APFCB News

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

APFCB News
Volume 4 Issue 2, 2025

(Photo reprint from APFCB News 2016 Issue 2)

2025
Issue 2

APFCB Membership

Council Members

Australasian Association of Clinical Biochemists (AACB)
Association of Clinical Biochemists of India (ACBI)
Association for Clinical Biochemistry, Sri Lanka (ACBSL)
Chinese Society of Laboratory Medicine (CSLM)
Chinese Association for Clinical Biochemistry, Taiwan (CACB)
Hong Kong Society of Clinical Chemistry (HKSCC)
Indonesian Association for Clinical Chemistry (IACC)
Iranian Association of Clinical Laboratory Doctors (IACLD)
Japan Society of Clinical Chemistry (JSCC)
Korean Society of Clinical Chemistry (KSCC)
Malaysian Association of Clinical Biochemistry (MACB)
Mongolian Association of Health Laboratories (MAHL)
Nepal Association for Medical Laboratory Sciences (NAMLS)
Pakistan Society of Chemical Pathologists (PSCP)
Philippine Association of Medical Technologists (PAMET)
Singapore Association of Clinical Biochemistry (SACB)
Thailand Association of Clinical Biochemists (TACB)
Vietnamese Association of Clinical Biochemistry (VACB)

Affiliate Members

Association of Medical Biochemists of India (AMBI)
Chinese Association of Clinical Laboratory Management (CACLM)
College of Chemical Pathologists of Sri Lanka (CCPSL)
Macao Laboratory Medicine Association (MLMA)
Nepalese Association for Clinical Chemistry (NACC)
Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL)

Corporate Members

Abbott Laboratories (Singapore) Pte Ltd.
Beckman Coulter Hong Kong Ltd.
Becton Dickinson Holdings Pte. Ltd.
Bio-Rad Laboratories (Singapore) Pte Ltd.
DiaSys Diagnostic Systems GmbH
Greiner Bio-One Singapore Pte. Ltd.
QuidelOrtho Pvt Ltd
RCPA QAP Pvt Ltd Sydney, Australia
Roche Diagnostics Asia Pacific Pte Ltd.
Roche Diagnostics Pte Ltd.
Siemens Healthcare Pte Ltd.
Snibe Diagnostics Pte Ltd.
Sukraa Software Solution Pvt Ltd.
sysmex Pte Ltd. Singapore
Thermo Fisher Scientific
Waters Pacific Pte Ltd.

Submission

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: "Lupine-A Souvenir from Birmingham". Contributed by Tan It Koon

Founding and Past President APFCB

Address

Publisher Details:
Corresponding Address for APFCB News, India:
Dr. Pradeep Kumar Dabla
Chair APFCB- Communication Publication Committee
Chief Editor APFCB News
Professor, Department of Biochemistry
G.B. Pant Institute of Postgraduate Medical Education Research (GIPMER), JLN Marg, Delhi-110002, India

Email: c-cp@apfcb.org
Head Office:
APFCB, c/o Solid Track Management Pte Ltd. 150 Cecil Street, #10-06,
Singapore 069543
Email: afpcbofficial@apfcb.org

Contents

From the desk of APFCB President 01

From the desk of Chief Editor, APFCB News 02

APFCB Activities 2025

APFCB Communication And Publication Committee (C-CP) Report 03

APFCB Congresses And Conferences Committee (C-CC) Report 06

Announcement- 34th Waspalm & 51st ACBICON 2025, Pune, India 08

Member Societies (Activities Reports)

National Society Report – CACB Taiwan 09

National Society Report – AACB Australia 12

National Society Report- SACB Singapore 16

National Society Report – NACC Nepal 21

National Society Report – IACC Indonesia 27

National Society Report – ACBI India 43

National Society Report – MACB Malaysia 52

National Society Report – AMBI India 68

National Society Report – JSCC Japan 82

Young Scientists Column

Empowering Tomorrow's Leaders: Highlights From The IFCC Task Force For Young Scientists (IFCC TF-YS) At Euromedlab 2025 86

Expert Interview- Nafija Serdarevic, M. Pharm, MSc, PhD, Spec. Clinical Chemistry 90

Industry Voice Section

New Breakthroughs in Clinical Testing: The Future of Small Molecule Detection and Smart Laboratories 93

Expert Opinion

Precision Healthcare in India: Integrating Omics Science with Digital Health Innovation 95

Expert Interview-Clinical Lab Accreditation ISO 15189:2022 & its Implementation Strategies 105

Effectiveness of PlGF as a Point of Care Tool for the Prediction of Preeclampsia in High-Risk Pregnancies 114

Special Report

APFCB Webcast & e-Learning Programme Activities (January – June 2025) 121

Enhancing Core Laboratory Excellence through GLP System Track Automation at Sunway Medical Centre 124

International Federation of Clinical Chemistry (IFCC) Education and Management Division. Visiting Lecturer Program (VLP), June 5-6, 2025, Kathmandu, NEPAL 129

Clinical Case

The Non-Malignant Face of CA-125 136

Long-Term Follow-up of Congenital Hypothyroidism with Delayed Diagnosis 139

Unveiling the clinical conundrum: coexistence of Gilbert's syndrome and Thrombocytopenia 143

Quiz Section!! 150

Answer Section!! 151

Painting Story 153

From The Desk of APFCB President

President, APFCB
Dr. Tony Badrick

Dear APFCB members,

Welcome to the August Edition of the APFCB News. This publication introduces a new feature, Question and Answer, that we hope will provide readers with insights from experts on critical aspects of laboratory practice. New technology often features heavily in our meetings and discussions, but it is frequently unavailable, affordable, or practical in many countries. Medical laboratory staff must contend with challenging situations of unreliable equipment, limited resources, and stressful working conditions. But our results make a difference to patients' outcomes and the healthcare systems of our countries. We know that results must be obtained to diagnose malaria, TB, or diabetes, regardless of resource restrictions. That is our challenge, calling, and why we work in medical laboratories.

However, no matter what equipment or resources we use to provide a clinical service, we know that the fundamentals of clinical laboratory practice are that accurate, precise results and trustworthy advice are always essential for reliable health outcomes. These fundamentals are coded in ISO 15189, which represents the combined expertise of hundreds of medical laboratory specialists. These include standard operating processes, ethical practice, documented training and competence assessment, equipment maintenance, QC, EQA and method validation. All laboratories should implement these, though not all can afford an independent assessment against the Standard. Accreditation is a goal of many, but it cannot be achieved by all.

The theme of the first QNA is Accreditation and the value of the process. Remember that core laboratory competencies include QC and EQA, and these will feature in future APFCB News.

Best Wishes
Dr Tony Badrick
President, APFCB

From the desk of Chief Editor, APFCB News

Prof. Pradeep Kumar Dabla
Chief Editor, APFCB News

Dear Readers,

The Communication and Publication Committee (C-CP) remains committed to advancing the APFCB's academic mission through strategic dissemination of knowledge, digital engagement, and educational outreach. The recent eLearning webinars held in May and June 2025 addressed timely topics in chronic disease mechanisms and external quality assurance in resource-constrained settings, receiving broad participation and positive feedback.

Central to our initiatives is the recognition that high-quality patient care is directly linked to the competence of clinical laboratory professionals. The C-CP strongly advocates for continuous education and structured training in quality management systems, laboratory best practices, and technological innovation. Strengthening the capacity of laboratory staff is essential to ensure diagnostic accuracy, patient safety, and system-wide quality improvements.

This issue of *APFCB News* will reflect this focus, featuring contributions on laboratory accreditation frameworks, practical tools for ISO 15189:2022 implementation, AI-integrated diagnostics, case-based learning modules, and advancements in quality assurance. These articles are designed to support the professional development of both emerging and experienced laboratorians.

We extend our sincere appreciation to all contributors, member societies, and partners, and invite continued collaboration in our shared pursuit of laboratory excellence across the Asia-Pacific region.

Prof. (Dr.) Pradeep Kumar Dabla
Chair, APFCB Communication & Publication Committee (C-CP)

Happy Reading!!
Team APFCB C-CP

APFCB Communication and Publication Committee (C-CP) Report

Committee Chair:
Prof. (Dr.) Pradeep Kumar Dabla

Members:

- Dr. Ryunosuke Ohkawa
- Dr. Mingma Lhamu Sherpa
- Dr. Alireza Lotfi Kian
- Dr. Deepak Parchwani (Web Editor)
- Dr. Mayank Upadhyay
- Dr. Vivek Pant (Social Media Coordinator)

Report Summary: January 2025 – June 2025

The Communication and Publication Committee (C-CP) continues to actively steer APFCB's digital presence, academic outreach, and publication initiatives. The following report summarizes the major activities and progress achieved during this reporting term.

1. **Successful Conduct of APFCB eLearning Webcast activities (May & June 2025)**
   Under the APFCB eLearning initiative, two academic webinars were successfully organized:

   - **9th May 2025:** "The Interplay of Biological Factors in Chronic Disease Pathogenesis". Speakers were **Prof. Nafiza Serdarevic**, Faculty of Health Studies, University of Sarajevo, Bosnia and Herzegovina & **Prof. Ketut Suastika**, Faculty of Medicine, Udayana University, Indonesia. Moderated by **Prof. Ryunosuke Ohkawa**, Graduate School of Medical and Dental Sciences, Tokyo, Japan.
   - **26th June 2025:** Webinar organized by **PCQACL, Philippines** on A practical approach to Enhancing Lab Quality with External Quality assurance (EQA) in resource-limited areas. Speakers were **Prof. Rodelio D. Lim**, Institute of Pathology at St. Luke's Medical Center – Global and QC & **Prof. Paulo Enrico P. Belen**, Institute of Pathology, Quezon City and Global City hospitals. Moderated by **Prof. Sarah Jane L. Datay-Lim**, San Beda University and Ateneo School of Medicine & Public Health.

Both webinars received enthusiastic participation and positive feedback. The sessions were widely promoted via official APFCB e-mailers, website banners, and through social media outreach campaigns. APFCB EB members were encouraged to circulate the invitations within their respective national networks.

The webinar recordings remain available for members on the APFCB website's eLearning section:
https://apfcb.org/Webcast&e-Learning

2. **APFCB member societies to Join APFCB eLearning Platform**

APFCB member societies and Functional Committees are invited to collaborate and join with the APFCB eLearning platform. The APFCB Webcast & e-Learning Programme is an open educational online program that is freely available to all APFCB members & laboratorians, whether as professionals or trainees. The program is committed to develop platform for webinars on current advancements and need-based topics for the continued professional development of all stakeholders.

Please use the following link to propose topics/themes, or contributions with the tentative date to conduct 1-hour session (1 moderator and 2 speakers, 20 minutes for each speaker).

Link prog webpage for details: https://www.apfcb.org/Webcast&e-Learning

3. **Global Medical Laboratory Week (GMLW) Prize Ceremony**

The APFCB C-CP coordinated the prize distribution for the three GMLW 2025 APFCB winners at EuromedLab Brussels 2025:

- India: [Dr. Akila Prashant]
- Indonesia: [MD Ferdy Royland Marpaung]
- Sri Lanka: [Dr. N.E.Galmangodage]

Two awardees (India and Indonesia) attended EuromedLab 2025 in Brussels, while the Sri Lanka winner was nominated to a regional congress.

4. **APFCB Website — Continuous Enhancements and Updates**

Key updates to the APFCB website include:

- **New Appointments:**
  - **Treasurer:** Dr. Woei-Horng Fang
  - **Chair, Congresses & Conferences Committee:** Dr. Raja Elina Raja Aziddin

Event announcements, webinar recordings, and APFCB News issues have been consistently uploaded, ensuring the site remains dynamic and informative.
☞ https://www.apfcb.org

5. **APFCB News DOI allotment and ISSN registration initiative**

In a significant development towards academic standardization and enhanced indexing, the C-CP has successfully secured DOI numbers for expert opinion papers/clinical cases published in each issue of the APFCB News.

This will bolster the academic visibility, citation potential, and scholarly impact of APFCB News articles within the clinical laboratory medicine community.

Furthermore, the formal process for obtaining an ISSN registration for the entire APFCB News e-publication is underway and is expected to be finalized shortly. This will provide official recognition and improved indexing credibility on international library and publication databases.

The **APFCB News** is currently available in **both e-book and PDF formats** for open access and download:

☞ https://www.apfcb.org/APFCB_News/

It includes varied information, news & updates from different sections,

- Member society activity reports
- Laboratory quality management and AI in healthcare
- Young scientist features
- Case studies and clinical challenges
- Sustainable laboratory practice reports
- Industry partner innovations

Submission guidelines are available at:
☞ https://www.apfcb.org/APFCB_News/authorguideline

Conclusion and Future Directions

The APFCB Communication & Publication Committee remains committed to strengthening its educational activities, scholarly resources, and digital outreach platforms. Future focus areas include:

- Expanding the APFCB eLearning webinar series
- Broader social media visibility, especially among younger professionals
- Launch of expert video blogs and academic bytes
- Structured email marketing campaigns for APFCB announcements
- Regular DOI allotment for published content
- Completing ISSN registration for APFCB News
- Continuing clinical case discussions and laboratory challenges in upcoming issues

We sincerely thank the APFCB Executive Board, member societies, and corporate members for their consistent support and active involvement in making these initiatives successful.

Report compiled by:

Prof. (Dr.) Pradeep Kumar Dabla
Chair APFCB C-CP

APFCB Congresses and Conferences Committee (C-CC) Report

Dr. Raja Elina Raja Aziddin (MACB)
Chair APFCB C-CC

I am pleased to introduce the newly appointed members of the APFCB Congresses and Conferences Committee (C-CC) for the 2025–2026 term, as listed below:

1. Dr. Raja Elina Raja Aziddin (MACB) – Chair
2. Dr Rajiv Ranjan Sinha (ACBI) – member
3. Ram Vinod Mahato, Nepalese Association for Clinical Chemistry (NACC) – member
4. Vincent Chen (SNIBE) - corporate member
5. Romina De Leon (Thermo Fisher Scientific) - corporate member

For the year 2025, APFCB auspices has been granted to:

1. College of Chemical Pathologists of Sri Lanka for the 10th Annual Academic Sessions 2025 which was held on the 11th-2th July 2025 at the Monarch Imperia l Hotel, Colombo.

Photo 1: CCPSL 10th Annual Academic Sessions Event Flyer

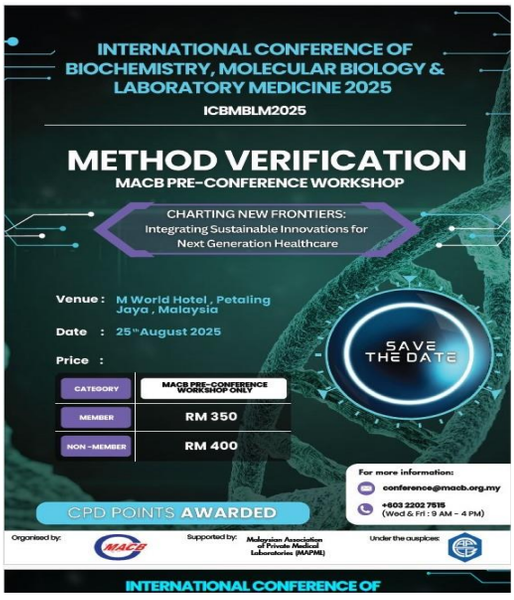


Photo 2: 35th MACB Pre-Conference Workshop 2025 Flyer

Photo 3: 35th MACB Conference 2025 Flyer

2. Malaysian Association of Clinical biochemists (MACB) for the International Conference of Biochemistry, Molecular Biology and Laboratory Medicine 2025 (ICBMBLM 2025) in conjunction with the 35th MACB Annual Conference 2025 on 25-27 August, 2025 at M Hotel, Petaling Jaya, Malaysia.

The APFCB schedule a Pre-Conference Workshop on Method Verification on 25th August 2025, followed by a Symposium titled Building a Greener Tomorrow: Sustainability Strategies for Clinical Laboratories on Day 1 of the conference.

Submitted by:

Dr. Raja Elina Raja Aziddin (MACB)
Chair APFCB C-CC

Announcement- 34th Waspalm & 51st ACBICON 2025, Pune, India

Association of Clinical Biochemists of India would be hosting the 34th WASPaLM (XXXIV World Congress of the World Association of Societies of Pathology and Laboratory Medicine) and the 51st Annual National Conference, 14th to 17th October 2025 at the WESTIN, Koregaon Park, Pune, INDIA

Dear Friends & Colleagues,

It is a pleasure to invite you to participate in the XXXIV World Congress of the World Association of Societies of Pathology and Medicine of Laboratory (WASPaLM), together with the 51st National Conference of Association of Clinical Biochemists of India (ACBI) and the 4th International Meeting of Medical Residents in Pathology and Laboratory Medicine, to be held from October 14th to 17th, 2025, at The Westin Koregaon Park, Pune, India. The theme of the Congress is "Laboratory Medicine at the Frontier of Patient-Centered Care."

Our scientific program, curated by eminent members of the scientific committee, will offer an exciting and informative program on the cutting edge of the science of laboratory medicine. Our endeavor would be to present an exemplary science which would be of interest to one and all, allowing them to update their knowledge on recent developments and advances, share expertise and experience, as well as discuss problems in their field of practice. The programme would feature various parallel sessions covering a wide variety of topics, enabling you to tailor the programme as per your own interests and clinical practice, along with information packed Pre Congress-Workshops.

For more details visit: www.waspalm2025.org

Best regards,

Dr. Rajiv R. Sinha
WASPaLM 2025 Congress President

National Society Report – CACB Taiwan

NAME OF SOCIETY	Chinese Association for Clinical Biochemistry (CACB-Taiwan)
OFFICIAL SOCIETY EMAIL ADDRESS	office@cacb.org.tw
NAME OF PRESIDENT & EMAIL ADDRESS	Sandy Huey-Jen Hsu sandyhsu@ntu.edu.tw
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Woei-horng Fang whfang@ntu.edu.tw

REPORT ON SOCIETY ACTIVITIES

Submitted by: Dr. Woei-horng Fang

The CACB annual conference and scientific symposium were held in conjunction with the 39th Joint Annual Conference of Biomedical Science (JACBS) on March 22nd and 23rd, 2025. The main theme for JACBS 2025 was "Advancing Therapies in Cancer and Diseases". Dr. Tang-Long Shen, Professor in the Department of Plant Pathology & Microbiology, National Taiwan University, delivered a keynote speech regarding exosome as a rising star in biomedicine. Three speakers, Professor Howard Doong, Dr. Kuender D. Yang, and Dr. Chih-Yuan Wang were invited to share their expertise of "Exosome in clinical applications". Prof. Doong shared clinical applications of stem cell-derived exosomes. Dr. Yang focused on development of mechanism-driven clinical applications of umbilical cord mesenchymal stem cell-derived exosomes across three generations. Dr. Wang emphasized on urinary exosomal peptides as a naïve incident biomarker. Following the symposium, student's research oral presentation competition and poster contest were also held. Overall, the two-day conference was very stimulating and truly a delightful academic gathering for the attending members of CACB.

Photo 1: Keynote speaker Prof. Tang-Long Shen (left) and and CACB president, Dr. Sandy Huey-Jen Hsu (right) at the 39th JACBS.

Photo 2: CACB board members and invited speakers at the 39th JACBS.

Photo 3: Winners of the oral contest and CACB president, Dr. Sandy Huey-Jen Hsu (center-right).

Upcoming events for 2025:

CACB will actively invite emerging talents in academia, medicine, and clinical biochemistry to join as members, fostering the next generation of leaders in the field. We will also strengthen collaboration and engagement with the biotechnology industry. Participation in international clinical biochemistry organizations will be one of our key priorities. Furthermore, we will establish a dedicated policy task force to address future developments and revisions in national legislation.

Photo 4:

CACB National Representative Dr. Woei-horng Fang and IFCC EMD Chair Prof. Nader Rifai met in Brugge, Belgium to discuss encouraging CACB members and Lab Med students in Taiwan to use the Traditional Chinese version of Learning Lab to update their Laboratory Medicine knowledge.

National Society Report – AACB Australia

NAME OF SOCIETY	Australasian Association for Clinical Biochemistry and Laboratory Medicine (AACB)
OFFICIAL SOCIETY EMAIL ADDRESS	lisa@aacb.asn.au
NAME OF PRESIDENT & EMAIL ADDRESS	President: Mr Greg Ward E-mail: greg_ward@snp.com.au
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Secretary: Dr Fernando San Gil E-mail: fred@aacb.asn.au

AACB Executive Board

Director – Scientific and Regulatory Affairs
Robert Flatman, Sullivan Nicolaides Pathology

Director – Education and Training
Wayne Rankin, SA Pathology – Adelaide

Director – Finance, Branches and Strategic Planning
Kate Driver, DiaSorin

Director – Media and Communications
Chanika Ariyawansa, Pathwest/Western Diagnostic Pathology

Chief Executive Officer
Lisa King, AACB

Photo 1: AACB Hosts the 17th APFCB Congress in Sydney, Australia 31 October – 3 November 2024

The Australasian Association for Clinical Biochemistry and Laboratory Medicine (AACB) proudly hosted the 17th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) Congress in Sydney from 31 October to 3 November 2024. The event attracted 905 delegates from across the region and beyond.

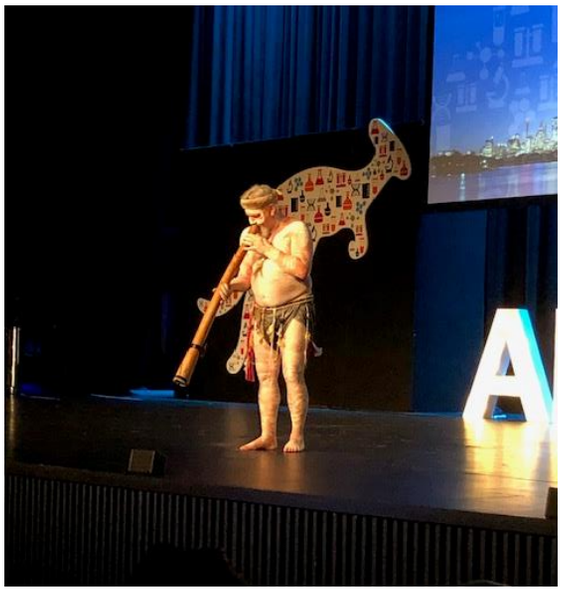


Photo 2: Welcome to Country at the Opening

Over four days, the Congress offered a dynamic program combining cutting-edge science, professional development, networking, and social events.

The scientific program featured four distinguished plenary speakers:

- A/Professor Ken Sikaris opened the Congress with “Analysing Clinical Governance”.
- Dr Carla Cuthbert spoke on “The Changing Landscape of Laboratory Testing” on Friday.
- Professor Gerald Watts spoke on “Navigating Risk of Inherited Heart Disease” on Saturday.
- Professor Maxine Whittaker closed with a talk on the vital role of laboratory services in universal health coverage.

Other highlights included presentations on neonatal bilirubin test standardisation, laboratory risk management, genetic challenges in paediatrics, and pregnancy complications such as pre-eclampsia.

The Congress fostered valuable dialogue and collaboration aligned with APFCB’s mission to advance laboratory science and improve healthcare outcomes in the Asia-Pacific.

Beyond science, the event celebrated community with two memorable social occasions:

- A Welcome Reception featuring Indigenous artist Victoria Doyle live-painting a piece inspired by the APFCB kangaroo.
- A sold-out Halloween-themed Congress Dinner at Doltone House, Jones Bay Wharf, complete with costumes, cocktails, and spectacular harbour views.

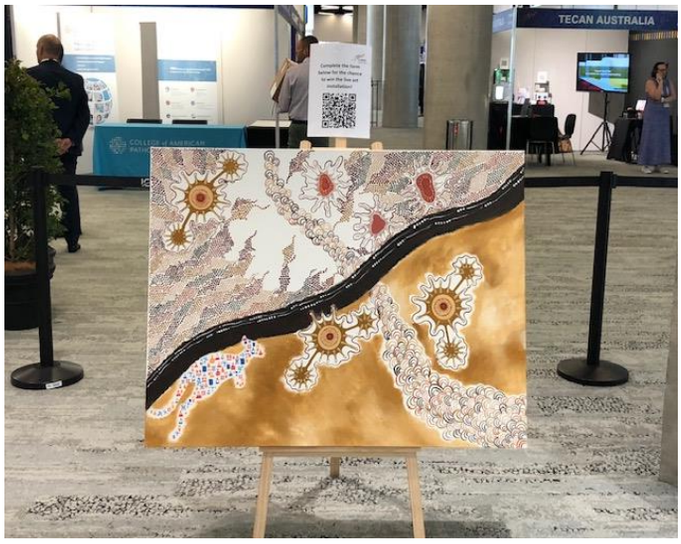


Photo 3: Live painting by artist Victoria

Photo 4: Halloween themed Congress Dinner

This successful Congress was made possible by generous sponsors, including Platinum sponsors Roche and Snibe, Silver sponsors Abbott and Werfen, and Congress sponsors Thermo Fisher Scientific and Quidel Ortho, as well as our exhibitors. Their support ensured a high-quality program and memorable experience for all delegates.

AACB 62nd Annual Scientific Conference, 13-16 October 2025, Auckland, New Zealand

AACB is delighted to host the 62nd Annual Scientific Conference in October 2025 at the Grand Millennium Auckland, New Zealand. We're especially excited to return to Aotearoa, famous for its stunning landscapes, rich Māori culture, and legendary hospitality – perfect for both science and sightseeing.

Set against Auckland's lush forests, volcanic peaks, and sparkling harbours, this conference offers more than just cutting-edge scientific talks. Take time to explore the city's vibrant culture, sample world-class cuisine, or visit nearby gems like the Waitākere Ranges or Waiheke Island's vineyards.

With this year's theme, *"Shedding Light on the Medical Laboratory 'Black Box',"* expect a dynamic program covering the latest in pathology and laboratory testing, with insights from international and local experts.

Highlights include the David Roth field Memorial Oration, the David Curnow Plenary Lecture, concurrent symposia, industry presentations, proffered papers, a bustling exhibition, and engaging oral and poster sessions.

Over the last 6 months

In February, AACB successfully hosted the 2025 RCPA-AACB Chemical Pathology Course in Adelaide. The Organizing Committee delivered a thorough program aligned with the AACB exam curriculum, featuring over 40 presentations, case discussions, method moments, meet-the-examiners sessions, and interactive quizzes.

The course attracted over 135 delegates, including 40 speakers, from Australia, New Zealand, Hong Kong, India, and Singapore. Generous support came from DiaSorin and Abbott.

In June, the AACB-RCPA 12th Harmonisation Workshop took place as a hybrid event with nearly 100 delegates. Over two days, discussions delved into Ferritin harmonisation, universal adoption of BCP albumin assays, harmonised reference intervals for AST/ALT (P5P) and ALP, outcomes of the 2014 Harmonised RI review, updates on ADIPS 2024 recommendations, plus briefings on CKD-EPI and FIB-4.

The workshop kicked off with a half-day Endocrine Educational Workshop, hosted jointly with the RCPAQAP Endocrine Advisory Committee, setting the stage for a dynamic program.

Additionally, AACB continued its collaboration with the RCPAQAP through a series of joint events, strengthening professional development and fostering closer ties within the laboratory medicine community.

AACB remains committed to providing valuable events and ongoing education for members and the laboratory medicine community.

Report Submitted by:
AACB Chief Executive Officer
Lisa King, AACB

National Society Report- SACB, Singapore

Name of Society	**Singapore Association of Clinical Biochemists (SACB)** (www.sacb.org.sg)
President (APFCB Representative)	Dr Leslie Lam Email: leslie.lam@parkwaylabs.com.sg
Vice-President	Mr Johnson Setoh
Treasurer	Dr Tan Jun Guan
Secretary	Dr Kho Shu Hui
Assistant Secretary	Ms Chong Ai Teng
Council Members	Ms Joanne Lee Ms Ummi Kulsum Ms Siti Rahmah
Co-opted members	Dr Shaun Tan Ms Andrea Goh Ms Ho Mun Jun

Submitted by: Ms Chong Ai Teng

ANNUAL SCIENTIFIC MEETING AND ANNUAL GENERAL MEETING 2025

The Singapore Association of Clinical Biochemists (SACB) convened its Annual Scientific Meeting (ASM) and Annual General Meeting (AGM) on 12th April 2025 at Concorde Hotel Singapore. The landmark event drew 170 delegates and garnered support from 17 industry partners, underscoring its significance in the field. Dr Leslie Lam, the Association's fourth President, delivered the opening address, setting the stage for an enriching programme that featured a plenary lecture followed by two parallel sessions. The AGM proceedings included comprehensive presentations of SACB's financial performance and a detailed review of the previous year's initiatives. The event's exhibition area buzzed with activity as industry partners showcased their latest innovations and technological advances. Adding to the occasion's significance, SACB unveiled its new line of merchandise (see Figure 1), further strengthening the Association's brand presence in the professional community.

Figure 1. SACB's new merchandise.

Photo 1

Photo 2

The scientific programme featured an impressive array of presentations from distinguished speakers across various specialties in clinical biochemistry and laboratory medicine. The comprehensive agenda addressed critical developments in the field. This diverse programme reflected the latest advancements in clinical biochemistry, offering delegates valuable insights into both current practices and emerging technologies.

- "Lot to Lot Variability: Identifying, Managing and Minimising Risk" – by Dr Loh Tze Ping, Senior Consultant, Clinical Chemistry Division, Department of Laboratory Medicine, National University Hospital.
- "PCOS Unveiled: Exploring the Latest Advances" – by Dr Christine Dizon, Medical Scientific Affairs Manager, Women's Health, Roche.
- "Anticipating the Unexpected - Antigen Excess" – by Dr Wei Hong Tay, Scientific Marketing Manager Binding Site, part of Thermo Fisher Scientific.
- "Updates in Test Algorithm for 2º Hypertension (Primary Aldosteronism)" – by Ms Kate Driver, Senior Product Manager APAC, Diasorin.
- "Lessons Learnt from Implementing Multi-Site POCT Device Connectivity" – by Mr David Rice, Senior IT Director, Radiometer HGM APAC.
- "The Challenges in Blood Specimen Tube Verification" – by A/Prof Snežana Jovičić, Consultant - Expert Global Medical & Clinical Affairs, Greiner Bio-One GmbH.
- "APOE4 Genotyping and Digital Biomarkers in the era of DMT" – by A/Prof Nagaendran Kandiah, Associate Professor of Neuroscience, Lee Kong Chian School of Medicine.
- "Cervical Cancer Screening in a New Era" – by Dr Tessa Riandini, Greater Asia Health Economics and Public Health Senior Manager, Becton Dickinson.
- "Blood-based Biomarkers for Mild Traumatic Brain Injury – Present State of the Art" – by Adjunct Associate Professor Peng Li Lee, Senior Consultant, Emergency Medicine, National University Hospital.
- "Updates on SACB Lipids Reporting Workgroup" – by Dr Clement Ho, Senior Consultant, Chemistry Pathology, Sengkang General Hospital.
- "Advancing Multiple Sclerosis Diagnosis & Management: Neurofilament Light Chain as a Transformative Marker" – by Dr Zuzana Hruskova, Clinical Marketing Manager, Lab Solutions, Asia Pacific & Japan, Siemens Healthineers.

SACB EDUCATION PROGRAMME 2024

The Singapore Association of Clinical Biochemists (SACB) successfully concluded a comprehensive ten-week learning initiative. The annual event took place every Wednesday, from 4th September 2024 to 13th November 2024. The programme was conducted via a hybrid mode, utilising both Zoom and physical attendance. The hybrid format proved particularly effective, allowing healthcare professionals to participate through their preferred mode of attendance, whether remote or in-person, thereby maximising engagement and learning opportunities across the sector. Notably, the education programme drawn more than 180 participants from diverse healthcare institutions across Singapore, the series underscored the strong demand for continued professional education in the field.

Date	Topic	Speaker
4-Sep-24	How to interpret Liver Function Tests?	Dr Bobby Li Registrar Tan Tock Seng Hospital
11-Sep-24	How to interpret Endocrine Dynamic Tests?	Dr Amas Lee Registrar Tan Tock Seng Hospital
18-Sep-24	How to perform Method Evaluation?	Ms Heng Ping Ying Principal Medical Laboratory Scientist Khoo Teck Puat Hospital
25-Sep-24	Clinical Cases	Prof. Aw Tar Choon Senior Consultant Changi General Hospital
2-Oct-24	How to perform Molecular Testing in the Clinical Laboratory?	Dr Karen Tan Consultant National University Hospital
9-Oct-24	How to determine lipid targets?	Dr Michael Lau Registrar Changi General Hospital
16-Oct-24	How to set up and perform critical results notification?	Dr Sharon Saw Principal Scientific Officer National University Hospital
23-Oct-24	How to perform Quality Control?	Ms Yang Zhixin Senior Medical Laboratory Scientist National University Hospital
30-Oct-24	APFCB CONGRESS BREAK	
6-Nov-24	How to perform Mass Spectrometry in Clinical Laboratory?	Ms Jayme Wong Senior Principal Medical Laboratory Scientist Singapore General Hospital
13-Nov-24	How to prepare for Risk Management ISO 15189:2022?	Prof. Robert Hawkins Senior Consultant Tan Tock Seng Hospital

SACB EDUSERIES 2024 – 2025

The Singapore Association of Clinical Biochemists (SACB), in collaboration with industry partners, successfully hosted its Evening Eduseries, combining professional development with networking opportunities. This innovative format featured expert speakers sharing insights on emerging assays and laboratory practices, preceded by a sponsored networking dinner.

The topics are as follows:

Date	Topic	Speaker
17-Oct-24	Quality Assurance in Blood Gas analysis	Mr David Colombo Global Expert Acute Care Diagnostics
26-Feb-25	Preanalytical Implications in Blood Gas Testing	Dr Sorin Taus Finder Senior Clinical Support Manager Radiometer Medical

OTHER COLLABORATIVE EVENTS

SACB demonstrated its commitment to professional development through strategic collaborations with industry partners, hosting a series of enriching educational initiatives. These partnerships enabled the Association to deliver diverse learning opportunities that expanded clinical knowledge across the laboratory medicine community. Through these collaborative events, SACB facilitated valuable knowledge exchange between industry experts and healthcare professionals, covering emerging technologies, innovative methodologies, and best practices in clinical biochemistry.

Date	Event (Venue)	Collaborating Partner
13-Mar-25	Roche CyberCare 2025 (Venue: Marriott Tang Plaza Hotel, Singapore)	Roche
14-Jun-25	World Hypertension Day Clinical Meeting (Venue: Gleneagles Hospital Auditorium, Singapore)	Diasorin

APFCB CONGRESS 2024

The Singapore Association of Clinical Biochemists (SACB) maintained its strong presence at the Asia-Pacific Federation for Clinical Biochemistry (APFCB) Congress, with distinguished representatives contributing to the educational workshop on 3rd November 2024. The delegation delivered a comprehensive series of presentations focused on thyroid diagnostics and clinical management.

The SACB representatives provided expert insights through three complementary presentations:

- Dr Tan Jun Guan delivered an authoritative overview on "The Thyroid Gland - Biochemistry and Pathology", establishing the fundamental scientific framework
- Ms Joanne Lee shared valuable technical expertise in her presentation "Thyroid Assays - Methods, Tricks and Tips", offering practical insights for laboratory professionals
- Dr Leslie Lam rounded out the session with "Clinical Case Studies - Thyroid", bridging theoretical knowledge with practical applications through real-world scenarios

This participation underscores SACB's commitment to sharing expertise and contributing to the advancement of clinical biochemistry knowledge across the Asia-Pacific region. SACB's past President, A/Prof Sunil Sethi received the APFCB Distinguished Service Award during the Congress.

Figure 2. Singapore delegates, including SACB representatives, at APFCB Congress 2024.

Figure 3. Dr Leslie Lam receiving the APFCB Distinguished Service Award on behalf of A/Prof Sunil Sethi.

SACB-APFCB 2024 Sponsorship

SACB reinforced its commitment to professional development by awarding the SACB-APFCB 2024 Sponsorship to two outstanding recipients: Ms Chew Suru and Ms Danielle Andrea Francisco, following a rigorous selection process. The candidates' abstracts underwent thorough evaluation by distinguished assessors A/Prof Wong Moh Sim and Prof Aw Tar Choon, ensuring a merit-based selection aligned with academic excellence. The competitive selection process, overseen by these esteemed professors, underscores SACB's commitment to maintaining high academic standards and recognising exceptional contributions to the field. Their expertise in abstract assessment helped identify submissions that demonstrated scientific rigour and innovative approaches in clinical biochemistry. This sponsorship initiative was specifically designed to support participation in the Asia-Pacific Federation for Clinical Biochemistry (APFCB) Congress.

National Society Report – NACC Nepal

Name of Society	Nepalese Association for Clinical Chemistry
Email	nacc2070@gmail.com
Name of President	Prof. Dr. Madhab Lamsal (madhab.lamsal@bpkihs.edu)
Name of National Representative General Secretary	Dr. Ram Vinod Mahato (ramvinodmahato42@gmail.com)
Senior Vice President	Prof. Dr. Prabodh Risal
Vice President	Dr. Vijay Kumar Sharma
Secretary	Mr. Raju Kumar Dubey
Treasurer	Dr. Santosh Pradhan

Submitted by:
Dr. Vivek Pant
Scientific Chair, NACC Conference 2025

A Resounding Success: 5th NACC Conference 2025 Advances Laboratory Medicine in Nepal

The vibrant city of Kathmandu played host to the 5th Annual Conference of the Nepalese Association for Clinical Chemistry (NACC), on May 3–4, 2025 held in partnership with the Association for Diagnostic and Laboratory Medicine (ADLM). This landmark event, accredited with 12 CPD points by the Nepal Medical Council, unfolded at the prestigious Square Hotel, Simrik Hall, drawing a diverse gathering of laboratory professionals, clinicians, researchers, and industry leaders from Nepal and abroad. The conference served as a dynamic hub for exchanging groundbreaking ideas in clinical chemistry, diagnostic advancements, and laboratory medicine. Through keynote lectures, oral and poster presentations, scientific discussion, and corporate exhibitions, attendees explored the latest trends shaping the future of diagnostics.

Day 1: Elevating Quality and Strategic Excellence

1. Mastering Quality in Laboratory Medicine

   Prof. Dr. Qing H. Meng captivated the audience with his deep dive into quality indicators, stressing their pivotal role in enhancing lab accuracy and patient safety. His call for continuous training and measurable benchmarks resonated strongly with professionals striving for excellence.

2. AI and Data Science: Revolutionizing Diagnostics

   Prof. Dr. Y. Victoria Zhang unveiled the transformative power of AI and machine learning in diagnostics. Her session showcased real-world applications, demonstrating how data-driven decision-making can redefine patient outcomes.

3. Risk Management and ISO 15189:2022 Compliance

   Dr. Anu S. Maharjan delivered a masterclass on risk management, decoding the updated ISO 15189:2022 standards. Her insights into proactive risk mitigation equipped labs with strategies to enhance safety and compliance.

4. Point-of-Care Testing (POCT): Best Practices

   In a follow-up session, Dr. Maharjan outlined effective POCT implementation, emphasizing structured training, quality control, and rapid diagnostics for improved patient care.

Day 2: Breakthroughs in Research & Public Health

1. Combating Lead Toxicity: A Lab-Driven Approach

   Dr. Vivek Pant spotlighted Nepal's lead exposure crisis, advocating for routine screening and lab-led public health interventions to protect vulnerable communities.

2. Automation in Urine Analysis: The Future is Here

   Prof. Dr. C. N. Srinivas showcased cutting-edge automated urine diagnostics, highlighting gains in speed, precision, and standardization for high-volume labs.

3. MicroRNAs: A New Frontier in Diabetes Detection

   Prof. Dr. Daya Ram Pokharel introduced circulating microRNAs as early diabetes biomarkers, opening doors for personalized medicine and early intervention.

4. Nepal-Specific Reference Intervals: Closing the Gap

   Dr. Ram Vinod Mahato presented findings from a landmark multicenter study, making a compelling case for population-specific reference ranges to improve diagnostic accuracy.

5. Spotlight on Emerging Research
   - 10 Oral Presentations explored AI in labs, genetic influences on vitamin D, newborn screening, and NIH-backed encephalitis research.
   - Nepal's first clinical chemistry digital poster session featured 30 innovative posters, setting a new benchmark for scientific engagement.

6. Recognizing excellence
   - Travel Grants for young scientists (sponsored by Techno Biomed) empowered regional researchers to present their work.
   - Cash Awards honored the best oral and poster presentations, inspiring the next generation of lab professionals.

7. Industry Innovations

   Leading firms like Wondfo Biotech, SNIBE, and East West Concern showcased next-gen lab technologies, strengthening industry-academia ties

For further information, Please visit https://conference.nacc.org.np/

Photo1: Token of appreciation to Dr. Anu S. Maharjan (L) by Prof Dr. Madhab Lamsal (R)

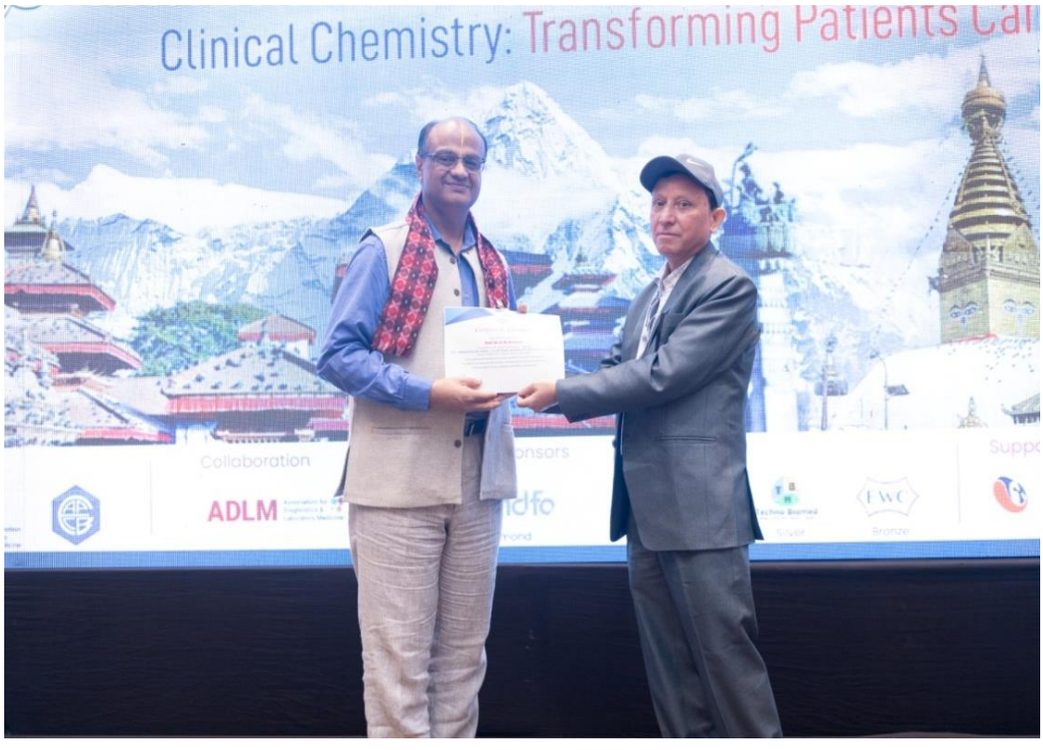


Photo 2: Certificate of Appreciation to Prof. Dr. C. N. Srinivas (L) by Prof Dr. Madhab Lamsal(R)

Photo 3: NACC officials meeting [Left row front to back- Dr. Santosh Pradhan, Dr. Ranjan Suwal, Prof Bharat Jha][Right row front to back- Prof Dr. Daya Ram Pokharel, Prof Dr. Madhab Lamsal, Dr. Shyam Sundar Malla]

Photo 4: Poster Session

Photo 5: Happy Participants

Photo 6: Group photo after the event

Photo 7: Lab Visit, Left to Right- Dr. Abha Shrestha, Dr. Ram Vinod Mahato, Dr. Devish Pyakurel, Prof. Dr. Qing H. Meng, Dr. Anu S. Maharjan, Prof. Dr. Y. Victoria Zhang, Dr. Neha Neupane, Dr. Santosh Pradhan and Dr. Vivek Pant

Photo 8: Corporate Session, L to R- Dr. Bishal Raj Joshi, Prof. Dr. Daya Ram Pokharel, Dr. Bijaya Mishra, Mr. Tapeshwor Yadav

Photo 9: Corporate Session, L to R- First two: Representatives from WTC [corporate member of NACC], Dr. Ranjan Raj Bhatta, Prof Dr. Madhab Lamsal, Dr. Binod Kumar Yadav, Representative from WTC

PERKUMPULAN KESEMINATAN KIMIA KLINIK DAN LABORATORIUM INDONESIA
INDONESIAN ASSOCIATION FOR CLINICAL CHEMISTRY

National Society Report – IACC Indonesia

NAME OF SOCIETY	Indonesian Association of Clinical Chemistry (IACC)
OFFICIAL SOCIETY EMAIL ADDRESS	secretariat@iacc.web.id
NAME OF PRESIDENT & EMAIL ADDRESS	President: Tjan Sian Hwa MSC, Clin Pathol E-mail: sianhwa_tjan@yahoo.com
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Secretary: ArwinPrasasto , Clin Pathol E-mail: secretariat@iacc.web.id

Indonesian Association of Clinical Chemistry Report

Submitted by:
Secretariat; Arwin Prasasto, Darmastanti Widi

Webinar Series ISO 15189:2022

Between June and November 2024, a four-part webinar series titled **"Laboratory Accreditation Analytical Quality Requirements – ISO 15189:2022"** was held, offering an in-depth exploration of quality management principles in clinical laboratories aligned with the latest ISO standard revisions. This series attracted thousands of participants and featured internationally recognized experts in laboratory medicine and diagnostics.

The series commenced on **15 June 2024**, with **740 participants** attending the inaugural session. This first installment focused on introducing the key updates in ISO 15189:2022. Dr. Tjan Sian Hwa opened the session by outlining the critical changes introduced in the new standard. Following this, Professor Tony Badrick delivered a session on the importance of traceability in clinical measurements, while Professor Ken Sikaris addressed the often-challenging concept of measurement uncertainty in laboratory settings.

Photo 1

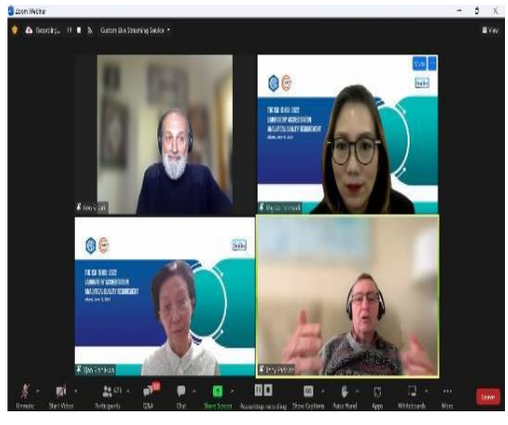


Photo 2

The second webinar, held on **27 July 2024**, witnessed a surge in attendance with **3,320 participants** joining. This session concentrated on **Internal Quality Control (IQC)** and the application of **Sigma metrics** in laboratory processes. Professor Khosrow Adeli presented strategies for planning effective IQC programs, followed by a talk from Dr. Thyrza on implementing Sigma metrics and the Westgard Sigma Rules. The session concluded with Rozita Abdulla from Hospital Sungai Buloh (Malaysia), who offered practical guidance on troubleshooting IQC issues in routine clinical practice.

Photo 3

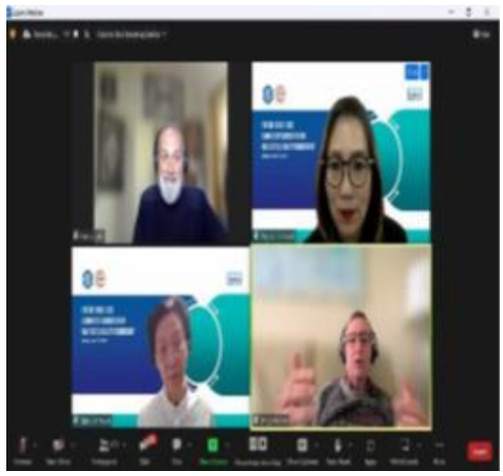


Photo 4

On **28 September 2024**, the third webinar shifted focus to **External Quality Assessment (EQA)** and **Proficiency Testing (PT)** programs. The session began with Professor Yusra elaborating on how laboratories can select appropriate EQA providers. Then, Mario Plebani explored the harmonization of EQA schemes, emphasizing international best practices, while Dr. July Kumalawati provided insights on interpreting and addressing EQA result discrepancies.

Photo 5

The final installment on **23 November 2024** covered **Method Validation**, **Verification**, and **Reference Interval Establishment**. Tran Thi Chi Mai outlined the foundational elements of validation and verification methods. Barnali Das followed with a step-by-step walkthrough of method verification tailored for clinical laboratories. Finally, Dr. Sam Vasikaran closed the series with a discussion on defining reference intervals and verifying clinical decision limits to ensure reliable test results in patient care.

Photo 6

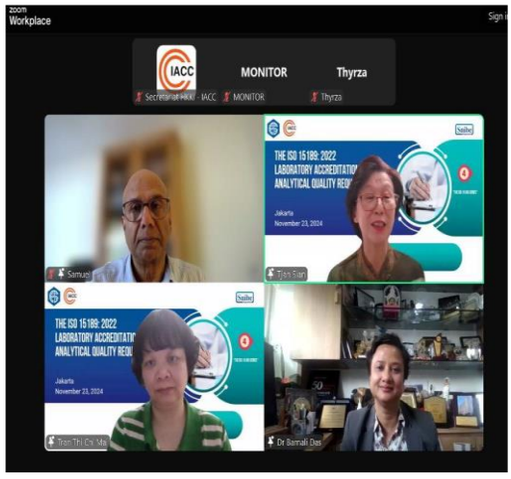


Photo 7

National Conference Workshop & Seminar NBS Day 2024

The **National Conference, Workshop, and Seminar for NBS Day 2024** took place on **28–29 June 2024**, uniting healthcare professionals in a two-day program rich in knowledge-sharing and public engagement. The event featured a blend of awareness campaigns, interactive workshops, and a hybrid-format scientific conference, underscoring the importance of early detection and communication in newborn screening.

Photo 8

Photo 9

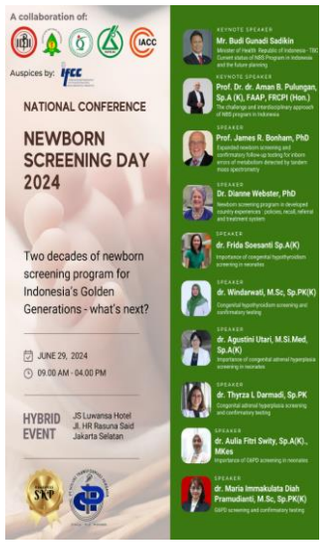


Photo 10

Leading up to the main conference, organizers held a nationwide **educational video competition** that encouraged creative approaches to public health communication. In parallel, an impactful **Instagram Live campaign** brought the conversation to social media, featuring discussions with public figures and medical experts including **Dr. Reisa Brotoasmoro**, **Dr. Faisal, Sp.A(K)**, and **Dr. Reiva, Sp.PK**. These sessions effectively reached a broad audience with accessible, science-backed messaging on the critical role of newborn screening.

Photo 11

On **28 June 2024**, two **offline workshops** were conducted to enhance professional capacity in key areas of NBS implementation. The first, titled *"Communication Strategies for NBS Champions,"* gathered **45 participants** from diverse institutions. The program focused on equipping health workers with refined communication techniques through a structured two-session format. Participants first received refresher content on screened conditions and NBS-related messaging strategies, followed by interactive group discussions and roleplay exercises that brought theory into practice. The sessions were led by **Dr. Faisal, Sp.A(K), M.Kes**, and **Dr. Ghaisani, Sp.A(K)**, with facilitation by **DR. Dr. Dana Nur Prihadi, Sp.A(K)**.

Simultaneously, a second workshop centered on the **proper collection of dried blood spot samples for newborn screening**. With **64 attendees**, the full-day program emphasized technical proficiency and standardization in heel-prick sampling techniques. Expert insights were delivered by **Dr. Ina S. Timan, SpPK(K), MARS** and **Dr. Lovely Daisy, MKM**, with practical demonstrations facilitated by a seasoned team of instructors: **Dr. Thyrza L. Darmadi, SpPK**, **Dr. Desi Natalia, SpPK**, **Dr. Dr. Delita Prihatni, SpPK(K)**, and **Ms. Megawati Kartika, S.Si, M.Biomed**.

Photo 12

Photo 13

The culmination of NBS Day 2024 was the **National Scientific Conference**, which brought together stakeholders across Indonesia through both **online and onsite** participation. A total of **199 participants** joined virtually, while **139 participants** attended the event in person. The conference offered a platform for presenting current research, exchanging best practices, and reinforcing the national commitment to improved newborn health outcomes.


NATIONAL CONFERENCE
2024
esia's Golden Generations - what's next?
NEWBORN SCREENING DAY

Photo 14

Workshop Travelling Lecture: Implementation of Patient-Based Quality Control

On **Saturday, 3 August 2024**, a full-day seminar titled **"Implementation of Patient-Based Quality Control"** was held at the **Aryaduta Hotel, Tugu Tani, Menteng, Jakarta**, bringing together **170 participants** from a variety of clinical laboratory settings across the region. The program aimed to enhance laboratory professionals' understanding and application of modern quality control strategies, with a particular focus on patient-based methods as an evolving complement to traditional techniques.

The seminar was moderated by **Tjan Sian Hwa**, and featured expert insights from **Loh Tze Ping** and **Low Hui Qi**, both of whom brought substantial experience in laboratory quality management.

The day began with an overview of **traditional internal quality control practices**, including a candid discussion about their limitations in dynamic clinical environments. This laid the groundwork for deeper exploration into **patient-based quality control (PBQC)**—a progressive approach that leverages patient test data to monitor and validate analytical performance.

Topics throughout the sessions covered key aspects of PBQC, including:

- An **introduction to the principles** and rationale behind patient-based quality models
- **Parameter selection strategies**, essential for tailoring PBQC to specific laboratory needs
- A **roundtable discussion** encouraging attendees to share real-world practices and challenges from their own labs
- **Verification processes** required to implement PBQC effectively and sustainably
- Guidance on **running PBQC protocols** and conducting appropriate follow-up actions when deviations are identified

The seminar concluded with a **hands-on workshop using Excel-based tools**, allowing participants to simulate and visualize PBQC implementations in a practical context. This session was followed by a debriefing to consolidate learning and address lingering questions.

Overall, the event provided both theoretical grounding and technical guidance, empowering laboratory professionals to elevate their quality control practices through innovative, patient-centered approaches.

Photo 15

Photo 16

IACC 2024 Working Conference

The IACC 2024 Working Conference was successfully held at the Four Points by Sheraton Hotel, Manado, from September 12-14, 2024. The three-day event featured four specialized workshops and a comprehensive symposium, bringing together a total of over 450 enthusiastic participants. Among the attendees were clinical pathologists, medical laboratory technologists, general practitioners, and other healthcare professionals.

The workshops welcomed 200 participants and covered highly relevant topics, including:

- **Six Sigma Approach in Laboratory Medicine**
- **Flow Cytometry for Diagnosis and Management of Cancer**
- **Accreditation Requirements on Analytical Quality**
- **MALDI-TOF Utilization in Microbiology**

Meanwhile, the symposium, attended by 250 participants, featured in-depth discussions on a wide range of subjects such as Women's Health, Pediatric Laboratory Practices, Laboratory and Quality Control Management, Mass Spectrometry, Wellness Testing, and more.

The conference was enriched by distinguished speakers from both national and international institutions, including:

- Dr. Tjan Sian Hwa, SpPK, MSc
- Prof. Aman Pulungan, Sp.A
- Prof. Khosrow Adeli
- Prof. Dr. dr. Sidartawan Soegondo, Sp.PD-KEMD
- Drs. Andi Wijaya, PhD

- Prof. dr. Marzuki Suryaatmadja, Sp.PK(K)
- Prof. Dr. dr. AA Wiradewi, Sp.PK(K)

...and many more esteemed experts.

This event underscored IACC's commitment to elevating standards in clinical laboratory medicine and fostering collaborative progress within the healthcare sector.

Photo 17


LABORATORY MEDICINE UPDATES :
FROM NEWBORN TO ELDERLY
XVI


LABORATORY MEDICINE UPDATES :
FROM NEWBORN TO ELDERLY
XVI

Photo 18

Photo 19

IACC's Participation in EuroMedLab 2025

The Indonesian Association of Clinical Chemistry (IACC) proudly sent a delegation of six representatives, including board members and several young scientists, to participate in the EuroMedLab 2025. Among the highlights of the event, young scientists took part in the international poster competition.

Photo 20

Photo 21

Dr. Ferdy brought honor to IACC by securing the Second Place Winner in Global Med Lab Week 2025. Meanwhile, Dr. Lia Partakusuma attended the general conference and actively participated in green lab meeting that contributed to international collaboration.

Endang Hoyaranda not only joined multiple strategic discussions but also served as a speaker at one of the featured seminars, sharing valuable insights with a global audience. Likewise, Professor Wiradewi was present and contributed to CRIDL Committee meetings, representing IACC with distinction.

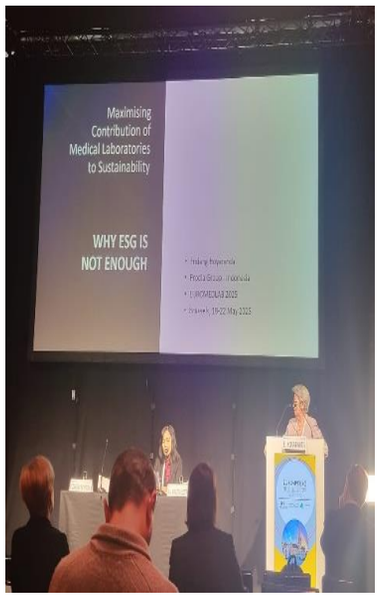


Photo 22

Photo 23

Photo 24

Photo 25

Photo 26

Photo 27

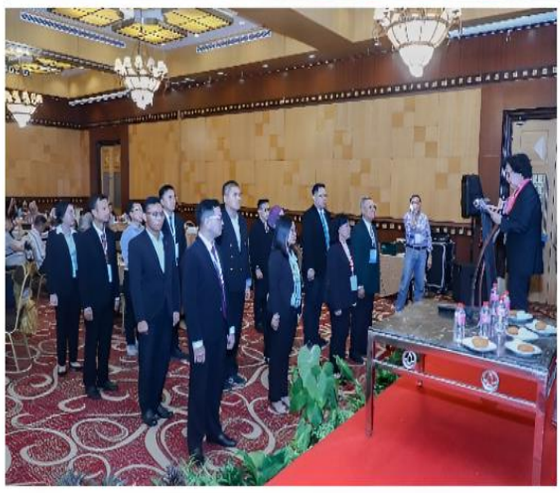
IACC Manado Symposium & Board Inauguration of North Sulawesi and Gorontalo

On Saturday, November 30, 2024, the city of Manado hosted an important gathering at the Swiss-Bel Hotel. The IACC Manado Symposium, organized by the IACC Manado Branch in partnership with PT. Snibe Diagnostic, brought together medical professionals and marked the official inauguration of the IACC Regional Board for North Sulawesi and Gorontalo.

The event welcomed a wide range of participants—clinical and general doctors, medical laboratory technologists (ATLM), students, and other healthcare professionals—who came together to share knowledge and ideas. With the theme *"Understanding Malignancies of Women's Reproductive Organs: Challenges and Advances,"* the symposium focused on cancer in women's reproductive health and highlighted recent developments in diagnostic technology and the use of tumor markers.

Throughout the sessions, participants engaged in meaningful discussions and learned from one another. The symposium wasn't just a place for presentations—it became a collaborative space where medical knowledge met practical use. The event showed a strong commitment to improving diagnostic skills and strengthening healthcare across the region.


Kemenkes
Snibe




Kemenkes
Snibe
The Inauguration of the IACC Manado Branch and Scientific Seminar:
Understanding Malignancies of Women's
Reproductive Organs: Challenges and

Photo 28

Photo 29

Instagram Live Series: IACC's Ongoing Educational Initiative on Tuberculosis

As part of its regular educational programming, IACC held a two-part Instagram Live series focused on raising awareness about Tuberculosis (TBC). The sessions aired on **March 22, 2024**, and **April 5, 2024**, and aimed to deliver accessible, expert-led health education to the public.

Photo 30

The **first session**, held on March 22, explored the dangers of TBC in children. The discussion was guided by host **Dr. Tri Kusuma Widiasih, SpPK**, featuring insights from guest speaker **Dr. Ni Sayu Dewi, SpPK**.

The **second session**, on April 5, continued the conversation on the broader risks of TBC. It was hosted by **Dr. Arwin Prasasto, SpPK**, with guest expert **Dr. Dewi Yennita Sari, SpPK** offering clinical perspectives and practical advice.

Photo 31

Both sessions highlighted IACC's commitment to inclusive health education, encouraging engagement from the medical community and the public in addressing the ongoing challenges of Tuberculosis prevention and care.

National Society Report – ACBI India

NAME OF SOCIETY	Association of Clinical Biochemists of India (ACBI)
OFFICIAL SOCIETY EMAIL ADDRESS	kpsacbi@yahoo.co.in
NAME OF PRESIDENT & EMAIL ADDRESs	President: **Prof. Indu Verma** E-mail: kpsacbi@yahoo.co.in
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Secretary: Prof. Rajiv Ranjan Sinha E-mail: kpsacbi@yahoo.co.in

Report submitted by:
Prof. Rajiv Ranjan Sinha

Scientific activities held in different parts of the country under ACBI banner:

SOUTH ZONE ACBI CONGRESS 2025 JIPMER, PUDUCHERRY

The South Zone Conference of the Association of Clinical Biochemists of India (SZACBICON-2025) was successfully hosted on 24-25 January 2025 in hybrid (both online and onsite) mode at JISPH Auditorium, JIPMER, Puducherry with the theme "Translation from the bench to the bedside: Emerging trends in clinical biochemistry to improve patient outcomes" by Department of Biochemistry, JIPMER, Puducherry, in collaboration with Department of Biochemistry, IGMC&RI, Puducherry. This flagship event brought together clinicians, researchers, academicians, and students from across the biomedical spectrum under the central theme of translational science in clinical biochemistry. The event unfolded over two days of intensive academic exchange, showcasing state-of-the-art research, emerging diagnostic technologies, and opportunities for professional development.

Inauguration and Keynote Address

The conference commenced on 24 January 2025 with an elegant inauguration ceremony, beginning with a warm welcome address by Dr. Medha Rajappa, Organizing Secretary, SZACBICON-2025. The highlight of the session was the keynote address delivered by Prof. Thuppil Venkatesh, a stalwart in the field of laboratory quality assurance. In his talk titled "Management System Requirements (MSR) for Bench to Bedside Diagnosis – A Futuristic Approach," Dr. Venkatesh emphasized the transformative impact of laboratory standards in enhancing diagnostic accuracy and improving patient care.

The ceremony was further enriched by the presence of Dr. Gautam Roy, Director of JIPMER, who addressed the gathering and acknowledged the dynamic progress in laboratory medicine. He commended the collaborative spirit of the scientific community and encouraged continued interdisciplinary efforts. Dr. C. Udayashankar, Director of IGMC&RI, also addressed the audience, highlighting the pivotal role of academic partnerships and innovation in advancing modern healthcare. The inauguration set an inspiring tone for the scientific sessions that followed, reinforcing the conference's central theme of promoting excellence in clinical laboratory practice.

Scientific Sessions

A rich and diverse academic schedule unfolded over both days, comprising 9 scientific sessions with 27 esteemed speakers from various premier institutes across the country.

The day started off with Scientific session 1 which highlighted recent advances in molecular biology and genetic interventions for complex diseases:

- **Dr Manjula Das – "Translating The Micro-RNA"** Focused on the role of micro-RNAs as regulators of gene expression, with potential utility in clinical diagnostics and therapeutic modulation.
- **Dr Mohan Kumar – "Therapeutic Genome Editing for Hematological Disorders"** Presented breakthroughs in genome editing for blood disorders using CRISPR/Cas9, highlighting translational potential.
- **Dr Raghu – "ER Stress and Cardiomyopathy"** Explored ER stress in cardiac pathology and the protective role of chlorogenic acid as a therapeutic agent.

Scientific session 2 explored personalized approaches to cancer diagnosis and therapy, using cutting-edge biomarkers and pharmacological interventions targeting tumor biology:

- **Dr Prasanth Ganesan – "Personalized Treatment of Cancer"** Emphasized the clinical relevance of tailoring cancer therapy based on tumor-specific molecular profiles.
- **Dr Mayank Sharma – "Liquid Biopsy for HPV cfDNA"** Demonstrated the potential of HPV cfDNA detection via liquid biopsy as a non-invasive monitoring tool in cervical cancer.
- **Dr Gopalan – "Targeting Glycosylation in Melanoma"** Investigated glycosylation pathways as therapeutic targets in melanoma for enhanced treatment specificity.

Scientific session 3 focused on improving diagnostic accuracy and operational efficiency in clinical laboratories through updated reference ranges, automation, and novel biomarkers:

- **Dr Kannan Vaidyanathan – "Geriatric Reference Intervals"** Addressed the clinical significance of age-appropriate reference intervals in elderly patients.
- **Dr Sudip Kumar Datta – "Total Laboratory Automation"** Outlined the integration of automation to improve laboratory efficiency and result reliability.
- **Dr Barnali Das – "Autoimmune and Neuroimmune Markers"** Reviewed emerging biomarkers in autoimmunity and neuroinflammation, relevant to laboratory diagnosis.

Scientific session 4 delved into immune regulation in chronic diseases and highlighted the gut microbiome's role in systemic health:

- **Dr Alpana Sharma – "CCR5 Modulation in Atherosclerosis"** Proposed CCR5 as a therapeutic target to reverse immune dysfunction in early atherosclerosis.
- **Dr Archana Singh – "Monocytes and TB Resistance"** Discussed cytokine-secreting monocytes as potential indicators of host resistance to tuberculosis.
- **Dr Balamurugan Ramdass – "Gut Microbiome in Anemia"** Highlighted the interplay between gut microbial composition and iron absorption in anemia.

Scientific session 5 focused on identifying and validating new molecular targets for cancer diagnosis and therapy, as well as potential diagnostic adjuncts:

- **Dr Sathees Raghavan – "Disarib – A Novel BCL2 Inhibitor"** Introduced Disarib, a promising anti-cancer compound with selective BCL2 inhibition.
- **Dr Savita Yadav – "Multimerin-1 in Ovarian Cancer"** Investigated the tumor-promoting effects of Multimerin-1 and its potential as a biomarker.
- **Dr Sadhana Sharma – "Complement Components as Diagnostic Markers"** Explored the role of complement proteins as supportive markers in clinical diagnostics.

Day 2 started with **scientific session 6, which** presented the application of advanced genomic technologies:

- **Dr Ashwin Dallal – "PRaGeD: Rare Pediatric Genetic Disorders"** Described a mission-based approach to identify and manage rare pediatric genetic conditions.
- **Dr Divya Tej Sowpati – "Optical Genome Mapping"** Highlighted genome mapping as a next-generation cytogenetic tool offering enhanced resolution.
- **Dr Anand Srivastava – "Drug Design for Disordered Proteins"** Showcased computational methods for targeting intrinsically disordered proteins via simulation and AI.

Scientific session 7 explored novel compounds and clinical biochemistry approaches for managing infections and endocrine disorders:

- **Dr Vijay Kutala – "Modified Curcumin as Antimicrobial Agent"** Discussed enhanced antimicrobial efficacy of chemically modified curcumin compounds.
- **Dr Jayaprakash Sahoo – "Clinical Biochemistry in Endocrinology"** Reviewed current advances in biochemical diagnostics for endocrine disorder management.
- **Dr Joe Varghese – "Iron in Diabetes and Wound Healing"** Explored iron metabolism's role in diabetic complications and tissue repair mechanisms.

Scientific session 8 addressed both technical and educational aspects of laboratory medicine, including sample integrity and curriculum development:

- **Dr Archana Bhatnagar – "Oxidative Stress in Lupus"** Proposed antioxidant therapy as a novel intervention for systemic lupus erythematosus.
- **Dr Seema Bhargava – "Hemolyzed Samples Audit"** Presented a clinical audit on hemolyzed specimens and corrective quality assurance measures.
- **Dr Ramesh Ramasamy – "Lab Medicine in Medical Education"** Advocated for structured inclusion of laboratory medicine in undergraduate medical training.

The final **scientific session 9** presented translational research on brain tumors, focusing on diagnostic advancements and tumor suppressor discovery:

- **Dr Sujan Dhar – "IDH Mutation Detection in CNS Tumors"** Demonstrated hybrid diagnostic approaches combining ddPCR and AI for IDH mutation analysis.
- **Dr Nandakumar DN – "Immune Microenvironment in Glioblastoma"** Investigated glutamate signalling and cytokine profiles as therapeutic targets in glioblastoma.

- **Dr Arnab Pal – "Cornulin as a Tumor Suppressor"** Identified Cornulin as a potential prognostic biomarker with tumor-suppressive properties.

Poster and Oral Presentations

Over 80 abstracts were submitted, with selected papers presented during digital poster and oral presentation sessions. These sessions provided a platform for budding researchers and postgraduates to showcase original work on topics such as:

- Risk factors, biomarkers and novel diagnostics
- Quality Lab Management and accreditation
- Metabolic, cardiac & kidney diseases
- Molecular diagnostics
- Stem cell and lab medicine
- Free radicals in health and disease
- Point of Care testing
- Clinical phytochemistry
- Environmental biochemistry and metabolism
- Cancer tumor markers
- Approaches in system biology, use of bioinformatics and translational research
- Endocrinology / hormones
- Life style interventions and alternative medicine
- Biochemistry of reproduction, infertility, IVF and latest trends

Awards and Valedictory Function

The conference also fostered peer interaction and mentoring opportunities through informal interactions and Q&A sessions. The valedictory function on 25 January 2025 recognized outstanding presenters and contributors with awards and certificates. The conference ended with a vote of thanks to all those who immensely contributed to the resounding success of this event.

The awardees are as follows:

Oral paper - award list Archana L	Madras Medical College, Chennai
Saravanan Ramanujam	National Institute of Ayurveda
Kamila Thalapalliyil	JIPMER, Puducherry
J Gnanapriya	Indira Gandhi Medical College & Research Institute, Puducherry

Photo 1

Photo 2

Photo 3

Photo 4

Photo 5

EAST ZONE ACBI CONGRESS 2025
AIIMS, Kalyani & COMJNMH, Kalyani

The Department of Biochemistry, AIIMS Kalyani, in collaboration with the Department of Biochemistry, College of Medicine & JNM Hospital (COMJNMH), Kalyani, successfully organized the Eastern-Zone Conference of the Association of Clinical Biochemists of India (EZACBICON 2025) as well as pr-conference workshops from 27th February to 1st March 2025. The conference was held under the aegis of ACBI, with the theme "Molecular & Cellular Basis of Bio-Medicine: Basic Insight for Translation."

The conference was conducted under the leadership of the Organizing President, Prof. (Dr.) Kalyan Goswami (HOD, Biochemistry, AIIMS Kalyani & Dean Academics); Organizing Chairman, Prof. (Dr.) Subir Kumar Das (HOD, Biochemistry, COMJNMH, WBUHS); and Organizing Secretaries, Dr. Atanu Kumar Dutta and Dr. Tanmay Saha, both from the Department of Biochemistry, AIIMS Kalyani. Their relentless effort, along with the dedicated team including mainly, Dr. Sibasish Sahoo as Additional organizing secretary and Dr. Amit Pal, Dr. Amitava Das along with Dr. Asmita Hazra as joint secretary also Dr. Som Dev and Dr. Nihar Ranjan Mishra as treasures with Dr. Ibanylla Hadem in local hospitality ensured the seamless execution of this academic event.

Pre-Conference Workshops – 27th February 2025

The conference commenced with three thematic pre-conference workshops held at AIIMS Kalyani and COMJNMH, Kalyani:

1. "Meta-analysis as a Tool for the Study of Problems in Biochemistry" at COMJNMH, coordinated by Dr. Amit Pal, Dr. Nihar R. Mishra, Dr. Kaushik Mukhopadhyay, and Dr. Mohan Raj PS, along with Dr. Sk Sabir Ali.
2. "Application Potential of Epifluorescence Microscopy" at AIIMS Kalyani, led by Dr. Sibasish Sahoo and Dr. Rachita Nanda
3. "Molecular Genetic Applications in Clinical Diagnosis", coordinated by Dr. Atanu Kumar Dutta and Dr. Sarama Saha

These sessions offered hands-on training into high-impact research tools and fostered early networking among attendees.

Day 1 – 28th February 2025

The scientific sessions began following spot registration and breakfast, with a keynote address by Prof. Subrata Sinha (President, AIIMS Patna). This was followed by the inaugural session and souvenir release, graced by senior dignitaries, namely Professor (Dr.) Sunil Khare, Director, IISER, Kolkata as Chief guest and Professor (Dr.) Indranil Chakrabarty, as guest of honour and Professor (Dr.) Manideep Pal, Principal, College of Medicine & JNM Hospital (COMJNMH), Professor (Dr.) Subir Kumar Das, HOD, Biochemistry, COMJNMH, WBUHS and past president of ACBI along with Professor (Dr.) Kalyan Goswami (HOD, Biochemistry, AIIMS Kalyani under the patronage and mentoring of Professor (Dr.) Ramji Singh, Executive Director, AIIMS, Kalyani.

Session 1: Frontiers of Basics Towards Translation Featured speakers included Dr. Bidhan Chandra Koner (MAMC, New Delhi) and Dr. Nandakumar D. N. (NIMHANS, Bangalore) in Session 1A, followed by Dr. Arindam Maitra (NIBMG, Kalyani), Dr. Priyadarshi De (IISER Kolkata), and Dr. Partha Chakrabarti (CSIR-IICB, Kolkata) in Session 1B.

- A Poster Presentation Session was held in the auditorium lobby area, showcasing over 15 scientific posters from diverse fields in clinical biochemistry and translational research.

- Session 2: Cellular & Molecular Biology – Contribution to Biomedical Research

This included engaging lectures by Dr. Tushar Kanti Maiti (RCB, Haryana), Dr. U. Mabalirajan (CSIR-IICB, Kolkata), and Dr. Rupak Datta (IISER Kolkata). Simultaneously, parallel sessions featured around 8 experts such as Dr. Sukhes Mukherjee, Dr. Chandan Nath, Dr. Debapriya Bandyopadhyay, and others from institutions across various parts of India.

Day 2 – 1st March 2025

The second day began with a Corporate Session, coordinated by Dr. Asmita Hazra (AIIMS Kalyani), followed by a keynote address by Prof. Debabrata Dash (Professor, BHU, Varanasi).

- Session 3: Advancement in Cell Biology Research Featured speakers included Dr. Arnab Pal (PGIMER, Chandigarh), Dr. Amitava Das (CSIR-IICT, Hyderabad), and Dr. Sunil K. Raghav (ILS, Bhubaneswar).

- This was followed by another session comprising Dr. Amitava Das (IISER Kolkata), and Dr. Sadhana Sharma (AIIMS Patna).
- The Panel Discussion titled “Basic Research – The Pathway for Future Biomedical Research”, moderated by Dr. B. C. Koner, had active participation from Dr. Sunil K. Raghav, Dr. Sonali Roy, Dr. Dibyajyoti Banerjee.

The event concluded with the Prize Distribution and Valedictory Ceremony, recognizing outstanding oral and poster presentations. The collaborative efforts of the scientific committee, volunteers, and organizers were widely appreciated by all participants.

EZACBICON 2025 emerged as a highly successful academic conclave that brought together distinguished scientists, passionate researchers, and enthusiastic students. The event upheld the legacy of ACBI in promoting translational biochemistry and strengthened academic interactions across institutions in Eastern India and beyond. The collective vision and leadership of the organizing team at AIIMS Kalyani and COMJNMH was instrumental in the event's success and left a lasting impression on all attendees.

Photo 6

Photo 7

Photo 8

Photo 9

Photo 10

India International Convention & Expo Centre, New

Photo 11

National Society Report – MACB Malaysia

Name of Society	MALAYSIAN ASSOCIATION OF CLINICAL BIOCHEMISTS (MACB)
Email	MACB_secretary@yahoo.com
Name of President & National Representative	Raja Elina Raja Aziddin E-mail: rajaelina@gmail.com, president@macb.org.my
Secretary	Chuo Pek Ham E-mail: phchuo@yahoo.com, MACB_secretary@yahoo.com

1. MACB CKD TASK FORCE ACTIVITIES

The previous CKD Task Force was formed in December 2017 and finalised its recommendations in 2019 and uploaded onto the website on 20th November 2019. The CKD Task Force was reconstituted on 1st March 2024 for a period of two years by the MACB president, YM Dr Raja Elina Raja Aziddin to update the CKD recommendations. The task force is chaired by Dr. Leslie Charles Lai Chin Loy.

The MACB CKD Task Force held an inaugural meeting on 30th March 2024. At the meeting, members agreed to embark on a KATALYST project which is a collaboration between AstraZeneca and various associations and Private Laboratory Chains. The objective of the project is to promote the incorporation of the Kidney Failure Risk Equivalent (KFRE) in blood reports for individuals who have eGFR less than 60 ml/min/1.73m^2 so that individuals with a high risk of progression to ESKD can be referred to nephrologists early in order to retard the progression to ESKD.

The KATALYST project was launched on 7th May 2024 at Menara Ken, Taman Tun Dr Ismail, under the project title "Smart Partnership for Early Actions in Chronic Kidney Disease".The event was graced by the Ministry of Health (MOH) medical practice division director, Dr MohamedIqbal Hamzah and it is a first-of-its-kind innovative partnership between multiple health care players and medical societies.

Photo 1: Speech by the Ministry of Health (MOH) medical practice division director Dr Mohamed Iqbal

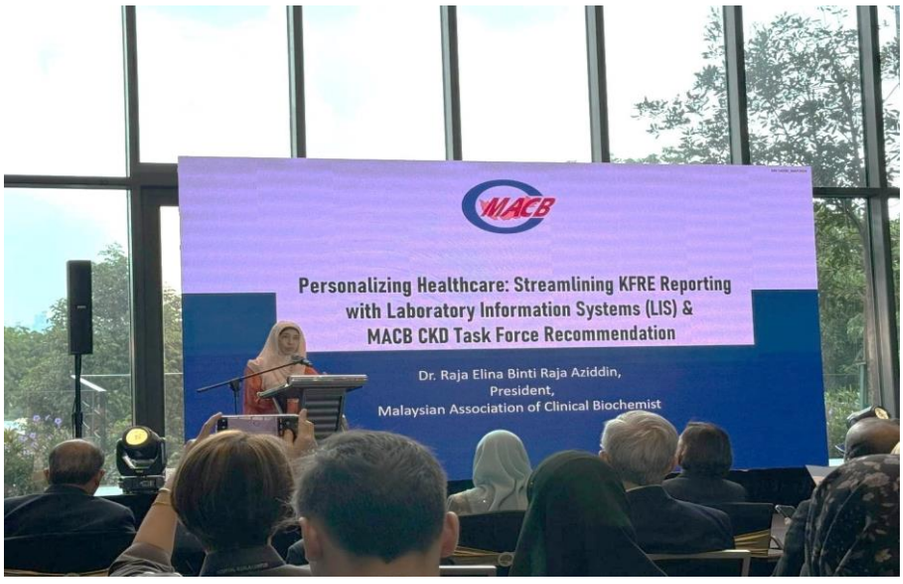


Photo 2: MACB President delivering a lecture at the KFRE Media

This smart partnership embarked on several initiatives which includes the creation of **MY CKD CPG Web App** by the Malaysian Society of Nephrology (MSN) in collaboration with Malaysian Association of Clinical Biochemists (MACB) and AstraZeneca Malaysia. This app is a comprehensive one-stop digitalplatform for healthcare professionals, providing holistic decision aid approaches for CKD management needs to facilitate early diagnosis and optimal management. In addition, the app will also incorporates **Kidney Failure Risk Equation (KFRE) into clinical practice** including auto laboratory reporting to enable for a refined risk stratification and prompting appropriate intervention to delay CKD progression.

This event received good media coverage.

Home » Pemimpin industri kesihatan lancar MyCKD CPG intervensi penyakit buah pinggang

NEGARA

Pemimpin industri kesihatan lancar MyCKD CPG intervensi penyakit buah pinggang

Oleh NUR FATIN ZAHRA 7 Mei 2024, 1:36 pm

Dr. Mohamed Iqbal (enam dari kiri) melakukan gimik pelancaran aplikasi MyCKD CPG ketika ditemui di Majlis Pelancaran MyCKD CPG di Menara KEN, Taman Tun Dr Ismail di ibu negara hari ini.

KUALA LUMPUR – AstraZeneca bersama beberapa pemimpin industri kesihatan hari ini melancarkan aplikasi kesihatan, MyCKD CPG dan Persamaan Risiko Kegagalan Buah

Photo 3: Partners which include the Malaysian Society of Nephrology (MSN), Malaysian Association of Clinical Biochemists (MACB), Chapter of Chemical Pathology and Metabolic Medicine, College of Pathologists, Academy of Medicine of Malaysia (CPMM, CPath AMM), Premier Integrated Labs, Innoquest Pathology, Labink Medical Laboratory, and Sunway Medical Centre Laboratory – articlepublished in Kosmo

2. SYSMEX URINALYSIS FOCUS GROUP MEETING: THE ART AND SCIENCE OF URINALYSIS

Sysmex Malaysia organised a Urinalysis Focus Group Meeting with the theme "The Art and Science of Urinalysis" under the auspices of Malaysian Association of Clinical Biochemist (MACB). It was held onTuesday, 14th May 2024 at the Everly Putrajaya Hotel with a total of 68 participants across Malaysia. Theaudience consisted of Chemical Pathologists, Lab Managers, Scientific Officers, and Medical LaboratoryTechnologists.

Professor Dr. C.N Srinivas, dubbed the "Father of Urinalysis" from Kauvery Hospital in India, delivered a talk on “Give PeeIt’s Due Value” to emphasise on the importance of urinalysis biomarkers and the era of automation. The second topic was given by Mr Shanmuganathan Arumugam, a Scientific Officer from PPUM to share his “Journey from Manual Microscopic to Automated Urine Particle Flow Cytometry”. The final topic was “Urine Particle Flow Cytometry: What Can It Do for Renal and Urological Diseases” by Dr Jeffrey Susilo,Scientific Affairs Liaison from Sysmex Asia Pacific in which he shared on clinical utilities of the advanced clinical parameters on UN Series. An Expert Forum Discussion was carried out after the presentations.

Photo 4: Sysmex the Art and Science of Urinalysis flyer

Photo 5: The "Father of Urinalysis," Professor Dr. C.N. Srinivas of Kauvery Hospital in India, and demosession by Sysmex Application specialists.

Photo 6: Participants and invited speakers at the Sysmex Urinalysis Focus Group Meeting under MACBauspices

3. SEMINAR ON RCPAQAP : "THE IMPACT OF QUALITY PATHOLOGY ON THE HEALTH ECONOMY" ON 11th JUNE 2023 AT THE PAVILION HOTEL, KUALA LUMPUR

The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) conducted a joint meeting with Malaysian College of Pathologists (CPath) and Malaysian Association of Clinical Biochem ists (MACB) to celebrate their 35th anniversary of RCPAQAP.

Photo 7: Officials from PRPAQAP, CPath and MACB at the opening ceremony of The Impact of QualityPathology in He alth Economics the Seminar

Photo 8: Panel discussion on Key Impact of ISO 15189:2022 Standards

Topics presented and discussed at the seminar were focused on:

- QC and EQA
- Laboratory cyber security
- Changes with the new ISO 15189:2022 Standard
- The economics of community screening tests
- Lessons during the pandemic
- Providing optimal pathology services for non-communicable disease monitoring

4. MACB-APFCB WORKSHOP ON PATIENT-BASED QC

The PBQC workshop was supported by APFCB and featured APFCB travelling lecturer, Dr Loh Tze Pingfrom Singapore. It was held on 12th June 2024 at Cititel, Kuala Lumpur and focused on practical discussion of key concepts of patient-based QC, recommended ways to select the parameters, how to undertake performance verification of the patient-based quality control algorithm and how to apply it in routine practice. It also included a hands-on session with an Excel tool with real-world data and a discussion on areas of uncertainty or interest.

Photo 9: PBQC

Photo 10

Photo 11: Opening remarks by Dr Tony Badrick, APFCB President at the PBQC Workshop in Cititel

Photo 12: Lecture by Dr Loh Tze Ping, APFCB Travelling Lecturer at the PBQC

Photo 13: Participatns at the PBQC Workshop. The workshop was attended by 60 participants.

5. NATIONAL ABG SYMPOSIUM 2024 : TOWARDS IMPLEMENTATION OF ISO 15189WITH iQM

The "National ABG Symposium: Towards Implementation Of ISO 15189 with iQM" was held at Royale Chulan Hotel, Kuala Lumpur on 20th June, 2024. The symposium, under the auspices of the Malaysian Association of Clinical Biochemists (MACB), was jointly organized by the Straits Scientific and Werfen. Over 88 people attended the Symposium which comprised of a virtual session, series of lectures and interactive discussions with Blood Gas analyser users.

The welcoming speech was delivered by Dr. Raja Elina Raja Aziddin, the president of MACB. The event featured five plenary lectures followed with interactive sessions between participants and esteemed speakers. The first lecture which was delivered by Professor Sharon Ehrmeyer of the University of Wisconsin-Madison, focused on the risk management system including thorough risk assessment and effective risk mitigation for quality results and patient safety. The second lecture that was delivered by Dr.Hanisah Abdul Hamid addressed current challenges of POCT blood gas testing as well initiatives to overcome them. Prof. Sharon Ehrmeyer then continued, outlining how to accomplish ISO 15189 quality targets using iQM Technology. The evening sessions were delivered by Davide Colombo, the global acutecare expert from Werfen, USA.

Photo 14: National ABG Symposium 2024 event flyer

Photo 15: Opening remarks by MACB President, YM Dr Raja Elina binti Raja Aziddin

His sharing involved field experiences using ISO15189, followed by pre-analytical, analytical and post-analytical journey in blood gas testing. The symposium recognized the contributions of all presenters, who presented insightful points of view on the highlighted topics. Participants were actively involved throughout the symposium, raising their concerns and engaging in open discussions. Overall, the NationalABG Symposium was a resounding success, bringing healthcare professionals to share their valuable knowledge and experience.

6. MACB ON RTM'S SELAMAT PAGI MALAYSIA LIVE MORNING SHOW

The MACB President was featured on RTM's Selamat Pagi Malaysia talk show on 23rd June 2024. The main objective of the talk shpw was to emphasize on the importance of having one's kidney status regularly checked and to be able to predict the risk of getting chronic kidney disease. Revolving around the slot's theme, which was on "*Kesedaran Malaysia Tentang Penyakit Buah Pinggang*", Dr Raja, introduced the Kidney Failure Risk Equation (KFRE), a derived calculative measurement, which can be utilized for the early detection and timely intervention ofCKD. The regular Sunday slot is a morning show broadcasted every Sunday to thousands of viewers, andwas also on the live stream footage online. It was the first ever MACB live event of this scale at which itwas able to actively engage with and reach out to a wider viewer across Malaysia.

Representing the medical laboratory professionals, Dr. Raja explained that MACB is leading an initiativeto further elevate KFRE clinical utility by integrating it into lab reports. The impact of KFRE automationinto clinical practice is pivotal for primary care physicians to improve on early detection as well as to optimally manage CKD patients to delay CKD progression. Importantly this will help patients with CKDto make informed health decisions and take a proactive approach to manage underlying risk factors.

Dr Raja was also accompanied by Dato' Dr Lily Mushahar, President of the Malaysian Nephrology Association, who presented the clinical perspective of kidney disease in Malaysia. Apart from presentingthe data of diabetes, kidney disease and management, Dr Lily also emphasized on the importance of laboratory's effort in the management of kidney disease by applying KFRE values.

Photo 16: MACB President introducing the KFRE values on RTM

Photo 17: President of MACB and MSN on the RTM morning show

7. MACB SAFETY & HEALTH TRAINING-WORKSHOP ON CHEMICAL MANAGEMENTIN HEALTHCARE FACILITIES

The training-workshop took place on 22-23 April 2024 at Palace Hotel, Kota Kinabalu, Sabah. The two- day programme was specially designed for participants who handle chemicals and responsible for chemical management at their workplace. It was aimed to help participants understand the types of chemical exposure and hazards at the workplace, ways to handle and manage the chemicals safely throughthe application of chemical registry and safety data sheets, and lastly, ways to minimize exposure of chemicals from potential adverse health effects.

Participants were taught on safe practices for chemical storage and waste disposal, appropriate responsesto emergency situations, chemical spillage and basic first aids. In addition, the requirement to comply to the Use and Standards of Exposure of Chemical Hazardous to Health (USECHH 2000) and Classification,Labeling and Safety Data Sheet of Hazardous Chemicals (CLASS 2013) regulations were also discussed.The training also emphasized the requirements of the accredited laboratory to comply to MS 1042 (Safetyin Laboratories -Code of Practice) and MS ISO 15190:2020.

A total of 43 participants were from across Malaysia and comprised of laboratory scientists, medical lab technologists, pharmacists, researchers, laboratory managers, company directors and various other categories of laboratory professionals from government and private institutions. The training-workshop was co-sponsored by DW Labs Sdn Bhd, Tru One, Merck Sdn Bhd (Weitengen-local agency) and DOSHdepartment.

Photo 18: MACB Safety & Health Training-Workshop On Chemical Management Workshop Flyer

Photo19: Participants from East and Westt Malaysia

8. GREEN LABS: ADVANCING ENVIRONMENTAL SUSTAINABILITY WEBINAR

In conjunction with World Environmental Day on June 5th, MACB had organized a webinar focused on advancing environmental sustainability within laboratory practices. This webinar provided valuable insights into the intersection of healthcare and environmental sustainability, emphasizing the importance of adopting eco-friendly practices in laboratory operations.

Photo 20: MACB-APFCB Green labs: Advancing Environmental Sustainability flyer

9. 34th MACB ANNUAL CONFERENCE 2024

The 34th MACB Annual Conference, in collaboration with the 2nd MYBIOMED Symposium, was held from 21st to 23rd July 2024 at The Royale Chulan KL with the theme "Towards Holistic, Integration and Sustainability in Medical Laboratories." The event began with a pre-conference on July 21st focused on "Risk Management In Medical Laboratory" which attracted 91 participants and was supported by Chemopharm Group. The pre-conference featured four speakers, two international and two local.

The main conference took place on 22nd to 23rd July 2025 with a total of 344 participants, MACB accounted for 255 participants, while MYBIOMED had 87 participants. The conference included an opening ceremony, a keynote lecture on the Health White Paper and its impact on Medical Laboratories, and several symposiums covering topics such as General Chemical Pathology, Molecular Diagnostics, Value-Based Laboratory Medicine, Vaccinology, Paediatrics Chemical Pathology, Natural

Product Research, Digital Technology, and Toxicology & Pharmacology. Plenary lectures covered Bone Markers and Hormones in CKD-MBD, One-World One-Health, and Updates in MACB CKD Recommendations. There were also industrial talks, poster (20) and oral (8) presentations, Young Scientist Awards for both MACB and MYBIOMED, and AGMs for both organizations.

A total of 74 poster submissions and 16 oral submissions were received, with 20 posters and 8 oral presentations finalized. Winners were selected for both poster (6) and oral (3) presentations. The conference featured 18 speakers, including 7 international and 11 local speakers. Sponsorship was provided by Pantai Integrated Lab, DWLab, Siemens, Utas Maju, Waters, and MACB. Post-conference activities included the issuance of certificates and e-certificates, and the collection of feedback

Photo 21: 34th MACB Conference Flyer

Photo 22: Pre-Conference session supported by Chemopharm, featuring speakers Dr. Nico Vandepoele and John Yundt Pacheco.

Photo 23: MACB Young Scientists recipients, Dr.Apeksha Niraula (Institute of Medicine Tribhuvan University Teaching Hospital, Nepal) and Dr Azzah Hana (National Institute Health, Malaysia)

Photo 24: Opening ceremony of the 34th MACB Annual Conference, in collaboration with the 2nd MYBIOMED Symposium

10. MACB COLLABORATION WITH UKM TO SET UP THE PROFESSIONAL COURSE IN CHEMICAL PATHOLOGY LABORATORY.

UKM's Faculty of Health Sciences proposed a 6-month Professional Certificate Course in Chemical Pathology in collaboration with MACB. The objective of the course is to provide opportunity for Medical Lab Scientists to pursue further training and strengthen their knowledge in chemical pathologyfield.

Photo 25: Meeting held at Faculty of Health Sciences, UKM on setting up the Professional Certificate Coursein Chemical Pathology

A series of r
coursein Chemical Pathology Laboratory (PC-PL).

11. MACB PARTICIPATION AT APFCB CONGRESS 2024 IN SYDNEY, AUSTRALIA

At the APFCB Congress 2024 in Sydney, Australia, the MACB hosted Symposium 20, titled 'Advancing Health: Bridging Gaps in Endocrine Test Reporting and Novel Lipid Profiles in Malaysia', which was held on 3rd November 2025. The lectures delivered were as follows:

1. 'Standardised laboratory reporting for prediabetes: An initiative of the 'Stand Against Prediabetes national campaign' by Dr. Leslie Charles Lai
2. 'Screening for Macroprolactinaemia: Malaysian Scenario' by Assoc. Prof Dr. Pavai Sthaneshwar
3. 'A Closer Look: Malaysian Insights into Atherogenic Pattern B Lipoprotein Profile by Dr. Subashini C. Thambiah

Photo 26: Dr. Leslie Lai delivering a lecture at the APFCB Congress

The MACB symposium was chaired by Dr. Raja Elina, President of MACB. Dr. Elina also delivered 2 lectures at the congress. On Friday, 1 November 2024 in Educational Workshop 1 on Risk Management in Clinical Laboratory she delivered a lecture on 'Applying Risk Management for Continuous Improvement'. Another lecture onthe topic "Challenges in the interpretation of drugs of abuse tests" was delivered on Saturday, 2 November 2024 in Educational Workshop 4 on Result Interpretation

Photo 27: The Malaysia team at the APFCB Congress 2024

Photo 28: MACB booth at APFCB Congress 2024

Photo 29: Delegates at MACB booth

The MACB was an active participant at the APFCB Congresss 2024. In addition to hosting a symposium and bringing a large delegate of more than 20 people to attend the congress in Sydney, the MACB took an exhibition booth at the congress to promote the 18th APFCB Congress 2027 which will be held in Kuala Lumpur, Malaysia.

Photo 30: Handing over ceremony of the 24th APFCB Congress to MACB

The handing over of the APFCB Congress from the Australasian Association of Clinical Biochemists (AACB) to the Malaysian Association of Clinical Biochemists (MACB) was a colourful and memorable event, highlighted by vibrant cultural attire and enthusiastic participation. The ceremony began with the rhythmic beats of the kompang (traditional drum) and a compelling video showcasing Malaysia, building anticipation for the upcoming Congress. It was a meaningful celebration of scientific camaraderie and regional collaboration.

National Society Report – AMBI India

31st Annual Conference, AMBICON 2024, December 19 – 21, Club 07, Ahmedabad, Gujarat, India

"Through the Lens of a Biochemist: Advancing Medicine. Breakthrough Innovations"

NAME OF THE SOCIETY	Association of Medical Biochemists of India (AMBI)
OFFICIAL SOCIETY EMAIL ADDRESS	drvgovindaraju@gmail.com
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Dr Anitha Devanath, ambihonorarysecretary@gmail.com

"CONFERENCE REPORT"

AMBICON 2024, the 31st annual conference of the association of medical biochemists of India was the first ever AMBICON hosted by the Gujarat chapter. All the members from Gujarat state were excited to host it in the best possible way. After extensive deliberations, Club O7 in the city outskirts was selected as the venue and soon the dates were finalized from 19 – 21 December 2024 with the pre-conference workshop on the 18th December. Pre-conference workshops were organized in collaboration with Gujarat Biotechnology University and Gujarat Biotechnology Research Center, along with other institutions. Registration for the conference opened on 7th July 2024 and we soon achieved a good response. We had 510 registrations. The conference organizing committee was duly formed with Dr. Ramesh Pradhan as organizing secretary. The scientific, registration, accommodation and logistics committees effectively handled all procedures, queries and carried a balanced scientific schedule. The theme of the conference was "Through the lens of a biochemist: Advancing Medicine, Breakthrough innovations". The committees progressed through different stages of team development, culminating in a high level of collaboration.

The conference was held under the aegis of International Federation of Clinical Chemistry (IFCC) and Asia-Pacific Federation of Clinical Biochemistry (APFCB). The academic program, featuring renowned national and international speakers, including IFCC visiting lecturers, was very much appreciated. The program schedule tried to cover all aspects related to Biochemistry. There were orations, invited guest lectures, IFCC visiting lecturer program, symposiums, Panel discussions, Post-graduate Quiz as well as the paper and poster presentations. Gujarat medical council granted 8 credit hours to this 3-day conference.

The Gujarat chapter expresses gratitude to the AMBI central body for the opportunity to host AMBICON. We would also like to thank all our industry partners for the immense support. Diasys, Abbott, Transasia, Agappe, Kopran, Quidel Ortho, BioRad, Snibe, Roche, Sysmex, Siemens, Microlab, BD and Zellen biotech.

Oration	Title	Speaker
Dr C Sita Devi Oration	Breaking the shackles – Interference in Laboratory Testing and How Advancements in Laboratory Technology Helps to Tackle this Perpetual Problem	Dr Malavika Barman (Guwahati)
Dr B Sadasivudu Oration	Salivary Analysis: Advancing Non-Invasive Diagnostics for Systemic Diseases	Dr Himanshu Madaan (Karnal)
Dr S Gopalkrishnan Oration	Outcome of Studies of ECG and Biochemical Changes in primary Hypothyroidism	Dr Biswajit Saha (Tripura)
Dr Akhouri S S Sinha Presidential Oration	Quizzes and Games in Teaching Learning Biochemistry: Why can't learning be Fun?	Dr Ramesh Pradhan (Ahmedabad)
Dr Sheela Devi Kodliwadmath Oration	Innovative Breakthrough Screening of Early Hepatic Cancer: GALAD & HES-V2 Serum Biomarker Model	Dr Shilpa Jain (Bathinda)
Dr A S Saini Oration	Mass Spectrometry in Clinical Laboratory – Where to from Here?	Dr Mahesh Hampe (Bengaluru)

Photo 1

Visting Lecture Programme (VLP) by IFCC (Compiled by : Dr Ashish Agravatt, Dr Ramesh Pradhan, Dr Shanti K Naidu)

The IFCC-Abbott Visiting Lecture Program (VLP) successfully took place during the 31st Annual National Conference of the Association of Medical Biochemists of India (AMBICON 2024), held in Ahmedabad, Gujarat, India, from December 19 to 21, 2024. The conference served as a dynamic platform for knowledge exchange, skill enhancement, and networking among clinical biochemists and laboratory medicine professionals, with over 522 attendees, including 184 faculty members, 167 postgraduate

Photo 2

The program featured three distinguished international speakers who delivered lectures on critical and contemporary topics in clinical laboratory medicine:

1. **Prof. Sedef Yenice** delivered two insightful lectures:

   Precision in Practice: Utilizing Data-Driven Decision-Making in Clinical Laboratories emphasized the integration of big data and analytics to improve diagnostic accuracy and patient care. Prof. Yenice highlighted how laboratories can implement precision-based approaches to enhance operational efficiency. Navigating the New Regulatory Landscape for Laboratory-Developed Tests explored the evolving regulations for laboratory-developed tests (LDTs) and their implications for clinical laboratories, underscoring the importance of compliance and innovation in the face of regulatory changes.

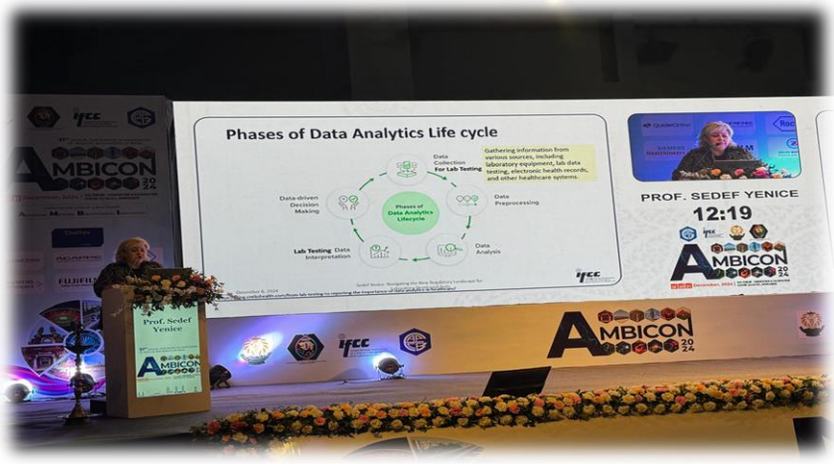


Photo 3

2. **Prof. Rajiv Erasmus** presented:

   Impact of Point of Care Testing on Patient Outcomes: Challenges and Prevention of Errors, which outlined the advantages of point-of-care testing (POCT) in improving patient outcomes while addressing potential sources of error and proposing preventive strategies.

   Leadership in the Medical Laboratory for Effective Patient Care provided an in-depth discussion on the role of leadership in fostering effective teamwork and implementing quality management systems to enhance laboratory performance.

Photo 4

3. **Prof. Tahir Pillay** contributed with:

   Practical Considerations for Performing Lipid Profiling in the Assessment of Cardiovascular Risk, which detailed best practices in lipid profiling and their importance in cardiovascular risk stratification.

   Challenges with Immunoassays: Dealing with Standardization, Harmonization, and Interferences, addressing technical challenges in immunoassays and offering strategies to achieve standardization and harmonization in clinical testing.

Photo 5

The lectures stimulated engaging discussions, offering practical insights and actionable recommendations for enhancing laboratory practices. Participants praised the speakers' ability to bridge theory with real-world applications, making the sessions highly relevant to their clinical and academic responsibilities.

The conference's objectives of fostering knowledge exchange, collaboration, and capacity building were effectively met. The sessions enabled participants to gain a deeper understanding of advanced topics, including the role of precision medicine, leadership in laboratory settings, and the technical nuances of POCT and lipid profiling.

The event's success was evident from the positive feedback received from attendees, who appreciated the opportunity to interact with global experts and discuss challenges faced in the field of laboratory medicine. The IFCC-Abbott VLP played a crucial role in enriching the scientific and educational content of AMBICON 2024 and contributed significantly to the professional development of the participants.

We express our gratitude to the IFCC and Abbott for their support in making this program a remarkable success and look forward to continued collaboration in future initiatives.

Pre-conference Workshop was held on 18.12.2024

- ✓ LC-MS/MS QTOF and MALDI-TOF
- ✓ Proteomic and Metabolomics characterization of body fluids for biomarker discovery using
- ✓ High resolution mass spectrometry
- ✓ Basic genomic techniques
- ✓ Nucleic acid extraction and PCR techniques
- ✓ Isolation, enumeration, and characterization of umbilical cord and cord Blood-derived stem cells.
- ✓ Internal Quality Control (IQC) in Clinical Laboratory
- ✓ HPLC for HbA1c estimation and hemoglobinopathies screening and its application
- ✓ Electrophoresis and its application
- ✓ Instrumentation- photometry and potentiometry
- ✓ Entrustable Professional activities -MEU (EPA)

Report on Branch Academic Activities 2024

Name of the meeting	Organising Secretary	Date	Society's contribution for the meeting
1st State level CME by Jharkand chapter, AMBI was organized by Dept. of Biochemistry, RIMS, Jharkand	Dr Santosh Kumar	27.01.2024	A newer insight of glucose –A novel Biomedicine
State Level Symposium of Gujarat Chapter –AMBI was organized by Dept. of Biochemistry, GMERS, Gandhinagar	Dr Kiran Kumar Chauhan	18.02.2024	Analytical & Clinical Validation of Laboratory Investigations
State level CME organized by GMERS, Gujarat Chapter	Dr Shilpa Jain	30.06.2024	Awareness towards laboratory-based screening and diagnosis of genetic & Inborn Metabolic disorders
3rd National PG Update cum CME organized by Department of Biochemistry, Govt Medical College and Hospital, Chandigarh	Dr Shivani J and Dr Jasbinder Kaur	26.04.2024 to 28.04.2024	National PG Update
CME organized by Dept. of Biochemistry, Lt. Shri Lakhiram Agrawal Mem. Govt. Medical College, Raigarh	Dr Harish Kumar	22.04.2024	Information regarding molecular diagnosis in medicine
CME organized by Dept. of Biochemistry, GMCRH, Patiala	Dr Maninder Kaur	04.05.2024	Laboratory Medicine Update
6th State Conference of Telangana Chapter –AMBI was organized by Osmania Medical College, Hyderabad, Telangana	Dr N Jaya	01.07.2024 to 02.07.2024	Tiny treasures, Big Impact: Micronutrients revolutionizing Diabetes Care
6th State level Workshop of Telangana Chapter –AMBI was organized by Osmania Medical College, Hyderabad, Telangana	Dr N Jaya	01.07.2024	Exploring protein structure, prediction and primer design: An In Silico approach
CME organized by Dept. of Biochemistry, Deccan College of Medical Sciences, Hyderabad	Dr Syyeda Anees	02.03.2024	Biochemical Markers in Liver Disorders & Orientation to Molecular diagnostic Procedures
Workshop organized by Dept. of Biochemistry, Deccan College of Medical Sciences, Hyderabad		02.03.2024	Basic techniques of molecular diagnostics
2nd Annual conference of AMBI Kerala State Chapter	Dr Lekshmi G S	29.09.2024	
AMBI State Chapter Karnataka (AMBKC) at Adichuncunagiri Institute of Medical Sciences, Belur	Dr N Asharani	10.07.2024 to 12.07.2024	Revolutionizing Renal Disease Diagnostics: The lab's pivotal role in precision healthcare

State level Conference and Pre-conference workshop of Andhra Chapter-AMBI was organized by AIIMS, Mangalagiri	Dr Desai Vidya Sripad	11.07.2024 to 13.07.2024	Molecular insights into immune regulation
Workshop was organized by West Bengal Chapter, AMBI	Dr Priyanka Datta	10.07.2024	Indirect Immunofluorescence
CME organized by Dept. of Biochemistry, under the aegis of AMBI – Rajasthan Chapter	Dr Anita Verma	01.08.2024	Biochemistry Update
State Conference of Maharashtra Chapter –AMBI	Dr Archana Dhotre	17.10.2024 to 19.10.2024	Foundation to foster Clinical Biochemistry Basics and Beyond.
14th State Conference of Odisha Chapter –AMBI	Dr. Parsuram Nayak	29.09.2024	
State level CME organized under the aegis of AMBI – Assam Chapter	Dr Madhurima Bora	10.09.2024	To create awareness about urbanization and its impact on Mental health
State level CME organized under the aegis of AMBI – Assam Chapter	Dr Tridip Kutum	07.06.2024	SEPSIS – The Silent Killer
J&K State Chapter's First CME under the aegis of AMBI – J & K Chapter	Dr Rachna Sabharwal	12.11.2024	Recent trends in laboratory practices
19 Meetings were held under the aegis of AMBI in different states of the country. Majority of the attendees are the young post graduate students of this speciality, after their medical degree.Younger faculty of this speciality attend in large numbers. Senior and professors interact and exchange of ideas takes place with newer aspects and understanding the working of different institutes in progress of this speciality.			

Two new state chapters were initiated under AMBI in Himachal Pradesh a Jammu & Kashmir. 2025

Photo 6

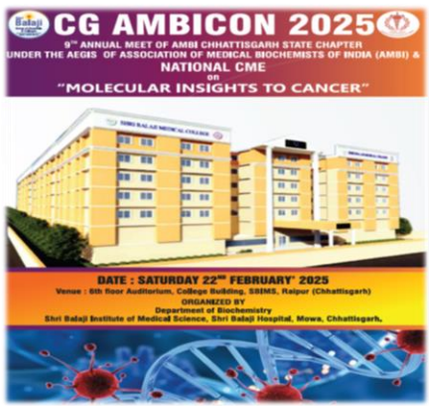


Photo 7

Photo 8

Workshop on "Application of AI tools in Medical Education" on 30th March 2025
Dr B C Roy Institute of Medical Sciences, IIT Khargpur

CME cum Workshop on Mastering ANA: a Hands-on Workshop
p-ANCA and C-ANCA Insights CME cum Workshop on 12th March 2025
Bankura Sammilani Medical College, West

Photo 9

Photo 10

Photo 11

Photo 12

Photo 13

Photo 14

Photo 15

Photo 16

Photo 17

Photo 18

CME on NABL Awareness Program for Laboratory personnel on 14th May 2025
B S Medical College, Bankura, West Bengal

CME on BIOBOOST on 21st May 2025, 23rd May 2025, 9th, 13th and 25th June 2025
NRSMCH, Kolkata, CNMC, Kolkata, West

Hands On Workshop on Six Sigma in Clinical Laboratory on 26th July 2025
Tata Medical Centre, Kolkata, West Bengal

Photo 19

Photo 20

The 4th National Post Graduate update, 2025 an annual event was conducted by the Biochemistry Department, Government Medical College, Chandigarh.

Photo 21

Photo 22

Photo 23

AMBI ACADEMICS

AMBI Academics was conceptualized during one of the Executive Body meetings of AMBI. This is successfully running for the past 2 years. It is carried out under the leadership of Dr Bharti Uppal (Chairperson & Head, Academic Cell), Dr Shanthi K Naidu (Secretary General, AMBI), Dr Shivani Jaiswal (National Coordinator, AMBI). Dr Ashish A (IT cell, AMBI) and Dr Animesh Bardoloi (Jt Secretary, AMBI). The advertisement for AMBI Academics is available on the website www.ambi.co.in. Registration for the webinar is complementary but compulsory to all the members of AMBI.

Month	Name of Speaker	Designation	Topic
Webinars in the year 2023 by AMBI Academics			
January	Dr G Jeyachandran	Professor & Head, PSG Institute of Medical Education and Research, Coimbatore, Tamil Nadu	Understanding Automation in Diagnostics Lab
February	Dr S M Patel	Prof & Head, Govt Medical College, Surat	ABC of molecular visualisation
March	Dr Syeda Mohsina Rohman	Professor, State Cancer Institute, Gauhati Medical College and Hospital, Guwahati	Hallmarks of Cancer
April	Dr.Syyeda Anees	Professor and Head, Deccan Medical College, DMRL 'X' Road, Kanchanbagh, Hyderabad	Application of Beer Lambert Law in analytical chemistry
May	Dr.Parul Singla	Consultant, Sir Ganga Ram Hospital, New Delhi	Significance of Calibration Verification and evaluation in Clinical Biochemistry
June	Dr. Kinjalka Ghosh	Professor and Consultant Biochemist, Tata Memorial Hospital, Mumbai	Role of the Clinical Biochemistry Lab in Management of Plasma Cell Dyscrasia
June	Dr Vinodh Kumar	Assistant Professor, Institute of Child Health, Madras Medical College, Chennai	Establishment of Age-Specific Reference Interval for Aminoacids In Dried Bloodspot By Tandem Mass Spectrometry
July	Dr Debapriya Rath	Associate Professor, Pt JNM Medical College, Raipur	Proteomics toolkit for biomarker discovery
August	Dr Qazi Najeeb Ahmad	Professor & Head, Dept. of Biochemistry Government Medical College & Associated Hospital, Rajouri (J&K)	Diagnostic approach of the Thalassemia's
September	Dr Debojyoti Bhattacharya	Professor and Head of The Department of Biochemistry at Bankura Sammilani Government Medical College, Bankura.	HLA Typing

October	Dr Rebecca James	Associate Professor Dept of Biochemistry, Govt Medical College, Kozhikode.	Familial Hypercholesteremia
November	Dr Sumita Sharma	Associate Professor AIIMS, Bilaspur	Solving the Out-of-Control Situations in Clinical Biochemistry
Webinars in the Year 2024 by AMBI Academics			
January	Dr Suvarna Prasad	Additional Professor, AIIMS, Deoghar	Inborn Error of metabolism: An Update
February	DR ANUJ PARKASH	Senior Consultant & Head - Biochemistry, Medanata Hospital, Gurugram	Unveiling the Genomic Wonders in Biochemistry with Next-Generation Sequencing (NGS)
March	Dr Prakruti Dash	Addl Professor, AIIMS, Bhubaneswar	Diversity in PD-1/PD-L1 pathway exploring its role in immunotolerance-is it a double-edged sword?
April	Dr Minakshi	Associate Professor and HOD Biochemistry, GMC Dausa Rajasthan	Preanalytical variables affecting biochemical investigation
May	Dr Haren Baruah	Professor and Head, Zoram Medical College, Mizoram	Cells Sensitization and Adaptation to O2 availability
June	Dr RamaDesikan	Senior consultant Clinical laboratory services Clinical Biochemistry, Sundaram Medical Foundation Dr Rangarajan Memorial hospital Annanagar Chennai 40	MEASUREMENT UNCERTAINTY
June	Dr Puneet Nigam	Chief Quality Officer, Metropolis	Method Comparison
June	Dr Mousumi Saikia	Consultant Biochemist, Quality Incharge, Laboratory Medicine, Apollo Hospitals Guwahati	
June	Dr Ashishkumar Agravaat	Associate Professor, PDU Medical College Rajkot	Role of AI in smart implementing Quality in a clinical lab
July	Dr. Anikha Bellad	Physician Scientist, Institute of Bioinformatics, Bangalore	Integrative Bioinformatics: An essential tool leveraging Multi-Omics in Clinical Laboratory
August	Dr Kavitarati Dharwadkar	Prof and Head, Director, Clinical Biochemistry, Sri Aurobindo Medical College, Indore, Madhya Pradesh	Interesting Case Scenario where Biochemistry made a Difference
November	Dr Barnali Thakur	Professor and Head, Nagaon Medical College	Obesity - Molecular and Biochemical Aspects . Fight the fat , Choose Health

Photo 24

Photo 25

Photo 26

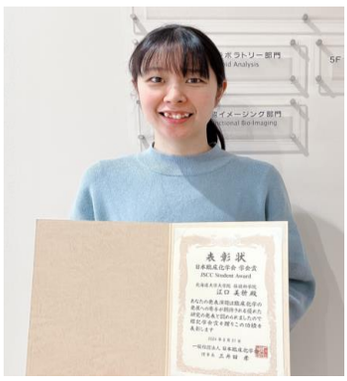
Photo 27

National Society Report – JSCC Japan

NAME OF SOCIETY	Japan Society of Clinical Chemistry (JSCC)
OFFICIAL SOCIETY EMAIL ADDRESS	h-sakamoto@kobe-tokiwa.ac.jp
NAME OF PRESIDENT & EMAIL ADDRESS	Dr. Takashi Miida E-mail: tmiida@juntendo.ac.jp, jscc@mc-i.co.jp
NAME OF NATIONAL REPRESENTATIVE TO APFCB & EMAIL ADDRESS	Dr. Hideo Sakamoto, International Exchange Committee of JSCC E-mail: h-sakamoto@kobe-tokiwa.ac.jp

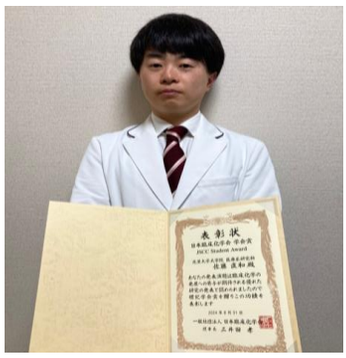
Report submitted by: Dr. Hideo Sakamoto, International Exchange Committee of JSCC

The Japan Society of Clinical Chemistry (JSCC) Student Award is a prestigious honor given to student members of the JSCC who have demonstrated exceptional research skills in clinical chemistry. In 2024, many students applied for the award. As a result, 10 students were elected as finalists and delivered presentations at the 64th Annual Meeting of the JSCC in Tochigi, Japan, held the Students Symposium on August 30, 2024. In this issue, we introduce five individuals who shared their research and aspirations with the JSSC to celebrate their achievements.



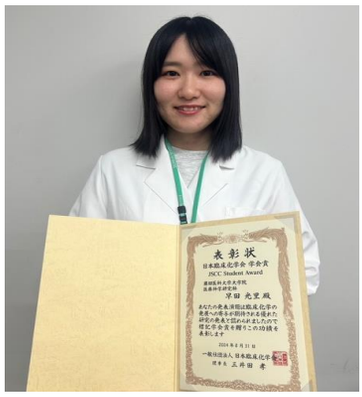
Miki Eguchi (Graduate School of Health Sciences, Hokkaido University).

Entitled with “Protective effect of antioxidant flazin on ferroptosis in human renal tubular cells”. Ferroptosis is a type of programmed cell death characterized by the accumulation of lipid peroxides, which results from iron-dependent reactive oxygen species. It has been implicated in various pathological conditions, including kidney diseases. Flazin, an alkaloid commonly found in fermented foods, has been previously reported to have health-beneficial effects. However, its specific effects on ferroptosis remain inadequately understood. In this study, they investigated the effect of flazin on ferroptosis using renal tubular epithelial cells (TECs). The results demonstrated that flazin effectively protected TECs from ferroptosis. Additionally, it was found that part of this protective effect is dependent on an antioxidant enzyme-related pathway. Future research will focus on exploring the potential of flazin for treating damaged kidney associated with ferroptosis. She was honored to receive this prestigious award and is committed to advancing the field of clinical chemistry and contributing to the community through continued research. She would like to express her sincere appreciation for all the guidance and support she has received.



Naokazu Sato (Graduate School of Medical Sciences, Kitasato University).

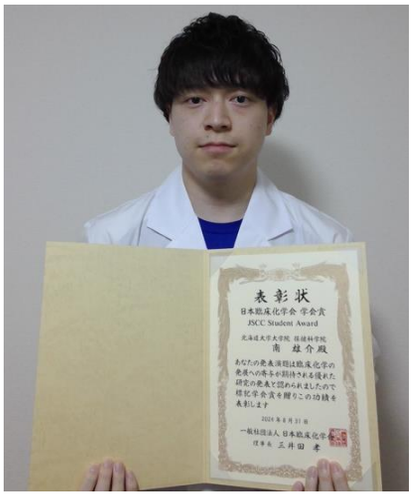
Entitled with “Mitochondrial and lysosomal quality control mechanisms in renal cortex during the normoalbuminuric stage of diabetes mellitus”. Renal cortical mitochondria are damaged by oxidative stress even during the normoalbuminuric stage of type 1 diabetes mellitus (DM). Mitochondrial quality control is important because the accumulation of damaged mitochondria causes the onset and progression of diabetic nephropathy. The functions of mitochondria-selective autophagy (mitophagy), which is responsible for degradation and elimination of damaged mitochondria, and lysosomes, which are essential for the mitophagy process, as a quality control mechanism are unknown. The purpose of this study was to determine if oxidative stress in DM triggers not only renal cortical mitophagy, but also lysosomal repair and elimination through lysosome-selective autophagy (lysophagy). Consequently, DM-induced renal cortical mitophagy, lysosomal repair, and lysophagy were blunted by the antioxidant effects of TLM. Therefore, these should be closely related quality control mechanisms triggered by oxidative damage during the normoalbuminuric stage of DM. He was truly honored to receive the 2024 JSCC Student Award and was very grateful to Prof. Naohito Ishii, Dr. Yoshifumi Kurosaki, and Dr. Akemi Imoto for their guidance. In the near future, he is eager to conduct research that will contribute to global health care.



Hikari Hayata (Graduate School of Medical Sciences, Fujita Health University).

Entitled with “Analysis of serum tryptophan metabolites in patients with COVID-19 using mass spectrometry”.

Tryptophan, an essential amino acid, is not only used for protein synthesis, but is also catalyzed into several metabolites with important physiological activities, such as kynurenine and serotonin. Imbalances of serum tryptophan metabolism have been reported in several diseases, such as neuropsychiatric, infectious, and immune diseases. Analysis of metabolic changes by measuring tryptophan metabolites may be useful in the development of disease biomarkers and understanding the pathophysiology of these diseases. Her study revealed that the levels of kynurenine and serotonin in serum may be early markers of the severity of COVID-19. Furthermore, correlation analysis between tryptophan metabolites and several laboratory tests suggested that tryptophan metabolites are associated with inflammation and impairment of the blood coagulation system. She was deeply honored to receive the JSCC Student Award at such a prestigious conference. She was grateful to all of the people who helped her and hopes to continue her research diligently.



Yusuke Minami (Graduate School of Health Sciences, Hokkaido University).

Entitled with “Effect of Hydrogen Gas on Lipid Metabolism in a Rat Model of Hepatic Ischemia-Reperfusion”. The shortage of donors for liver transplantation is a significant issue, prompting the advocacy for the utilization of grafts that do not strictly adhere to established indication criteria, such as those sourced from donors after circulatory death (DCD). These grafts are particularly susceptible to ischemia-reperfusion injury (IRI), necessitating the implementation of effective organ protection strategies. Their research team indicated that the integration of hypothermic machine perfusion (HMP) and hydrogen gas administration in DCD rat livers resulted in a decrease in organ damage. Nonetheless, the underlying protective mechanism remained unclear. Consequently, they investigated the impact of the combined application of HMP and hydrogen gas on lipid profiles in DCD rat livers. A thorough investigation of lipid metabolism could enhance the understanding of pathophysiology and facilitate the identification of new therapeutic targets.

Yusuke Minami feels deeply honored to have been awarded the JSCC student award. He wishes to convey his heartfelt appreciation to all his collaborators. Motivated by this recognition, he intends to dedicate himself even more fervently to his research endeavors moving forward.

Ayaka Yagi (Laboratory of Biomolecule and Pathophysiological Chemistry, Graduate School of Pharmaceutical Sciences, Tohoku University).

Entitled with “Development and clinical application of a liquid chromatography–tandem mass spectrometry method for measuring plasma posaconazole concentrations”. Posaconazole (PSCZ), the broad-spectrum azole antifungal, strongly inhibits the drug-metabolizing enzyme CYP3A4, and thus drug-drug interactions with other CYP3A4 substrate drugs should be carefully considered in patients taking PSCZ. However, few studies had measured plasma PSCZ concentrations in Japanese patients. Therefore, she established a method for measuring plasma PSCZ concentrations and confirmed its reliability. This method demonstrated sufficient performance for measuring plasma drug concentrations in patients taking PSCZ. Additionally, she measured plasma PSCZ concentrations in a patient taking a CYP3A4 substrate drug (venetoclax) concomitantly, and showed that PSCZ remaining in the body even after its discontinuation could cause drug-drug interactions. This indicated that measurement of plasma PSCZ concentrations may be useful for adjusting the dosage of concomitant CYP3A4 substrate drugs. She would like to express her gratitude for receiving this award and will continue to dedicate herself to further research.

Empowering Tomorrow's Leaders: Highlights From The IFCC Task Force For Young Scientists (IFCC TF-YS) At Euromedlab 2025

Marie Lenski, France (Société Française de Biologie Clinique, SFBC), IFCC TF-YS member

Santiago Fares Taie, Argentina (Confederación Unificada Bioquímica de la República Argentina, CUBRA), IFCC TF-YS chair

Ashlin Rampul, South Africa (South African Association for Clinical Biochemistry and Laboratory Medicine, SAACB), IFCC TF-YS member

Sean Campbell, USA (Association for Diagnostics & Laboratory Medicine, ADLM), IFCC TF-YS member

Udara Senarathne, Sri Lanka (College of Chemical Pathologists of Sri Lanka, CCPLS), IFCC TF-YS member

Claudia Imperiali, Spain (Sociedad Española de Medicina de Laboratorio, SEQCML) , IFCC TF-YS member

EuroMedLab 2025 in Brussels was not only a showcase of scientific excellence in laboratory medicine—it was also a celebration of the next generation of professionals shaping the future of the field. The IFCC Task Force for Young Scientists (TF-YS), in collaboration with the EFLM Committee Young Scientists (C-YS) and the Association des Assistants en Biologie Clinique (AABC, local partners), orchestrated a dynamic series of events that combined academic rigor, innovation, and international camaraderie. From high-impact presentations to interactive tours and festive gatherings, young scientists took center stage in ways that were both meaningful and memorable.

The week began with the fourth edition of the IFCC Forum for Young Scientists, which brought together early-career researchers from around the world for a day of shared learning and discussion. The forum featured a rich program of talks covering key areas in laboratory diagnostics, including clinical chemistry, biomarker discovery, and artificial intelligence. Whether exploring the prognostic value of platelet-to-lymphocyte ratios in cancer, debating the challenges of fT4 assay standardization, or unveiling AI-based tools to optimize lab workflows, each speaker contributed unique insights and spurred engaging discussions. The diversity of voices—from Uruguay to Türkiye, Sri lanka to South Africa—reflected the global spirit of the event and underscored the relevance of these topics across contexts.

Adding to the scientific momentum was the highly anticipated Young Scientists Poster Tour, a three-day interactive initiative that turned poster sessions into vibrant hubs of dialogue and exchange. Held in an informal and collegial format, the tour enabled 40 young scientists from 26 countries to present their work in short, focused sessions followed by peer feedback.

For many, it was a first opportunity to present at an international congress—a milestone that was both empowering and inspiring. The tour stood out not only for the quality of the research showcased but also for its ability to foster confidence, connection, and cross-border collaboration among participants.

Beyond the lecture halls and poster boards, the program extended into the laboratories themselves. On the opening weekend, young scientists had the privilege of visiting the Cliniques Universitaires Saint-Luc, one of Belgium's leading medical laboratories. Hosted by Professor Damien Gruson, the visit offered a rare, behind-the-scenes look at a fully digitized, ISO-accredited facility managing over 6,500 samples a day. From the fully automated central lab and cutting-edge toxicology units to the haematology and microbiology departments, participants gained a tangible appreciation for the scale, precision, and complexity of modern diagnostics. The experience was enriched by a leadership workshop and capped with a guided walking tour of Brussels—blending professional discovery with cultural exploration.

Of course, no scientific gathering is complete without space for informal connection—and the Young Scientists Social Event delivered exactly that. Held at the charming Le Flore in Bois de la Cambre, the evening welcomed over a hundred young professionals for a night of laughter, games, and meaningful encounters. Interactive icebreakers like "Find your missing half" and social bingo encouraged guests to mingle beyond borders and disciplines, reinforcing the human bonds that underpin professional collaboration. Under the warm Brussels sky, new friendships and future partnerships were sparked—many over Belgian fries and smiles.

Thanks to the remarkable support of the IFCC and notable figures such as Prof Tomris Ozben (IFCC President), Prof Mario Plebani (EFLM President), Prof Damien Gruson (Congress President), Dr Eduardo Freggiaro (TF-YS Liaison), and Prof Rajiv Erasmus, the TF-YS programme at EuroMedLab 2025 supported and celebrated young scientists. Through intellectually stimulating sessions, practical learning experiences, and vibrant social exchanges, it brought the global community of young professionals closer, laying the groundwork for continued engagement and leadership in laboratory medicine. The energy, openness, and excellence on display in Brussels reflect the bright future of the field, and the continued success of the IFCC's mission to empower those who will shape it.

Looking ahead, the momentum continues. The next IFCC WorldLab Congress will take place in New Delhi, India, in 2026. We are confident that it will offer equally inspiring and inclusive opportunities for young scientists worldwide. The IFCC TF-YS is look forward to seeing familiar faces—and welcoming new ones—at the next congress in New Delhi, India.

Photo 1: Participants to the IFCC Forum for Young scientists.

Photo 2: Lab visit at the Cliniques Universitaires Saint-Luc in Brussels.

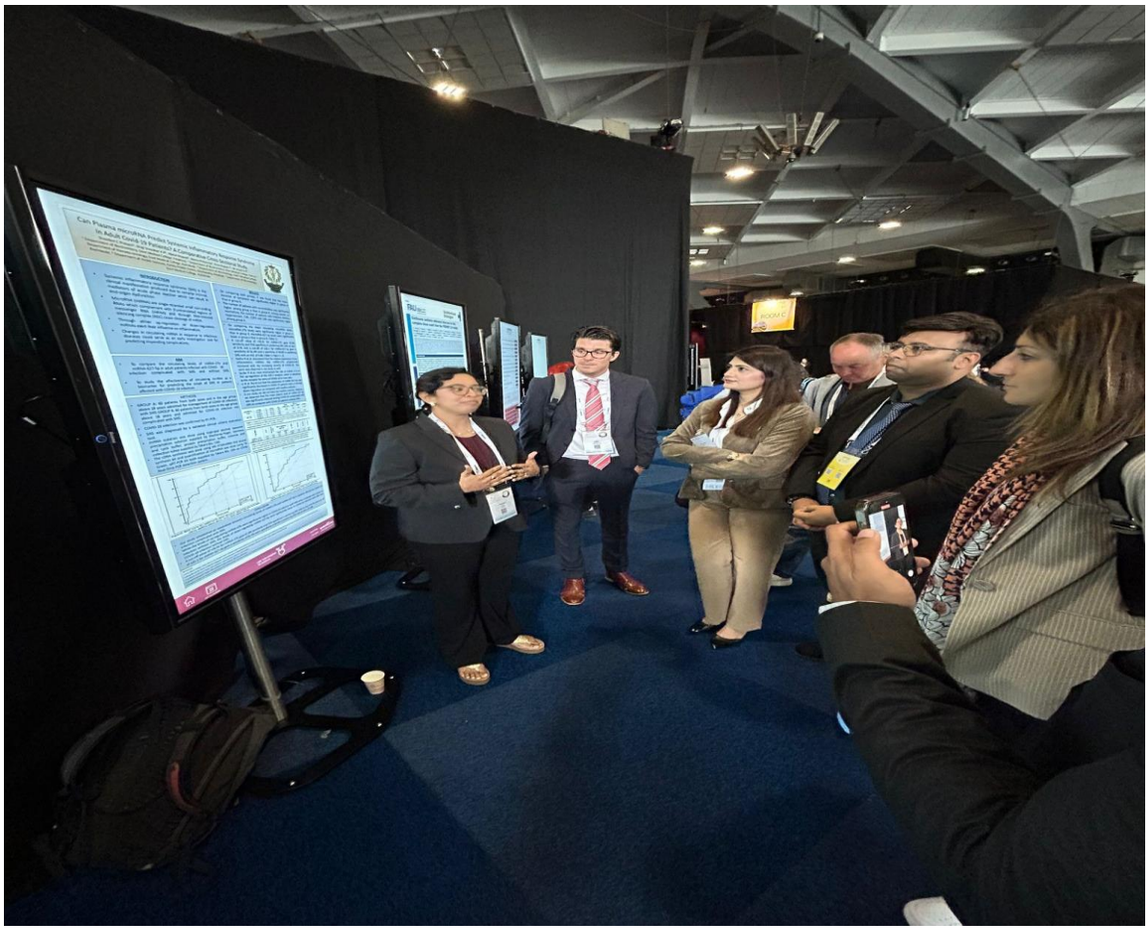


Photo 3: Poster Tour dedicated to Young Scientists.

Photo 4: Young Scientists Social Event organized by the Association des Assistants en Biologie Clinique, AABC.

Expert Interview- Nafija Serdarevic, M. Pharm, MSc, PhD, Spec. Clinical Chemistry

Expert: Nafija Serdarevic, M. Pharm, MSc, PhD, spec. Clinical Chemistry

Affiliations & Associations: Department of Clinical Biochemistry and Laboratory Medicine, Clinical Center University of Sarajevo,

Senior researcher in the Laboratory for Clinical Biochemical Diagnostics,

Please Introduce Yourself?

My name is Nafija Serdarevic, M. Pharm, MSc, PhD, spec. Clinical Biochemistry. I am a clinical biochemist and pharmacist. My studies at the Faculty of Pharmacy, University of Sarajevo, I completed in 1998. I was a visiting researcher (1998-1999) in the Pharmacology Department in Frankfurt am Main, Germany (DAAD fellowship). The project of the DAAD fellowship was "St. John's Wort and Kava Kava on Brain Neurotransmitter Levels in the Mouse" under the mentorship of Dr. W.E. Muller, professor at the Department of Pharmacology, Faculty of Pharmacy, Biozentrum Niederursel, University of Frankfurt/Main.

The postgraduate studies in clinical biochemistry at the Faculty of Pharmacy in Ljubljana, Slovenia, I completed in 2004. I specialized in clinical biochemistry at the Faculty of Medicine, University of Sarajevo, in 2008. I received a Ph.D. degree in pharmacy from the Faculty of Pharmacy in Tuzla, University of Tuzla, Bosnia and Herzegovina, in 2009.

Currently I am working at the Department of Clinical Biochemistry and Laboratory Medicine, Clinical Center University of Sarajevo. My office is located at Clinical Center University of Sarajevo, Bolnicka 25, in Sarajevo, Bosnia and Herzegovina. I am now a full professor in the Faculty of Health Sciences-Laboratory Technology, University of Sarajevo, Bosnia and Herzegovina. I am also serving as a full professor in the PhD program in pharmacy at the University of Tuzla, Bosnia and Herzegovina.

From 2013 to the present, I participated as a member of the commission for taking the specialist exam in medical biochemistry for doctors of medicine and masters of pharmacy at the Federal Ministry of Health of the Federation of Bosnia and Herzegovina. I am a member of the commission for taking the professional exam for medical laboratory diagnostic engineers at the Federal Ministry of Health of the Federation of Bosnia and Herzegovina.

In the period from 2012 to the present, I participated as a member of the committee in the selection of scholarship recipients for DAAD (German Academic Exchange Service) scholarships in Germany for citizens of Bosnia and Herzegovina. The scholarships are intended for master's and doctoral studies as well as research scholarships in Germany.

I have published four books: Control in Laboratory Medicine (2013), Diagnostic of Homocysteine (2014), Cardiac Biomarkers in Laboratory Medicine (2019) and Emergency Conditions in Laboratory Medicine (2020). I hold 2 intellectual property rights: Cupper determination (2013) and Mucopolysaccharide determination (2017). I have authored and co-authored 45 scientific papers in scientific journals and 97 abstracts that are presented in international and national symposiums and conferences.

What is your main focus?

In my career I am involved in education as well as laboratory investigation. As a senior researcher, I have been a mentor of residents in clinical biochemistry and laboratory medicine. At the University of Sarajevo and the University of Tuzla, I have been a professor for more than 15 years. In Association of Medical Biochemists of Bosnia and Herzegovina, I am actively involved in the education and training programs for future specialists in clinical biochemistry and laboratory medicine.

As a part of the Institute for Medicinal Biochemistry and Laboratory Medicine at the Clinical Center, University of Sarajevo, I am involved in the investigation of the determination of PBG and ALA in the diagnosis of secondary porphyria.

The part of my research interest in laboratory work includes the determination of copper in the urine and the serum for the purpose of treatment for patients with Wilson's disease (hepatolenticular degeneration). I am responsible for therapeutic drug monitoring of antiepileptic, cardioactive, antipsychotic, and immunosuppressant drugs, tumor and cardiac biomarkers.
I am a member of the Health Research Ethics Committee of Clinical Center University of Sarajevo and

A member of the Task Force on Ethics (TF-E). One of my obligations is the implementation of the core ethical principles: in blood sampling, the pre-analytical phase, respect for patients' identities, AI in laboratory medicine, and the duty or obligation to treat patients equally and to distribute, by allocating fairly, what is rightly due in terms of benefits, risks, and cost.

It is important as a member of the laboratory to have more contacts with medical doctors and advise them about the importance of lower blood sampling, especially in pediatric patients, oncology patients, and patients with anemia.

What else is important to you?

I like to spend my free time in nature and I like hiking. In Bosnia and Herzegovina, there are numerous possibilities for spending time in nature as well as hiking. In addition, I spend my free time in humanitarian work with children without parental care. I try to help these children with schoolwork and the importance of learning and knowledge. My biggest wish is that all these children one day be good people.

What are your interests in biomedical laboratory medicine?

As long as I work in the field of laboratory medicine, I believe that medicine will be blind without a laboratory. Currently my research areas are focused on the determination of tumor markers and cardiac biomarkers.

In tumor markers, I work on the investigation of possible correlation of PIVKA and AFP in HCC and other liver diseases.

My particular area of interest is in cardiac biomarkers for acute cardiac diseases (troponin, B-type natriuretic peptide, and novel biomarkers of ACS and heart failure). The cTnI assays use various standard materials and antibodies with different epitope specificities; therefore, the results could be unique to a certain method or instrument to the point that values for the same patient sample may differ depending on the assay and platform used. I believe that achieving better harmonization (i.e., a reduction of heterogeneity) among the results of cTnI provided by different methods is possible.

What are your future goals?

Laboratory investigations are always a challenge. One of my goals is the development of a toxicology laboratory as a part of clinical biochemistry/laboratory medicine. The identification of heavy metals is very important for us because we are a post-war country. The land is polluted with shells made of lead and nickel. In the last few years, the number of cancer patients has increased, which could be related to soil and river pollution. Establishing the determination of heavy metals in the blood presented a great challenge for me.

Interviewer: Dr. Ryunosuke Ohkawa (Member APFCB C-CC)

Professor, Department of Clinical Bioanalysis and Molecular Biology, Graduate School of Medical and Dental Sciences, Tokyo

New Breakthroughs in Clinical Testing: The Future of Small Molecule Detection and Smart Laboratories

Submitted by:
Snibe Scientific Affair Team
Vincent Chen, Head of Global Marketing
Email: vincent.chen@snibe.com

The Challenge of Small Molecule Detection Technology

Clinical laboratory testing plays a crucial role in providing physicians with valuable experimental data, enabling accurate diagnosis and treatment planning for patients. It facilitates the assessment of patient conditions, formulation of therapeutic strategies, and monitoring of treatment efficacy and disease prognosis.

However, clinical testing faces numerous challenges due to limitations in current detection technologies. Issues such as sample contamination and degradation during collection, prolonged processing times, and insufficient sensitivity and specificity in small molecule assays can compromise the accuracy and timeliness of test results. Among these, the detection of small molecule antigens remains the most pressing challenge.

Small molecule compounds typically refer to substances with a molecular weight below 1000 Daltons and a relatively simple structure. Commonly used small molecules in clinical practice include estradiol, progesterone, aldosterone, 25-hydroxyvitamin D, and tacrolimus. Detecting these molecules is essential for clinical diagnostics, environmental monitoring, and food safety. Advances in small molecule research are expanding their applications in medicine. However, due to their structural characteristics—limited molecular volume, spatial hindrance, and usually only one antigenic epitope—traditional chemiluminescent immunoassays (CLIA) often encounter challenges such as low sensitivity, weak specificity, and a narrow linear range, which fail to meet clinical demands.

Liquid chromatography-tandem mass spectrometry (LC-MS/MS), considered the gold standard for small molecule detection, offers high specificity and accuracy. However, it suffers from low throughput, complex sample preparation, and high requirements for both equipment and personnel, limiting its widespread adoption. Therefore, CLIA remains the commonly used method in clinical settings. Nevertheless, this approach presents significant challenges, particularly regarding its poor correlation and accuracy compared to LC-MS/MS. Test results for small molecules, such as 25-hydroxyvitamin D, estradiol, and aldosterone, often vary significantly across different manufacturers.

Advancements in Small Molecule Detection

Recent research has focused on developing non-competitive small molecule detection technologies, leading to substantial progress. These efforts have established technical pathways for the development of complex antibodies targeting small molecules and have resulted in the creation of a comprehensive sandwich detection platform for small molecule analysis. This platform includes modules for raw material development and reagent process optimization.

The platform enables stable modification of small molecule antigens and full-process monitoring, ensuring the production of complete antigens that meet technical specifications. High-affinity first antibodies specific to small molecule antigen epitopes are screened using hybridoma technology.

In the critical stage of second antibody complex antibody preparation, a comprehensive technical framework and quality control strategy have been developed, covering aspects such as binding site design, epitope expansion, and epitope recognition. These measures ensure the high specificity and affinity of anti-complex antibodies, laying a solid foundation for the realization of sandwich detection methods.

Notably, Snibe has successfully developed and commercialized products such as 25-hydroxyvitamin D, estradiol, and aldosterone based on this platform, positioning itself as a leader in the field. Numerous studies have shown that immunological methods for estradiol detection exhibit significant inconsistency with LC-MS/MS in populations with low estradiol levels, such as males, preadolescent children, and postmenopausal women, with generally low correlation coefficients. A recent study demonstrated that Snibe's "sandwich method" E2 assay kit achieved a correlation coefficient of 0.9810 with LC-MS/MS, compared to 0.9270 for the competitive method. In a comparative analysis of 548 estradiol samples, the sandwich method showed a correlation coefficient of 0.977 with LC-MS/MS and an intercept of only 0.1. When analyzing values below 50 pg/ml, the correlation coefficient was 0.915, indicating excellent accuracy and consistency.

Extensive evidence supports the high concordance between the small molecule sandwich method and LC-MS/MS, with notable improvements in sensitivity and specificity. This advancement opens new avenues for clinical application research and provides robust scientific support for the standardization of small molecule detection protocols.

Smart Laboratories and Artificial Intelligence

Technological innovation extends beyond detection methodologies. Amid the digital transformation and the rise of artificial intelligence (AI), laboratories are undergoing profound changes. Complex data management, repetitive standardized procedures, routine calculations for reagents and consumables, and tasks such as drafting reports based on data all demand more efficient solutions. Full automation has become essential for enhancing laboratory efficiency and accuracy.

The healthcare industry is on the brink of a transformative revolution, with AI playing a central role in reshaping diagnostic and therapeutic approaches. Many traditional chemiluminescence manufacturers have not only improved instrument throughput but also integrated various AI functionalities into their systems. Snibe has introduced iXLab, an intelligent laboratory solution software, and SATLARS-T8, a versatile total laboratory automation system. These solutions offer comprehensive capabilities in testing, management, quality control, and academic research, addressing most daily operational needs. They help streamline workflows, enhance productivity, and reduce the workload for laboratory personnel.

Medical laboratory services and clinical diagnostics serve as the eyes of clinicians. Whenever challenges arise, they catalyze technological innovation, driving revolutionary breakthroughs. The continuous evolution of small molecule detection techniques and the implementation of automation solutions provide strong support for laboratories, assisting operators in managing increasingly complex data and workflow demands. Clinical laboratories are progressing toward greater efficiency and precision. Looking ahead, as technology continues to advance, laboratory performance in terms of work efficiency and diagnostic accuracy will further improve, offering more reliable support for both scientific research and clinical practice

Precision Healthcare in India: Integrating Omics Science with Digital Health Innovation

DOI- https://doi.org/10.62772/APFCB-News.2025.4201

Swarup A. V. Shah,[1,3], Bernard Gouget,[2,3]

[1] University of Mumbai, Mumbai, India; Senior Molecular Scientist -Human Genetics, Hinduja Hospital, Department of Laboratory Medicine [Biochemistry section] Mahim, Mumbai 400016. India;

[2] President, National Committee for the Selection of Reference Laboratories (LBMR); Department of Health and Access to Care, Paris 75007; Chair IFCC-TF on History, Labac IFCC/EFLM representative

[3] IFCC Emerging Technology Division (ETD-EC)

Corresponding author: Swarup A V Shah, PhD; Senior Molecular Scientist -Human Genetics, Hinduja Hospital, Department of Laboratory Medicine [Biochemistry section] Mahim, Mumbai 400016. India; **Email:** dr_swarup.shah@hindujahospital.com

Abstract:

India is undergoing a transformative shift toward precision healthcare, driven by the convergence of large-scale omics initiatives and digital health innovations. This article reviews three landmark programs, Genome India, Phenome India, and the Bharat Cancer Genome Atlas (BCGA), that are systematically mapping the nation's genomic, phenotypic, and cancer-specific diversity. Together, these projects aim to enhance disease prediction, early diagnosis, and personalized treatment for the Indian population by building comprehensive and publicly accessible data resources. Simultaneously, India's digital health ecosystem, including the Ayushman Bharat Digital Mission, eSanjeevani, CoWIN, and AI-driven surveillance platforms, is enabling broader access, longitudinal data integration, and precision public health interventions. This synergistic integration of omics science with digital platforms exemplifies a shift from reactive to proactive, personalized, and equitable healthcare. The article highlights how these national efforts collectively advance the principles of 4P medicine: Predictive, Preventive, Personalized, and Participatory, and set a precedent for precision health implementation in diverse, resource-limited settings globally.

Keywords: Precision medicine, Omics, Digital health, India, Public health, 4P medicine, Artificial intelligence, Health equity.

In line with its mission to identify, monitor and evaluate emerging scientific developments, the IFCC Emerging Technologies Division (ETD) has undertaken a focused analysis of recent advancements in omics sciences, institutional initiatives, and strategic collaboration opportunities. This effort is particularly timely as the global laboratory medicine community prepares for the upcoming IFCC WorldLab in New Delhi in 2026.

India is rapidly positioning itself at the forefront of precision healthcare, driven by a convergence of scientific ambition, pressing public health challenges, and the extraordinary genetic and cultural diversity of its population. Since the launch of the National Biotechnology Development Strategy (2015–2020) by the Department of Biotechnology (DBT), Government of India, the country has witnessed a strategic shift toward data-driven, personalized healthcare.

Flagship national programs such as Genome India (2020), the Bharat Cancer Genome Atlas (2020), and Phenome India (2023) reflect a coordinated, government-led effort to integrate genomics into public health, spearheaded by national research institutions and primarily funded through public grants. These initiatives are not isolated research ventures but are embedded within a broader national vision that connects innovation, equity, and digital health aligning with India's goal of self-reliance (Atmanirbhar Bharat). By mapping the country's rich genetic and phenotypic diversity, these programs aim to uncover how biological and environmental factors influence disease risk and progression across populations. The resulting insights are expected to accelerate the development of predictive, preventive, and personalized healthcare solutions with wide-reaching implications for public health, research, and policy.

This article explores these landmark initiatives in detail, examining their goals, progress, and the transformative potential they hold for precision medicine in India and beyond. Genome India, launched by the Department of Biotechnology, is a flagship consortium project involving 20 leading institutions, created to build a comprehensive map of Indian genomic diversity. Its primary objective is to create a catalogue of genetic variations that reflects the unique ancestral and ethnic diversity of India.

Key achievements and goals of Genome India include:

- Nationwide Genome Sequencing: Collected over 20,000 DNA samples from 83 diverse populations across India, ranging from metropolitan areas to remote indigenous groups. Whole-genome sequencing has been completed for 10,000 individuals, creating the first large-scale reference dataset of Indian genomes. This provides an unprecedented representation of India's genetic richness and population structure.
- Reference Genome and Biobank: The project established a robust biobank of Indian samples and is assembling a representative reference genome for the Indian population. All genome data (10,000 genomes) are archived at the Indian Biological Data Centre (IBDC) for open access by researchers, under national guidelines.
- Insights for Health and Diagnostics: By analyzing this trove of genomic data, scientists can identify genetic variants associated with disease susceptibility and drug response specific to Indians. Genome India's data is expected to facilitate affordable genetic tests and diagnostic tools tailored to Indian populations for example, developing India-specific SNP arrays for disease risk screening. Such a reference will improve understanding of how genetic differences contribute to disease in various ethnic groups, paving the way for precision medicine in India.
- Public Health Impact: The Genome India dataset serves as a critical national resource for public health research. It enables epidemiologists and policymakers to study genetic risk factors for common diseases (like diabetes, cardiovascular disease, cancers) in different regions and communities. Ultimately, this empowers data-driven policy decisions, ensuring that preventive health programs and therapies can be tailored to India's genetic diversity, rather than relying on one-size-fits-all approaches developed in Western populations.

Genome India marks a milestone in India's scientific landscape. It lays the foundation for genomics-based health interventions by cataloguing how one's genetic makeup may influence disease risk and treatment outcomes. By sequencing 10,000 genomes across India, this project has created the first holistic reference that will inform everything from new drug targets to personalized treatment guidelines for Indian patients.

While Genome India focuses on the genome, Phenome India (also known as the CSIR Phenome India-CSIR Health Cohort Knowledgebase, PI-CHeCK) targets the "phenome", the full set of observable characteristics and clinical parameters in individuals. Launched in late 2023 by the Council of Scientific & Industrial Research (CSIR), Phenome India is the first ever pan-India longitudinal health study aimed at understanding how lifestyle, environment, and biology together influence major diseases in Indians. Its emphasis is on cardio-metabolic diseases, conditions like diabetes, heart disease, and liver disorders that are rising in India.

Key aspects of Phenome India include:

- 10,000-Strong Health Cohort: In its first phase, the project enrolled nearly 10,000 adult participants across 17 states and 24 cities of India. Uniquely, this cohort includes people from diverse regions and backgrounds (initially CSIR employees, pensioners and spouses, as volunteers). Each participant contributes extensive health data, creating a rich longitudinal dataset for analysis.

- Comprehensive Health Data Collection: Phenome India collects a wide array of phenotypic data for each participant. This includes detailed clinical questionnaires, lifestyle and dietary profiles, physical measurements (anthropometry), imaging and scanning results, and a battery of biochemical and molecular tests on blood samples. By tracking individuals over time, the study captures how risk factors and health indicators change and potentially lead to disease onset.

- Aim: India-Specific Risk Prediction Models: A core objective is to develop better algorithms to predict and prevent non-communicable diseases (especially diabetes and cardiovascular illnesses) tailored to the Indian population. Currently, many health risk calculators and guidelines are based on Western data (primarily Caucasian populations). Indian populations have different genetic backgrounds, diets, and lifestyle patterns, meaning Western risk factors or thresholds may not apply directly. Phenome India addresses this gap by identifying India-specific risk factors and biomarkers. For example, what triggers diabetes in an Indian context might differ from the West – the study is poised to find such nuances, ensuring that "one-size-fits-all" models are replaced with more accurate, ethnicity-specific risk stratification.

- Precision Medicine and 4P Healthcare: Phenome India exemplifies the Predictive, Preventive, Personalized, and Participatory (4P) medicine model in action. By generating a comprehensive phenome database of Indian individuals, it allows researchers and clinicians to identify early warning signs (predictive), engage participants in their own health monitoring (participatory), devise targeted prevention strategies (preventive), and ultimately tailor interventions to individual risk profiles (personalized). The project's success in collecting nationwide data also encourages similar large-scale studies, setting the stage for a new era of precision public health in India.

Phenome India is creating an invaluable health dataset for India, linking lifestyle and clinical information with molecular data. Its longitudinal design (following participants over time) will shed light on how diseases develop and progress among Indians, and why certain populations are more vulnerable. Insights from this cohort will directly feed into public health planning; for instance, informing dietary guidelines, screening recommendations, or community interventions that are tailored to India's diverse population and its specific needs.

- The Bharat Cancer Genome Atlas (BCGA) is another landmark project, focused on mapping the genomic landscape of cancers in the Indian population. Initiated in 2020 and spearheaded by IIT Madras in collaboration with national research and clinical partners, BCGA was conceived to address a critical gap: India's cancer patients have been under-represented in global cancer genomics studies, meaning many genetic mutations common in Indian cancers are not recorded in international databases. BCGA aims to build a comprehensive cancer genome database for Indian patients, which will inform better diagnosis and treatment. Key highlights of BCGA include:

- **India's First Cancer Genome Atlas:** BCGA is the country's first comprehensive cancer genome mapping effort, analogous to the international Cancer Genome Atlas but focusing on Indian demographics. Its pilot focus has been on breast cancer, one of the most prevalent cancers in India. As of early 2025, the program has completed genomic sequencing of 480 breast tumor samples (performing 960 whole exome sequences, tumor and normal) collected from patients across India. This dataset represents the largest collection of Indian breast cancer genomes to date.

- **Publicly Accessible Database:** The anonymized genetic data from these tumors have been compiled into the Bharat Cancer Genome Atlas database, which was launched in February 2025 and is openly accessible to clinicians and researchers at bcga.iitm.ac.in. This atlas provides a compendium of genetic variants observed in Indian cancer patients, filling a crucial knowledge gap. It allows scientists to catalog which mutations are frequent in Indian breast cancers and how they might differ from Western patients. Ultimately, it helps classify genetic variants in terms of their relevance to early diagnostics, disease progression, and treatment outcomes in Indian contexts.

- **Insights for Early Detection and Treatment:** By analyzing the BCGA data, researchers have begun identifying cancer-specific biomarkers in Indians. These biomarkers (e.g., particular gene mutations or signatures) could enable earlier detection of cancers – for instance, blood tests or screenings that catch breast cancer at an earlier, more treatable stage, based on genetic markers prevalent in Indian women. Moreover, the data reveal potential novel drug targets, guiding the development of therapies that specifically target mutations common in Indian patient. This is especially important as some genetic drivers of cancer might differ in frequency from those seen in Western populations, necessitating different therapeutic strategies.

- **Toward Personalized Cancer Care:** BCGA is a steppingstone toward personalized medicine in oncology for India, Understanding the genetic basis of tumor development and drug response in Indian patients means oncologists can eventually tailor treatment plans to the genetic profile of each patient's cancer. For example, if a subset of Indian patients has a unique mutation that responds well to a specific targeted drug, this can

be incorporated into treatment guidelines. The BCGA initiative is also expanding to other cancer types, it invites researchers nationwide to contribute genomic data across various cancers. By federating data from multiple institutions, BCGA will grow into a pan-Indian cancer genomics resource to identify high-risk genetic profiles, monitor how cancers progress in different populations, and optimize treatment strategies for Indian patients.

- Through BCGA, India is addressing health disparities in oncology, ensuring that the genetic understanding of cancer is not biased toward Western countries alone. As one oncologist noted, genetic heterogeneity across ethnicities means "we can't absolutely rely on Western data" for treating Indian patients. BCGA's Indian-specific cancer genome data thus equips doctors with more relevant knowledge to improve cancer outcomes, from earlier diagnosis to choosing the most effective, personalized therapies.

- Together, Genome India, Phenome India, and BCGA represent a comprehensive approach to integrating genomic and phenotypic information for improving health outcomes. By mapping both the genetic blueprint and the observable health traits of Indians at scale, these initiatives are enabling a shift toward data-driven, predictive, and personalized healthcare. Below we discuss the broader implications and how these efforts support India's healthcare innovation and policy goals:

- **Enabling Precision Medicine:** The integrated genomic-phenomics approach directly fuels precision medicine in India – delivering the right intervention to the right patient at the right time. Genomic data from Genome India provides insights into genetic predispositions (e.g., variants that affect drug metabolism or disease risk), while Phenome India's longitudinal data add context about lifestyle and environmental exposures. The result is a more complete picture of individual risk profiles. For example, a person might carry a genetic variant that mildly raises diabetes risk but combined with certain dietary habits uncovered in the phenomics data, their risk could be substantially higher. By accounting for both, doctors can predict and prevent disease more effectively, advising personalized lifestyle changes or surveillance for those at high risk, long before illness develops. This embodies the preventive and predictive aspects of the 4P healthcare model.

- **Early Disease Detection and Public Health Planning:** These initiatives improve our ability to catch diseases early and guide public health strategies. The BCGA's identification of genetic biomarkers for cancer means screening programs can be more targeted, for instance, if certain mutations associated with early breast cancer are common in a region or community, screening tests in that area can incorporate those markers, leading to earlier detection and treatment. Similarly, phenotypic risk models from Phenome India can flag warning signs of cardio-metabolic disease in specific demographics (say, unanticipated risk in younger urban populations), prompting public health officials to implement targeted interventions or awareness campaigns. In essence, the data from these projects allow India's health planners to move from reactive care to proactive care, using risk maps and health forecasts to allocate resources and design programs tailored to the needs of each region and community. This is crucial for a country as diverse as India, where health disparities exist between different ethnic groups, rural and urban populations, and socioeconomic strata.

- **Tailored Treatment and Drug Development:** As India builds its own genomic databases, treatment guidelines can be customized for its population. For example, the Genome India data can inform pharmacogenomics, understanding how genetic differences affect drug response. If certain populations in India have variants that make standard doses of a drug less effective or more toxic, clinicians can adjust prescriptions accordingly, improving safety and efficacy of treatments. In cancer care, insights from BCGA mean oncologists can choose therapies that target mutations found in an Indian patient's tumor genome, rather than relying solely on protocols developed from Western patient data. Additionally, these initiatives spur local drug and diagnostic development: pharmaceutical researchers can use the identified genetic targets (from BCGA or Genome India) to develop new medications or repurpose existing ones for Indian-specific cancer subtypes or genetic disorders. Diagnostic companies can create affordable genetic tests (for example, a genotyping chip with variants common in India. to aid in routine clinical decision-making. Such innovations not only personalize treatment but also make healthcare more inclusive of India's genetic diversity.

- **Informing Healthcare Policy and Reducing Disparities:** The knowledge generated by these projects supports evidence-based policymaking. Health authorities can utilize the findings to update screening guidelines (e.g., start colon cancer screening at an earlier age if genomic data shows higher early-onset risk in Indians) or to introduce population-specific recommendations (such as different BMI cut-offs for obesity in South Asian populations, if phenomics data suggests different body composition). Importantly, by capturing data from under-represented and tribal communities (a priority stated by Genome India's future these initiatives ensure that health disparities can be identified and addressed. If certain genetic diseases or risk factors are found to be more prevalent in marginalized groups, resources can be directed to those communities (for example, targeted genetic screening or specialized clinics). Over time, this helps bridge the gap in health outcomes between different groups, aligning with India's policy goals of equitable healthcare access.

- **Research and Innovation Ecosystem:** These large-scale projects are creating a rich resource for the scientific community, sparking innovation in biomedical research. The open data sharing (Genome India's data via IBDC, and BCGA's public portal) means researchers anywhere can mine this information to uncover new disease associations or develop AI algorithms for risk prediction. Indian researchers and startups can build on this data to create home-grown healthcare solutions, supporting the country's vision of self-reliance (Atmanirbhar Bharat) in science and technology. Moreover, training the next generation of scientists and clinicians in genomics and data science is an explicit goal, Genome India, for instance, hopes to "inspire the next generation of genomic innovators" in India. This capacity building will ensure that India not only gathers data but also has the expertise to translate it into clinical practice and health policy.

Digital Health and ICT Innovations in India

In parallel with its omics initiatives, India is also pursuing a range of digital health and information communication technology (ICT) innovations to strengthen healthcare delivery. These programs provide a digital backbone that complements personalized and precision medicine by enhancing data availability, connectivity, and intelligent analysis in healthcare. Key government-led digital health initiatives include:

- **Ayushman Bharat Digital Mission (ABDM):** Launched in 2021, ABDM aims to create a unified national digital health infrastructure. It provides every citizen with a unique digital Health ID (now called ABHA – Ayushman Bharat Health Account) to link their electronic health records across providers. This interoperability enables longitudinal patient records and easier sharing of medical data, which is foundational for personalized care. For example, as of 2024 ABDM has generated over 670 million (67 crore) health IDs and linked more than 420 million health records, illustrating its massive scale. By making an individual's complete health history accessible to clinicians (with consent), ABDM supports more tailored treatment decisions and continuity of care across different facilities.

- **eSanjeevani Telemedicine Service:** India's national telemedicine platform eSanjeevani has dramatically expanded access to healthcare, especially for remote and underserved populations. Since its launch in 2019, eSanjeevani has facilitated over 340 million doctor-to-patient consultations as of early 2025, offering free online medical advice across the "length and breadth" of the country. The service operates in both hub-and-spoke clinic-to-clinic mode and a direct-to-public OPD mode, which proved crucial during the COVID-19 pandemic for continuity of care. By enabling patients to consult doctors via video from their homes, eSanjeevani reduces the need for travel and overcrowding at hospitals. This tele-healthcare model makes healthcare more accessible and patient-centric, allowing personalized medical consultations (including follow-ups and specialist advice) regardless of geographic location.

- **Aarogya Setu:** This mobile application, launched in April 2020 for COVID-19 contact tracing and health status monitoring, became one of the fastest-adopted digital health tools in the world. Aarogya Setu reached 100 million users within 41 days of its release, reflecting its rapid nationwide uptake. The app uses Bluetooth and GPS data to alert individuals if they may have been exposed to someone with COVID-19, effectively providing each user a personalized risk assessment. It also offers a self-assessment quiz and up-to-date health advisories, empowering citizens to take personalized precautions and seek testing or medical help early. Aarogya Setu demonstrated how smartphone technology can be leveraged for precision public health, delivering timely, individualized alerts and guidance to millions of people during a pandemic.

- **CoWIN Platform:** The COVID-19 Vaccine Intelligence Network (CoWIN) is India's digital platform for managing its unprecedented vaccination drive. CoWIN served as the digital backbone for administering COVID-19 vaccines to India's 1.3 billion people. Through a website and app, it enabled citizens to register, schedule appointments, receive reminders for second doses, and download digital vaccination certificates. CoWIN's real-time dashboards allowed for efficient logistics and minimized gaps in coverage. By March 2023, India had delivered over 2.2 billion vaccine doses via this platform, covering 95% of the eligible population with at least one dose. The individualized tracking ensured that each person got the right vaccine at the right time, exemplifying precision at population scale. CoWIN's success has shown how a robust ICT system can orchestrate a personalized healthcare intervention (vaccination with proper follow-ups) for hundreds of millions of people.

- **National AI Mission (#AIforAll):** Recognizing the transformative potential of artificial intelligence, the Government of India (through NITI Aayog) launched a National Strategy for AI in 2018, branding it "AI for All." Healthcare is a priority sector in this strategy, which envisions deploying AI to improve both access and quality of care. Under this mission, India is investing in AI-based healthcare solutions — for example, **AI-driven diagnostics, predictive analytics, and decision support tools** that can assist doctors. Pilot projects have applied AI for tasks like screening medical images (e.g., detecting diabetic retinopathy or tuberculosis from scans) and analyzing large health datasets to identify risk patterns. Such tools augment clinicians' capabilities, enabling more accurate and personalized treatment by rapidly processing patient-specific data (like scans, health records, or genomes). The National AI Mission thus supports precision medicine through technology, aiming to democratize advanced care (e.g., early detection of diseases and tailored therapies) across India's health system.

- **Integrated Health Information Platform (IHIP):** Launched nationwide in 2021 by the Ministry of Health's NCDC, IHIP is a next-generation digital disease surveillance system. It integrates data from hospitals, laboratories, and community health centers in near real-time under the Integrated Disease Surveillance Programme. By aggregating and analyzing this data (including trends on 30+ diseases) on a single platform, IHIP enables early detection of disease outbreaks and health trends across India. Health officials receive **timely, geo-tagged alerts** of anomalies, allowing swift, targeted public health responses. This facilitates **precision public health** – interventions (such as containment, vaccinations, or resource deployment) can be directed to specific locations or populations as soon as a threat is identified. As an example of the "One Health" approach, IHIP even plans to incorporate animal health and environmental data to predict zoonotic disease risks. Overall, the IHIP's data-driven surveillance enhances India's ability to monitor health threats and respond with pinpoint accuracy, protecting communities through informed decision-making.

India is advancing toward precision healthcare through a powerful integration of omics research and digital health technologies. Genome India, Phenome India, and the Bharat Cancer Genome Atlas (BCGA) are landmark initiatives capturing the country's genetic, phenotypic, and cancer-specific diversity. These efforts enable population-specific disease risk prediction, early diagnosis, and the development of personalized therapies tailored to India's unique genomic landscape.Simultaneously, digital platforms like the Ayushman Bharat Digital Mission, eSanjeevani telemedicine, Aarogya Setu, and CoWIN are revolutionizing healthcare access and delivery. With the support of AI-driven tools and real-time disease surveillance through platforms like IHIP, India is equipping its health system for data-driven, inclusive care.

Together, these initiatives represent a strategic shift toward predictive, preventive, and personalized medicine—ensuring healthcare is both evidence-based and equitable, and setting a strong foundation for India's long-term health innovation and resilience

Authors Contribution: All authors are independent experts and equally contributed to the expert article published.
Funding: None declared
Conflict of Interest: None declared

References

1. Genome India. Indian Biological Data Centre. https://ibdc.rcb.res.in/ CSIR Phenome India (PI-CHeCK). https://www.csir.res.in/
2. Bharat Cancer Genome Atlas (BCGA). https://bcga.iitm.ac.in/
3. National Health Authority. Ayushman Bharat Digital Mission. https://abdm.gov.in/
4. Ministry of Health and Family Welfare. eSanjeevani – National Telemedicine Service Dashboard. https://esanjeevani.in/
5. Ministry of Electronics and IT. CoWIN: Winning the COVID-19 Vaccine War. https://www.mygov.in/cowin
6. NITI Aayog. National Strategy for Artificial Intelligence #AIforAll. 2018. https://www.niti.gov.in/
7. National Centre for Disease Control (NCDC). Integrated Health Information Platform (IHIP). https://ihip.mohfw.gov.in/idsp/#!/home

Precision Healthcare in India
Integrating Omics Science with Digital Health Innovation

Abstract India is advancing precision healthcare through large-scale genomics and phenomics projects alongsid digital health advancments. Genome India maps genetic diversity val-applieations for diagnostics and public health. Phenome India collects longitudinal health, lifestyle, and biomolecular data for predicting and preventing disease. The Bharat Cancer Genome Atlas (BCGA) catalogues cancer-specific-genefic variants to e-nable early diagnosis and tailored therapies. Complementing th-ese Initiatives, digital heaith platforms like Ayushman Bharat Dj gital Mission, eSanjeevani telemedicine, and CoWIN vaccination management

Omics Initiatives

Gonome India
- 10,000 genomes sequenced
- Reference genome & biobank
- Genetic insights for diagnostics

Phenome India
- 10,000-strong health cohort
- Longitudinal phenotypic data
- Lifestyle & biomolecular factors
- Disease risk models

BCGA
- Cancer genome atlas
- Early detection biomarskers
- Personalized therapies

Digital Health

Ayushman Bharat Digital Mission
- Digital health IDs
- Health record platform

eSanjeevani
- Telemedicine network
- Remote consultations

CoWIN
- Vaccination program

AI & Surveillance
- AI-based healthcare
- Disease monitoring

Expert Interview-Clinical Lab Accreditation ISO 15189:2022 & its Implementation Strategies

DOI- https://doi.org/10.62772/APFCB-News.2025.4202

Moderator & Corresponding Author(s):

1. Prof. Pradeep Kumar Dabla, Department Biochemistry, G.B.Pant Institute of Postgraduate Medical Education & Research (GIPMER); NABL Quality Council of India, Lead & Technical Assessor Medical Laboratories ISO 15189:2022 & PTP ISO 17043:2023, INDIA; pradeep_dabla@yahoo.com

2. Prof. Tony Badrick, CEO The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP), AUSTRALIA; tony.badrick@rcpaqap.com.au

Expert(s):

1. Prof. Tomas Zima, MD, DSc.
   Head Institute of Medical Chemistry and Laboratory Medicine of the First Faculty Medicine and General University Hospital, PRAGUE

2. Marissa A. Orillaza, MD, FPSP, MSCE Director, Tagaytay Medical Center, Pathology Department Past president, Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL) and the Philippine Society of Pathologists (PSP), PHILIPPINE

3. Josefina S. Soriano, RMT Chief Medical Technologist National Kidney and Transplant Institute (NKTI), Quezon City, PHILIPPINE

4. Sarah Jane L. Datay-Lim, MD, FPSP Laboratory Quality and Safety Consultant Director, The Medical City Past president and current chair of the Committee on Education, Training and Research, Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL), PHILIPPINE

5. Paulo Enrico P. Belen MD, DPSP, MMHoA Assistant Chair, Institute of Pathology, St. Luke's QC and BGC Past president, Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL), PHILIPPINE

6. Tjan Sian Hwa MSC, Clin Pathol Head of Clinical Laboratory Department, Premier Jatinegara Hospital, Jakarta, INDONESIA Clinical Pathologist at Westerindo Private Clinical Laboratory, Jakarta, INDONESIA

Introduction

This is a new section of the APFCB New where we will invite experts in a particular topic in laboratory medicine to answer some practical questions.

We have started with ISO 15189, the most widely recognised medical laboratory standard, and one many countries in the Asia-Pacific region use. The importance of using a common, independently written by international experts cannot be overemphasised, and even though many laboratories may not be able because lack of resources, to be accredited against the Standard, it serves as a model that all clinical laboratories should follow.

The three fundamental factors that lead to improvement in healthcare, and most other human endeavours, are (a) technical/equipment/automation, (b) process management, and (c) operator competence. ISO 15189 provides the requirements for the specific management of clinical laboratories. The latest version includes more emphasis on the competence of the humans in laboratories, a key area where there will be improvements for patient outcomes.

ISO 15189 which is based on ISO 17025:2022 General requirements for the competence of testing and calibration laboratories was first published in 2003. It has been revised in 2007 to align more closely to ISO/IEC 17025. A third edition of the standard was published in 2012, which revised the layout again and added a section on laboratory information management.

The 2022 version differs from the 2012 edition in several areas including the following.

- A realignment with the latest version of ISO/IEC 17025:2017 in terms of structure and approach.
- There are now requirements for POCT included as an Appendix which were previously in ISO 22870.
- There is a move away from a compliance standard to an increased emphasis on risk management, particularly a greater focus on clinical risk and the impact of services on patients.
- There is a much greater focus on laboratory management and personnel.

The expert group identify key changes with the 2022 edition of ISO 15189, how laboratories should adopt risk-thinking, what are the new expectations of staff training and competence assessment and using AI tools.

Questions:

1. What key changes in ISO 15189:2022 must labs prioritize?

Prof. Tomas Zima

The ISO 15189:2022 revision introduced significant updates to align with modern quality management principles, increased digitalization, and greater emphasis on risk and competence and less perceptive. The 2022 version aligns more closely with other ISO standards to support integration in multi-disciplinary labs. Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated. Risk-based thinking is embedded throughout the standard, replacing the older emphasis on preventive action. Competency is now explicitly tied to specific tasks and roles, not just education or job title. Labs should prioritize the changes that impact quality, safety, and compliance most directly with more emphasis on patient safety, result interpretation, and communication

Dr. Marissa A. Orillaza

External quality assessment in ISO 15189:2022 is one of the changes that needs prioritization. It allows the medical laboratory to use a wide range of techniques aside from the usual simple participation in the proficiency testing or survey either given at the national or international level. POCT is also another key change with limited approach which has been introduced and very popularly being accepted in modern world. Lastly, advanced automation is widely used by big hospital laboratories from pre-examination to post-examination that increases the risk of legal problems. Careful attention should be placed on cybersecurity.

Ms. Josefina S. Soriano

Implementation of risk-based thinking and inclusion of Point-of-Care Testing (POCT).

Dr. Sarah Jane L. Datay-Lim

Laboratories must prioritize integration of risk-based thinking, shifting the culture of the laboratory into something that is proactive rather than reactive. The potential risks must be identified and this must be integrated into the quality management system and the decision-making process (from equipment selection to staffing). This would also benefit patient welfare and safety which is also contributes to the requirement for increased patient-centered care.

Dr. Paulo Enrico P. Belen

In some standards that might need some level of prescriptiveness to meet the requirements it might be better to add some degree of prescriptiveness. Not all laboratories are capable of buying CLSI standards to review the best practice to meet each area of the standards.

Tjan Sian Hwa

POCT as part of laboratory medicine services is included in the scope of ISO 15189: 2022. Therefore, the whole ISO 15189 standard applies to POCT, as for any lab-based test. It specifies the laboratory's responsibility towards the selection of devices, training personnel, quality assurance and management review of the complete POCT process. There must be service agreements between laboratory and other parts of the organization using POCT. The laboratory should appoint a person who will be responsible for POCT quality and to manage training and competency assessment of personnels performing POCT.

In ISO 22870:2016 manufacturer's recommendations regarding minimum quality control of an instrument may be accepted following documented review and an instrument-generated quality control shall be acceptable provided that regulatory authorities have accepted it. However, in ISO 15189:2022 IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result. Method comparison should be performed among POCT instruments and with central laboratory equipment throughout the clinically significant intervals. As with other tests performed by different methods or in different location, user should be aware of the discrepancies.

2. How can labs apply risk-based thinking effectively?

Prof. Tomas Zima

Applying risk-based thinking effectively in laboratories under ISO 15189:2022 means integrating proactive risk identification, evaluation, and control into all aspects of lab operations—not just reacting to errors after they happen. ISO 15189:2022 emphasizes preventive actions over corrective actions. Identify and Prioritize Risks and ask: What could go wrong? What is the likelihood of it happening? What would be the impact on patient care or data quality? And use a simple risk matrix – risk level (low, medium, high) and Likelihood x Severity (rare error, low impact, occasional, moderate impact, likely or serious consequences). Labs should focus on the most effort on high-likelihood, high-severity risks and tailor risk controls to the severity and frequency of the risk.

Dr. Marissa A. Orillaza

Medical laboratories that are ISO-9001 certified do not have difficulty applying risk-based thinking in the quality management part of ISO 15189:2022. They can use 5 steps: 1. Identify potential problems or risks before they occur in the 3 phases of examination, taking note of the likelihood and impact on conformity. 2. Implement actions to be taken 3. Regular monitoring and analysis of its effectiveness 4. Risk evaluation, which is the best part of this activity that results to quality improvement. However, before this can happen, risk awareness culture should be in place.

Ms. Josefina S. Soriano

By identifying risks across all laboratory processes, prioritizing high-risk areas, assessing their impact, implementing appropriate control, monitoring outcomes and documenting all risk management activities.

Dr. Sarah Jane L. Datay-Lim

Risk-based thinking can be applied effectively by first identifying the risks using tools that fit their needs (such as SWOT, FMEA or risk registers) and then start analysis of the different sections and laboratory processes from pre-analytic to post analytic. I think this can be more effective if they integrate it into their daily operations rather than doing it for compliance only. This way, laboratories may truly benefit from risk-based thinking because the culture of awareness and accountability is nurtured and operational efficiency is also increased.

Dr. Paulo Enrico P. Belen

Labs can apply risk based effectively if they seriously apply the entries in the risk analysis matrix. Some laboratories just enter the items for compliance purposes

Tjan Sian Hwa

Risk based thinking should be part of laboratory culture and implemented in every laboratory process. The laboratory should have a system that encourage every staff to identify and manage potential risks on patient care in the pre-examination, examination and post-examination processes. This system should be consistently reviewed and updated. Laboratory personnel should be taught how to evaluate the risk with Failure Mode Effect Analysis. Laboratory staff should be able to assess and mitigate risk (by avoiding threat, eliminate risk source, reduce the risk, transfering risk, taking a risk for an opportunity for improvement, or accepting risk by informed decision) and monitor the effectiveness of the mitigation processes with Plan Do Check Action (PDCA). The laboratory should appoint a person to ensure the whole risk management process is implemented. It is a continuing process; thus, the commitment of the higher management level is very essential.

3. What are the new expectations for staff training and competence?

Prof. Tomas Zima

Under ISO 15189:2022, the expectations for staff training and competence have been expanded and clarified to reflect the growing complexity of laboratory work, especially with the integration of technologies like AI, RPA, and advanced informatics systems. ISO 15189:2022 shifts from checking educational credentials to demonstrated, role-specific competence. Competency should be proven through observation, assessment, or audit and training should align with the actual tasks performed—not just job titles. Competency is not a one-time event—it should be assessed regularly. Competency checklists should include both technical and behavioral aspects (e.g., problem-solving, effective communication with patients and clinicians) with new focus on soft skills, especially around patient confidentiality, ethical responsibilities, team coordination, and error disclosure.

Dr. Marissa A. Orillaza

The new expectations for staff training and competence are: 1. The internal and external training will be checked regularly for its effectiveness 2. The staff should be qualified to train for the position with regular performance evaluation 3. The staff should be competent to do the specific responsibilities assigned to them and checked during internal audit and external audit. 4. The staff's competency and authorization are monitored

Ms. Josefina S. Soriano

Staff must be trained in risk-based thinking, understand their role in maintaining quality and the risk register and undergo regular competency assessments.

Dr. Sarah Jane L. Datay-Lim

I think for staff training and competence, it must be an ongoing process with periodical assessments rather than just one-time training. They must be evaluated not just by examination but also other tools such as observation, practical or simulated exercises. It must be tailored to the role of the staff, specific duties and responsibilities and must be varied depending on the complexity of the work that they do. New methods available such as the use of technology can be utilized to help in the training (digital materials, etc.).

Dr. Paulo Enrico P. Belen

For the 2022 version compared to the previous version I think the new expectations are more job specific training and competence compared to the previous versions that are more generalized.

Tjan Sian Hwa

The laboratory shall ensure all personnels to have the competence to perform laboratory activities of which they are responsible. First, the laboratory shall specify the competence framework for each function (education, qualification, training, re-training, technical knowledge, skills, and experience) and ensure the competency by having a process for competence assessment by among others direct observation of an activity, monitoring the recording and reporting of examination results, review of work records, assessment of problem-solving skills, and examination of specially provided samples. The ongoing staff competency should be monitored and documented

4. How should labs validate RPA (robotic process assessment) and AI (artificial intelligence) tools under ISO 15189?

Prof. Tomas Zima

Validating Robotic Process Automation (RPA) and Artificial Intelligence (AI) tools under ISO 15189:2022 requires a structured and risk-based approach, ensuring that these tools consistently produce accurate, reliable, and clinically relevant results. While ISO 15189 does not explicitly name RPA or AI, its principles for validation, verification, and risk management of laboratory processes apply to these technologies. Lab should define the task the tool performs and Its impact on patient results or clinical decision-making. For AI and RPA tools define performance specifications (e.g., accuracy, sensitivity, specificity for AI e.g. compare AI output with a gold standard or human expert interpretation) and acceptable outcomes for process efficiency and error rate (RPA e.g. confirm that automation performs tasks correctly, simulate interruptions or errors and assess recovery logic). AI models and RPA need to set triggers for revalidation (e.g., software updates, changes to input data structure).

Dr. Marissa A. Orillaza

RPA is a technology that uses new and advanced software to automate repetitive processes within digital workflows to achieve higher productivity, accuracy, and precision. Similar to other processes that are manually done, this can validate RPA and AI by checking their: 1. defined objectives 2. Assessment and analysis of the chosen process.3. if there is multi-collaboration of IT, management, and operation team for client's satisfaction 4. if the right tools are used with vendor support 5. if the staff are prepared with training for continual improvement 6. if there is nonconformity to change

Ms. Josefina S. Soriano

Laboratories must validate RPA and AI tools in accordance with ISO 15189:2022, ensuring they meet requirements for accuracy, quality, traceability and patient safety.

Dr. Sarah Jane L. Dataу-Lim

Laboratories can validate RPA and AI by ensuring that there is someone qualified in the laboratory assigned to monitor and maintain human oversight. Although this is quite new to us and a lot of laboratories in the Philippines may not have these available currently, we can prepare by ensuring that all processes are traceable. We must put in place policies to safeguard safety, requiring that there must be logs, documentation and that it can be audited easily.

Dr. Paulo Enrico P. Belen

Resources are always scarce, especially in third world countries. So I think the risk based approach is a practical way of doing it so that we will be able to prioritize where to focus the limited resource.

Tjan Sian Hwa

A process is a set of interrelated or interacting activities that use inputs to deliver an intended result. Inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (data, information or knowledge). An output of a process can be an input for the next process. We can use **the Plan Do Check Action cycle for each process.** Starting with planning the process, identify all the required and the availability of resources for each process, identify the required output and determine the quality indicator of each process (PLAN). Perform the process (DO) and monitor and evaluate the process implementation and output (CHECK) and do the corrective action (ACTION).

Concluding remarks

The aspects of clinical laboratories discussed by the experts in this article are those places where patient safety is compromised. We all need to focus on staff and patient risk, staff competence and the opportunities and risks of using AI, which has already become an essential, if uncontrolled, part of our daily life.

Experts Curriculum Vitae:

1. Prof. Tomáš Zima, MD, DSc, is a distinguished medical biochemist who graduated from the First Faculty of Medicine, Charles University, in 1990. He has served as Professor and Head of the Institute of Medical Biochemistry and Laboratory Medicine since 2001. He was Dean (2005–2012) and later Rector (2014–2022) of Charles University, and a visiting professor at Università degli Studi di Milano in 2024. His research spans oxidative stress,

AGEs, experimental nephrology, tumour markers, and laboratory management. He authored over 550 publications and 10 books, he holds leadership roles in major scientific bodies, including President-Elect of EFLM (2024–2025).

2. Dr. Marissa Orillaza, an accomplished Anatomic and Clinical Pathologist, graduated from FEU-NRMF in 1981 and earned recognition as Most Outstanding Intern in 1982. She is Head of Laboratory Medicine at Tagaytay Medical Center and two Unihealth hospitals, and a founding Board Member of ACE Group of Hospitals. Actively engaged in quality management, she has led ISO/IMS certification initiatives and served as Vice-Chair of the DTI-PAB ISO 15189 Committee. A past president of PSP, PCQACL, and ANCLS, she also chaired national trainings. Beyond medicine, she co-founded SLDC, supporting students in Laguna, and advises The Solid Truth, Inc.

3. Ms. Josefina Soriano, BS Medical Technology (University of Santo Tomas), is the Chief Medical Technologist at the National Kidney and Transplant Institute (NKTI), a leading National Reference Laboratory in the Philippines. Under her leadership, NKTI became the first government laboratory in the country to attain ISO 15189 accreditation, marking a significant milestone in national laboratory standards. A respected authority in clinical laboratory quality, she serves as Treasurer of the Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL). She is also a sought-after speaker and senior auditor, widely recognized for her expertise in ISO 15189 and quality management systems.

4. Dr. C. Sarah Jane L. Datay-Lim, MD, FPSP is a Laboratory Quality and Safety Consultant Director at The Medical City. She also holds the position of past president and current chair of the Committee on Education, Training and Research for the Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL). She is a Doctor of Medicine and a Fellow of the Philippine Society of Pathologists.

5. Dr. Paulo Enrico P. Belen is a graduate of the University of Santo Tomas with a Doctor of Medicine degree. He completed his residency in Pathology at St. Luke's Medical Center – Quezon City, where he now serves as Assistant Chair of the Institute of Pathology in both the Quezon City and Global City hospitals. A past president of the Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL), he has long been active in education and training. Dr. Belen is also a certified ISO 15189 auditor and has completed multiple trainings in laboratory quality systems and management.

6. Dr. Tjan Sian Hwa, MSc, MD is a distinguished Clinical Pathologist with a strong background in laboratory medicine, tropical diseases, and quality systems. She earned her medical degree and specialization in Clinical Pathology from the University of Indonesia and holds a Master of Science in Clinical Tropical Diseases from Mahidol University, Thailand. She currently serves as Head of the Clinical Laboratory Department at Premier Jatinegara Hospital and Laboratory Director of Westerindo Private Medical Laboratory in Jakarta. Dr. Tjan is President of the Indonesian Association for Clinical Chemistry, Chair of the APFCB Laboratory Management Committee, and a Lead Assessor for ISO 15189.

Authors Contribution: All authors are independent experts and equally contributed to the expert interview article published.

Funding: None declared

Conflict of Interest: None declared

Effectiveness of PlGF as a Point of Care Tool for the Prediction of Preeclampsia in High-Risk Pregnancies

DOI- https://doi.org/10.62772/APFCB-News.2025.4203

Dr. Snehal S. Dhobale [1], Dr. Revathi Soundararajan [2], Dr. Kamini A. Rao [3]

[1] Maternal-Fetal Medicine, Senior Consultant, Milann Hospital, Bengaluru, India..

[2] Maternal-Fetal Medicine, Associate Fellow, Milann Hospital, Bengaluru, India.

[3] Medical Director, Milann Hospital, Bengaluru, India.

Corresponding author: Dr. Revathi Soundararajan,
Maternal-Fetal Medicine, Associate Fellow, Milann Hospital, Bengaluru, India;
Email: drrevathi.smfmi@gmail.com

Objective

To evaluate the effectiveness of PlGF-POC (Triage®) testing in predicting preeclampsia in high-risk pregnant women (20-24 weeks gestation) and compare outcomes with historical controls.

Background

Preeclampsia (PE) remains a leading cause of maternal and perinatal morbidity and mortality worldwide, affecting approximately 3% to 5% of all pregnancies and representing the most prevalent medical complication during gestation. It is associated with a combined maternal and perinatal mortality rate of around 10%.1 PE often presents with atypical features and can progress rapidly, necessitating prompt recognition and intervention. Potential complications include eclampsia, HELLP syndrome, fetal growth restriction, and intrauterine fetal demise. Identified risk factors include primiparity, multifetal gestation, and preexisting conditions such as obesity, chronic hypertension, renal disease, and autoimmune disorders.[1] The International Society for the Study of Hypertension in Pregnancy (ISSHP) recommends incorporating angiogenic biomarkers, such as placental growth factor (PlGF), into clinical assessments to enhance diagnostic accuracy. Nevertheless, further research is required to validate the routine implementation of these biomarkers, with the overarching goal of reducing adverse outcomes through timely and accurate diagnosis and management.[2]

Pathophysiology of PE

PE arises from abnormal placentation, including:

- Incomplete spiral artery remodelling
- Oxidative and hydrostatic injury
- Endothelial dysfunction

This leads to systemic maternal inflammation and vascular pathology.

Role of PlGF in early prediction of PE

Placental Growth Factor (PlGF) is a biomarker of placental dysfunction, with reduced levels in early-onset severe preeclampsia and fetal growth restriction. Between 20 and 34+6 weeks of

gestation, PlGF enhances diagnostic accuracy, demonstrating high sensitivity (94.5%) and specificity (95%) for early-onset pre-eclampsia3. PlGF testing guides decisions on surveillance and referral, improving outcomes. The Triage PlGF assay on POC shows superior performance, enabling earlier detection and targeted surveillance.4

Integrating PlGF testing into antenatal care enables the earlier detection of complications and improved outcomes in preeclamptic mothers through targeted surveillance.

Materials and Methods

This single-center prospective observational study was conducted at Milann Hospital, Bengaluru, from April 2012 to April 2014. It enrolled 313 pregnant women, mostly high-risk (80%), with conditions like thrombophilia, hypothyroidism, autoimmune disorders like SLE, and hypertension. Participants underwent PlGF screening using (Triage®) and uterine artery Doppler studies between 20 and 24 weeks of gestation. PlGF levels below the 5th percentile were considered test-positive.[5] The study aimed to evaluate the effectiveness of PlGF screening in predicting preeclampsia in this high-risk population.

Triage PlGF Percentile (pg/mL)

GA Bin	N	5th %	50th %	95th %
GA < 19	276	56.2	123	365
19 ≤ GA < 24	324	62.9	154	452
24 ≤ GA < 29	359	130	407	1296
29 ≤ GA < 32	377	128	494	1460
32 ≤ GA < 35	416	70.4	399	1406
GA ≥ 35	455	14.6	53.9	327

Table 1: Gestational age-based PlGF reference centiles (5th, 50th, 95th) from the Triage® POC insert (2009), which was used as a reference for risk stratification in the patients.

Participants were followed longitudinally for adverse pregnancy outcomes, including the development of preeclampsia, fetal growth restriction (FGR), and intrauterine fetal demise (IUFD) in the same lines as in the Pelican Study.6 Women who tested positive with low PlGF were subjected to enhanced surveillance protocols, which included initiation or titration of antihypertensive therapy where appropriate, serial fetal growth scans, Doppler assessments, and modified biophysical profiles, customized according to the gestational age and severity of the condition.

To evaluate the impact of PlGF-based risk stratification, maternal and fetal outcomes of test-positive participants were compared with those of **100 historical controls** who had delivered prior to the adoption of PlGF testing at the same institution.

Results

- PlGF demonstrated predictive value for preeclampsia in specific subgroups, including patients with thrombophilia (15/26; $p = 0.065$) and hypothyroidism (18/26; $p = 0.069$), which were close to significance.
- Effective lead time (the interval between test positivity and clinical diagnosis) was significantly prolonged in the PlGF-positive group, as shown by a marked difference in mean ranks ($p < 0.05$, Mann–Whitney test).

- Among patients who developed preeclampsia with severe features, the lead time was notably longer ($p = 0.0001$), offering a critical window for intervention, compared to historical controls.
- Interestingly, 61% of PlGF-positive patients were uterine artery Doppler screen negative, highlighting PlGF's ability to identify at-risk pregnancies that Doppler may miss.
- ·Among women who developed PE with severe features, those identified via PlGF testing and subjected to close surveillance delivered at higher gestational ages and had improved birth weights compared to historical controls.
- Patients with very low PlGF levels (<12 pg/ml) showed improved outcomes following aggressive monitoring, with a lead time of 4-7 weeks, enabling delivery closer to the threshold of viability.
- However, 13.3% (4/30) of PlGF-positive patients did not develop PE, and three PlGF-negative patients developed severe PE, all of whom were carrying twin pregnancies, suggesting unique dynamics in multifetal gestation.

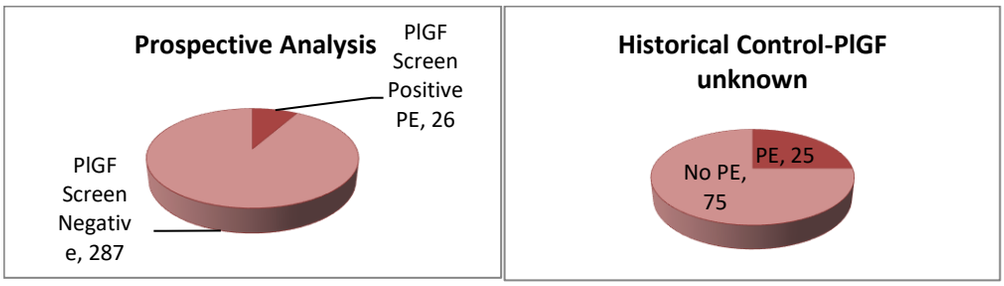


Figure 1: Summary of Statistics

Disease	PlGF positive PE	Control	Total
Positive	11	17	28
Negative	15	8	23
Total	26	25	51

Table 2: Patients with Thrombophilia (p=0.065)

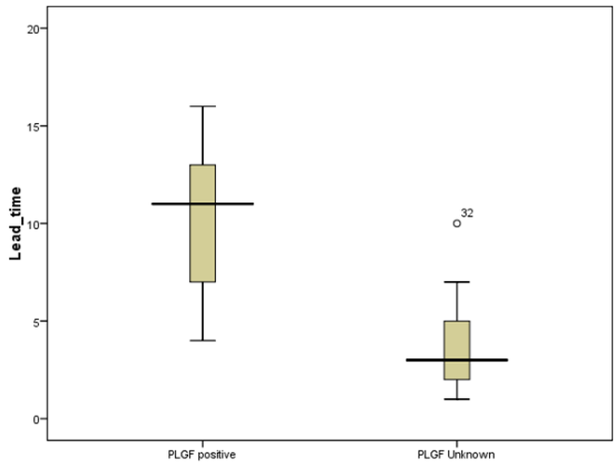
Disease	PlGF positive PE	Control	Total
Positive	8	14	22
Negative	18	11	29
Total	26	25	51

Table 3: Patients with Hypothyroidism (p=0.069)

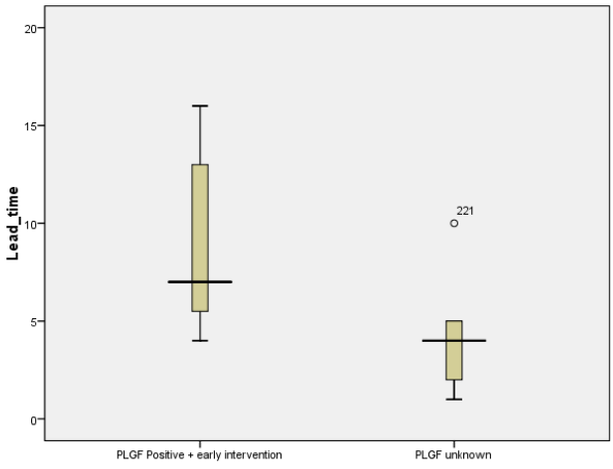
	Number	Mean Rank	Sum of Rank
PlGF positive (<12 pg/mL)	16	20.12	322.00
Control (PE with severe features)	13	8.69	113.00
Total	29		

p=0.0001

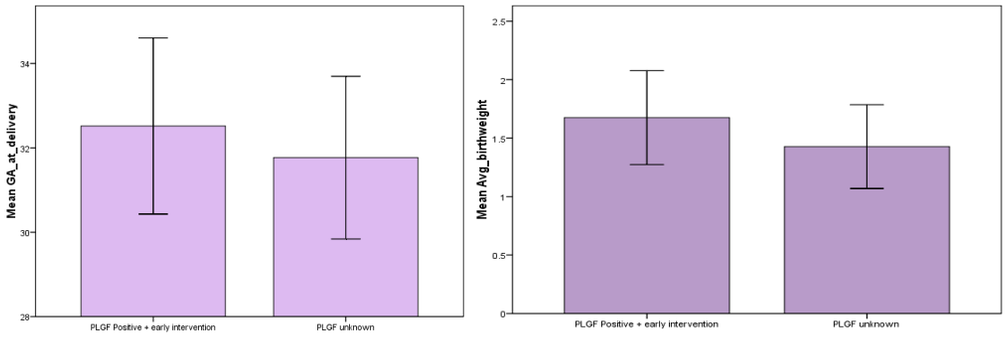
Table 4a and 4b: Mann-Whitney Test for Lead Time (Test to Delivery Time)



Graph for Table 4a: Mann-Whitney Test for Lead Time (in weeks) – in PlGF positive cases (<5th centile for GA) vs controls who developed PE



Graph for table 4b: Mann-Whitney Test for Lead Time (in weeks) – in PlGF very-low positive cases (<12 pg/mL) vs controls who developed PE with severe features



Gestational Age at Delivery **Birthweight**

Figure 2: Trends in Gestational Age at Delivery and Birth Weight in those with Preeclampsia with severe features (PlGF positive vs Controls with PE)

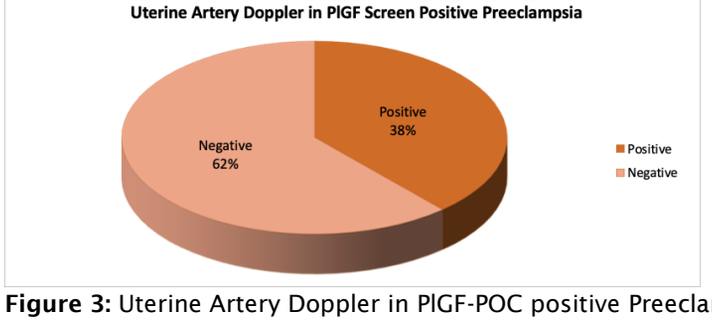


Figure 3: Uterine Artery Doppler in PlGF-POC positive Preeclampsia

Lead Time (weeks)	No. of Cases	Birth Weight (kg)	No. of Cases
4	2	0.5	2
5	2	0.75	1
6	1	1.7	1
7	1	2.3	2
Total	6	Total	6

GA at Delivery (weeks)	No. of Cases
25	1
26	1
28	1
30	1
35	1
36	1
Total	6

Table 5: Cases with Very Low PlGF (<12 pg/ml)

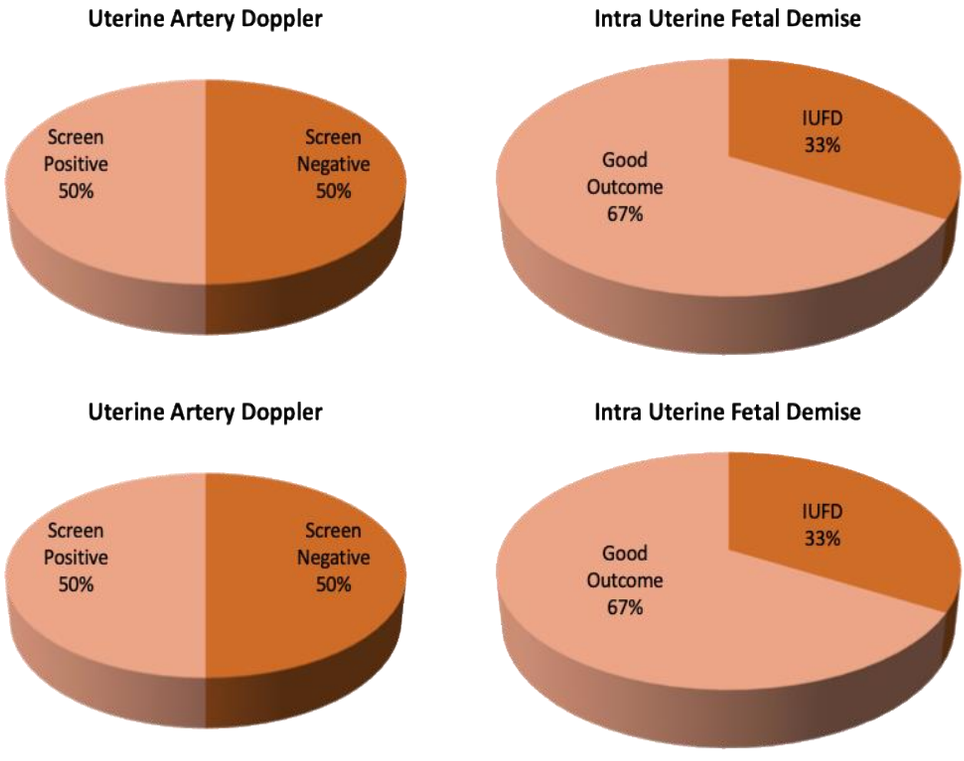


Figure 4: Uterine Artery Dopplers and Perinatal Outcome in those cases with very low PlGF (<12 pg/ml).

Discussion

Preeclampsia remains a significant global health challenge, and early diagnosis using reliable biomarkers is essential to improve maternal and fetal outcomes. Early diagnosis is key—but traditional tools don't always catch it in time. Placental Growth Factor (PlGF), a novel angiogenic marker, shows promising predictive value and enhances clinical decision-making through timely surveillance and intervention. As a novel angiogenic biomarker, PlGF offers a more precise way to identify at-risk pregnancies earlier. In our study, it proved especially helpful in high-risk women, even detecting cases missed by standard Doppler scans. By enabling timely intervention and closer monitoring, PlGF testing led to better outcomes, including higher birth weights and longer gestation. It's a step toward more proactive, personalized prenatal care.

Key Takeaways from Our Study:

- PlGF is a biomarker of placental dysfunction with reduced levels in early-onset severe preeclampsia and fetal growth restriction.
- Between 20 and 34+6 weeks, PlGF enhances diagnostic accuracy with high sensitivity (94.5%) and specificity (95%) for early-onset preeclampsia.
- PlGF testing guides decisions on surveillance and referral, improving outcomes.
- The Triage PlGF assay is more effective, enabling earlier detection and targeted surveillance when compared to historical controls who were monitored without the test.

Larger multicentric studies are needed to validate the utility of second-trimester PlGF screening and support its broader clinical implementation.

Conclusion

PlGF-POC (Triage®) testing is a powerful tool for predicting and managing preeclampsia, especially in resource-limited settings.

Acknowledgment

The investigators and authors acknowledge Dr. Gautham Pranesh for his contribution to the statistical analysis of this study.

Conflicts of Interest

The Investigators/authors declare that they have no conflicts of interest related to the conduct of the study

Presentation History

This study was presented at the ISOM-ISSHP World Congress 2014 and will resume with new research after the re-launch of the test in April 2025 in India.

- The Alere Triage PlGF POC test is currently available as Quidel Triage® PlGF Test.
- The Investigators have been tagged with the designations that they held at the time of the conduct of this study. However, currently their designation are as follows:

- Dr Snehal Dhobale Kohale [1], Consultant Fertility Specialist and Clinical Director, Ova Fertility and Women Care, Thane, India.
- Dr Revathi Soundarajan [1*], Managing Director, Mirror Health, Bengaluru, India, Secretary, SMFM (I), Organizing Secretary, ISSHP World Congress 2023, Indian Co-Chair, PEN (I)
- Dr Kamini Rao 2, Co-Founder and Chairman, Dr Kamini Rao Hospitals, Bengaluru, India.

Authors Contribution: All authors are independent experts and equally contributed to the expert article published.

Funding: None declared

Conflict of Interest: None declared

References

1. Obstetrics & Gynecology Clinics of North America. June 2010; 37(2).
2. Magee LA, Brown MA, Hall DR, Gupte S, Hennessy A, Karumanchi SA, Kenny LC, McCarthy F, Myers J, Poon LC, Rana S, Saito S, Staff AC, Tsigas E, von Dadelszen P. The 2021 International Society for the Study of Hypertension in Pregnancy classification, diagnosis & management recommendations for international practice. Pregnancy Hypertens. 2022 Mar; 27:148-169. doi: 10.1016/j.preghy.2021.09.008. Epub 2021 Oct 9. PMID: 35066406.
3. Knudsen UB, et al. Pregnancy Hypertension. 2011; 2:8–15.
4. Benton SJ, et al. Am J Obstet Gynecol. 2011;205: 469.e1–469.e8.
5. Saffer C, et al. Pregnancy Hypertension. 2013; 3:124–132.
6. Chappell LC, et al. Circulation. 2013; 128:2121–2131 (PELICAN Study).

APFCB Webcast & e-Learning Programme Activities (January – June 2025)

Introduction

The APFCB Webcast & e-Learning Programme, an initiative of the APFCB Communication and Publication Committee (C-CP), has emerged as a dynamic academic platform fostering continuous professional development for laboratory medicine professionals across the Asia-Pacific region. The programme is designed to deliver expert-led webinars on contemporary and practical topics, offering a virtual learning opportunity irrespective of geographical boundaries.

In the current calendar year 2025 (up to June), three webinars have been successfully conducted under this programme, each drawing substantial participation and positive feedback.

Details of Conducted Webinars

1st APFCB Webcast & e-Learning Webinar

Date: 21st February 2025

Theme: Advancing Medical Laboratory Practices with ISO 15189:2022 – The Future of Quality and Competence

Speakers & Contributions:

- **Prof. Tomas Zima (Czech Republic)**
  Prof. Zima delivered an insightful lecture on "Risk Management in Medical Laboratories: Practical Applications of ISO 15189:2022". He discussed the practical aspects of risk identification, assessment, and mitigation in laboratory workflows, emphasizing the role of ISO 15189:2022 in ensuring patient safety and laboratory competence.

- **Prof. Tony Badrick (Australia)**
  Prof. Badrick presented on "Transitioning to ISO 15189:2022: Key Changes and Implementation Strategies". His talk highlighted the significant updates introduced in the latest ISO standard, providing laboratories with a clear roadmap for successful adoption and compliance.

Moderator:

Prof. Pradeep Kumar Dabla (India) expertly moderated the session, steering the discussion, managing audience Q&A, and contextualizing the talks within the broader framework of APFCB's commitment to laboratory quality improvement in the region.

2nd APFCB Webcast & e-Learning Webinar

Date: 9th May 2025

Theme: The Interplay of Biological Factors in Chronic Disease Pathogenesis

Speakers & Contributions:

- **Prof. (Dr.) Ketut Suastika (Indonesia)**
  Prof. Suastika spoke on "The Effect of Local Gut Microbiota in Diabetes", elucidating the emerging role of gut microbiota in glucose metabolism and its implications in the pathogenesis and management of diabetes. His talk provided both mechanistic insights and potential clinical applications.

- **Prof. (Dr.) Nafija Serdarevic (Bosnia and Herzegovina)**
  Prof. Serdarevic's presentation focused on "Homocysteine & Lipid Values in Patients with Stroke & Vascular Dementia", sharing critical data on how biochemical markers influence cerebrovascular disease risk, diagnosis, and management in elderly populations.

Moderator:

Dr. Ryunosuke Ohkawa (Japan) effectively guided the academic discourse, maintained session flow, and facilitated an engaging Q&A, ensuring the complex inter-disciplinary subjects were accessible to the diverse audience.

3rd APFCB Webcast & e-Learning Webinar

Date: 26th June 2025

Theme: A Practical Approach to Enhancing Lab Quality with External Quality Assurance (EQA) in Resource-Limited Areas

Speakers & Contributions:

- **Prof. (Dr.) Rodelio D. Lim (Philippines)**
  Prof. Lim delivered a practical session on Troubleshooting and Practical Tips: How to Utilize Data for Quality Improvement. He provided pragmatic approaches for laboratories to interpret EQA data, identify performance gaps, and implement corrective actions within limited-resource settings.

- **Dr. Sarah Jane L. Datay-Lim (Philippines)**
  Dr. Datay-Lim's talk on Basics of EQAP and Interpretation of Results demystified EQA processes for participants, explaining result analysis, reporting, and follow-up actions, which are essential for maintaining diagnostic accuracy and patient safety.

  Moderator:

  Prof. (Dr.) Paulo Enrico P. Belen (Philippines) skillfully moderated the session, integrating audience queries, summarizing key takeaways, and relating the content to practical laboratory operations, especially for participants from small and mid-sized laboratories.

Participation and Engagement Overview

A standout feature of the programme has been its impressive registration and participation metrics:

- The 5th webinar on 26th June 2025 attracted 5000 registrations — the maximum capacity of the webinar platform. Owing to this limit, the registration process had to be closed ahead of schedule despite continued demand.
- The 3rd and 4th webinars also recorded strong participation, reflecting consistent regional interest and the programme's growing academic reputation.

This substantial engagement highlights APFCB's increasing influence in digital medical education within the Asia-Pacific laboratory community

Conclusion and Way Forward

The APFCB Webcast & e-Learning Programme has successfully positioned itself as a leading virtual academic forum for laboratory medicine professionals. The C-CP proposes:

- Procuring the webinar platform to accommodate expanding interest.
- Broadening topic diversity based on emerging trends and member feedback.
- Involving additional member society experts and IFCC representatives to enrich content and foster international collaboration.

The APFCB C-CP extends sincere thanks to all speakers, moderators, participants, APFCB leadership, and corporate partners for making these webinars highly successful and impactful.

Report compiled by:
Team APFCB C-CP
Dr. Deepak Parchwani (Coordinator, APFCB Webcast & e-Learning Programme)

Enhancing Core Laboratory Excellence through GLP System Track Automation at Sunway Medical Centre

DOI- https://doi.org/10.62772/APFCB-News.2025.4204

Authors:

Dr. Jamuna Jairaman[1]*, Azana Suria[2], Annie V V Thomas[3], Nurull Hedayu[4]

[1]Director, Allied Health Services; Laboratory, Sunway Medical Centre, Kuala Lumpur, Malaysia

[2] Manager, Laboratory, Sunway Medical Centre, Kuala Lumpur, Malaysia

[3]Assistant Manager, Laboratory, Sunway Medical Centre, Kuala Lumpur, Malaysia

[4] Senior Medical Laboratory Scientist, Laboratory, Sunway Medical Centre, Kuala Lumpur, Malaysia

Corresponding Author*: Dr. Jamuna Jairaman, Director, Allied Health Services; Laboratory, Sunway Medical Centre, Kuala Lumpur, Malaysia; email- jamunaj@sunway.com.my

Abstract

This study presents a transformative initiative undertaken by Sunway Medical Centre to enhance diagnostic laboratory operations through the implementation of the GLP System Track Automation. Faced with increasing test volumes and stringent regulatory requirements, the laboratory aimed to modernize its Immunoassay and Clinical Chemistry (IACC) workflows by integrating a modular automation platform with its Laboratory Information System (LIS) and middleware. The project, executed from September 2023 to October 2024, focused on achieving end-to-end sample traceability, reducing manual handling, improving turnaround times, and promoting sustainability. Key outcomes included an 81% reduction in manual touchpoints, a 36% decrease in pre-analytical processing time, and significant improvements in Laboratory Turnaround Time (L-TAT) despite a surge in test volumes. Staff satisfaction rose markedly, and digital transformation efforts led to substantial environmental savings. This initiative not only reinforced compliance with MS ISO 15189, ACHS, JCI, and MSQH standards but also positioned the laboratory as a regional benchmark for innovation, efficiency, and sustainable healthcare delivery.

Keywords: Laboratory Automation, GLP System Track, Digital Transformation, Sample Traceability, Operational Efficiency, Sustainability, Clinical Chemistry, Immunoassay

Introduction

Sunway Medical Centre (SMC), Sunway City laboratory serves as the central hub within the Sunway Healthcare Group (SHG) hospital network laboratories. Diagnostic tests that are not processed at individual SHG Medical Diagnostic Laboratories are routed to the centralized laboratory at SMC in Sunway City. With increasing diagnostic demands and evolving regulatory requirements, SMC Laboratory recognized the need to establish an integrated, standardized, and traceable workflow within its pathology operations.

Today, the SMC Laboratory processes over 3.8 million immunoassay and chemistry tests annually, covering inpatient, outpatient, and SHG-wide testing needs. To advance clinical excellence and long-term sustainability, the Medical Diagnostic Laboratory at SMC partnered with a laboratory solutions provider to implement a comprehensive transformation initiative.

This project focused on Total Laboratory Automation (TLA), digital integration, and workflow reengineering to enhance efficiency, scalability, and diagnostic accuracy.
Previously, the laboratory faced challenges due to manual processes across the sample lifecycle including labelling, tracking, pre-analytical handling, and documentation which posed risks to sample integrity, turnaround time, and audit readiness. Fragmented specimen tracking, human error, and inefficient documentation further threatened compliance with accreditation standards and service excellence, ultimately impacting patient safety and institutional credibility.

To address these challenges, the GLP System Track Automation Project was launched in 2023, specifically targeting the Immunoassay and Clinical Chemistry (IACC) Laboratory. This initiative was designed to modernize sample journey management, emphasizing traceability, real-time visibility, and quality assurance. The goal was to align laboratory operations with both regulatory standards and internal quality benchmarks by implementing a fully traceable system integrated with the Laboratory Information System (LIS) and automation platforms.

At the heart of this transformation is the GLP System Track automation a modular platform comprising key components such as the Bulk Loader Module, Input/output Module, Tube Assessment Centre, Centrifuge, Decapper, Buffer, Recapper, Storage, and Remover Modules. This comprehensive infrastructure seamlessly integrates with the LIS and middleware (Analyzer Management System or AMS) to enable end-to-end traceability through sample handling, middleware coordination, and real-time dashboards.

Materials and Methods

The GLP System Track Automation at Laboratory, Sunway Medical Centre, Sunway City
The system automates data capture at every stage of sample handling, transfer, processing, archiving, and disposal ensuring a secure and auditable trail in compliance with Good Laboratory Practice (GLP) and accreditation requirements. Its validated architecture not only enhances compliance and reduces manual errors but also increases operational transparency, positioning it as a cornerstone of SMC's laboratory workflow transformation.

GOALS

The primary goal of the project was to automate and digitalize the complete sample tracking process from initial loading of samples to archiving and eventual disposal of those samples to improve accuracy, regulatory compliance, and operational efficiency. The key objectives were to:
1. Establish comprehensive, end-to-end traceability for all specimens to ensure regulatory compliance through automated audit trails and documentation.
2. Reduce manual handling by laboratory staff and minimize associated errors through automation.
3. Improve turnaround times and enhance sample visibility in clinical chemistry and immunoassay testing.
4. Enhance staff confidence, productivity, and job satisfaction by streamlining workflows.
5. Implement digital solutions that promote long-term sustainability in laboratory operations.

To support this transformation, a structured change management roadmap was adopted, consisting of three phases: Awareness, Training, and Go Live and Support. This approach targeted key stakeholders across a multidisciplinary team, including hospital leadership, department managers, medical technology director, laboratory scientists (as champion users), pathologists, IT specialists, quality assurance personnel, and vendor partners from both the LIS and GLP System Track automation. Together, these stakeholders collaborated to define workflows, conduct risk assessments, and implement a phased automation strategy. Key components of this implementation included the integration of IACC analyzers Alinity ci, middleware (Analyzer Management System or AMS) and track management solutions (TWM - Track Workflow Manager, TSM - Track Sample Manager), LIS and real-time performance dashboards.

Method

The project was executed in well-defined phases to ensure smooth implementation and minimal disruption to daily operations:

Phase 1 – Awareness: This phase centered on building understanding and engagement around the GLP System Track Automation. Communication of the overarching vision was carried out through presentations, site visits, and interactive system demonstrations.

Phase 2 – Training: Focused on role-specific education through cross-functional workshops, basic and advanced training modules, and detailed orientation for key users.

Phase 3 – Go Live and Support: Support mechanisms were established to ensure a successful transition, including access to job aids, checklists, help hotlines, on-demand support, and self-service guides.

Results

The project delivered substantial, quantifiable improvements:

1. Establish comprehensive end-to-end traceability for all specimens

The implementation of a fully integrated track management solutions (TWM - Track Workflow Manager, TSM - Track Sample Manager), and Analyzer Management System (AMS) enables 100% digital traceability of all specimens through precise, time-stamped events. This end-to-end visibility not only ensures accurate sample tracking but also strengthens regulatory compliance by generating automated audit trails and comprehensive documentation. These digital records enhance audit readiness and align with key accreditation requirements such as MS ISO 15189 and the College of American Pathologists (CAP) standards.

2. Reduce manual handling by laboratory staff and minimize associated errors through automation.

Previously, the laboratory's testing workflow required extensive manual intervention from sample reception to final unloading. With the implementation of the GLP System Track Automation, manual touchpoints were reduced by 81%, significantly lowering the risk of human error and enhancing the lab's capacity to accommodate growing test volumes. Automation also streamlined multiple stages of the process most notably, reducing pre-analytical processing time by 36%. Additionally, it eliminated inefficiencies in recursive

workflows and unnecessary sample aliquoting, achieving a 51% and 50% reduction. Recursive workflow refers to the repeated process of locating, identifying, and retrieving a sample tube to perform re-tests or additional tests using the same specimen.

3. Enhance turnaround times and sample visibility in clinical chemistry and immunoassay testing

Laboratory Turnaround Time (L-TAT), defined as the duration between sample registration and the release of test results, was used to assess the impact of automation on operational efficiency. A comparative analysis was conducted using time-stamped data from the Laboratory Information System (LIS) for the periods of January to March 2024 and January to March 2025.

For **Clinical Chemistry**, the average L-TAT **improved by 16.6%,** despite a **65.9% increase in test volume over the year**. Currently, **95% of Clinical Chemistry test reports are released within 133 minutes.**

For **Immunoassay**, an average **13% improvement** in L-TAT was recorded, even as test **volumes grew by 53.4%**. At present, **95% of Immunoassay reports are released within 156 minutes.**

These improvements demonstrate the effectiveness of digital sample tracking and automation in accelerating result delivery while managing increased workload.

4. **Enhance staff confidence, productivity, and job satisfaction** through streamlined workflows

Recognizing the importance of a positive work environment, the laboratory invested in a solution that fosters employee engagement, empowerment, and satisfaction. Following the implementation of the GLP System Track Automation, 80% of surveyed staff reported a 76% improvement in pre-analytical satisfaction, a 124% increase in post-analytical satisfaction, and a 90% overall rise in job satisfaction within just six months. These cultural shifts have strengthened staff confidence in sample handling, enhanced workload management, and contributed to higher productivity and retention of skilled personnel.

5. Drive long-term sustainability through digital transformation

As energy-intensive institutions, healthcare organizations are increasingly focused on reducing their environmental footprint. The laboratory embraced digital transformation as part of its commitment to sustainability. The implementation of the GLP System Track automation solution integrated with the Analyzer Management System (AMS) and the Laboratory Information System (LIS) enabled seamless data exchange across IACC instruments. This integration significantly reduced manual result verification and paper use, enabling faster, more accurate result validation and improving both patient care and operational efficiency.

The shift to digital workflows led to 81% results auto-verified, improving post-analytical turnaround time and reducing human error. Additionally, the reduction in paper usage estimated at 340,000 sheets annually which translated into substantial environmental savings: the equivalent of 171 trees, 3.59 million liters of water, 17,990 kWh of energy, and 1,799 kilograms of CO_2 emissions saved each year. These outcomes underscore the lab's commitment to sustainable and responsible healthcare delivery.

The system significantly improved operational visibility and control, enabling proactive quality management and reinforcing a culture of excellence within the pathology department.

Discussion

The GLP System Track Automation initiative marks a transformative milestone in Laboratory Sunway Medical Centre's digital journey, reinforcing its commitment to innovation, sustainability, and clinical excellence. Anchored by standardized SOPs, continuous staff development, and a validated, audit-ready infrastructure, the project ensures long-term viability and regulatory compliance.

With strong endorsements from Department of Standards Malaysia on the recent transition audit of MS ISO 15189: 2022 held in April 2025, the initiative showcases best practices in diagnostic safety, traceability, and operational efficiency. By fully automating the sample lifecycle and integrating real-time data management, Laboratory Sunway Medical Centre has not only enhanced its current capabilities but also built a scalable and resilient framework for future growth.

Conclusion

This transformation sets a new benchmark for laboratories regionally and globally demonstrating how thoughtful integration of technology and collaborative change management can lead to sustained improvements in diagnostic accuracy, turnaround time, environmental impact, and patient outcomes.

Ultimately, this initiative affirms Laboratory Sunway Medical Centre's position as a forward-thinking healthcare leader, delivering measurable results while advancing the vision of sustainable, digitally enabled, high-quality care.

Acknowledgement

We acknowledge the contributions of all laboratory staff, IT specialists, and vendor partners involved in the successful implementation of the GLP System Track Automation.

Authors Contribution: All authors are independent experts and equally contributed to the expert article published.

Funding: None declared

References

1. The Australian Council on Healthcare Standards (ACHS) The Australian Council on Healthcare Standards (ACHS) International, The ACHS EQuIP7 Guide for Hospitals, Sydney, Australia 2021

2. Joint Commission International Accreditation Standards for Hospital, 7th Edition 2021

3. Malaysian Society for Quality in Health (MSQH) Malaysia Hospital Accreditation Standards, 6th Edition 2021

4. Department of Standards Malaysia Medical Laboratories - Requirements for quality and Competence MS ISO15189:2022

5. References available upon request or as per institutional documentation on Policies and Procedures.

International Federation of Clinical Chemistry (IFCC) Education and Management Division VISITING LECTURER PROGRAM (VLP), 5-6 June 2025; Kathmandu, NEPAL

Program Title: **ISO 15189:2022 Internal Auditor Training**
Venue: **National Health Training Center, Teku, Kathmandu**
Number of participants: **30**

Objective:

The main objective of this training program was to enhance the knowledge and skills of laboratory professionals in Nepal on ISO 15189:2022 implementation. Improving quality with internal auditing practices. In addition, focusing Good Laboratory Practice, including Internal Quality Control (IQC) and External Quality Assessment (EQA), thereby promoting quality improvement in medical laboratories in Nepal.

Program Overview:

Formal program was started with welcoming IFCC resource persons of VLP and welcoming all the participants from the government hospital laboratories, stand-alone laboratories, private and non-government laboratories and academic institutes, vendors of quality control material supplies, biomedical engineers and administrators. Before starting the program, IFCC VLP lecturers were requested for lighting the traditional lamp to mark inauguration. After the welcoming note from the president of NAMLS and collaborator NAF, Professor Dr. Egon Amann started his training session “Enhancing quality on a global level”. He discussed and shared the experiences from IFC EQA pilot program. The program is followed by sessions as described in workshop schedule.

Prof. Dr. Rona Greaves focused Presentation on IQC topics and ISO 15189:2022: Practical method implementation tips and discussed the local scenario regarding IQC. Furthermore, she discussed about minimum requirements for method evaluation and auditing. She moderated workshop to facilitate the training with significant discussion and question answering. She shared experience from Australia and globe to enhance IQC and also discussed IFCC recommendations and the importance of ISO accreditation.

Prof. Dr. Pradeep Dabla, India made workshop more interactive by communicating in English as well as in local language friendly sharing the knowledge and experiences of quality management system. He emphasized the EQA to Improve Laboratory Performance and Special IQC topics (For example: Standardization of laboratory tests – Why it is needed and how to do it?). Sessions were significantly interactive and effective as per the feedback, question and answering during his lecture. He Moderated workshop effectively and discussed the EQA system, EQA providers, and the recommendations of IFCC. There was active discussion and sharing of knowledge and experiences not only in the session but also in the tea break and lunch.

Prof. Dr. Egon Amann described in his impressive lecture about Enhancing Laboratory quality on a global level: Results of the IFCC EQA pilot study, which is lesion learning for all of the participants to implement the quality management strategies in future. In successive session, he emphasised overview of ISO 15189:2022: Key standard for our profession: meaning, implementation, and he also conducted interactive discussion as Workshop Planner and Moderator. He discussed the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory providing examples of various scenarios for the discussion. In his insights into quality accreditation and improvement all the participants got benefitted regarding quality improvement. Moreover, he introduced about the IFCC activities, IFCC recommendations, reference and resources of IFCC helpful in improving global laboratory QMS.

Appreciating the support of IFCC to national society (NAMLS), myself, as a President of NAMLS (Prof. Dr. Mahendra Prasad Bhatt) added lecture on prospective approach of Machine learning and AI in research, practice and QMS system, their challenges and usefulness in TQMS in the field of laboratory Medicine.

In addition, CEO of NAF, Er. Mr. Abisekh Adhikari presented challenges and process of laboratory accreditation in Nepal. He addressed several questions from the participants, VLP lecturers and provided ideas to way forward about accreditation process.

Finally, program was concluded with vote of thanks to IFCC, IFCC trainers and organizer and collaborators. The Renowned VLP professors did certificate distribution to the participants. President of NAMLS and NAF presented Vote of thanks and token of love and appreciation to VLP Lecturers, including Prof. Dr. Egon, Prof. Dr. Ronda and Prof. Dr. Dabla. Dinner and discussion program was organized for the guest VLPs and it was fruitful time spent with them discussing various future development plans in improving quality of national health laboratory services.

Feedback of the participants:

Most of the participants provided positive feedback to the IFCC VLP program in which they get academic knowledge and professional skills on QMS guided as per IFCC recommendation. Moreover, participants expect frequent trainings on new insight into QMS,

advancement in laboratory technologies. Such global sharing of Knowledge and technology innovation periodically through national associations may improve laboratory quality worldwide and National societies may contribute the experiences and technology innovation worldwide through the IFCC. Participants expected to participate research programs regarding QMS and technology advancement such as AI in laboratory Medicine through IFCC. In these regards, NAMLS realized its National responsibilities to collaborate with IFCC in improving the quality of national laboratories. Overall, program was found beneficial to individual participants and laboratories.

IFCC Workshop Program Kathmandu, Nepal, June 5 & 6, 2025

Day 1 / SESSION 1: Assuring Quality in the Clinical Laboratory		
08:00-09:00	Registration of participants	
09:00-09:15	Welcoming remarks	Mahendra Prasad Bhatt, NAMLS Abishek Adhikari, NAF
09:15-10:00	Enhancing Laboratory quality on a global level: Results of the IFCC EQA pilot study	Egon Amann
10:00-10:45	Presentation on IQC topic	Ronda Greaves
10:45-11.00	COFFEE BREAK	
11:00-11:45	Using EQA to Improve Laboratory Performance	Pradeep Dabla
11:45-12:30	ISO 15189:2022: Key standard for our profession: meaning and implementation - an overview	Egon Amann
12:30 -14:00	LUNCH	
14:00-14:45	ISO 15189:2022: Practical method implementation tips / Minimum requirements for method evaluation / auditing	Ronda Greaves
14:45-15:30	Impulse lecture "Compliance with Quality Systems". Present the agenda, aims and instructions for activity. Group forming with max. 10 participants per group (Number of the groups depends on the total number of attending participants)	Egon Amann
Workshop: **"What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory?"** Moderators: Egon Amann, Pradeep Dabla, Ronda Greaves Total workshop time: 60 mins (15:30-16:30)		
16:30-17:00	Group discussion: Finding most burning top three issues and listing those issues on flip charts.	All
17:00-17:30	Presentations of Groups	
17:30-17:30	Concluding activity: Evaluating, deciding, and listing actions.	
17:30	END OF DAY 1	

Day 2 / SESSION 2: Quality challenges going forward: understanding the needs of Nepal		
09:00-09:30	Moving along the road to accreditation	Egon Amann
09:30-10:00	The challenges of maintaining and sustaining EQA programs in Nepal – lessons from the field	Abhishek Adhikari
10:00-10:30	Special IQC topics For example: Standardization of laboratory tests – Why it is needed and how to do it?	Pradeep Dabla
10:30-11:00	ISO 15189:2022: Open questions	All
11:00-11:15	COFFEE BREAK	
11:15-11:45	Revolutionizing Laboratory Quality with Artificial Intelligence (AI)	Mahendra Prasad Bhatt
11:45-12:45	**Panel Discussion** **Identify practical steps for improving quality in Clinical Laboratories in Nepal**	All
12:45-13:45	LUNCH	
13:45-14:25	Identified quality improvement needs. What are major hurdles?	Egon Amann
14:45-15:15	Workshop summary: Developing the road map	Facilitators / All
15:15-15:30	Concluding remarks	Mahendra Prasad Bhatt, NAMLS Abishek Adhikari, NAF
15:30	Certificate issuance ceremony	NAMLS/ NAF/Facilitators
16:00	END OF DAY 2 / END OF WORKSHOP	

Certificate distribution:

All the participants are provided Internal auditor training as per ISO: 15189 2022 individually and VLP lecturers are respectfully presented token of love and appreciation by NAMLS and NAF.

Achievements:

The entire participant are actively involved in discussion in every issues and local challenges regarding accreditation and Quality control/ EQA supply system. In Nepal, about 10 laboratories including the government laboratory, National Public Health Laboratory are accredited and certified by ISO 15189. We have 2 National accreditation bodies including AERSSC and NAF responsible for the accreditation and certification of diagnostic laboratory. Rest of all the hospital-based and stand-alone laboratoried in Nepal are locally acredited and monitored in different grade by the Ministry of health, National Public Health Laboratory. Moreover, some of the laboratories approach India for the accreditation from NABL India.

In this IFCC VLP program, participants get knowledge about the accreditation process, certification guidelines and use of Quality materials of IQC and EQA.

Benefit to the participants:

Benefit to the National Professional Society: On behalf of IFCC, NAMLS got chance to interact and train health laboratory professionals of Nepal. NAMLS also got insight into collaboration and participation in IFCC activities.

Future Expectations:

We would like to enhance Clinical laboratories to be involved in translational research, with national ethical guideline including bio banking of laboratory specimen and data sharing. Emergency preparedness and National health Security trainings. IFCC may play supportive role to construct national guidelines.

It is high time to conduct research on the rational use of Automation, Machine learning and AI in laboratory medicine. We expect research funding from the IFCC so that evidence-based laboratory practice model can be proposed in future enhanced with AI.

National Networking for capacity building of Laboratories:

Networking and capacity building of diagnostic laboratories in Nepal is challenging due to limited resources and budgets in geographically diverse areas of the country. NAMLS is willing to make a model Networking and capacity building programs nationwide. This new model of health laboratory sector strengthening can be developed and implemented by NAMLS in collaboration with Ministry of Health and population, Nepal. And collaborative support of IFCC is always needed and appreciated.

Report Submitted by:

Prof. Dr. Mahendra Prasad Bhatt

President, NAMLS, Nepal

Professor and Head

Department of Clinical Biochemistry and Laboratory Medicine,

Manmohan Memorial Institute of Health Sciences

Solteemode, Kathmandu, 15201, Nepal

Program Pictures:

Pic 1: Participants

Pic 2: Interactive Session

Pic 3&4: Lecture sessions

Pic 5: Lt to Rt- Prof. Dr. Rona Greaves, Prof. Dr. Egon Amann, Prof. Dr. Pradeep Dabla, Prof. Dr. Mahendra Prasad Bhatt

The Non-Malignant Face of CA-125

DOI- https://doi.org/10.62772/APFCB-News.2025.4205

Authors

Dr. Vivek Pant[1], Dr. Santosh Pradhan[2], Dr. Keyoor Gautam[3], Dr. Devish Pyakurel[3], Dr. Abha Shrestha[3], Dr. Neha Neupane[3]

[1, 2] Department of Clinical Biochemistry, Samyak Diagnostic Pvt Ltd, Kathmandu, Nepal

[3] Department of Clinical Pathology, Samyak Diagnostic Pvt Ltd, Kathmandu, Nepal

Corresponding Author

Dr. Vivek Pant

Department of Clinical Biochemistry, Samyak Diagnostic Pvt Ltd, Kathmandu, Nepal

Email: drvpant@gmail.com

Summary

Carbohydrate antigen 125 (CA -125) is widely used as a tumor marker for ovarian cancer, but elevations can occur in benign conditions, leading to diagnostic dilemmas. We report a case of markedly elevated CA 125 in a 62-year-old woman due to pericardial effusion secondary to idiopathic pericarditis. Her CA -125 normalized following pericardiocentesis and treatment, highlighting the importance of interpreting tumor markers within clinical context.

Keywords

CA-125; Pericardial Effusion; Non-malignant cause; Tumor Marker

Introduction

CA- 125 is a high molecular weight transmembrane glycoprotein. It was first detected in ovarian cancer cells, but several studies showed that it is normally expressed on different cell surfaces present in various organs (lung, prostate, pleura, pericardium, and peritoneum). (1-4) With rich oligosaccharide chains, the physiological role of CA-125 is considered to protect the epithelial luminal surfaces from physical stress through hydration or lubrication process thus protecting them from mechanical stress. (1)

Clinically, it has been used as a marker of ovarian cancer, in monitoring, risk stratification and prognostication. CA 125 levels also rise in other malignancies such as lung cancer, mediastinal teratoma and non-Hodgkin lymphoma. (5, 6) Although CA 125 is a well-known marker of ovarian cancer, its serum levels are also upregulated in multiple nonmalignant pathological states but also in physiologic conditions: pregnancy, menstruation, liver cirrhosis, pelvic inflammatory disease, peritoneal trauma, ascites, lung cancer and congestion due to heart failure. (7,8)

Understanding the alternative causes of raised CA 125 is essential for appropriate clinical decision-making. Elevated CA 125 in the absence of malignancy can lead to unnecessary anxiety, invasive procedures, and delays in identifying the actual underlying condition. Therefore, this case is reported to aware healthcare professional's that they should interpret CA 125 results within the broader context of the patient's clinical presentation, imaging findings, and other relevant laboratory parameters to avoid diagnostic pitfalls.

Case Report

A 62-year-old woman with a history of hypertension and coronary artery disease presented with progressive dyspnea and pleuritic chest pain for two weeks. She had no abdominal symptoms or weight loss. An incidental CA 125 test showed a markedly elevated level of 680 U/mL (normal <35 U/mL), while other tumor markers including CEA and AFP were within normal limits. Pelvic ultrasound confirmed normal ovarian and uterine structures. CT imaging of the chest and abdomen revealed a large pericardial effusion without abdominal masses, lymphadenopathy, or pelvic abnormalities. Echocardiography demonstrated cardiac tamponade physiology. Pericardiocentesis drained exudative fluid with a protein concentration of 4.2 g/dL. Cytological examination showed no malignant cells, and a diagnosis of idiopathic pericarditis was established. Following pericardiocentesis and NSAID therapy, her CA 125 decreased to 85 U/mL within two weeks and normalized to 22 U/mL after complete resolution of the effusion.

Discussion

CA 125 is produced by mesothelial cells lining the serous cavities, including the pericardium, pleura, and peritoneum. Elevated levels can therefore be seen in non-malignant conditions such as serosal inflammation and heart failure. In this patient, pericardial inflammation likely led to mesothelial activation and increased CA 125 release.

Stressed mesothelial cells produce CA 125 in response to both fluid overload and inflammation. For example, in heart failure, elevated venous pressure results in fluid congestion within mesothelial-lined spaces, triggering the release of inflammatory markers such as IL-6, IL-10, and TNF. (9) Mesothelial cells can be stimulated by inflammation, mechanical stress, or fluid accumulation to produce CA 125, and studies have shown that inflammatory cytokines such as IL-1 are potent inducers of CA 125 production. (10)

In pericardial effusion, congestion often causes fluid buildup not only in the pericardium but also in the pleural and abdominal cavities, worsening inflammation in a vicious cycle. High venous pressure in these areas, rich in mesothelial cells, further promotes CA 125 release. (11) Additionally, bacterial translocation or endotoxin production, especially in right heart failure with bowel congestion, can enhance CA 125 production even more. (11)

In large ovarian tumors with pleural effusion, as seen in Meigs syndrome, CA 125 levels are typically high. Here, the tumor induces fluid accumulation in the peritoneal cavity, and mechanical irritation from the fluid stimulates mesothelial cells to produce CA 125. Similarly, in our case, pericardial fluid accumulation and inflammation likely irritated the mesothelial cells lining the pericardium, resulting in elevated CA 125 levels. This rise reflects mesothelial activation rather than direct tumor secretion.

This case highlights the importance of interpreting CA 125 results in the context of clinical findings and imaging studies, and of considering benign causes before pursuing oncological referrals to avoid unnecessary investigations and patient anxiety.

Conclusion Clinicians should interpret elevated CA-125 with caution, especially in patients with serosal effusions, to avoid unnecessary oncologic referrals and patient anxiety

Authors Contribution: All authors are independent experts and equally contributed to the expert article published.

Funding: None declared

Conflict of Interest: None declared

References

1. Huang F, Chen J, Liu Y, Zhang K, Wang J, Huang H. New mechanism of elevated CA125 in heart failure: the mechanical stress and inflammatory stimuli initiate CA125 synthesis. Medical hypotheses. 2012 Sep 1;79(3):381-3.

2. Scholler N, Urban N. CA125 in ovarian cancer. Biomarkers in medicine. 2007 Dec 1; 1(4):513-23.

3. Lloyd KO, Yin BW. Synthesis and secretion of the ovarian cancer antigen CA 125 by the human cancer cell line NIH: OVCAR-3. Tumor biology. 2000 Dec 15; 22(2):77-82.

4. Lei Y, Zang R, Lu Z, Zhang G, Huang J, Liu C et al. ERO1L promotes IL6/sIL6R signaling and regulates MUC16 expression to promote CA125 secretion and the metastasis of lung cancer cells. Cell Death & Disease. 2020 Oct 14; 11(10):853.

5. Bottoni P, Scatena R. The role of CA 125 as tumor marker: biochemical and clinical aspects. Advances in cancer biomarkers: from biochemistry to clinic for a critical revision. 2015 Jan 1:229-44.

6. Miralles C, Orea M, Espana P, Provencio M, Sánchez A, Cantos B et al. Cancer antigen 125 associated with multiple benign and malignant pathologies. Annals of Surgical Oncology. 2003 Mar;10(2):150-4.

7. Núñez J, Minana G, Núñez E, Chorro FJ, Bodí V, Sanchis J. Clinical utility of antigen carbohydrate 125 in heart failure. Heart failure reviews. 2014 Sep;19(5):575-84.

8. Llàcer P, Bayés-Genís A, Núñez J. Carbohydrate antigen 125 in heart failure. A New era in the monitoring and control of treatment. Medicina Clínica (English Edition). 2019 Apr 5;152(7):266-73.

9. Kosar F, Aksoy Y, Ozguntekin G, Ozerol I, Varol E. Relationship between cytokines and tumour markers in patients with chronic heart failure. European journal of heart failure. 2006 May;8(3):270-4.

10. Turgut O, Tandogan I, Yilmaz MB, Gul I, Gurlek A. CA125 levels among patients with advanced heart failure: an emerging independent predictor for survival. International journal of cardiology. 2010 Nov 5;145(1):71.

11. Krack A, Sharma R, Figulla HR, Anker SD. The importance of the gastrointestinal system in the pathogenesis of heart failure. European heart journal. 2005 Nov 1;26(22):2368-74.

Long-Term Follow-up of Congenital Hypothyroidism with Delayed Diagnosis

DOI- https://doi.org/10.62772/APFCB-News.2025.4206

Author & Corresponding:

Dr. Gita Sharifi Dr. Sharifi Medical Lab, licensed by Shahid Beheshti University of Medical Sciences, Department of Clinical Laboratory Sciences. Tehran/Iran

Email: gitasharifi1@gmail.com

Abstract

This is a retrospective case report about a female patient with congenital hypothyroidism (CH), whose screening was missed at birth. Her mother noticed she was very calm, slept for long hours, including throughout the night, and had prolonged constipation. At 2.5 months, she was referred to a pediatrician after 20 days without stool excretion. Rectal touch by the pediatrician caused stool excretion in a large amount. Following a high TSH of 47 mIU/L, Levothyroxine 50 µg/day was prescribed and started at 3 months of age. TSH was reduced to 4.5 mIU/L soon after. At 3 years old, sonography showed a normal-sized thyroid gland in the correct position, but TSH increased to 13.8 mIU/L after stopping therapy for 18 days. Levothyroxine treatment was resumed and adjusted as needed. Thyroid function was followed and controlled with weekly 220 µg of Levothyroxine at the age of 20 years, and stopped after that, but some symptoms of subclinical hypothyroidism reappeared upon discontinuation, although endocrinologists believed that there is no need for treatment in TSH below 10 mIU/L. This case raises questions about the impact of early iodine exposure and familial hypothyroidism, too. Despite a 3-month delay in initiating therapy, the patient had normal IQ, EQ, and social intelligence according to the related tests.

Keywords

Congenital hypothyroidism; Delayed CH screening at birth; Delayed Levothyroxine treatment; Iodine exposure at birth; Subclinical hypothyroidism; Delayed growth rate

Introduction

Congenital hypothyroidism (CH) is one of the most common endocrine disorders in neonates. As thyroid hormones are so important for brain growth, neonatal screening allows early detection and treatment, but missed cases can result in delayed therapy. Symptoms such as excessive sleep, calmness, and prolonged constipation may suggest hypothyroidism but are often underestimated. This case shows a patient with missed screening and long-term follow-up up to adulthood.

Case Presentation

A female infant was not screened for CH several days after birth. She was a full-term newborn weighing 3 kg at birth. Her mother noticed excessive calmness and sleeping throughout the night, and sometimes long periods of sleeping in the evenings. At 2.5 months, after 20 days of no bowel movements and constipation, she was referred to a pediatrician. Following rectal touch, she had a large amount of stool excretion, and after that, thyroid testing showed TSH = 47 mIU/L. A pediatric endocrinologist started Levothyroxine 50 µg/day at age 3 months, and TSH dropped to 4.5 mIU/L soon after. At age 3, thyroid ultrasound confirmed normal size and location. When therapy was stopped for 18 days, TSH rose to 13.8 mIU/L (Table 1)

She was followed up regularly. TSH remained normal under consistent Levothyroxine therapy. At7 years, another endocrinologist recommended discontinuing Levothyroxine for 1 month. TSH increased to 8 mIU/L, but despite that, therapy was initially stopped. Later, other endocrinologists advised continuation, one of them believed to keep TSH under 5, and therapy resumed. From age 10, she was under pediatric endocrinologist visits every 4–6 months. For height growth delay, she received Diphereline (GnRH agonist) monthly and Nordilet (growth hormone) daily. At age 14, after achieving physiological puberty, GH therapy was stopped. Levothyroxine continued until age 18,and the thyroid status was under control. After that the therapy was stopped for 1 year, causing TSH to rise to 5.5 to 6 mIU/L. Then at the age of 20 the endocrinologist asked her to take Levothyroxine 220 ug/week, resulting in stable TSH between 3–4 mIU/L, but each time she was stopping treatment, TSH would rise to 4.8 to 5.2mIU/L, and she experienced some hair loss, hypersomnia, and occasional constipation, indicating subclinical hypothyroidism after discontinuation of Levothyroxine. The test results with ECL method at the age of 20 were as below:

TSH= 3.33 mIU/L, FT4= 1.42 ng/dL, Total T4= 8.62 ug/dL, T3= 86.8ng/dL, FT3= 3.9pmol/L

Endocrinologists now suggest that TSH levels below 10 mIU/L do not always require treatment, but FT4 must be considered. So now at the age of 22 she has stopped the treatment for 2 years, and the test results are as follows: TSH(ECL)=5.64mIU/L, FT4(ECL)=1.17 ng/dL (RR=0.7-1.8), Total T4=7.36 µg/dL.

Table 1. Serial TSH Measurements and Treatment Timeline

Age	TSH (mIU/L)	Treatment Status
3 months	47	Before treatment
3.5 months	0.5	After starting Levothyroxin50 µg/day
5.5 months	0.2	Continued treatment
8 months	0.5	Continued treatment
3 years	13.8	18 days after stopping 25 µg/day
3.5 years	4.9	Treatment resumed
3y& 9m	2.2	Stable on treatment
6 years 7 years	3.08 8.0	Stable on treatment 1 month after stopping treatment
8.5 years	4.9	5 days after stopping 50 µg every other day
9 years	5.56	9 days after stopping 50 µgevery other day
9.5 years	3.69	25 µg & 50 µg alternating every other day
14 years	4.9	On treatment
16 years 17 years	4.8 6.2	On treatment On treatment
17.5 years	3.33	On treatment (T4= 9)
19.5 years	4.7	On treatment
20 years	5.0	"Other Thyroid panel tests are the same as 6m ago

Discussion and Suggestions for Further Studies

It was a retrospective study on a case of congenital hypothyroidism from birth through adolescence. The diagnosis was delayed and confirmed at 2.5 months of age, and Levothyroxine therapy was initiated thereafter at the age of 3 months and continued until the age of 20 years. After discontinuation of Levothyroxine, TSH stabilized around 5 mIU/L. After that, it was asked about whether this condition still qualifies as subclinical hypothyroidism and whether continued treatment is necessary, and whether there are some problems left.

There are some guidelines in AAP(American Academy of Pediatrics) or ESEP(European Society for Pediatric Endocrinology) about the appropriate time for screening and diagnosis after birth (for example CH screening is necessary for all newborns up to 48 to 72 hours after birth and before hospital discharge), treatment and its follow-up and discontinuation of treatment (for example, short-term discontinuation at the age of 3 years and recheck the TSH and FT4 after 1 month) to check whether it is transient or temporary CH and the definition of the term subclinical hypothyroidism. (1-3) Necessary to say that in this case, after rising TSH>10 mIU/L following discontinuation of treatment at the age of 3 years, the endocrinologist strictly didn't allow stopping the medication again until around the age of 7 years due to its adverse effects on brain development.

There are some articles and their links related to this subject that refers to AAP and ESEP guidelines. (4-6)

Suggestions for further studies:

Future studies should investigate the impact of early iodine exposure, such as Betadine use, in neonates with a genetic predisposition to hypothyroidism. It is also recommended to assess the long-term outcomes of patients with congenital hypothyroidism (CH) who discontinue treatment despite having TSH levels above 5 mIU/L. Further research should explore whether clinical symptoms like hair loss, hypersomnia, and constipation justify restarting therapy in patients with TSH levels between 5 and 10 mIU/L. Additionally, surveying adults with undiagnosed CH who present with mild thyroid dysfunction could provide insights into the relationship between delayed treatment during childhood and their psychosocial development. Finally, studies should examine any association between CH and delays in physical growth rate, particularly around puberty or earlier stages of growth.

Conclusion

CH can be a temporary position, and severity may decrease after birth, and shortly delayed diagnosis may be managed successfully, especially if the thyroid gland is normal in size and structure, and position, and therapy is maintained soon after. This patient showed normal intellectual, emotional, and social development. In this case, a 3-month delay in starting treatment had no negative impact on IQ or developmental outcomes. Symptoms like hypersomnia and hair loss reappeared upon discontinuation at the age of 22 years, indicating persistent subclinical hypothyroidism, but now some endocrinologists believe that TSH around 5 mIU/L is normal and these symptoms are not related to thyroid status, and even with TSH up to 10 mIU/L but FT4 within the Reference range, there is no need for treatment.

Authors Contribution: All authors are independent experts and equally contributed to the expert article published.

Funding: None declared

Conflict of Interest: None declared

References

1. Léger, J., Olivieri, A., Donaldson, M., Torresani, T., Krude, H., Van Vliet, G et al. European Society for Paediatric Endocrinology consensus guidelines on screening, diagnosis, and management of congenital hypothyroidism. The Journal of Clinical Endocrinology & Metabolism, 99(2), pp.363-384. 2014;81(2):80-103.

2. Van Vliet G, Grosse SD. Newborn screening for congenital hypothyroidism and congenital adrenal hyperplasia: the balance of benefits and costs of a public health success. Medecine sciences: M/S. 2021 May 18;37(5):528

3. Kapelari K, Kirchlechner C, Högler W, Schweitzer K, Virgolini I, Moncayo R. Pediatric reference intervals for thyroid hormone levels from birth to adulthood: a retrospective study. BMC endocrine disorders. 2008 Nov 27;8(1):15..

4. Rose SR, Wassner AJ, Wintergerst KA, Yayah-Jones NH, Hopkin RJ, Chuang J et al. Congenital hypothyroidism: screening and management. Pediatrics. 2023 Jan 1;151(1).

5. Behura SS, Nikhila GP, Panda SK. Screening and management of congenital hypothyroidism—Guidelines by American academy of pediatrics, 2023. Indian Pediatrics. 2023 Oct;60(10):855-8.

6. Grob F, Lain S, Olivieri A. Newborn screening for primary congenital hypothyroidism: past, present and future. European Thyroid Journal. 2025 Apr 1;14(2)

Unveiling the clinical conundrum: coexistence of Gilbert's syndrome and Thrombocytopenia

DOI- https://doi.org/10.62772/APFCB-News.2025.4207

Authors

Dr. Cheteny Cheteny[1], Dr. Enitarast Sympli[2], Dr. Kapil Kumar[3], Dr. Chillarige Sudha Ankita[4], Dr. Swati Singh[5]

[1,2,4,5]Department of Biochemistry, Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, New Delhi, India

[3]Department of Gastroenterology, Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, New Delhi, India

Corresponding Author:

Dr Swati Singh

Department of Biochemistry

Govind Ballabh Pant Institute of Postgraduate Medical Education and Research

New Delhi, India. 110002

Email: swatisingh17392@gmail.com

ABSTRACT

Gilbert's syndrome (GS) is a benign hereditary disorder of bilirubin conjugation resulting in an isolated, elevated blood level of unconjugated bilirubin. An individual with GS is typically asymptomatic and does not require treatment. Thrombocytopenia is not a known feature of GS and may suggest an alternate or co-existing pathology. We report a rare case of a 40-year-old male, with an incidental finding of mildly increased unconjugated bilirubin levels on two different occasions with moderate thrombocytopenia in the absence of any aggravating factors. Further investigations were done to rule out autoimmune, infectious or hemolytic causes. This report underscores the need to consider genetic disorders in the differential diagnosis of patients with unexplained thrombocytopenia, it also highlights the critical value of laboratory findings in avoiding misdiagnosis of GS.

KEYWORDS: Unconjugated Bilirubin, Thrombocytopenia, Hyperbilirubinemia, Case report, Platelets, Incidental

INTRODUCTION

Gilbert's syndrome (GS) is an autosomal recessive disorder caused by a defect in bilirubin conjugation, due to mutations in in the promoter region of the Uridine Glucuronosyltransferase 1A1 (UGT1A1) gene, resulting in diminished UGT1A1 enzyme activity. This enzyme typically conjugates bilirubin, facilitating its clearance from the bloodstream [1]. It has about ~20% prevalence among the Indian population [2]. The global incidence of GS is about 5%, more common in males, often manifesting as mild jaundice, without liver dysfunction, but some patients have abdominal discomfort, fatigue, nausea, etc., which may be caused by anxiety and other psychological factors. Albeit 33% of individuals remain undiagnosed due to the asymptomatic nature of the condition [3,4].

Literature suggests that GS is associated with a mild unconjugated hyperbilirubinemia, increased circulating antioxidant capacity, and reduced cardiovascular disease (CVD) risk [5]. Prior studies have substantiated that circulating unconjugated bilirubin (UCB) is negatively associated with multiple thrombotic risk factors including platelet activity, hemostatic function, and inflammation in individuals with GS [6-9]. Here, we present a rare case of a 40-year-old man found to have Gilbert's syndrome, who presented with moderate thrombocytopenia, with no known trigger or coexisting condition. It is important to clarify the cause of thrombocytopenia in individuals with GS, as such cases are often clinically misdiagnosed as hemolytic jaundice, and may lead to repeated liver tissue biopsies, thereby causing psychological and economic strain on individuals with GS.

CASE REPORT

A 40-year-old male laboratory staff presented for the voluntary routine health check-up at Govind Ballabh Pant Hospital, New Delhi, in June 2025, where laboratory investigations revealed elevated levels of unconjugated bilirubin. On detailed questioning, he reported that he had no complaints of jaundice, fatigue, bleeding, bruising, abdominal pain, pale stools, dark urine or any constitutional symptoms and also had no history of alcohol consumption and chronic drug intake. His past medical history was positive for thrombocytopenia.

On examination, he was noted to be in apparently healthy state, with a robust build and stable vital signs. Abdominal findings were otherwise unremarkable and there were no stigmata of chronic liver disease on systemic evaluation. Laboratory results revealed a hemoglobin of 13.8 g/dL, MCV of 87 fL and a normal white blood cell count, while platelet count was low at 43,000/µL. No hemolysis was evident on peripheral smear: His direct bilirubin, LDH and liver function tests were all within normal limits (Table 1 and 2). Viral hepatitis serologies (HBsAg and anti-HCV) were negative, and abdominal ultrasound did not indicate abnormal liver morphology. Fibroscan showed no signs of liver fibrosis and the liver elasticity was within normal limits. ANA, dsDNA and RA factor were performed to rule out autoimmune causes for hemolysis and were found to be within normal limits.

The diagnosis was made on the basis of a mild unconjugated hyperbilirubinemia in the presence of repeated normal liver function tests and absence of overt signs of hemolysis on clinical presentation.

Table 1 Biochemical test results of the case

Biochemical parameter	Results (04/06/2025)	Results (12/07/2025)	Biological Reference Interval
Aspartate Aminotransferase	26	34	10-40 U/L
Alanine Aminotransferase	27	52	10-40 U/L
Alkaline Phosphatase	104	115	30-115 U/L
Total Protein	8.4	8.4	6-8 gm/dL
Albumin	4.7	4.9	3.5-5 gm/dL
Gamma-Glutamyl Transferase	37	92	<85 U/L
Total Bilirubin	1.7	1.6	0.3-1.2 mg/dL
Conjugated Bilirubin	0.4	0.5	0.5-1.0 mg/dL
Unconjugated Bilirubin	1.3	1.1	0.2-0.8 mg/dL
Random Blood Sugar	130	153	<140 mg/dL
HbA1C	5.2	5.3	<5.7%
Total Cholesterol	153	156	<200 mg/dL
Triglycerides	217	202	<150 mg/dL
High-Density Lipoprotein	32	35	40-60 mg/dL
Low-Density Lipoprotein	78	81	<100 mg/dL
Lipoprotein (a)	121	93	<75 nmol/L
Iron	72	78	F=28-170 µg/dL; M=45-182 µg/dL
Homocysteine	20	15	<15 Umol/L
High-Sensitivity C-Reactive Protein.	3.8	1.3	<3mg/L
Urea	36	24	<50mg/dL
Creatinine	0.9	0.8	F =0.5-0.9 mg/dL; M= 0.7-1.2 mg/dL
Uric Acid	7.7	7.1	F=2.4-5.7 mg/dL; M =3.4-7 mg/dL
Creatine Kinase-Total	147	115	F =34-145 U/L; M=46-171 U/L
Lactate Dehydrogenase	180	173	110-240 U/L
Free T 3	2.9	2.9	2.0-4.4 pg/mL
Free T 4	1.1	1.1	0.93-1.7 ng/dL
Thyroid Stimulating Hormone	2.2	3.6	0.27-4.2 ulU/mL
Procalcitonin	NA	<0.020	<0.05 ng/mL

Table 2 Complete blood count and coagulation profile of the case

Test	Results (04/06/2025)	Result (12/07/2025)	Reference interval
Hemoglobin	14	13.8	12-15.5g/dl
Hematocrit	40.9	42.6	35-45%
WBC	6360	8,680	5000-10,000
Platelets	41,000	43,000	1.25-3.5L
DLC (P/L/M/E/B)	74/19/5/1/0	52/42/4/2/0	60-70%/20-40%/2-6%/1-3%/0-1%
RBC count	5.39	5.15	4.5-5.5 M
Reticulocyte	1.43	1.6	0.2-1.5%
ESR	19	30	M: 0-9, F: 0-20
PT	12.2	10.5	9.6-12.4 Sec
INR	1.1	0.9	0.9-1.1
aPTT	32.4	33.7	22-34 Sec
D-Dimer	NA	0.13	<1 ug/mL

WBC: White Blood Cell; DLC: Differential Leukocyte Count; P: Polymorphonuclear leukocytes; L: Lymphocytes; M: Monocytes; E: Eosinophils; B: Basophils; ESR: Erythrocyte Sedimentation Rate; PT: Activated Partial Thromboplastin Time; INR:International Normalized Ratio; aPTT:Activated Partial Thromboplastin Time; NA: Not available

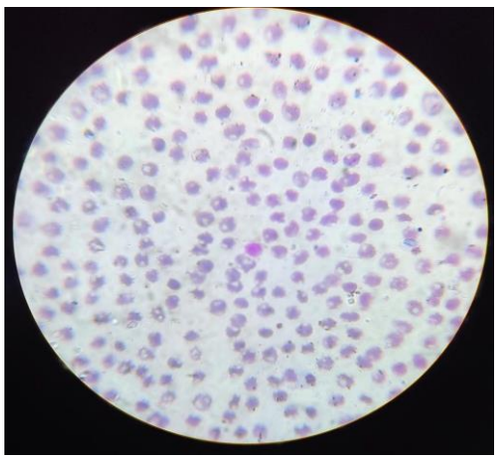


Figure 1 Peripheral blood film of the case showing normocytic normochromic RBCs with reduced platelet count 50,000/μL. Wright-Giemsa stain, magnification ×100

DISCUSSION

The incidence of a thrombocytopenia in Gilbert's syndrome is rare. What renders our case particularly unique is the markedly reduced platelet count (43,000/μL) in the absence of any overt clinical manifestations. This value is lower than any previously documented case in the existing literature. Several publications were reviewed in an attempt to identify potential pathophysiological mechanisms underlying comparable observations within the GS population.

In a previous investigation by Sarlak et al. involving 1,082 individuals with GS and 1,084 healthy controls, the researchers documented significantly reduced platelet counts among GS cohort (240300/μL) compared to control group (258000/μL) ($p<0.001$). Additionally, they identified an inverse association between UCB levels and neutrophil-to-lymphocyte ratio and platelet-to-lymphocyte ratio. The authors proposed that UCB confers cardioprotective effects by exerting antioxidative and anti-inflammatory mechanisms [6]. In line, a recently published study involving 68 individuals with GS and 68 healthy controls demonstrated that mean platelet volume ($P < 0.001$) was significantly reduced in the patient group compared to the controls [7]. Kumar N et al. observed that elevated UCB contributes to thrombocytopenia via mitochondrial ROS-driven

antioxidative and anti-inflammatory mechanisms [6]. In line, a recently published study involving 68 individuals with GS and 68 healthy controls demonstrated that mean platelet volume ($P < 0.001$) was significantly reduced in the patient group compared to the controls [7]. Kumar N et al. observed that elevated UCB contributes to thrombocytopenia via mitochondrial ROS-driven activation of p38 and p53 pathways. They found that UCB induced platelet apoptosis, marked by increased ROS, mitochondrial depolarization, calcium influx and cardiolipin peroxidation [8]. In an earlier in-vitro investigation, Suvansri U et al demonstrated that exposure of platelets to UCB induced morphological alterations such as swelling, filamentous membrane formation and lysis. Additionally, pretreatment with UCB impaired thromboplastin generation, and inhibited clot retraction. The authors suggested that these abnormalities in platelet function were related to an inhibitory effect of bilirubin on ATP-ADP-dependent systems [9]. Similarly, Kundur et al. and Tapan et al. reported reduced soluble P-selectin levels in GS, which may decrease thrombus risk by limiting stable platelet-leukocyte aggregate formation [10,11]. Taken together, these findings suggest that UCB confers anti-thrombotic and cardio-protective effects by exerting anti-oxidative and anti-inflammatory mechanisms.

Several case reports have described an association between GS and reduced oxidative stress induced platelet hyper-reactivity. Haixia L and Li R discussed a case involving a primigravida identified having gestational diabetes mellitus with GS. Bilirubin has been negatively associated with type 2 diabetes, likely due to its lipid-lowering and antioxidant effects. Authors posited inhibition of NAD(P)H oxidase activity may reduce superoxide production in diabetic vascular tissue, thereby mitigating oxidative stress and preventing vascular complications [12]. Bilirubin's ability to attenuate various pathways that promote platelet hyper-reactivity and thrombus formation has, to date, been largely under-appreciated in the literature. To our knowledge, the current report is the first documented case report to specifically detail thrombocytopenia in association with Gilbert’s syndrome.

CONCLUSION

In this paper, we reported a case of Gilbert’s syndrome with moderate thrombocytopenia, which is a rare āclinical finding. Our case did not have the severe symptoms or outcomes as other reported patients. This study underscores the need for a comprehensive approach when managing patients with unexplained thrombocytopenia, where genetic disorders should be considered in the differential diagnosis. It also highlights the diagnostic complexity and the importance of laboratory findings, which is crucial for avoiding misdiagnosis in GS.

ACKNOWLEDGMENT

The authors acknowledge the support and assistance provided by the laboratory staff of the Department of Biochemistry, GIPMER

AUTHOR CONTRIBUTIONS

Cheteny C identified the patient case, coordinated with the patient and completed the diagnostic workup and prepared the initial draft of the manuscript. Sympli E assisted in taking a detailed clinical history, was responsible for blood sample withdrawal and collection of biochemical test reports. Kumar K aided in the clinical diagnosis and

provided valuable clinical insights. Ankita CS conceived the idea, helped in writing and provided intellectual content, contributed in extended clinical workup and investigations. Singh S supervised the entire study, contributed in writing and critical review of the manuscript. All authors reviewed and approved the final manuscript.

CONSENT

The patient provided his written informed consent to participate in this study and for the publication of any potentially identifiable images or data included in this article in accordance with the 1964 Helsinki declaration and its later amendments.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

REFERENCES

1. De Silva AP, Nuwanshika N, Niriella MA, de Silva HJ. Gilbert's syndrome: The good, the bad and the ugly. World J Hepatol. 2025 Feb 27;17(2):98503. doi: 10.4254/wjh.v17.i2.98503. PMID: 40027563.

2. Black M, Billing BH. Hepatic bilirubin udp-glucuronyl transferase activity in liver disease and gilbert's syndrome. N Engl J Med. 1969 Jun 5;280(23):1266-71. doi: 10.1056/NEJM196906052802303. PMID: 5770050.

3. Sticova E, Jirsa M. New insights in bilirubin metabolism and their clinical implications. World J Gastroenterol. 2013 Oct 14;19(38):6398-407. doi: 10.3748/wjg.v19.i38.6398. PMID: 24151358

4. mellie WS, Ryder SD. Biochemical "liver function tests". BMJ. 2006 Sep 2;333(7566):481-3. doi: 10.1136/bmj.333.7566.481. PMID: 16946336

5. Vítek L, Jirsa M, Brodanová M, Kalab M, Marecek Z, Danzig V, Novotný L, Kotal P. Gilbert syndrome and ischemic heart disease: a protective effect of elevated bilirubin levels. Atherosclerosis. 2002 Feb;160(2):449-56. doi: 10.1016/s0021-9150(01)00601-3. PMID: 11849670.

6. Sarlak H, Arslan E, Cakar M, Tanriseven M, Ozenc S, Akhan M, Bulucu F. Relation between unconjugated bilirubin and RDW, neutrophil to lymphocyte ratio, platelet to lymphocyte ratio in Gilbert's syndrome. Springerplus. 2016 Aug 22;5(1):1392. doi: 10.1186/s40064-016-3085-5. PMID: 27610311

7. Cure MC, Cure E, Kirbas A, Cicek AC, Yuce S. The effects of Gilbert's syndrome on the mean platelet volume and other hematological parameters. Blood Coagul Fibrinolysis. 2013 Jul;24(5):484-8. doi: 10.1097/MBC.0b013e32835e4230. PMID: 23348429.

8. NaveenKumar SK, Thushara RM, Sundaram MS, Hemshekhar M, Paul M, Thirunavukkarasu C, Basappa, Nagaraju G, Raghavan SC, Girish KS, Kemparaju K, Rangappa KS. Unconjugated Bilirubin exerts Pro-Apoptotic Effect on Platelets via p38-MAPK activation. Sci Rep. 2015 Oct 13;5:15045. doi: 10.1038/srep15045. PMID: 26459859

9. Suvansri U, Cheung WH, Sawitsky A. The effect of bilirubin on the human platelet. J Pediatr. 1969 Feb;74(2):240-6. doi: 10.1016/s0022-3476(69)80071-5. PMID: 4303069.

10. Kundur AR, Singh I, Bulmer AC. Bilirubin, platelet activation and heart disease: a missing link to cardiovascular protection in Gilbert's syndrome? Atherosclerosis. 2015 Mar;239(1):73-84. doi: 10.1016/j.atherosclerosis.2014.12.042. Epub 2014 Dec 24. PMID: 25576848.

11. Tapan S, Dogru T, Tasci I, Ercin CN, Ozgurtas T, Erbil MK. Soluble CD40 ligand and soluble P-selectin levels in Gilbert's syndrome: a link to protection against atherosclerosis? Clin Biochem. 2009 Jun;42(9):791-5. doi: 10.1016/j.clinbiochem.2009.02.005. Epub 2009 Feb 13. PMID: 19232335.

12. Haixia L, Li R. Gilbert's Syndrome With Diabetes Mellitus. Cureus. 2021 Jul 22;13(7):e16557. doi: 10.7759/cureus.16557. PMID: 34322357

Quiz Section!!

Question 1

Which of the following statements about the Michaelis-Menten equation is correct?

Assume [S] is the substrate concentration, Vmax is the maximum reaction velocity, and Km is the Michaelis constant.

1. When Km << [S], the reaction approximates first-order kinetics.
2. In competitive inhibition, Vmax decreases and the Km value increases.
3. For end-point assays to measure [S], an enzyme with a large Vmax is used.
4. A larger Km value indicates a greater affinity between the enzyme and the substrate.
5. Initial rate assays for [S] measurement are performed in the zero-order reaction region.

Question 2

An enzyme has a Michaelis constant (Km) of 20 mmol/L. What substrate concentration ([S]) is required to achieve 90% of the maximum reaction velocity (Vmax), assuming the enzyme reaction follows Michaelis-Menten kinetics?

1. 10 mmol/L
2. 20 mmol/L
3. 90 mmol/L
4. 180 mmol/L
5. 200 mmol/L

Contributed by:

Dr. Ryunosuke Ohkawa, PhD

Professor of Clinical Analysis and Molecular Biology, Graduate School of Medical and Dental Sciences, Institute of Science Tokyo. Committee member of Communication & Publications Committee

Answer Section!!

Answer for question 1

3. For end-point assays to measure [S], an enzyme with a large Vmax is used.

Let's analyze each statement regarding the Michaelis-Menten equation:

$v=(V_{max}[S])/(K_m+[S])$

1. When Km << [S], the reaction approximates first-order kinetics.

Incorrect. When the substrate concentration [S] is much greater than the Michaelis constant Km (i.e., Km << [S]), the term (Km + [S]) in the denominator approximates [S]. Therefore, the equation simplifies to $v \approx V_{max}[S]/[S] = V_{max}$. This means the reaction rate is independent of the substrate concentration, which is characteristic of zero-order kinetics. First-order kinetics occurs when [S] << Km.

2. In competitive inhibition, Vmax decreases and the Km value increases.

Incorrect. In competitive inhibition, the inhibitor competes with the substrate for binding to the enzyme's active site. This effectively reduces the enzyme's apparent affinity for the substrate, leading to an increase in the apparent Km value. However, if enough substrate is added, it can outcompete the inhibitor, allowing the enzyme to eventually reach its original Vmax. Therefore, Vmax remains unchanged in competitive inhibition. (A decrease in Vmax is typically seen in non-competitive or uncompetitive inhibition.)

3. For end-point assays to measure [S], an enzyme with a large Vmax is used.

Correct. In an end-point assay (also known as a fixed-time assay), the reaction is allowed to proceed for a set amount of time until the substrate is either completely consumed or a known fraction has been converted to product. To ensure that the reaction reaches completion quickly or proceeds efficiently within the defined time, the enzyme's activity must not be the limiting factor. This means using a sufficient amount of enzyme or an enzyme with a naturally high Vmax (i.e., high catalytic efficiency) to ensure the substrate is converted effectively, leading to an accurate measurement of the initial substrate concentration.

4. A larger Km value indicates a greater affinity between the enzyme and the substrate.

Incorrect. The Km value represents the substrate concentration at which the reaction velocity is half of Vmax ($v = V_{max}/2$). A smaller Km indicates that the enzyme can achieve half its maximum velocity at a lower substrate concentration, implying a greater affinity for the substrate. Conversely, a larger Km means that a higher substrate concentration is needed to reach half Vmax, indicating a lower affinity.

5. Initial rate assays for [S] measurement are performed in the zero-order reaction region.

Incorrect. Initial rate assays are used to measure enzyme activity, or to determine the concentration of a substrate or enzyme. When measuring substrate concentration using an initial rate method, the reaction should be performed in the first-order reaction region (where v is proportional to [S]). This allows the reaction rate to be directly correlated with the initial substrate concentration. If performed in the zero-order region, the rate would be near Vmax and largely independent of [S], making it impossible to accurately quantify the substrate.

Answer for question 2

4. 180 mmol/L

Solution

The Michaelis-Menten equation describes the rate of enzyme-catalyzed reactions:

v=(Vmax[S])

/(Km+[S])

Where:

- v is the reaction velocity
- Vmax is the maximum reaction velocity
- [S] is the substrate concentration
- Km is the Michaelis constant

We are given the following information:

- Km =20 mmol/L
- We want to find [S] when v = 0.90 Vmax (90% of the maximum reaction velocity).

Substitute these values into the Michaelis-Menten equation:

0.90 Vmax =(Vmax[S])/(Km+[S])
Divide both sides by Vmax:
0.90 =([S])/(Km+[S])
Now, solve for [S]:
0.90 (Km +[S]) = [S]
0.90 Km + 0.90[S] = [S]
0.90 Km = 0.10 [S]
[S] = 9 Km
Finally, substitute the given Km value:
[S] = 9 × 20 mmol/L
[S] = 180 mmol/L
Therefore, a substrate concentration of 180 mmol/L is required to achieve 90% of the maximum reaction velocity. The correct answer is 4.

Lupine - A Souvenir from Birmingham

Dr Tan It Koon

My first overseas study trip covered 3 medical centers best known for their excellence in facilities and training for Clinical Biochemistry in the United Kingdom. The Department of Clinical Biochemistry was headed by the three prominent "W"s: IDP Wootton of the Royal Postgraduate Medical School in London, TP Whitehead in Birmingham, and LG Whit by in the Edinburgh Royal Infirmary in Scotland.

In the springtime of 1968, I moved from London to Birmingham, the second destination of my postdoctoral fellowship program, where I met Professor Whitehead, Head of Clinical Chemistry Department at the Queen Elizabeth Medical Centre of the University of Birmingham. I shared an office at the Wolfson Research Laboratories with Dr Peter Wilding who subsequently moved to the USA and became a President of the American Association for Clinical Chemistry.

At that time, in addition to being well-known for his work on laboratory automation which led to highly efficient testing for large panel of tests as well as data handling using on-line computers, Professor whitehead was a pioneer in internal and external quality assessment of laboratory analyses which evolved into the United Kingdom National External Quality Assessment Service (UK NEQAS), a network of programs that now covers many disciplines within laboratory medicine. Professor Whitehead was an enthusiastic and readily approachable mentor who had a profound influence on my work when I returned to Singapore.

We collaborated in the promotion of quality assurance through WHO and APFCB educational programs for the South-East Asian Region. The efficiency, reliability, and turn-around-time of analyses and reporting of test results to clinical colleagues were greatly improved by my introduction of automated analysers, use of computer system, and implementation of quality assurance programs in the Clinical Biochemistry Laboratories, Department of Pathology, of the Singapore General Hospital and Ministry of Health. During my stay in Birmingham and long-weekend trips to the countryside organised by the British Council, an unusually beautiful and captivating flowering plant caught my attention.

From a distance, it appeared as long stalks of flower in a variety of colours. They were about a meter tall and usually planted as a group on open meadows or a patch in private home gardens. They looked lovely swaying in the same direction in the wind. I was told that the name of this flowering plant is "Lupine". As I usually saw them unexpectedly while travelling on a bus or car, I could not take a closer look and was curious about the structure of the flower. The opportunity came when Professor Whitehead invited me to his home at Leamington Spa, a spa town in Warwickshire, England. He and I shared a common passion for flowers and gardening. He was nationally renowned for cultivating and exhibiting a variety of sweet pea flowers which won him many top floral awards in Britain. While I enjoyed his garden, I spent more time admiring the large patches of lupines (also belonging to the pea family) in his neighbours' gardens. The flowers were seen in the full range of colours of the rainbow, in different shades of the same colour or combinations of different colours. Each stalk of flower consisted of multiple small blossoms attached by short pedicelsin vertical rows along an elongated axis and each leaf had five or more leaflets radiating outward from a single point on the stalk.

As my accommodation in Birmingham was a short walking distance from the city's Botanic Garden, I was able to make this colour sketch of the lupine flower in the style of a botanic painting at my leisure in the garden. This has served as a souvenir for my time in Birmingham and long-lasting memory of a pea-flower loving professor who had made outstanding contributions to the practice of Clinical Chemistry worldwide.