g. healthcare workers, customer service and retail personnel, food service crews, and transport or delivery workers) have a higher reproduction number. The simulations show that both the frontliners and the general public should be protected or resilient against the disease. Protecting only the frontliners will not result in flattening the epidemic curve. Protecting only the general public may flatten the epidemic curve but the infection risk faced by the frontliners is still high, which may eventually affect their work. The simple model does not consider all factors involved in COVID-19 transmission in a community, but the insights from the model results remind us of the importance of community effort in controlling the transmission of the disease. All in all, the take-home message is that everyone in the community, whether a frontliner or not, should be protected or should implement preventive measures to avoid being infected.

7. A Star-Studded Chapters' and Fellowship Night Hosted

Last December 2, 2021, the Committee on Socials, headed by National P.R.O. Mark Raymund G. Nava, hosted the first virtual chapters and fellowship night. A talent competition entitled "PAMET GOT TALENT" was held with 11 competing local chapters. Three (3) chapters represented the Southern Luzon Region namely: Palawan, Quezon, Laguna; and six (6) chapters, Bulacan, La Union, Ilocos Norte, Nueva Vizcaya-Ifugao and Pampanga, were from Northern Luzon. The Visayas and Mindanao were represented by one (1) contestant each - Antique and North Cotabato respectively. The event was graced by performances from celebrity guests Rachel Alejandro and Geneva Cruz. The event was hosted by Dr. Philip Bujongan.

Invited judges for the event were also celebrities: MightyMyke, a famous Medical Technologist vlogger and content creator; Isa Avendaño-Umali, a GMA/DZBB News Reporter who have been advocating for Medical Technologists as frontliner thru her platforms; and Dr. Rona Libby-Narvaez, former PBB Teen Plus Edition housemate who later became a Safeguard scholar and a Registered Medical Technologist and Physician.

The winners of this year's competition were:

Champion – Nueva Vizcaya-Ifugao Chapter – Aubrey Baby Ruth Nidea:

a. 1st Runner-up – Palawan Chapter – Jewel Darlene Flores.
b. 2nd Runner up – Pampanga – Paula Caryl Aquino.

Chapters who celebrated their milestone anniversaries and those who hosted the 2021 Midyear Convention and Regional Conferences were also awarded. Thirty (30) lucky viewers were treated with raffle prizes of 300 e-Cash and one (1) lucky winner got a 3 days and 2 nights roundtrip to Boracay or Bohol for 2.

This year's chapters night was chaired by the national PRC Mr. Mark Raymund Nava. The prizes were made possible through the generous help of PAMET's company sponsors.

Guardian of the genome and cancer research

Cancer is the leading cause of death worldwide. Currently, cancer treatment strategies include surgery, chemotherapy, radiation therapy, hormonal therapy, immune therapy, and targeted therapy which can be used alone or in combination. However, some cancers are still not curable, and the treatment outcome is poor. Moreover, acquired drug resistance is a major limitation for the successful treatment of several cancers. Related to this, Dr. Chotiros Plabplueng of Mahidol University in Thailand delivered a very comprehensive lecture in advances in cancer research with focus on tumour suppressor protein.

Tumour suppressor protein p53 (TP53) is a nuclear transcription factor known as "Guardian of genome". It has been well accepted that TP53 plays a critical role in maintaining genomic stability of the cells and prevent the proliferation of cells with serious DNA damage through an activation of numerous target genes involved in the induction of cell cycle arrest, senescence and apoptosis. TP53 is the most frequently mutated gene in cancer. More than 50% of human cancers loss TP53 function or have TP53 mutation. Importantly, it has been shown that cancers harbour TP53 mutations or loss TP53 function frequently progress more rapidly, have a poor response to anticancer therapy, and have a poor prognosis.

Therefore, TP53 becomes valuable target for cancer research. For cancer treatment, TP53 plays a major role in the response of cancer cells to many anticancer drugs, particularly those that cause DNA damage. Therefore, the study to investigate the strategy for manipulation of TP53 in order to either target mutated TP53 or restore normal TP53 function to increase treatment efficacy and suppress the formation of cancer as well as mechanism study to provide information about what the TP53 response will be: arrest, senescence, or apoptosis are still attractive and needed. This information will provide a great benefit in designing a personalized tumour treatment regimen in the future.

Virtual Event: Roche Experience Days 2021

Roche Experience Days (RED) is an educational, non-product promotional event focusing on a myriad of topics ranging from laboratory testing efficiency to the broader topic of healthcare trends and landscape. First started in 2016, its objective was to fill a gap in the in vitro diagnostics (IVD) industry as a platform to exchange, share and network amongst healthcare professionals.

Since then, RED has evolved into an annual staple event for Roche Diagnostics APAC where thought leaders, key opinion leaders (KOLs), healthcare innovators across the global come together to deep dive into topics to shape the rapidly changing healthcare landscape.

Evolution of Roche Experience Days.

RED 2021 was held on the 16th and 17th November 2021 with the overall theme of **Recognise**, **Empower** and **Discover**.

As the world continues to battle COVID, the RED 2021 organising team aspires to Recognise the efforts from all levels within the healthcare industry; continue to Empower our healthcare professionals with the latest diagnostic technology to fight the long-running battle efficiently and concurrently, Discover the vital role that diagnostics play in the shaping of healthcare landscape's present and future.

The year 2021 is the second consecutive year in which the event is run virtually. With the ambition of bringing a bigger and better virtual experience for the participants – the event catered to real-time language interpretation and parallel programme tracks to allow for a wider and customisable selection according to individual preferences.

Agenda

Tuesday, November 16th 2021 (GMT+8)
THEME: Powering Diagnostics
Track 1 - Strengthening the Core; Track 2 - Expanding the Core
TOPIC: Laboratory Management & Digital Transformation

14:00 -14:10	Welcome Address	Dr. Thomas Schinecker *CEO, Roche Diagnostics*
14:10 –14:40	Life after COVID: Disease Management and Diagnostics in the Post-Pandemic Era	Prof. Teo Yik Ying - Moderator *Singapore* Mr. Anand K *India* Mr. Anand Swaminathan *Singapore* Dr. Chris Douglas *Australia* Dr. Harish Pillai *Philippines*
14:40 –15:20	Track 1: Strengthening the Core Case Study from India: Managing Lab Challenges in times of Pandemic Track 2: Expanding the Core Post-COVID-19 Policies and Impact	Ms. Ameera Shah *India* Dr. Khor Swee Kheng *Malaysia*
15:20 – 15:35	Drawing Patient Closer to Lab: The Journey of a Breast Cancer Survivor, Member and Volunteer of Breast Cancer Foundation	Ms. Noren Suseno *Singapore*
15:35 –16:15	Track 1: Strengthening the Core Challenges in "New Normal": Medical Laboratory Management Track 2: Expanding the Core Picking Up the Pieces after COVID-19 Tsunami: Building-back-better Health System in India	Col. Pitipat Jamnarnwej M.D *Thailand* Dr. Indu Bhushan *India*
16:15 – 16:30	Drawing Patient Closer to Labs: Enabling Patient's Access to Healthcare by GIVE.asia	Mr. Dennis Yeo *Singapore* Mr. Pong Yu Ming *Singapore*
16:30 –17:00	Virtual Reference Site Visit: Taipei Veterans General Hospital – Impact of Innovation on Patients and Society	Prof. Chou Teh Ying *Taiwan*

RED 2021 Event Agenda, Day 1

Agenda

Wednesday, November 17th 2021 (GMT+8)
THEME: Venturing in Space
Track 1 - Breaking Boundaries; Track 2 - Exploring Beyond
TOPIC: Hospital Management, Business Strategy, Economic & Regulatory, Digital Technology & Innovation

13:30 – 13:40	Welcome Address	Ms. Wendy Bao *Chapter Lead,* *Innovation & Strategy* *Roche Diagnostics Asia Pacific*
13:40 – 14:15	Track 1: Breaking Boundaries Leading Innovation as Future-Proof Hospital Track 2: Exploring Beyond Shaping a Healthcare Ecosystem: Perspective of a Non-Healthcare Player	Adj. Prof. Hananiel Widjaya *Indonesia* Mr. Dirk Dumortier *Singapore*
14:15 – 14:30	Featured Startup – Fertility Care	Ava *Switzerland*
14:30 – 15:05	Perks of the Pandemic – Patient Reflections	Ms. Jessica Bean *Australia*
15:05 –15:20	Featured Startup – Diabetes Care	Fitterfly *India*
15:20 – 15:55	Virtual Home Monitoring Point-of-Care Testing in Country Practice	Ms. Rosy Tirimacco *Australia*
15:55 – 16:10	Featured Startup – Diabetes Care	Gemii *China*
16:10 – 16:45	Track 1: Breaking Boundaries Precision Public Health - What is it and Why Should Anybody Care? Track 2: Exploring Beyond Changing Insurance Landscape	Associate Prof. Jeremy Lim *Singapore* Ms. Susan Fanning *Thailand*
16:45 – 17:00	Closing Remarks	Mr. Lance Little *Managing Director,* *Region Asia Pacific* *Roche Diagnostics Asia Pacific*

RED 2021 Event Agenda, Day 2.

Day 1 of the event explored the theme of **Powering Diagnostics**. Bringing perspectives from both sides of the coin – from KOLs to patients on how the COVID-19 pandemic has brought about a change in disease management, clinical and laboratory practices to ensure that every individual's medical needs are met. Another facet is added by peering into how non-profit organisations such as GIVE.asia support those who have fallen through the cracks of life, ensuring that medical care is also accessible to those who need it when they need it.

Day 1 ended on a high note with a virtual reference site visit to Taipei Veterans General Hospital (VGH-TPE). It is during this segment that we see how VGH-TPE leverage the latest technologies and innovative solutions to improve not only healthcare outcomes, but also paved the way towards their vision as a trendsetter of healthcare standards in Taiwan and beyond.

Behind-the-scenes, Part 1: Day 1 emcees – Ms. Jessica Lim (Lab Consulting Manager, Application & Consulting Team, Lab & C-Suite Value Stream, Roche Diagnostics APAC) & Ms. Yvonn Ong (Multi-Channel Marketing Manager, Customer Engagement Team, Business Excellence Chapter, Roche Diagnostics APAC), preparing themselves for the live action.

The theme of Day 2 is **Venturing in Space**. While the COVID-19 pandemic has definitely affected everyone one way or another, it has also accelerated the implementation and adoption of revised healthcare policies and practices by increasing awareness on the importance of insurance and digitalisation in the healthcare space.

On Day 2, industry leaders and experts spoke on how the various healthcare stakeholders and start-ups can potentially synergise to build a more sustainable healthcare ecosystem. With the increased emphasis on patient-centricity, RED 2021 brought a strong voice in the form of a patient advocate who shared candidly her experience being a patient in this era of rapid change and what she would like the industry, healthcare providers and decision-makers to consider as next steps of improving digital health technology.

Day 2's highlights are a series of short talks featuring selected start-ups. These talks are distilled down to the essence with the aim to inspire the healthcare community to challenge status quo and drive transformation.

Behind-the-scenes, Part 2: One of our Day 2 emcees, Ms. Polly Wu (Business Lead, Lab IT & Workflow Automation, Lab & C-Suite Value Stream, Roche Diagnostics APAC) with one of our many prestigious speakers, A/Prof. Jeremy Lim during the live Q&A session.

The event was brought to a memorable end with an emphatic message of diagnostics being the backbone of healthcare in the closing remarks delivered by Mr. Lance Little, Managing Director of Roche Diagnostics APAC. As part of the closing, participants were encouraged to reflect on the key takeaways and how they could be applied in the real world.

The closing of one chapter marks the opening of another – planning of RED 2022 is very much already underway. The event will strive to revamp itself while staying true to its purpose. Stay tuned!

Written by:

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Toward a rapid digital health transformation

Bernard GOUGET; *Chair-IFCC Committee on Mobile Health and Bioengineering in Laboratory Medicine (C-MHBLM), Chair IFCC-TF on History, SFBC-International Committee, President-Human Health Care Committee-Cofrac, President-National Committee for selection of the French Reference Laboratories, Ministry of Health (France).*

E-health is a field in full development that takes various forms in response to the many challenges that health systems currently face or will face in the next few years. E-health, also called digital health or connected health, is not limited to teleconsultation, the use of which has accelerated considerably due to the COVID-19 epidemic. According WHO, The term digital health may conjure images of advanced, futuristic technology, but in fact it can include a range of interventions, including: electronic health records and standards underpinning the exchange of data; mobile health apps for monitoring and prevention; public health portals that provide transparent access to an individual's personal health records and contacts with the health system; telemedicine; teleconsultation, medical telemonitoring, as well as mobile health (or m-health) which covers a wide universe of connected objects and mobile applications; integrated care delivery; clinical decision-making support tools in primary care; robotics; personalized medicine; nanotechnologies; and artificial intelligence.

Digital health has been seen for years as an emerging strategic health priority and its potential role has come under the spotlight during the COVID-19 pandemic when physical distancing measures and mobility restrictions were gradually adopted. The COVID-19 is redefining how and what care is delivered. Digital tools can provide effective support for institutions, allowing the deployment of novel digital healthcare models at different stakeholder levels from healthcare and research, to government and general population. All countries around the world are facing the challenge of ensuring that their health services are affordable, accessible, equitable, and of high quality. An increase in the deployment of digital health tools has been recorded in a number of countries and regions, which has helped make digital health tangible to many people for the first time. However, the WHO estimates that 3.6 billion people are completely offline. For the most part, they live in low-income countries, where barely two out of ten people on average have Internet access. More than ever, these new digital applications should make it possible for everyone to access the information they need. The COVID-19 pandemic is the first pandemic in human history in which technologies and social media have been used on a massive scale so that people can remain safe, productive and connected without being physically in contact. Health is now seen as one of the most important sectors for the introduction and deployment of digital technology as a way to strengthen and reform health systems, ensure continuity of care, and enable new ways to connect health professional, patients and other stakeholders with one another to improve patient care.

The pandemic represents an unprecedented worldwide crisis and has put pressure on health systems. It has been necessary to fight the pandemic and simultaneously care for the people affected and preserve the rest of the population, while continuing to care for other patients. These constraints have tested every organization and every staff member as well all the tools in place and has highlighted the key role of digital health. Governments have mobilized as much as possible to better integrate digital technologies such as contact tracing systems to monitor epidemic outbreaks. Given the need to control the coronavirus as quickly and effectively as possible, it is perhaps not surprising that the introduction of contact-tracing coronavirus apps has so far generated mixed results. In some countries adoption has been relatively slow, development has been difficult, and trust has not been sufficiently built up yet at the population level. Medical laboratories found themselves on the front line to manage processes encompassing testing and associated diagnostics, viral genomic monitoring and contact tracing with COVID-19 patients. Databases and data processing have been deployed on the national scale. Laboratory medicine specialists have also often been often called upon for intelligent vaccination management.

The introduction of digital tools also highlighted some of the challenges that naturally occur during any significant technological transition and will need to be addressed to safeguard the successful integration of digital tools into health systems, the recent developments of e-health are demonstrating how digital tools and services are becoming more concrete and valuable for end users. E-health takes various forms in response to the many challenges that healthcare systems currently face or will face in the next few years. It has quickly proven its usefulness to alleviate certain issues with health care accessibility. Online consultations made it possible to ensure the safety of healthcare professionals and patients as well as the continuity of care. In this context, it is essential that communication networks and services are reliable. Digital technology is present in many health organizations and professions. The crisis has generated a tremendous momentum for initiatives, in a very responsive environment: many digital solutions have been deployed on a large scale, start-ups and manufacturers have adapted their products almost in real time and new organizational methods have emerged to adapt to the constraints induced by the crisis. The need to urgently deal with lockdown and social distancing rules as well as the need to manage the health dimension has led to simplifying decision-making circuits. Procedures have given way to an action/reaction approach.

The acceleration of the deployment of these new tools has shown the need to reinforce the dissemination of knowledge in this area to guarantee good service delivery and to ensure that health systems benefit from new technologies. The crisis has been a vector for the global acculturation of patients around digital health. The outlook of both professionals and patients has changed with regard to digital technology thanks to the development of uses. Some patients and healthcare professionals thought that digital technology would dehumanize their relationship. The COVID crisis has concretely demonstrated the value of digital technology and how it can be an additional connection or support. However, digital technology introduces a third party into the patient/caregiver relationship and the healthcare professional may appear less expert than the patient in the digital field.

The crisis has also generated a strong growth in the need for medical data exchange and sharing. The instantaneous addressing made possible by digital means may also have led the patient to think that the healthcare professional could be constantly on call. Nevertheless, the expected benefits are now widely recognized in terms of facilitating pathways, improving the appropriateness of care and limiting redundant examinations.

The crisis has accelerated the digital shift in hospitals, introduced all the possibilities of digital technology in medical and social institutions and improved the care of patients with chronic diseases. Many, technological platforms have been developed to ensure follow up at home of patients with COVID, thus limiting overcrowding of hospital services. The crisis has also highlighted the value of paperless approaches for certain processes such as making appointments and paperless collection of information and documents. Teleconsultation and telemedicine have exploded. Successive lockdowns have required patients and providers to use it extensively. Even when not in lockdown, the volume of teleconsultations has not necessarily declined. New practices have become permanent. The specialties that particularly made use of teleconsultation during the COVID crisis have been: general medicine, anaesthesia, obstetric and gynaecological follow-up, midwifery consultations, oncology follow-up, psychological follow-up, particularly relating to addictions, minor psychiatric care and patient triage to direct them according to the description of their symptoms.

Making health, medical and social processes paperless is currently a major efficiency challenge for the future. There are still several obstacles of a medical, technical and organizational nature. Teleconsultation can generate a loss of information in the absence of clinical examination. It is also felt to be more tiring than in-person consultation and requires greater concentration. The physician is often obligated to rephrase what patients say. Telemedicine requires appropriate equipment. Technical problems, such as sound and image as well as insufficient tools appropriation can disrupt the smooth progress of the teleconsultation. Except for managing laboratory data and simple prescriptions, management related to administrative tasks may be experienced at first as more important. These drawbacks are largely counterbalanced by the benefit of meeting patient needs in terms of saving time and improving quality of life and care of patients whose scheduled treatments have been cancelled. Teleconsultation also makes it possible to improve certain practices such as prescription adjustment or renewal for people having difficulty getting around and visual exchanges facilitate a close bond.

The development of telemedicine effectively proceeds through the democratization of connected health objects in the contexts of teleconsultation, medical telemonitoring or patient self-assessments. Numerous delocalized laboratory medicine tools facilitate communication between physician and patient. Beyond the simple use for one's own comfort or convenience, medicalized uses in connection with these objects must be developed within the framework of specific protocols. These remain to be built with healthcare professionals, especially prior to medical consultations or in the context of regular follow-up. The massive use of teleconsultation tools during the crisis has encouraged healthcare professionals to make these tools part of their everyday practice as long as they are solution-driven and benefit from good training in the rules and good remote work practices. The tools must make it possible to ensure the continuity of digital communication during the patient's pathway. The patient necessarily must be familiar with digital uses to be comfortable with these tools, which therefore introduce a new digital divide among patients, with digital illiteracy. E-health can also provide responses to demographic change, and in particular to the aging of the population, which is accompanied by an increase in medical needs. Among the promising prospects for e-health, the empowerment of patients with chronic diseases is often highlighted. Digital services can empower citizens, making it easier for them to take a greater role in the management of their own health from following prevention guidelines and being motivated to lead healthier lifestyles, to managing chronic conditions and providing feedback to healthcare providers. Health systems will also benefit from innovative care models that use telehealth and m-Health to address the rising demand for healthcare, helping to shift progressively towards integrated and personalised care systems.

Health data protection in digital health services is a central challenge to create trust. Cybersecurity remains another ongoing challenge, before, during and after the crisis. During COVID-19, illicit tracking applications hacked phones and phishing emails proliferated. Attacks on hospitals and healthcare companies have exploded. One of the common techniques consists of massive, organized attacks originating from all over the world which overload networks to render them unavailable. Secure access to data and secured sharing of these data are indispensable in order to allow healthcare professionals to exchange patient records and electronic prescriptions. For example, the European Commission is working on the creation of a European format for the exchange of electronic health records accessible to all EU citizens. Likewise, digital technology is set to play a key role in research data sharing, faster diagnosis and improved health.

There is a huge potential of health data to support medical research with the aim of improving prevention, diagnosis, treatments, drugs and medical devices. Several breakthrough technologies will certainly influence the development and prospects of digital health for the post-COVID period. This is primarily the case with artificial intelligence, whose potential has now been clearly demonstrated for applications in epidemiology, patient pre-orientation, rapid emergency triage, telemonitoring or diagnostic assistance, especially regarding medical imaging, laboratory medicine and drug prescription. The digital transition will be beneficial to everyone. Health is one of the target sectors, given the potential advantages that digital services can offer to citizens as well as healthcare institutions and businesses Digital solutions are also key to fighting climate change and achieving the green transition.

Exponential advancements in science and technology are transforming health and medicine and giving patients more control over their own health. The pandemic COVID-19 has forced eHealth into the lives of many. The influence of health technology in the fight against this pandemic is expected to be significant. The demand for eHealth is going viral and it is happening fast and globally. E-health therefore has many promising prospects to support the transformation of health systems faced with many current and future challenges. Its deployment represents major progress which, like all progress, involves overcoming certain challenges and considering certain watch points. It is still necessary to define a legal and regulatory framework suited to health innovation, to develop an appropriate assessment framework and to guarantee equitable access to e-health solutions to avoid increasing health inequality. Well defined and easy-to-understand guidelines for the day-to-day use of telehealth technologies in the context of COVID-19 are needed. They need to convey the message that eHealth solutions are a viable alternative in times of this pandemic and beyond. This requires more research and robust methods on validating online information while ensuring that human rights, privacy, and confidentiality are maintained.

Toxicology Testing and the Use of Rapid Test Kits

David W Kinniburgh, PhD, DABCC, FCACB and Melissa Bennett, PhD, MLT
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Testing for drugs (prescription or illegal) in biological fluids is useful in the management of potential overdose patients, as well as other clinical situations. Historically, the laboratory used simple chemistry, or spot tests, progressing to thin layer chromatography, laboratory-based immunoassays and specific chemical assays, gas chromatography/liquid chromatography coupled with mass spectrometry, and rapid test kits or Point of Care Test (POCT) devices. Modern toxicology laboratories in North America today still use immunoassays and specific chemistry tests, but sophisticated mass spectrometry systems and minimal sample pre-treatment methods are the gold standard in the opinion of toxicologists.

Knowledge of the specific substances involved in an overdose case can certainly be valuable to the medical team in determining and delivering treatment as rapidly as possible, particularly if an antidote is available for the toxin in question. In the past (and even in some labs today) mass spectrometry was employed to perform broad screens for drugs in patients presenting with suspected overdose (comprehensive drug screens). The limitation with such testing, even with today's modern equipment and methods, is that the turnaround time to produce results is not rapid enough to influence clinical decisions and treatment. Medical teams in emergency rooms evaluate patients on the basis of their signs and symptoms, plus any other available history or evidence, looking for toxidromes that suggest the class or type of drug or toxin involved, in order to provide lifesaving treatment as soon as possible. For example, if the patient has the typical signs and symptoms of an opioid overdose (pale and clammy skin, constricted pupils, limp body, purple/blue fingernails or lips, gurgling/vomiting, unresponsive/coma, respiratory and cardiac compromised/failure), or if this is even suspected, multiple doses of naloxone (Narcan) will be given and if the patient recovers the diagnosis is made.

Intensive supportive therapy, including mechanical ventilation, is used to keep the patient alive, while the clinical diagnosis progresses or until the effects of the drug are reduced, or an antidote has eased the symptoms. For the most part comprehensive drug testing, including that based on mass spectrometry, is not useful to guide clinical intervention for emergency overdose patients. Given these limitations, emergency room physicians and medical toxicologists recommend to evaluate emergency overdose patients on the basis of their signs and symptoms and treat patients with supportive measures as a first approach, unless rapid laboratory testing can identify a potential toxin with a high degree of certainty and an antidote is available (Christian et al., Clin. Tox. 10-21, 977-980, 2017; Stellpflug et al., J of Emerg. Nurs. Vol 46 (6), 923-931, 2020) Journal of emergency nursing, Vol.46 (6), 923-931, 2020).

However, specific chemical testing for salicylates, acetaminophen, ethanol, blood gases and basic chemistry parameters can be very useful, particularly where the results can be provided quickly (in less than an hour), are quantitative, and a specific antidote is available. In Alberta, the Toxicology Working Group, advising Alberta Precision Laboratories (the provincial laboratory service network), drafted a guideline for clinicians after a detailed investigation and consultation, stating, "Qualitative Toxicology Testing in an Emergent setting or situation is not recommended because it has not been shown to impact management or disposition of patients". While comprehensive drug testing is not considered useful for the emergency managing overdose patients, there is potential value in collecting patient samples, particularly early in the presentation before drugs may be metabolized or therapeutic medications can confuse test results. Such samples can then be tested as routine samples, if needed, with less impact on laboratory resources. Indeed, these results can be useful in confirming the clinical diagnosis and specific drugs involved, allowing for identification of trends in drug abuse, guiding potential improvements to medical care, and even influencing government action to address drug abuse. My laboratory has implemented a monthly report on the number of drug tests performed, the origin of the samples, and the drugs detected. Such information can be useful in the development of strategies to address drug abuse, and refine and improve the detection and management of overdose cases.

POCT devices, that typically use immunoassay technology to detect drugs, are widely used for drug testing applications, and may appear to be useful in managing overdose patients, particularly because of their technical ease of use and rapid test results, but there are many limitations. POCT devices are only able to detect a small number of the huge spectrum of legal and illegal drugs available, and as well many substances are known to cause false positive results with immunoassay tests, thus false negative and false positive results with POCT devices can be problematic. POCT devices do not have the sensitivity and specificity required to detect important, often very low levels of some drugs in biological fluids, as compared to MS systems. When considering a POCT, or any immunoassay-based drug test, it is important to recognize that not all test systems perform equally and their performance needs to be evaluated. Different manufacturers' assays for the same drug can be based on antibodies with different sensitivity, specificity and cross reactivity with the primary drug, metabolites and other substances, leading to widely different results when using different devices. For example, a test that detects only fentanyl would not be as sensitive or specific at detecting fentanyl use as a test that detected both fentanyl and the nor-fentanyl metabolite. POCT devices, like all immunoassay drug tests, are often directed at the family of drugs (opioids, amphetamines, benzodiazepines, barbiturates, etc.) and a positive result does not identify which specific drug in the family is actually present, as can be achieved with MS testing.

Be wary of sales people, or others, who minimize the technical challenges of using POCT devices for drug testing, and claim that such devices are "fool proof". In laboratories in North America, Laboratory Accreditation agencies have determined that all POCT testing is under the jurisdiction of the laboratory, even testing that is performed by non-laboratory staff, such as medical staff, nursing staff or others. As such it is the laboratory that is responsible to ensure that POCT drug testing devices are implemented and used appropriately, including test evaluation/validation, staff training, standard operating procedures, and appropriate internal and external quality control. That is not to say that POCT devices do not have a place in other types of drug testing aside from guiding the management of overdose patients. A warning regarding the potential problems that can be associated with the improper use of POCT devices is illustrated by a recent report in the New York Times of more than 1,600 inmates unjustly penalized based on incorrect use of rapid drug tests (NYT, Jan. 5, 2022).

Having outlined the limitations of POCT devices and immunoassay testing in emergency overdose testing, these devices do have applications in other non-emergency toxicology testing, when used appropriately and ideally when MS is available to confirm positive results (ie. non-emergency settings, psychiatric patients, pain management, drug treatment, employment drug testing, etc). However, it is important that laboratory toxicologists work with clinicians to determine what their testing needs and goals are, and if POCT/immunoassay testing will be appropriate, and establish the criteria under which testing can be used. Thereafter, laboratory toxicologists need to be available to provide advice and consultation to clinical staff on the use and interpretation of tests. Obviously, the evaluation and validation of POCT/immunoassays is the responsibility of the laboratory, as it would be for any other test. A cardinal rule with POCT testing is to always confirm a positive result by another more specific testing method, which is typically a mass spectrometry device. Given that MS confirmation is not feasible in all circumstances, a comment indicating that testing was performed by immunoassay, and was not confirmed by MS should be clearly added to the results.

It is understood that mass spectrometry is not available in many labs, even in North America, never mind in developing countries. These systems are expensive to purchase, maintain and operate and require a high level of specific staff expertise. In developing countries that can find the funds to purchase MS systems, finding qualified operators can be a limiting factor. Another problem is the lack of vendor support for systems to respond to the not infrequent technical problems and the routine maintenance that MS systems require. The most sophisticated equipment is useless if it does not have qualified staff to operate it and maintain and repair it. I recognize the serious limitation that these places on toxicology testing in developing countries, and innovative solutions are required.

Poisoning from alcohols, such as methanol, isopropyl alcohol, and ethylene glycol, presents a serious problem in North America and in many developing countries (Nekoukar et al., Annals of Medicine and Surgery, 06-01, Vol 66, 2021). Testing for alcohols is relatively quickly and easily accomplished by gas chromatography, and ethanol can also be conveniently measured by specific chemical methods. Again, gas chromatography systems are not readily available in most small rural laboratories in North America as well as in developing countries. An alternative is to use pH, anion gap and osmolal gap to screen for the presence of a toxic alcohol. There is mixed opinion on the specificity and sensitivity of this approach particularly in cases with early presentation, and it is certainly not comparable to gas chromatography (Krahn and Khajuria, Clin. Lab. 57, 297-303, 2011). A minimal requirement for implementation of this approach would be laboratory validation of the cut-off values and not simply using literature values. Small differences in the test methods used to calculate the anion/osmolal gap can result in significant differences in results between laboratories, and invalidates the application of reference ranges from another laboratory. It is also important to note that osmolal gap can only be calculated from measurements made using freezing point depression as opposed to a vapor pressure osmometer (Rifai et al., Tietz textbook of clinical chemistry and molecular diagnostics (sixth edition) Chap 41: 837-838, 2018). One possible benefit of this method may be to at least reduce the number of samples that need to be tested by a specific chromatographic method, if applying a wider cut-off range.

In summary, toxicology testing can be valuable in the diagnosis and management of drug overdose and drug use. While clinical utility in emergency settings is limited, it is useful in other situations, particularly when MS testing is available. The use of POCT devices without MS confirmation may be the only alternative to many laboratories in developing countries, and this type of testing should be implemented with a thorough understanding of the limitations, device evaluation/validation by the laboratory, and ongoing communication and support for clinical groups using the test results.

How coagulation diagnostics support COVID-19 vaccination and patient management

Contributed by Niti Dawar, MD, Medical & Scientific Affairs Manager (Coagulation), Roche Diagnostics Asia Pacific.

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Infection with COVID-19 has been associated with thrombosis, or blood clots, involving the veins and arteries. The risk of blood clots is highest for individuals admitted to hospital with COVID-19 infection, occurring in about 5% of people admitted to a regular hospital ward and up to 20% for those in the intensive care unit (ICU), on life-support. The risk of blood clots for individuals with COVID-19 but not requiring admission to hospital is lower at about 1% [1].

While highly uncommon, vaccination with adenovirus-based vaccines is also associated with blood clots through a condition called vaccine-induced thrombotic thrombocytopenia (VITT). To better understand the key coagulation risks and considerations around COVID-19 vaccination and patient management, Roche Diagnostics Asia Pacific recently spoke with Dr. Ng Heng Joo, Senior Consultant & Head of Department of Haematology at Singapore General Hospital.

Coagulation markers in COVID-19 care and post-vaccination evaluation

Accumulating laboratory evidence indicates that abnormal coagulation changes in COVID-19 infected patients may be a result of profound inflammatory response, and not associated with intrinsic procoagulant effect itself. Marked increases in coagulation proteins may occur in patients with severe COVID-19 infection, consistent with a profound acute-phase response. A subset of severe pneumonia patients developed viral sepsis, disseminated intravascular coagulation (DIC), and multi-organ failure.

Since D-Dimer is a positive marker for patients with thrombosis, studies have been done that attempt to incorporate D-Dimers into predicting the severity for COVID-19. "D-Dimer has been incorporated into some of these risk assessment scores for development of venous thromboembolism in COVID-19 patients," notes Dr. Ng. "It has been a bit difficult to define cutoff levels that constitute concern about increasing severity of the disease and how that would impact the escalation of therapy for patients."

"Common examples of some of the risk assessment models that were used include the Improved D-Dimer score as well as the Caprini score," he adds. "There have been some validation studies that show it works pretty well in helping to predict which of the patients can be classified as either low-risk, intermediate-risk or high-risk of developing venous thromboembolism and arising from that, the appropriate use of anticoagulation therapy for patients."

For patients with VITT, testing typically reveals low fibrinogen and very raised D-Dimer levels above the level typically expected in venous thromboembolism. "We know the potential onset for VITT usually is between 5 to 28 days post vaccination," highlights Dr Ng. "We do know that it causes unusual sites of thrombosis like cerebral venous sinus thrombosis splenic vein thrombosis."

Antibodies to platelet factor 4 (PF4) have been identified in patients with VITTence there are similarities to heparin-induced thrombocytopenia (HIT) despite the absence of prior exposure to heparin treatment. The anti PF4 antibodies can be detected by the ELISA HIT assay but not usually with the rapid tests which are usually based on chemiluminescence as well as latex assays.

Challenges in a coagulation laboratory in the COVID-19 era

By way of its association with thrombosis, COVID-19 has certainly brought on many challenges for patient diagnosis and management. In the early phase of the pandemic, one of these challenges was understanding the pathophysiology or the role of thrombosis in patients with COVID-19. Therefore, trying to stratify who is at high risk and the role of anticoagulation therapy for that group of patients has been challenging.

Another diagnostic challenge has been the entity of VITT. While the test against anti-PF4 antibodies has been well established for HIT, its use and its sensitivity for patients with VITT have been distinct and different. As a further adjunct to just the demonstration for anti-PF4 antibodies, there have been additional tests that have been developed to confirm the presence of antibodies that activate platelets [2].

This challenge led to the development of additional tests utilising what's available for example, the heparin-induced platelet aggregation assay (HIPAA). As a modification of the HIPAA test, investigators developed a platelet factor 4 induced platelet aggregation test to try to better define the aetiology or rather the diagnosis of patients with VITT. Platelet activation or the antibodies by using flow cytometry have been used as tests in the laboratory. These tests are useful as well as challenging to develop but they are diagnostic of VITT.

A new generation for coagulation diagnostics

COVID-19-induced coagulopathy is a distinct entity that exhibits a marked elevation of D-Dimer. COVID-19 is associated with high risk of micro- and macrovascular thrombosis and raised incidence of anticoagulation failure. Unlike conventional sepsis, anticoagulation plays a key role in the management of COVID-19 with a positive impact on survival. The biomarkers and the various scoring systems may be helpful in triaging patients to risk categories for the purpose of anticoagulation as well as diagnosing post-vaccination clots in COVID-19.

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CSF biomarkers and their role in Alzheimer's disease

Contributed by Samantha Yeoh, Digital Content Specialist, Roche Diagnostics Asia Pacific.

Amid the continued ageing of the global population, Alzheimer's disease is a serious and rapidly growing public health concern. The Asia Pacific region alone is estimated to have over 23 million cases today, and that figure is projected to be more than 70 million cases by 2050 [1]. While much attention is currently on a new therapeutic intervention recently approved by the FDA, clinical lab diagnostics will also be essential for helping to manage this growing crisis.

What are CSF biomarkers?

Multiple studies have shown the value of 3 core cerebrospinal fluid (CSF) biomarkers — β-amyloid 42 (αβ42), total tau (T-tau) and phosphorylated tau (P-tau) — within the diagnostic process for Alzheimer's disease. αβ42 levels are detected at lower concentrations in CSF and this change can already be seen at least 5 years before Alzheimer's disease is even formally diagnosed [2]. T-tau and P-tau, both markers for neuronal loss, are consistently found at increased levels above baseline [3].

CSF can be obtained through a lumbar puncture and its contents are taken to be a direct reflection of the brain's environment. Even so, CSF biomarkers are not widely used currently for clinical diagnosis. To date, there has not been any formal consensus on the established cut-off levels for the CSF biomarkers, but great effort is underway to agree on these cut-off values. Given the change to several clinical guidelines, such as the National Institute of Aging and Alzheimer's Association (NIA-AA) assessment that an Alzheimer's disease diagnosis can now be biologically based regardless of presence and severity of symptoms [4], as well as an external quality control programme by the Alzheimer's Association [5], there may now be room for greater use of CSF biomarkers in a clinical setting. If approved, the use of CSF biomarkers can also be increased with automation, reducing human handling and error.

The benefits of a timely diagnosis

Alzheimer's disease almost always starts with mild overlooked symptoms such as moments of forgetfulness, something easily attributable to age. At this point, the patient is most likely experiencing subjective cognitive decline; cognitive functions may be impaired but this cannot be confirmed solely through clinical assessments.

The next phase in this continuum is mild cognitive impairment (MCI), whereby clinical evidence via neuroimaging can be found. As MCI is also found in other neurodegenerative disorders, CSF biomarkers help with differential diagnosis. Given the time lag between physiological changes and clinical symptoms and given that MCI is a risk factor for Alzheimer's disease, the use of CSF biomarkers for timely diagnosis can impact the patient's experience with Alzheimer's disease.

Prior to CSF biomarkers, diagnosis of Alzheimer's disease relied on neuroimaging such as amyloid PET scans to detect amyloid plaques in the brain, a hallmark of Alzheimer's disease. However, this method has its limitations, ranging from late diagnosis to inaccessibility of equipment and specialised personnel. This could explain why 50 - 70% of patients do not even receive a formal diagnosis.

A timely diagnosis could allow for a definitive detection of Alzheimer's disease [6], and for applying intervention therapies or enrolment in clinical trials [7]. Outside of the clinic, patients are well informed and are able to make decisions about their own future, from deciding future living options to making appropriate legal arrangements. A timely diagnosis could also inform how healthcare systems in a country shape their policies for decades to come.

Potential use as companion diagnostics

CSF biomarkers have been used in clinical trials for disease-modifying therapies (DMTs) that aim to intervene in the clinical progression of Alzheimer's disease [8]. To appropriately stratify eligible patients for clinical trials, CSF biomarkers (and PET scans) are performed as confirmatory tests to show presence of physiological changes. With an increasing number of biomarker assays and progress in standardisation, CSF biomarkers could broadly support key milestones in clinical trials. A downside may be that multiple lumbar punctures may not be well tolerated by a patient, which drives the need for further research into developing blood-based biomarkers as an alternative.

Many studies have raised the potential benefits of timely diagnosis, including opportunities for earlier treatment or earlier intervention with DMTs. With a pharmacological agent on the market, this theoretical benefit now has the chance to become a reality. The advent of a new drug could provide an impetus for more healthcare practitioners to embrace the use of biomarkers for a definitive Alzheimer's disease diagnosis in their patients.

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Detection of the hepatitis B surface antigen (HBsAg) in patients with occult hepatitis B using a sensitive HBsAg assay

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Introduction

Patients with occult hepatitis B infection (OBI) have undetectable hepatitis B surface antigen (HBsAg) by conventional assays, but detectable hepatitis B virus (HBV) DNA in the blood and/or liver. Conventional HBsAg assays generally have a limit of detection (LLOD) of 0.02 – 0.05 IU/mL. Sensitive assays for HBsAg detection have been developed, one of which is the ARCHITECT HBsAg Next Qualitative Assay (Abbott Laboratories; referred as HBsAg NEXT), with an enhanced analytical sensitivity of 0.0052 IU/mL.1.

Aim

To evaluate the performance of HBsAg NEXT with respect to HBsAg detection in patients with OBI.

Materials & Methods

HBsAg was measured by HBsAg NEXT in archived samples collected from 4 groups of patients/subjects with undetectable HBsAg by conventional assays but with serological/clinical evidence of OBI:
Group 1: 200 HBsAg-negative, HBV DNA-positive blood donors.
Group 2: 38 HBsAg-negative patients receiving immuno-suppressive therapy.
Group 3: 800 chronic hepatitis B (CHB) patients with spontaneous HBsAg seroclearance.
Group 4: 100 HBsAg-negative subjects recruited from a community project.

HBsAg was measured by HBsAg NEXT on an ARCHITECT i2000SR analyzer (Abbott Laboratories). Results were expressed as signal over cut off (S/CO). A S/CO of ≥1 was considered initial reactive. Initial reactive samples were retested in duplicate and confirmed with the NEXT Confirmatory test.

Results

Group 1: **HBsAg-negative, HBV DNA-positive blood donors, 200 blood donors:**

- Undetectable HBsAg by the PRISM HBsAg Assay [Abbott].
- Detectable HBV DNA results by NAT (determined by Procleix [Grifols Diagnostic]; LLOD 3.4 IU/mL), followed by confirmation by an in-house PCR assay[2].
- Referred from the Hong Kong Red Cross Blood Transfusion Service to the Queen Mary Hospital, Hong Kong for clinical follow up during 2009 – 2020.
- **10/200 (5%) were confirmed positive by HBsAg NEXT. (mean S/CO 3.78 ± 1.17)** ***An increment of 5% detection rate if HBsAg NEXT was used instead of PRISM HBsAg Assay.***

Group 2: **HBsAg-negative patients receiving immuno-suppressive therapy:**

- 38 HBsAg-negative (determined by either ARCHITECT HBsAg Qual II or Elecsys HBsAg II [Roche]), anti-HBc-positive patients with haematological malignancies were followed up for 2 years after receiving either rituximab-containing therapy or allogeneic hematopoietic stem cell transplantation[3].
- 20 patients had HBV reactivation whereas the remaining 18 did not experience reactivation.
- **1/20 (5%) patients with reactivation had reactive HBsAg NEXT result at 4 weeks before reactivation.**

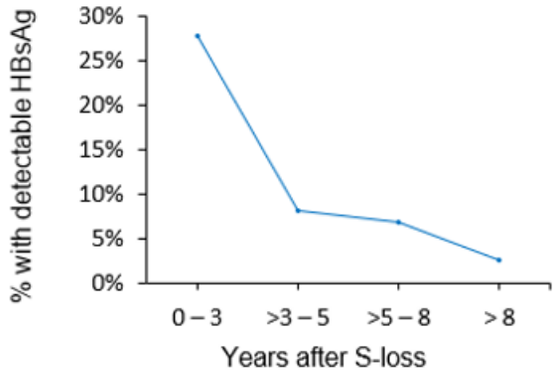
Table 1: The use of HBsAg NEXT could depict HBV reactivation prior to the emergence of HBV DNA

	Patients with detectable HBsAg by NEXT (%)		
	Baseline	Before reactivation	End of 2-year follow-up
18 patients without HBV reactivation	0	N/A	0
20 patients with HBV reactivation	0	1 (5%)*	N/A

* Sample at 4 weeks before HBV reactivation.

Group 3: Patients with HBsAg seroclearance:

- 800 patients with HBsAg seroclearance determined by either ARCHITECT HBsAg Qual II [Abbott] or LIAISON XL MUREX HBsAg Assay [DiaSorin]). Samples collected 0.5 – 29.7 years (median 7.8 years) after HBsAg seroclearance.
- **59 (7.3%) had detectable HBsAg by HBsAg NEXT.**
- Distribution of detectable HBsAg (by HBsAg NEXT) with sample collection time is as follows:



Total number of samples	90	146	174	390
No. of samples with detectable HBsAg by NEXT (%)	25 (27.8%)	12 (8.2%)	12 (6.9%)	10 (2.6%)

Fig 1: HBsAg NEXT detected HBsAg in 7.3% patients with HBsAg seroclearance determined by conventional assays.

Group 4: HBsAg-negative individuals from a community project:

- 100 HBsAg-negative apparently healthy subjects (determined by Elecsys HBsAg II) from a territory-wide community study[4], out of which 29 (29%) were anti-HBc positive.
- **7 (7%) had HBsAg detectable by HBsAg NEXT.**
- All 7 samples with detectable HBsAg were also anti-HBc positive:

Table 2: HBsAg NEXT could detect OBI in apparently healthy HBsAg negative and anti-HBcpositive subjects in the community.

	HBsAg NEXT-positive (n = 7)	HBsAg NEXT-negative (n= 93)	P value
Anti-HBc-positive (%)	7/7	22/93 (23.7%)	<0.0001
Median anti-HBs, IU/L	2.0	39.8	0.013

Conclusion

Overall, HBsAg NEXT conferred an increment of 5 – 7.3% detection rate when comparing with conventional HBsAg assays:

Table 3: HBsAg NEXT can improve the prevention of HBV transmission and HBV reactivation and allow a better policy implementation regarding the prevention of HBV-related complications.

Patient cohort	Number of samples tested	Increment detection by NEXT
Group 1: HBsAg-negative, HBV DNA-positive blood donors	200	10 (5%)
Group 2: HBsAg-negative patients with HBV reactivation	20	1 (5%)
Group 3: CHB patients with HBsAg seroclearance	800	59 (7.3%)
Group 4: HBsAg-negative individuals from a community project	100	7 (7%)

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Disclosures

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Analytical Performance evaluation of the New VITROS TSH3 assay on VITROS XT 7600 Integrated System

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Introduction

Thyroid stimulating hormone (TSH) has been used extensively as front-line test for the initial screening of patients to distinguish euthyroid status from both hyperthyroidism and hypothyroidism. Endocrinologists use the combination of TSH and thyroid hormones – Thyroxine (T4) and Triiodothyronine (T3) either free form or total, both free and bound forms together as thyroid function tests. While doing thyroid function tests, changes in the TSH level can serve as an 'early indicator' before the actual changes in the level of thyroid hormones (T3 and T4) in the circulation (Sheehan MT, 2016). The high level of TSH indicates hypothyroidism where the thyroid gland is unable to make sufficient thyroid hormones and low level of TSH indicates hyperthyroidism where the thyroid gland is making high level of thyroid hormones with some exceptions (Guerri G, 2019). There are multiple assays available for the measurement of TSH but there is not any harmonization between different methods. Systematic difference between various assays may produce misleading interpretation when samples of the same patients are measured using different assays based on different methodology (Clerico A, 2017). The IFCC Committee for Standardization of Thyroid Function Tests developed a global harmonization approach for TSH measurements using standards or calibrators which are traceable to APTM (All Procedure Trimmed Mean) – a panel of native materials with values assigned by the APTM as the surrogate Reference Measurement Procedure (Thienpont LM, 2017). Ortho Clinical Diagnostics introduced New VITROS TSH3 assay which is traceable to APTM Reference serum panel. The objective of this study is the evaluation of new VITROS TSH3 assay for its usage in our Thyroid Function tests panel.

Materials and Method

This analytical evaluation study was conducted at M/s Toprani Advanced Lab Systems, a NABL Accredited Pathology Laboratory in Vadodara, Gujarat, India. VITROS TSH3 reagent pack was calibrated in three VITROS XT 7600 Integrated system as per the manufacturer's Instruction for use manual and the calibration verification was done by processing three levels of Bio-Rad Immunoassay control and the obtained results were compared with the peer group mean value.

The accuracy and precision verification of VITROS TSH3 assay was carried out following the CLSI EP 15 A3 guidelines using two levels of VITROS Total Thyroid Immunoassay control samples, both Level 1 and Level 3 controls. Each sample was processed in five replicates in a single run, and 5 different runs in three days. The co-efficient of variation (CV%) was calculated and compared with the upper verification limit (UVL) of the manufacturer's performance characteristics of the assay in terms of repeatability and reproducibility as specified in the VITROS TSH3 Instruction for use manual.

The Analytical measurement range (AMR) of the VITROS TSH3 assay was verified by following the CLSI EP 06 guidelines. A linearity panel of 11 samples were prepared by proportional mixing of both high and low value samples in different proportions viz., 1:9, 2:8; 3:7;4:6; 5:5; 6:4; 7:3; 8:2; 9:1 and having low value sample as level 1 and high value sample as level 11. All the 11 samples were processed in duplicate, and the obtained value was compared with the mathematically expected value. The obtained results were plotted graphically with the expected value in the x-axis and the obtained value in the y-axis. The assessment criteria for the AMR verification was the visual examination of the plots for any potential outlier at any of the concentrations and the correlation coefficient (r).

The performance of VITROS TSH3 assay in clinical samples were evaluated by processing patient serum samples in both, the existing VITROS TSH assay and the new VITROS TSH3 assay simultaneously. A total of about 150 patient serum samples were collected randomly covering the analytical measurement range of the VITROS TSH assay, ranging from 0.1 to >100 µIU/mL based on the value obtained in the VITROS TSH assay. All the 150 samples were processed in the VITROS XT 7600 system in both VITROS TSH and VITROS TSH3 assay in the same system within an hour. The Passing – Bablok regression analysis was carried out to verify the comparability between both the assays. Further, to verify any statistically significant variation observed between the values obtained with both VITROS TSH and VITROS TSH3, the paired t-test was done.

Results

VITROS TSH3 assay was calibrated in three VITROS XT 7600 Integrated systems and verified using three level Bio-Rad Immunoassay controls. The obtained results were compared with the peer group mean value and found to be satisfactory (Table 1).

Table 1: Calibration verification of VITROS TSH3 assay.

Control Level	VITROS XT7600 – 1	VITROS XT76 00 – 2	VITROS XT7600 – 3	Peer Group Mean	Peer Group SD	Peer Group Range
Level 1	0.35	0.37	0.38	0.37	0.02	0.33 – 0.41
Level 2	4.84	4.70	4.78	4.74	0.16	4.42 – 5.06
Level 3	33.85	34.39	34.19	32.88	1.23	30.42 – 35.34

The analytical performance of VITROS TSH3 assay for accuracy and precision was verified using CLSI EP15A3 Guidelines. The verification study was performed using two concentrations of VITROS Total Thyroid Quality control samples (Level 1 and Level 3) in all the 3 VITROS analyzers and 25 replicates of QC samples per analyzer in 3 days. The Trueness or accuracy verification was done by calculating the Bias% between the obtained mean value of 25 replicates and the target value given by the manufacturer for the control samples. VITROS TSH3 assay showed results which are comparable with the target value with the bias% well within the maximum allowable bias% (Table 2) as per the desirable biological variation database specifications (Ricos et al., 2014)

Table 2: VITROS TSH3 – Accuracy verification.

VITROS XT 7600	Control Level	Target value (uIU/mL)	Range (uIU/mL)	Obtained (uIU/mL)	Bias %	Allowable Bias %
System 1	Level 1	0.078	0.062 – 0.094	0.073	6.41	7.80%
System 2				0.076	2.56	
System 3				0.082	5.13	
System 1	Level 3	19.68	16.33 – 23.03	19.1	2.95	
System 2				19.45	1.17	
System 3				19.81	0.66	

Imprecision estimates in the form of within-run or intra-assay precision (repeatability) and within-lab or inter-assay precision (reproducibility) were calculated in terms of CV% and compared. The precision study showed an acceptable inter and intra-assay precision when compared with the manufacturer's claim and the upper verification limit (UVL) (Table 3).

Table 3: VITROS TSH3 Inter and Intra assay Precision verification.

VITROS XT 7600	Control Level	Conc. (uIU/mL)	N	Repeatability (Intra assay Precision)			Reproducibility (Inter-assay Precision)		
				Obtained	Claim	UVL	Obtained	Claim	UVL
System 1	Level 1	0.07	25	1.30%	2.10%	2.80%	2.10%	4.60%	7.10%
System 2		0.08		1.10%			1.20%		
System 3		0.08		1.50%			2.20%		
System 1	Level 3	19.1	25	1.70%	2.70%	3.50%	2.30%	6.50%	10.40%
System 2		19.45		1.50%			2%		
System 3		19.81		3.00%			3.40%		

Analytical measurement range or linearity verification was carried out following the EP 06 guidelines. A linearity panel of 11 samples with expected value ranging from low to high (0.028– 147.32 µIU/ml) were processed using VITROS TSH3 assay on VITROS XT 7600. Each sample was run in duplicate and an average value was generated using the two values obtained. A regression graph was generated between the expected value and the obtained value for all the 11 samples. There was a significant correlation between the expected and the obtained TSH values as indicated by the slope of the graph (R2=0.9947), which verifies the linearity of the assay (acceptance criteria: CI 95%, linear regression r=0.950-1.00) (Fig 1).

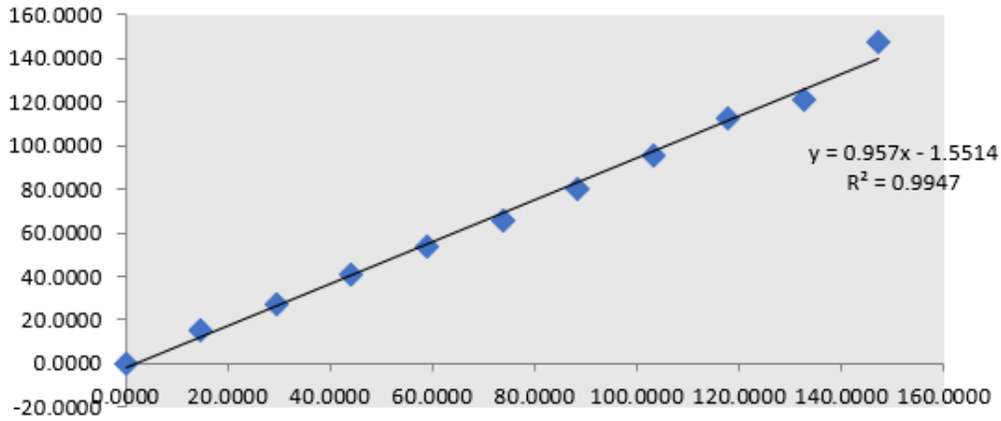

Fig 1: Linearity verification of VITROS TSH3 assay.

To evaluate the usefulness of the VITROS TSH3 with enhanced linearity up to 150 µIU/mL, a total of about 150 patient samples were analyzed using VITROS TSH3 along with VITROS TSH assay. For the sample comparison study, patient samples were selected from hyperthyroid (10 subjects), euthyroid (67 subjects) and hypothyroid (73 subjects) patients based on the values obtained with VITROS TSH assay. The mean serum TSH levels of hyperthyroid patients (10 subjects) was determined as 0.07± 0.09 and 0.09± 0.11 µIU/ml using the VITROS TSH and VITROS TSH3 assays, respectively. The mean serum TSH level of euthyroid patients (67 subjects) was determined as 2.53 ± 1.26 and 2.54 ± 1.29 µIU/ml using the VITROS TSH and VITROS TSH3 assays, respectively.

The mean serum TSH level of hypothyroid patients (64 subjects) was determined as 20.01 ± 21.86 and 22.60 ± 28.91 µIU/ml using the VITROS TSH and VITROS TSH3 assays, respectively. Overall, in all the 150 samples, a strong positive correlation was found between the results of the two assays (r=0.983) (Fig 2). As per the paired t-test, there was no statistically significant difference observed between the values ($p < 0.05$). The clinical interpretation of most of the subjects was similar in both the methods used, with 12 subjects out of 154 samples showing borderline hypothyroid status when evaluated by the VITROS TSH3 assay who were otherwise euthyroid when the VITROS TSH assay was used. This is mainly because of the variation in the reference range recommended in the Instruction for use manual of both the VITROS TSH3 (0.40 – 4.049 uIU/mL) and VITROS TSH (0.465 – 4.68 uIU/mL) assays. The regression analysis shows that there is a positive bias with the TSH3 assay when compared with the TSH assay (Y intercept – +1.116). The application of regression statistics at the clinical decision point of 5 µIU/mL shows that the percentage of difference at the medical decision point is 24.8 % which is less than the maximum allowable TeA % as per BV guidelines (38.2 %). Hence, the comparison correlates well both clinically and statistically.

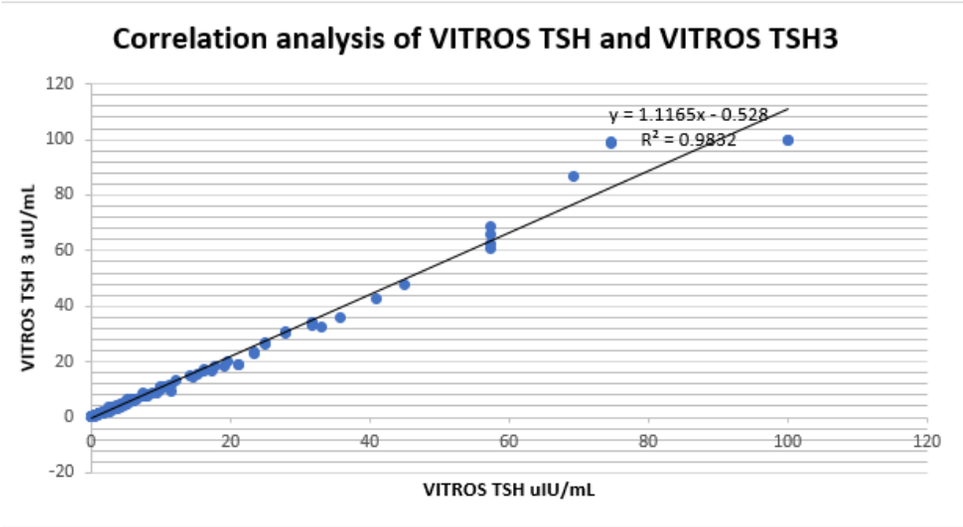

Fig 2: Correlation of VITROS TSH and VITROS TSH3 assays

One of the advantages of the VITROS TSH3 when compared to the VITROS TSH assay is that there is no biotin interference in the VITROS TSH3 assay. In the assay architecture, since the biotin-BSA coated wells are saturated with streptavidin-labelled mouse monoclonal anti-β subunit of TSH, there is no binding of endogenous biotin and, hence, no interference in the assay, whereas the VITROS TSH assay has the limitation of biotin interference at the concentration of 12.5 ng/mL (Ali M, 2017). Recently, we received a sample having a TSH value of > 100 µIU/mL in other commercially available assays showing a falsely low TSH value of 9.2 µIU/mL in the VITROS TSH assay on a neat serum sample, but using a dilution of 1:5 obtained a value comparable to the value obtained with commercially available assays. When the same stored sample was retested in the VITROS TSH3 assay along with the VITROS TSH assay, the sample showed a value of 124.2 µIU/mL in the VITROS TSH 3 assay and 4.64 µIU/mL in the VITROS TSH assay, indicating there is no interference in VITROS TSH3 assay when compared to VITROS TSH assay.

Discussion

TSH is an important assay for the evaluation of thyroid function (Sheehan MT, 2016) and has been recommended by recent guidelines as the first-line test for evaluation of thyroid hormone related disorders (Dittadi R, 2017), (Garber JR, 2012). This has led to the development of improved TSH assays with enhanced analytical sensitivity and reproducibility (Clerico A T. T., 2018). To harmonize results across different assays, the IFCC Committee for Standardization of Thyroid Function Tests has introduced APTM Reference serum panel (Thienpont LM, 2017).

The new VITROS TSH3 is a third-generation assay with a functional sensitivity of 0.01 µIU/mL, inter-assay CV of 20% and is traceable to the APTM reference serum panel. In this study, we have evaluated the usage of the new VITROS TSH3 assay in our thyroid function tests panel. The analytical performance of VITROS TSH3 assay was verified using CLSI Guidelines. Precision verification and accuracy verification showed an acceptable performance of the VITROS TSH3 immunoassay for both inter and intra-assay precision with the CV% below 3.5% and comparable to the manufacturer's claim. The VITROS TSH3 Assay passed the linearity verification acceptance limit and demonstrated excellent linearity.

High affinity of biotin-streptavidin interaction has been explored in in-vitro immunoassays. Despite the achievement of improved analytical sensitivity of the immunoassays using biotin-streptavidin complex, these assays are prone to interferences with endogenous biotin molecules, as biotin is commonly used for preventing and treating biotin deficiency associated with pregnancy, malnutrition, rapid weight loss, hair loss, brittle nails, skin rash in infants, diabetes, etc. Such interferences can affect clinical decisions and may lead to misdiagnosis and/or inappropriate management of the patients. New VITROS TSH3 Assay utilizes the biotin-streptavidin complex to enhance the sensitivity but without any endogenous biotin interference with the improved assay architecture and, thus, enhances the accuracy of the assay results which helps in enhancing clinical diagnosis of thyroid disorders.

Comparison of New VITROS TSH3 Assay with the currently available VITROS TSH Assay (a third generation Assay) was done to evaluate the clinical usefulness of the more sensitive assay. TSH levels in a broad range of donors (hyperthyroid, euthyroid, and hypothyroid) were compared using the two assays. Regression analysis showed a good correlation between the two assays. There was a good correlation with the clinical diagnosis of thyroid disorders in the subjects for both methods. When compared with the VITROS TSH assay, the VITROS TSH3 assay has an enhanced analytical measurement range (100 µIU/mL vs. 150 µIU/mL) which helps in getting more reliable results for all the hypothyroid patients. Thyroid hormones are essential for growth and development of the fetus during pregnancy and during infancy to childhood as well as regulating metabolic hemostasis. The VITROS TSH3 assay with the established trimester-specific pregnancy reference intervals as well as age-specific reference intervals from infancy to adulthood helps in the correct interpretation of individual TSH levels which aids in the diagnosis and management of thyroid diseases.

The adult reference interval for the VITROS TSH3 assay (0.4 – 4.049 µIU/mL) provided in the VITROS TSH3 Instruction for use manual is consistent with the range recommended by the American Thyroid Association (ATA) guidelines and the statement issued by the British Thyroid Association Executive committee (Jonklass, et al., 2014; Okosieme, et al., 2016. In our study, with the revised reference range, about 12 subjects showed borderline hypothyroid status when evaluated by VITROS TSH3 assay who were otherwise euthyroid when the VITROS TSH was used with the reference range of 0.465 – 4.68 µIU/mL). Further follow-up of those 12 patients will be required to assess their thyroid status, based on the mildly elevated TSH values in relation to the revised reference range. The prevalence of subclinical hypothyroidism is up to 11.3% in India (Deshmukh et al., 2013).

Conclusion

In our study, the VITROS TSH3 assay showed excellent analytical and clinical performance in the comparative study with the current VITROS TSH assay. In addition, VITROS TSH3 has the added advantage of enhanced analytical measurement range, established reference range for trimester-specific pregnancy terms of gestation as well as for the paediatric population from infancy to adulthood, with the calibration stability up to 40 days. The reduced turnaround time from 37 min to 24 min is an added advantage. Furthermore, there is no interference from endogenous biotin in the VITROS TSH3 assay. Our study demonstrated the superior performance of VITROS TSH3 assay and it is incorporated in our Thyroid Function Test panel of assays.

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Open vs. closed molecular testing platforms: choosing the right system for your clinical lab

Contributed by Michelle Chong, Product Manager (Molecular Lab), Roche Diagnostics Asia Pacific

With rapid evolution in the molecular platforms available for clinical testing, it can be challenging for lab managers to select the best option for their needs. Recently, one of the primary differences that has emerged in molecular platforms is open systems versus closed systems.

A closed system is often described as "sample to answer" or "sample to result." These systems require minimal hands-on time because all processes needed to generate a test result, including most sample prep steps, are performed automatically within the platform without the need for human intervention. Closed systems incorporate thermal cycling, quality control, and full protocols to generate a clinical result.

An open system, by contrast, involves multiple instruments and workflows. In this approach, laboratory staff move samples and plates around, add reagents as needed, and employ a workflow that may include both automated and manual steps.

Neither option is right for all labs and all types of tests. So how do you choose between them? Let's review several factors to consider in your decision-making process.

Capacity

One of the most important factors is throughput. For tests that labs rarely run, or for low-volume labs, an open testing platform is often sufficient. In these cases, there is little need to have a full system dedicated to a certain test or fixed menu of tests.

But for tests that are being run often, with many samples processed together, a closed-end system can be the better choice. These platforms are designed to be lab workhorses, capable of analysing dozens or hundreds of samples at once without requiring additional hands-on time from limited staff resources.

The COVID-19 pandemic has provided an excellent demonstration of this concept. For labs processing just a handful of samples per week, demand could be met with even the most manual workflows. But in laboratories that had to implement high-capacity testing to generate results from thousands of samples per week or even per day, closed systems provided the necessary throughput without overtaxing the staff.

Flexibility

When it comes to molecular testing, does your lab offer a broad test menu, or do you tend to run the same few tests all the time? The level of flexibility you need is another key factor in the choice of open or closed systems.

Typically, closed platforms are designed for either a single test or a small number of tests that all perform well in the same type of automated system. If your laboratory runs a lot of, say, oncology panel tests, then a closed system focused entirely on oncology analysis could be an excellent choice. Having a single automated system take care of a large proportion of the tests run in a laboratory frees up valuable resources for other higher-value medical tasks.

In addition, closed systems can be conducive to running highly regulated in vitro diagnostics. For clinical labs, they can be helpful for minimising the validation processes and registration challenges needed to get a new IVD routine test up and running.

But if your laboratory needs a high level of flexibility in testing, then a closed system is likely not the ideal choice. Open systems enable a much broader range of testing options and are a good match for laboratories that run many different tests from various vendors on a smaller number of samples each day, or often add new tests to their menu.

In addition, laboratory-developed tests require an open system. In labs that frequently run tests they have developed and validated internally, closed systems typically do not provide the flexibility needed to support such workflows.

Resources

While open systems are good for flexibility, they tend to require more resources — both in cost and in staff time. Open platforms need far more optimisation to implement, in part because they incorporate reagents and instruments from a number of different vendors. They also involve more experimental work, often in time-consuming manual steps.

During the COVID-19 pandemic, many lab teams discovered that they could produce more results with greater efficiency and at lower cost by using closed systems. An automated approach with true walkaway functionality contributes to lower costs by minimising sample preparation, freeing up staff to perform other tasks, and running more samples at a time. Closed systems also require less setup and training and are significantly easier to operate than open systems.

In addition, closed systems were less affected by supply constraints during the pandemic because all reagents and consumables came from a single vendor, whereas open systems are more vulnerable to supply chain issues because an entire testing procedure can become inoperable when a single type of pipette tip, sample plate, or buffer solution becomes unavailable.

For lab teams planning to purchase an automated system, it would be ideal to start by identifying which tests need to be automated, determining anticipated test volumes, and assessing the availability of expertise and resources needed to optimise tests in order to determine whether an open or closed system would be more beneficial for your current lab setup.

Total Lab Automation Integrated with Fleet of New Generation Atellica Solution: Driving Better outcomes

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The clinical laboratory plays an increasingly important role in the patient-centered approach to the delivery of healthcare services. It is estimated that more than 70% of clinical decisions are based on information derived from laboratory test results1. Any error during the laboratory testing process can affect patient care, including delay in reporting, unnecessary redraws, misdiagnosis, and improper treatment. Reduction in possible errors is one of the critical objectives targeted during automating action and decision workflows within the clinical laboratory. The Total Testing Process can be subdivided into three stages: Pre-analytical, Analytical and Post- analytical. The pre-analytical phase accounts for 46% to 68.2%2 of errors observed during the Total Testing Process (Tabe-1).

Table 1: Types and Rates of Error

'Quantity Not Sufficient' is one of the critical factors contributing to pre-analytical errors

Types and Rates of Error in the 3 Stages of the Laboratory Testing Process[1]		
Pre-analytical	Inappropriate test request Order entry errors Misidentification of patient Container inappropriate Sample collection and transport inadequate Inadequate sample/anticoagulant volume ratio Insufficient sample volume Sorting and routing errors Labeling errors	46%-68.2%
Analytical	Equipment malfunction Sample mix-ups/interference Undetected failure in quality control Procedure not followed	7%-13%
Post-analytical	Failure in reporting Erroneous validation of analytical data Improper data entry	18.5%-47%

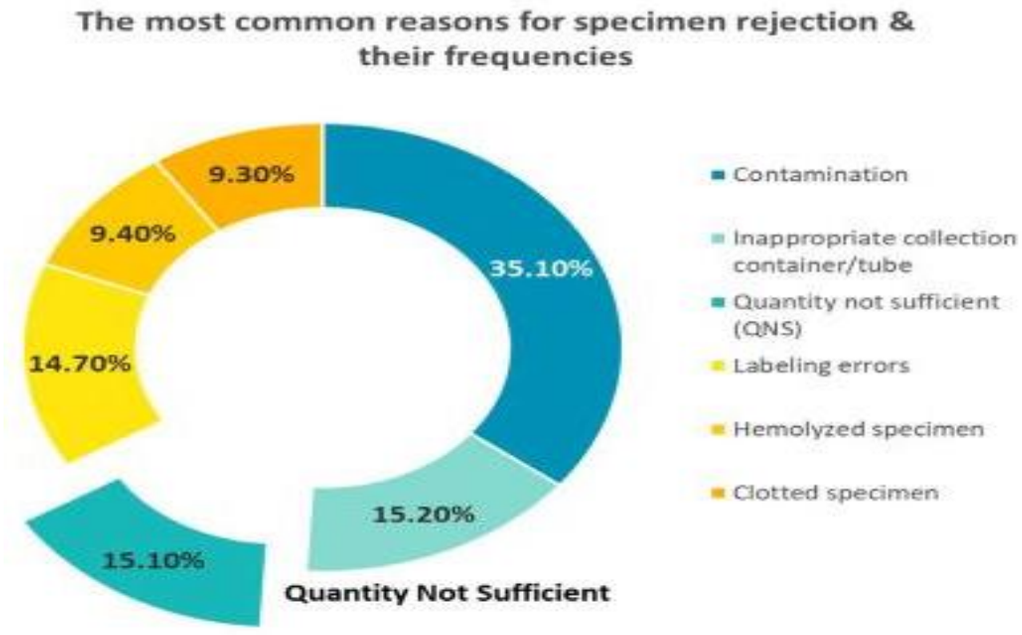

Figure 1: Common reasons for specimen rejection.

Quantity Not Sufficient (QNS) is a result of not having sufficient quantity (volume) of specimen to test for the parameter(s)/ panels ordered. The QNS was found to be one of the top-3 specimen rejection criteria contributing to approximately 15% (Fig 1) rejections in a study that retrospectively reviewed specimen rejections in a clinical chemistry laboratory during a 1-year period and analyzed for frequency, cause, circumstances, and impact[2].

The QNS specimen rejections can impact overall lab performance matrix as well as patient care pathway.

1. Increased turnaround time and cost resulting from re-collection of these specimens.
2. In some cases, it may impact patient care pathway due to inability to add or perform a specific test required by clinician.
3. It may also lead to loss of revenue/patient satisfaction due to cancelled tests or rejected specimen.

Some of the most common factors leading to QNS errors include:

- Specimen collected was less than the minimum published volume.
- Specimen depletion during the testing process due to
  - ✓ Aliquoting: specimens to be sent out to different departments may lead to deplete.
  - ✓ +on due to dead volumes and handling of specimens.
  - ✓ Retesting: Repeating a test due to technical errors or clinical verifications.
- Test addition request: Ordering of additional test post specimen collection by client or clinician.
- Specimen leakage during transportation.

Total Lab Automation at National Reference Lab, Dr Lal PathLabs Ltd (February Month)

The data suggests that in comparison to legacy workflow, total lab automation integrated with Atellica Solution has helped our lab in reducing specimen rejections due to QNS by

In addition, the solution has simplified workflow, specimens with QNS error can now be sorted in dedicated rack of error samples on Input-Output Module [IOM] on Aptio automation, reducing efforts and time spent to identify and report these specimens for further actions. Also, post analysis sample tubes are now stored in refrigerated storage module on automation, thus additional tests/panels if requested by clinicians or patients can be activated on-the-fly.

How total lab automation integrated with Atellica Solution helped in significant reduction in QNS

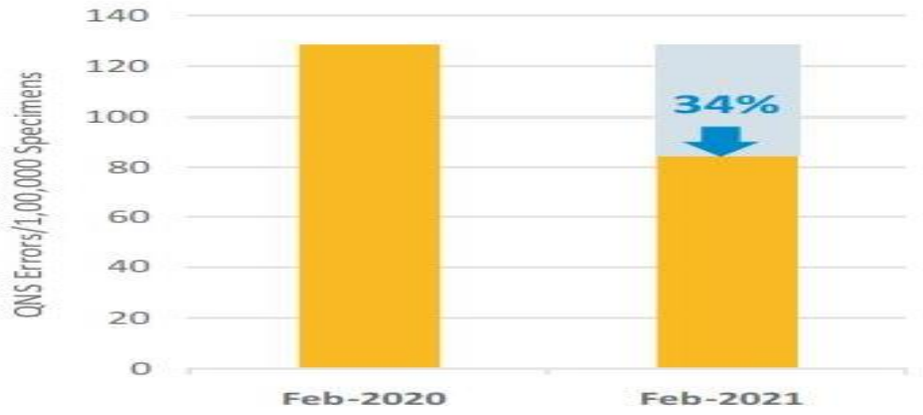

Figure 2: QNS data (February Month)

A. Consolidation of parameters and Reduction in Aliquot

- Total lab automation introduced a concept of one tube, one touch, one flow. It helped our laboratory consolidate immunoassay and biochemistry testing modalities across different departments and thereby completing maximum possible number of tests prescribed on the specimen from a single primary tube. In fact, 90-95% of tubes loaded on track automation complete their prescribed tests on automation without needing to be aliquoted before analysis.

- The consolidation helped in reducing interdepartmental and inter-instrumental aliquoting (Figure-3) thus eliminating the most critical factor that may attribute to sample insufficiency. It also automated necessary aliquoting and, thereby further reducing risk of manual errors & spillage.

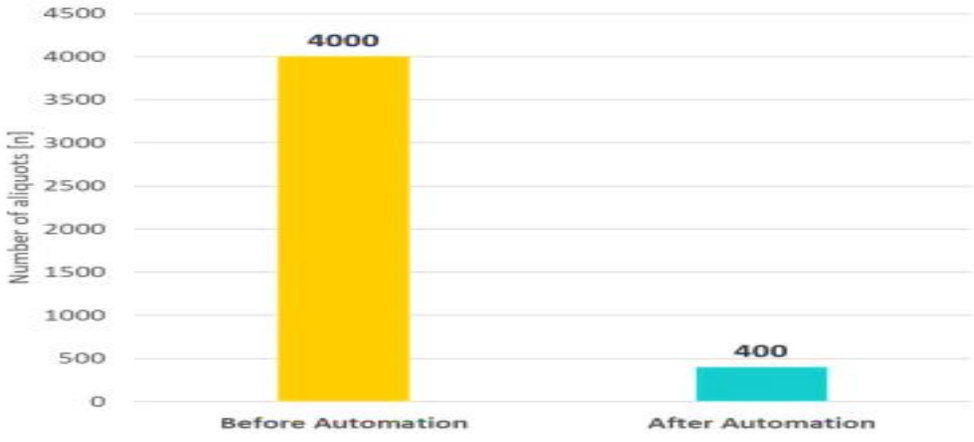

Figure 3: Number of Aliquots before and after automation

B. Micro-volume Technology

Atellica Solution Chemistry analyzer deploys microvolume technology that enables processing of up to 15 photometric assays from single aspiration (Figure-4). This feature enables completion of entire bio-chemistry panel ordered on a specific specimen in 1 or maximum 2 aspirations saving significant specimen volume for tests in comparison to legacy biochemistry analyzers other platforms. The reruns and dilutions are also performed using onboard aliquot, thereby further saving specimen volumes.

Figure 4: Micro volume Technology

C. volume requirement for Immunoassays

Specimen volume required for assay on Atellica Solution Immunoassay analyzer is 20%-50% less in comparison to that of its predecessors (Fig-5). This reduced specimen volume requirement has significant contribution in reducing QNS which is very evident in analysis below (Fig-6).

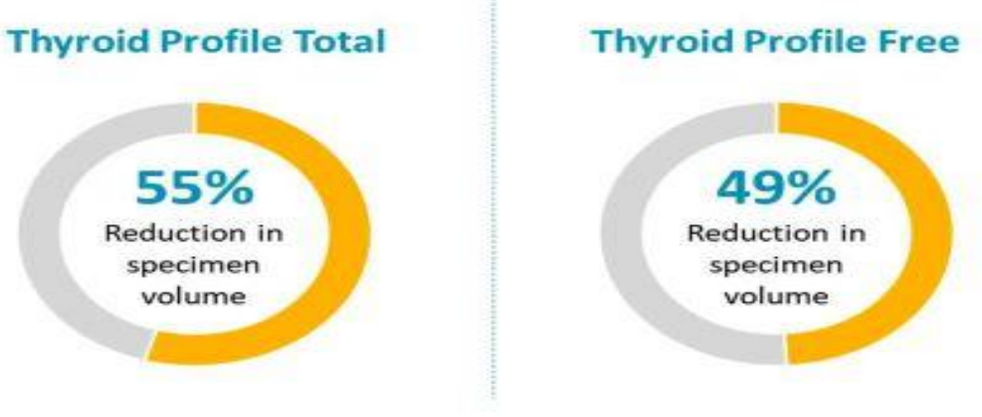

Figure 5: Thyroid Profile volume reduction

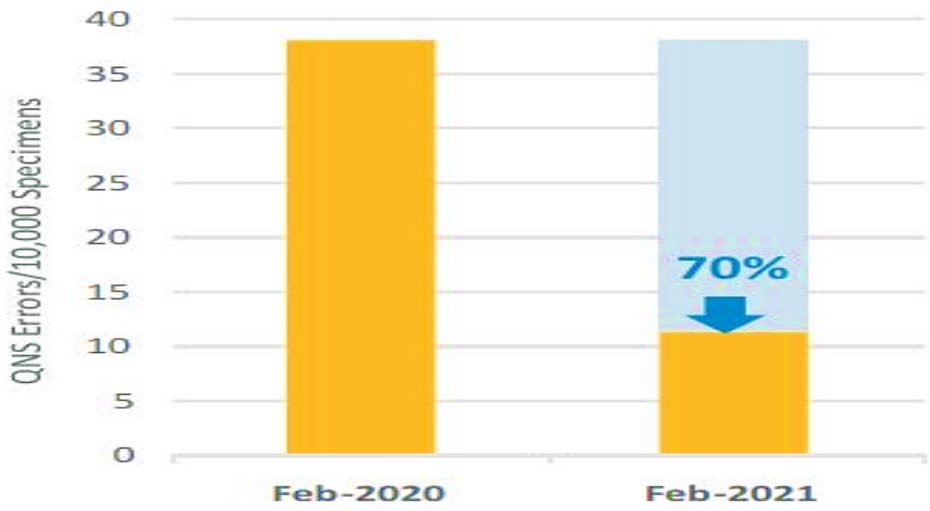

Figure 6: QNS data for Thyroid Profiles

Conclusion

We saw significant reduction in QNS errors post successful deployment of total lab automation integrated with fleet of new generation Atellica Solution as analytical platforms. This, in turn, has positive impact on reducing TAT, reducing cost and probable recollections, thereby providing better patient care and opportunity of revenue maximization for the laboratory.

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Section 1

Quiz based on APFCB Masterclass on Interpretative Commenting

Refer to our Thyroid Part 1 & Part 2 webinars, or the next APFCB newsletter for the answers.
Thyroid Part 1: https://www.youtube.com/watch?v=i0Wu5LOpGY4
Thyroid Part 2: https://www.youtube.com/watch?v=z6_BMr--wzI
https://www.apfcb.org/webinars.html

Question 1: (Case 3, Thyroid Part 1)
Patient: 57-year-old Female
Location: General Practice
Clinical information: Weight gain

TSH	7.3 mU/L	(0.50 – 4.0)

Which of the following is least appropriate?

a) Diagnose subclinical hypothyroidism
b) Diagnose non-thyroidal illness (sick euthyroid syndrome)
c) Suggest measuring FT3
d) Suggest measuring TSH, FT4 and TPO antibody in 6 weeks

Question 2: (Case 8, Thyroid Part 1)
Patient: 55-year-old Male
Location: General Practice
Clinical information: Feeling very tired

TSH	0.02 mU/L	(0.50 – 4.0)
Free T4	18 pmol/L	(10 – 20)

Which of the following suggestions is least useful?

a) Diagnose subclinical hyperthyroidism
b) Suggest measuring FT3
c) Suggest measuring TPO antibody

Question 3: (Case 8b, Thyroid Part 1)
Patient: 55-year-old Male
Location: General Practice
Clinical information: Hyperthyroid?

TSH	0.02 mU/L	(0.50 - 4.0)
Free T4	18 pmol/L	(10 – 20)
Free T3	6.1 pmol/L	(3.0 – 5.5)

Which of the following is not appropriate?

a) Diagnose primary hyperthyroidism
b) Suggest measuring TSH receptor antibodies
c) Suggest thyroid ultrasound
d) Suggest start on T4 replacement

Question 4: (Case 7, Thyroid Part 2)

Patient: 50-year-old Male
Location: General Practice
Clinical information: Family history of thyroid disease

TSH	4.2 mU/L	(0.50 – 4.0)
Free T4	11 pmol/L	(10 – 20)
TPO Ab	876 kU/L	(< 6)

Which of the following is most likely?

a) Familial Thyrotoxicosis
b) Graves disease
c) Subclinical hypothyroidism due to Hashimoto's thyroiditis
d) Non-thyroidal illness (sick euthyroidism)

Question 5: (Case 11, Thyroid Part 2)

Patient: 60-year-old Male
Location: General Practice
Clinical information: Previous raised TSH

TSH	4.5 mU/L	(0.50 – 4.0)
Free T4	8 pmol/L	(10 – 20)

Which of the following is least likely?

a) Subclinical hyperthyroidism
b) Pituitary dysfunction
c) Non-thyroidal illness (sick euthyroidism)
d) Primary hypothyroidism on treatment

Question 6: (Case 10, Thyroid Part 2)

Patient: 39-year-old Male
Location: Emergency Department
Clinical information: Acute general weakness

TSH	< 0.01 mU/L	(0.50 – 4.0)
Free T4	43 pmol/L	(10 – 20)
Free T3	22 pmol/L	(3.0 – 5.5)
Sodium	143 mmol/L	(134 – 146)
Potassium	2.4 mmol/L	(3.4 – 5.0)
Bicarbonate	18 mmol/L	(22 – 32)
Urea	6.0 mmol/L	(3.0 – 8.0)
Creatinine	62 µmol/L	(60 – 110)
eGFR	>90 mL/min/1.73 m^2	

Which of the following is the most likely?

a) Myxoedema coma
b) Thyrotoxic periodic paralysis
c) Thyroid storm
d) Barium poisoning

Question 7: (Case 12, Thyroid Part 2)

Patient: 66-year-old Female
Location: Emergency Department
Clinical information: Semi-coma

Sodium	107 mmol/L	(137 – 143)
Potassium	2.2 mmol/L	(3.2 – 4.3)
Chloride	68 mmol/L	(102 – 111)
Bicarbonate	26 mmol/L	(22 – 31)
Urea	3.4 mmol/L	(3.0 – 8.0)
Creatinine	96 µmol/L	(70 – 100)
Glucose	7.9 mmol/L	(3.0 – 5.5)
CK	888 U/L	(<150)
Cholesterol	8.7 mmol/L	(<5.5)
Triglycerides	1.8 mmol/L	(<1.8)

Which of the following is the most likely?

a) Myxoedema coma
b) Thyroid storm
c) Sepsis
d) Rhabdomyolysis

Question 8: (Case 6b, Thyroid Part 2)

Patient: 64-year-old Female
Location: Oncology clinic
Clinical information: Thyroid cancer. Post thyroidectomy, monitoring

Thyroglobulin	<0.1 µg/L	
Anti-thyroglobulin antibody	14 kU/L	(< 4)

Which of the following is the most appropriate recommendation?

a) Note that Tg <0.1 indicates a minimal risk of cancer recurrence.
b) Suggest use of anti-Tg antibody as a surrogate tumour marker.
c) Recommend stopping thyroglobulin monitoring.
d) Suggest increasing dosage of thyroxine.

Section 2

Quiz based on APFCB Preanalytical Masterclass Webinar Series

Refer to our Pre-Analytical Webinars 1, 2 and 3, or the next APFCB newsletter for the answers.

Webinar 1
Overview of the Preanalytical Phase and International Guidelines on Specimen Management.
https://event.webcasts.com/starthere.jsp?ei=1487201&tp_key=09615c085b

Webinar 2
Phlebotomist Attributes, Knowledge Expectations and Professionalism.
https://event.webcasts.com/starthere.jsp?ei=1487203&tp_key=5716058f54

Webinar 3
Blood Collection via Venipuncture – Patient Assessment and Procedure Preparation.
https://event.webcasts.com/starthere.jsp?ei=1487204&tp_key=d28983d5c7

Question 1 (Webinar 1)
Which of the following is included in Total Testing Cycle?

a. Examinations for laboratory technicians.
b. The clinical phase and the analytical phase.
c. The pre-clinical phase.
d. Training clinical staff.

Question 2 (Webinar 1)
The key pre-analytical priorities do NOT include which of the following?

a. Patient preparation including fasting.
b. Prevention of venous stasis.
c. Mixing and labelling primary blood tubes.
d. The doctor interpreting the result.

Question 3 (Webinar 1)
Which of the following is not in the continuity of care?
Which of the following is not in the continuity of care?

a. Staff training
b. Rehabilitation
c. Prevention
d. Screening

Question 4 (Webinar 2)
What are the key expectations for phlebotomists in regard to knowledge and professionalism? Select the correct answers from the following list:

a. Act as key stakeholder in the diagnostic process.
b. Demonstrate basic knowledge regarding human anatomy, laboratory medicine, healthcare worker and patient safety, infection control and common clinical situations that lead to blood collection challenges.
c. Follow compliance with institutional policies.
d. Pursue ongoing refresher training.

Question 5 (Webinar 2)

The 'Chain of Command' is an important concept in the context of infection control, healthcare worker and patient safety. Breaking the chain at one or more links will be effective in reducing cross infection. Selection from the following list the actions phlebotomists can take to assist in breaking the chain:

a. Proper hand hygiene.
b. Correct use of PPE (as per organizational guidelines).
c. Proper patient identification of specimen tube labelling.
d. Remaining mindful of potential sources of infectious agents (microorganisms).
e. Compliance with Standard Precautions.
f. Correct disposal of contaminated sharps and other potentially infectious waste.

Question 6 (Webinar 2)

Because phlebotomy carries a risk of needlestick injury (NSI), compliance with evidence-based practices to minimize the risk is essential. 22% of all NSI occur during specimen collection. What % of these occur immediately after the blood specimen is collected and before disposal of the collection device?

a. 15%
b. 20%
c. 25%
d. 40%

Question 7 (Webinar 3)

Which of the following items should be assessed prior to venipuncture?

a. Confirmation of fasting, when appropriate for the test types requested.
b. Time of collection when this may affect test results (e.g. for therapeutic drug testing, tests sensitive to circadian rhythm).
c. Recent vigorous exercise.
d. Susceptibility to syncope (fainting).
e. History of convulsion.

Question 8 (Webinar 3)

The size of needle should be determined based on characteristics of the vein and the required blood volume. Select the correct statement or statements from the following list.

a. The largest possible needle gauge should be chosen as these will provide the best blood flow and minimize trauma to the blood cells.
b. Small gauge needles are preferable because they lead to less trauma to the vein.
c. Small needles are associated with red cell rupture leading to hemolysis in the specimen.
d. New needle technology allows the use of small gauge needles (e.g. 23G and 25G) with lumen sizes equivalent to those seen with traditional larger gauge (e.g. 21G and 23G) needles.

Question 9 (Webinar 3)

Regarding hand hygiene, the use of an alcohol hand rub is acceptable in most circumstances. Select the two situations where this is not recommended.

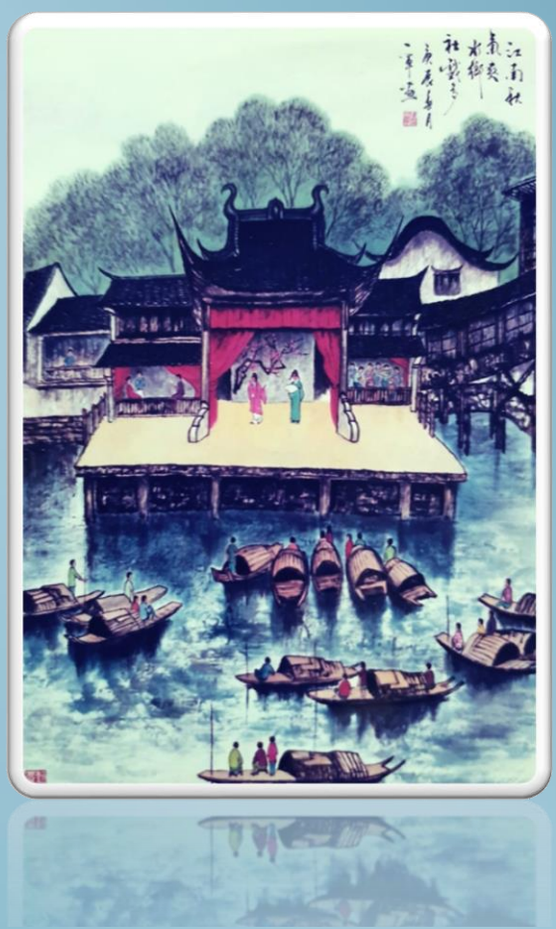
e. Visibly soiled hands.
f. Suspected infection with highly infectious agents (e.g. Clostridium difficile).
g. Pediatric patients.
h. Immunocompromised patients.

Watching Opera Performance on a River at an Ancient Water Village in China

Dr. Tan It Koon

In many Asian countries, it is customary to see local operas staged annually both to request and to express gratitude to heaven for the endowment of bountiful harvest, peace, good health and prosperity. Such operas are also frequently performed at important religious events and celebration of public festivals. Some wealthy families would also engage an opera troupe to perform for various private celebrations and family functions.

The Chinese word 社 (pronounced as She) originally referred to as the "Deity of the Earth" or "a temple dedicated to the worship of the earth". Later, it became a word which represents grassroot organizations or the name of a society, which is close to the concept of "village". The word 社 comprises two basic characters: "示 or show" on the left and "土 or earth" on the right. The Chinese Eastern Han Dynasty language expert Xu Shen 許慎 explained that the two horizontal lines above the word 示 represent the sky, and the three strokes below represent the sun, moon, and stars. Thus, the word means "Divine Directive or Instruction from Heaven". This appears to explain the common ancient practice of believing in the need for seeking divine instruction through sacrificial ritual for everything one seeks to do. The other half of the word "社" is "土 earth". The combination of these two basic characters produces the compound word "社", which is a place for offering sacrifices to The Earth and Deity of the Earth.



In China, "社 She" opera refers to the type of opera performances held specifically to express gratitude to the Deity of the Earth for bestowing good fortune, good weather and bountiful harvest for the community. However, it is not only an event to express appreciation to the Deity of the Earth. It is also a popular and much anticipated cultural entertainment event for the common people, as well as an important revenue-generating commercial activity. The temple for worship of the Deity of the Earth and its vicinity are often used as the venue. The Chinese regions that stage this kind of folk opera performances are represented by Shaoxing, Huanggang Anshun, Guangdong, Fujian, Hainan. This custom of staging opera performances based on legends, famous historical stories, and old folk tales continued for many years among the Chinese immigrants who settled in Southeast Asian countries like Singapore, Malaysia, and Thailand.

My painting features a "She" opera being performed on a stage built over a river at its bank, at a water village in China. The stage which protrudes out to the river forms part of a Temple for the Deity of the Earth. An actor and an actress are seen singing in a duet against a painted stage background of a plum blossom tree in full bloom. Members of a music ensemble play in the open-front house on the right, while stage prompters sit in the open room on the left. All the audience had their small boats anchored in front of the stage, and the whole families enjoyed the cool breeze while watching the show. On the right upper corner of the painting, I used running script to write the following couplet poem: 《江南秋气爽; 水乡社戏多》which may be translated as《Jiangnan area is cool and dry in Autumn; Many "She" Operas are performed at the Water Village》.

With Best Wishes
Dr. Tan It Koon