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APFCB News

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



2015

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Members

Australasian Association of Clinical Biochemists (AACB)
Chinese Society of Laboratory Medicine (CSLM)
Hong Kong Society of Clinical Chemistry (HKSCC)
Association of Clinical Biochemists of India (ACBI)
Indonesian Association for Clinical Chemistry (IACC)
Japan Society of Clinical Chemistry (JSCC)
Korean Society of Clinical Chemistry (KSCC)
Malaysian Association of Clinical Biochemistry (MACB)
Nepal Association for Medical Laboratory Sciences (NAMLS)
Pakistan Society of Chemical Pathologists (PSCP)
Philippine Association of Medical Technologists (PAMET)
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Affiliate Members

Chinese Association of Clinical Laboratory Management CACLM)
Association of Medical Biochemists of India (AMBI)
Macao Laboratory Medicine Association (MLMA)

APFCB Executive Board and Chairmen
of Committees, Elected October, 2015

Executive Board

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	Romeo Joseph Ignacio Vice President & General Manager Sysmex Philippines Inc. Ignacio.RomeoJoseph@sysmex.com.ph

Submissions

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

Cover page: "Playing music on a Chinese zither while crossing a bamboo-lined mountain stream by boat".

Contributed by Tan It Koon

Founding and Past President APFCB

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From the desk of Chief Editor...

Dear Colleagues,

Greetings!

It is with a deep sense of satisfaction and fulfillment that I am before you with this annual issue of APFCB News. It is my pleasure to come back to you with the new issue of APFCB news 2015.

This issue is special in a way since it is the last annual issue of APFCB news; henceforth the APFCB news shall be published biannually. It is due to the constant and unfailing efforts of all the member societies and the corporate that the APFCB news has become a successful and much awaited annual publication of APFCB.

I very much look forward to your sustained support in future to maintain APFCB website as a very interactive and well updated representing the active picture of APFCB and reflecting its activities. So friends, please use this forum effectively to share your progress, achievements and your thoughts and contributions on different issues related to the clinical biochemistry and laboratory medicine disciplines. My team shall be extremely pleased to hear from you and this shall make the APFCB community well communicated.

This issue features a special article on Tan It Koon, the founding president of APFCB, who has been a constant source of inspiration and has been actively involved in all the issues of APFCB news till date by contributing his marvelous art work as cover page. Once again the cover page of the current issue is an exemplary piece of art by Dr Koon, symbolizing the blending of creative spirits and science.

Endeavoring further to fulfill of my commitments as chief editor, I shall steadfastly continue my dedicated efforts to raise APFCB news to further heights.



Praveen Sharma
Editor in Chief



Message from APFCB President...

Greetings to all members of the APFCB.

I would like to begin by thanking Prof Praveen Sharma for the excellent work he is doing as Editor-in-Chief of the APFCB eNews. There will be two issues a year from 2016.

We had to say good-bye to Mr. Martin Fuhrer, Corporate Representative to the APFCB Executive Board as he resigned from Siemens on 31st August 2015. Mr Martin Fuhrer was Corporate Representative to the Executive Board from October 2010 till the end of August 2015. He was truly an asset to the APFCB and contributed significantly to the activities and growth of the APFCB. On behalf of the APFCB EB I would like to thank Martin for the great job he did as Corporate Representative and wish him well for the future. We will miss Martin.

The APFCB renewed its MoU with WASPaLM (World Association of the Societies of Pathology and Laboratory Medicine) in August 2014 effective for a three year period from 27th August 2014 and also signed an MoU with AACC on 11th December 2014 effective for a two year period from 1st January 2015 till 31st December 2016. We have two projects planned with WASPaLM, namely, a regional Chronic Kidney Disease project and one on Laboratory Accreditation. APFCB will be sponsoring a scientific symposium at the WASPaLM World Congress to be held in Cancun from 18th till 21st November 2015.

Mr. Alexander Wong, also from Siemens, has been appointed as Corporate Representative from 1st September 2015 till 31st December 2016 by the APFCB Executive Board with the agreement of the corporate members to replace Mr. Martin Fuhrer. Welcome Alexander!

The term of the current Executive Board ends on 31st December 2016. There will be a new Executive Board from 1st January 2017 for a three year term. Elections will take place for the new Executive Board on 26th November 2016 just prior to the commencement of the 14th APFCB Congress in Taipei this year.

I would like to invite all readers of the eNews to attend the 14th APFCB Congress in Taipei from 26th till 29th November 2016. The theme of the congress is 'Laboratory Medicine in Cloud' and this promises to be a wonderful congress with a very strong scientific programme and a good social programme. I would also like to thank in advance the international, regional and national associations for supporting our congress by sponsoring symposia and plenary speakers, including the IFCC, WASPaLM, EFLM, AACC, NACCCA and APFCB member societies. Thanks are also proffered to the Corporate sector for their invaluable support of our congress.

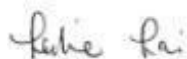
From 1st January 2018 the IFCC Executive Board will have regional federation representation. Each region will have to hold elections for its Regional Federation Representative to the IFCC EB in 2017.



The person elected must be able to present his/her region well. The APFCB Executive Board will discuss this matter with the APFCB Council members at the Council meeting on 26 November 2016 so that elections will proceed smoothly in 2017.

The Malaysian Association of Clinical Biochemists (MACB) celebrated its Silver Jubilee in August 2015 and I was privileged enough to participate and deliver a plenary lecture on tumour markers at the Silver Jubilee celebrations and annual scientific meeting of the MACB. On behalf of the APFCB I would like to offer our congratulations to the MACB for this important milestone.

Wishing all our readers a wonderful year ahead.



Dr Leslie Charles Lai
President, APFCB





ASIA-PACIFIC FEDERATION FOR CLINICAL BIOCHEMISTRY AND LABORATORY MEDICINE

Annual Report for 2015

1. APFCB Matters

Ordinary Members

The following National Societies are members of the APFCB:

1. Australasian Association of Clinical Biochemists (AACB)
2. Chinese Society of Laboratory Medicine (CSLM)
3. Hong Kong Society of Clinical Chemistry (HKSCC)
4. Association of Clinical Biochemists of India (ACBI)
5. Indonesian Association of Clinical Chemistry (IACC)
6. Japan Society of Clinical Chemistry (JSCC)
7. Korean Society of Clinical Chemistry (KSCC)
8. Malaysian Association of Clinical Biochemists (MACB)
9. Nepal Association for Medical Laboratory Sciences (NAMLS)
10. Pakistan Society of Chemical Pathologists (PSCP)
11. Philippine Association of Medical Technologists (PAMET)
12. Singapore Association of Clinical Biochemists (SACB)
13. Association for Clinical Biochemistry, Sri Lanka (ACBSL)
14. Chinese Association for Clinical Biochemistry, Taiwan (CACB)
15. Thailand Association of Clinical Biochemists (TACB)
16. Vietnamese Association of Clinical Biochemistry (VACB)
17. Mongolian Association of Health Laboratorians (MAHL)

Corporate Members

1. Abbott Diagnostics
2. BD Diagnostics
3. Beckman Coulter
4. Bio-Rad
5. Diasorin Ltd
6. Diasys Diagnostic Systems, GmbH
7. Guangzhou Wondfo Biotech Co
8. Kopran Laboratories Ltd
9. Ortho-Clinical Diagnostics
10. PM Separations
11. Randox Laboratories
12. Roche Diagnostics
13. Sekisui Chemical Co
14. Shenzhen Mindray Bio-Medical Electronics Co Ltd
15. Siemens
16. SNIBE (Shenzhen New Industries Biomedical Engineering Co Ltd)
17. Sukraa Software Solution Pvt Ltd
18. Sysmex
19. Technidata Medical Software

Affiliate Members

1. Chinese Association of Clinical Laboratory Management (CACLM)
2. Association of Medical Biochemists of India (AMBI)
3. Macao Laboratory Medicine Association (MLMA)
4. Nepalese Association of Clinical Chemistry (NACC)

Office Bearers (1 January 2014 till 31 December 2016)



Executive Board

President	Leslie Lai (Malaysia)
Immediate Past President	Joseph Lopez (Malaysia)
Vice-President	Sunil Sethi (Singapore)
Secretary	Endang Hoyaranda (Indonesia)
Treasurer	Elizabeth Frank (India)
Corporate Representative	Martin Fuhrer (Siemens)

Chairs of Committees

Communications (C-Comm)	Praveen Sharma (India)
Congress and conferences (C-CC)	Joseph Lopez (Malaysia)
Education Laboratory	Tony Badrick (Australia)
Management (C-LM)	
Scientific (C-Sci)	Kiyoshi Ichihara (Japan)

Executive Board meetings

The Executive Board held a meeting from 5th to 6th September 2015 in Singapore.

Resignation of Mr. Martin Fuhrer, Corporate Representative to the EB

The former Corporate Representative to the EB, Mr Martin Fuhrer, resigned from Siemens on 31st August 2015. EB would like to records its thanks to Mr Martin Fuhrer for his invaluable and tireless contributions to the APFCB which has helped greatly in the advancement and growth of the APFCB and its activities. Mr. Martin Fuhrer elected by the corporate members as Corporate Representative to the APFCB EB in October 2010 in Seoul, Korea re-elected for a second term in October 2013 in Bali, Indonesia.

New Corporate member to the APFCB EB

Agappe Diagnostics Ltd informed the APFCB in November 2014 that it no longer wished to be a member of the APFCB. The APFCB EB welcomed the new Corporate Representative, Mr. Alexander Wong of Siemens, when it held its EB meeting at the Siemens headquarters in Singapore on 5th and 6th September 2015. Mr. Alexander Wong was elected to be the new Corporate Representative with the agreement of the corporate members from 1st September 2015.

New MemberOrdinary member

MAHL was promoted from Affiliate membership to Ordinary membership in Mar 2015.

Affiliate member

NACC was accepted as an Affiliate member in October 2015.

Corporate members

Two new Corporate members joined the APFCB:

1. Guangzhou Wondfo Biotech Co in May 2015
2. SNIBE in October 2015

Memorandum of Understanding (MoU) between APFCB and AACC

An MoU between APFCB and AACC was signed on 11 December 2014 between the President of APFCB and the CEO of AACC, Dr Janet Kreizman. The MOU is effective for a period of two years from 1.1.2015 till 31.12.2016.



Silver Jubilee Celebration

The MACB celebrated its Silver Jubilee at its Annual Scientific Conference from 3rd to 5th August 2015 at the Double Tree Hotel in Kuala Lumpur, Malaysia. The President of APFCB presented the President of MACB, Dr Raja Elina Raja Aziddin with a crystal memento from the APFCB.



From left to right: Dr Leslie Lai, President of APFCB, VIP Dato' Tan Yoke Hwa, Director of Allied Health Sciences Division, Ministry of Health Malaysia, Dr Raja Elina Raja Aziddin. President of MACB.

2. APFCB Activities

I. APFCB Education and Laboratory Management Committee (C-ELM)

Chair: Associate Prof Tony Badrick (Australia)

1. **IFCC-Abbott Visiting Lecturer for 2015 and 2016: Prof Howard Morris (Australia)**
The topic of Prof Howard Morris's visiting lectureship was Vitamin D and bone disease. Prof Howard Morris delivered his talks in Hong Kong, Australia, Seoul Korea and Taipei.
2. **APFCB Travelling Lecturer for 2015 and 2016: Associate Prof Graham Jones**
Associate Prof Graham Jones spoke on the topic of Chronic Kidney Disease (CKD) in the following countries Singapore, Vietnam, India (AMBI), China and Mexico (WAS Pa LM World Congress). Associate Prof Graham Jones will deliver his lectures in Hong Kong in January 2016 and will deliver a Plenary Lecture at the 14th APFCB Congress in Taipei in 2016.
3. **APFCB-AACB Travel Scholarships**
The two winners of the 2015 APFCB-AACB Travel Scholarships to attend the AACB Annual Scientific Meeting in Sydney were:



Dr. Sudhesna Mohapatra of Neogen Labs Private Ltd, Bangalore, India who presented a poster entitled “Evaluation of newborn screening for the diagnosis of Carnitine Uptake deficiency in Indian Population” and Jinia Lilianty of PT. Prodia Widyahusada, Jakarta, Indonesia who presented a poster entitled “Vitamin A and Vitamin E deficiency development in Indonesian Population”.

4. Planning of future Courses and Congress Symposia and Workshops

There will be two workshops for to be held at the 14th APFCB Congress in Taipei in 2016. The first workshop is a Joint WASPaLM-APFCB Accreditation Workshop with the following topics covered by either APFCB or WASPaLM speakers;

1. Quality Systems Approach to Improvement
2. Introduction to ISO 15189
3. Ethical Practice/Governance
4. Staff training and competence
5. Request-Report cycle and error
6. QA/QC

The other workshop will be an APFCB Pre-analytical workshop with the following topics and speakers:

1. Introduction and Chair – Joseph Lopez
2. Pre-analytical errors and quality improvement – Qing He Meng
3. Phlebotomy competence – solutions – Endang Hoyaranda
4. Haemolysis an ongoing problem – Tony Badrick

Also at the 14th APFCB Congress will be a hypothetical entitled “the value of pathology” organized by the C-ELM in conjunction with Roche. The aim of this activity is to raise awareness of the importance of Pathology testing.

Planning began in 2015 with Roche Diagnostics to develop a series of **workshop /courses** dealing with Lean-Six Sigma. These workshops will be jointly organized by the local APFCB Ordinary Member or Affiliate Member Society, the APFCB and Roche Diagnostics. The first of these will be run in Vietnam in 2016.

The Committee is also planning for a **Chemical Pathology Course** to be run in Malaysia in 2016. The course will run for 3 days and will involve local and invited speakers. The content will be developed from a curriculum based on the AACB Chemical Pathology Course and is a pilot for this type of course in the region.

The APFCB will be sponsoring a symposium at the AACC 2016 Annual Meeting that has already been accepted by the Organizing Committee. The programme and speakers are as follows: Title of Symposium: Addressing pre and post analytical issues in developing countries. Chair: Tony Badrick.

The APFCB will be sponsoring a symposium at the AACC 2016 Annual Meeting that has already been accepted by the Organizing Committee. The programme and speakers are as follows:

Title of Symposium: Addressing pre and post analytical issues in developing countries. Chair: Tony Badrick.

1. Driving change in the pre-analytical phase of testing Endang Hoyaranda
2. Understanding the impact of race and ethnicity on common tests Kiyoshi Ichihara
3. Improving clinical commenting by a QA program Tony Badrick

5. Interpretative comments programme

There were six cases in 2015. The purpose of these cases and suggested responses is to provide some clinical cases for continuing education. Again there was a wide range of responses with between 15 and 45 participants for each case.



6. Young Scientist Competition (coordinated by Dra Endang Hoyaranda)

The APFCB Young Scientist Award Competition is a scientific paper competition conducted by the APFCB through C-ELM with the following objectives:

1. To foster and encourage scientific inter-exchange amongst young scientists within the Asia-Pacific region
2. To help and encourage young scientists in both written and oral communication of their research results

Scientists under the age of 40 on 26 November 2016 (opening of the 14th APFCB Congress in Taiwan) are eligible for this competition. There will be 5 (five) young scientists selected from all those who submit papers to present their papers as oral presentations at the 14th APFCB Congress in Taipei, Taiwan, on 26-29 November 2016. A dedicated symposium during this congress will be allocated to this competition. All five oral presenters will be sponsored by Siemens to attend the 14th APFCB Congress and the Congress Organizing Committee has kindly agreed to waive registration fees. There will be a first prize winner of SGD 1,000 and a second prize of SGD 500 sponsored by Siemens.

II. Scientific Committee (C-Sc)

Chair: Prof Kiyoshi Ichihara (Japan)

1. Regional reference interval study (chaired by Prof Kiyoshi Ichihara)

After completing the study in Japan, China, Pakistan, India, and Philippines, teams in Nepal, Malaysia and Bangladesh began to actively conduct the study for derivation of country-specific reference intervals. Representatives for Nepal, Malaysia, India, Pakistan are members of the C-Sci and all met and discussed the progress in Paris during Euro Med Lab 2015 at the IFCC C-RIDL meeting.

A web-site was developed in June 2015 for evidence-based laboratory medicine (EBLM) based on results from the 2009 Asian multicenter study which provides interactive viewing of information on sources of variations of reference values for 72 analytes: <http://c-sci-apfcb.net/eblm/index.html>.

Publications

Shimizu Y, Ichihara K. Sources of variation analysis and derivation of reference intervals for ALP, LDH, and amylase isozymes using sera from the Asian multicenter study on reference values. Clin Chim Acta 2015; 446: 64–72.

Masuda S, Ichihara K, Yamanishi H, Hirano Y, Tanaka Y, Kamisako T. The fluctuation of Clinical laboratory data across the menstrual cycle in healthy women with normal cycles. Submitted to Ann Clin Biochem (to be accepted soon).

Jono H, Su Y, Obayashi K, Tanaka Y, et al. Sources of variation of transthyretin in healthy subjects in East and Southeast Asia: Clinical and experimental evidence for the effect of alcohol on transthyretin metabolism. Submitted to Ann Clin Biochem (under evaluation).

2. New regional project on building a case record database of haematological malignancy (chaired by Prof Kiyoshi Ichihara)

Making best use of value-assigned serum panel, a new project of building a well-defined, case record database of hematological malignancy in collaboration with four Asian countries: Pakistan, Bangladesh, India, Japan is being planned. The purpose of the project is to explore possible country specific differences in clinical and laboratory test results of the disorders. The information will be useful for the practice of EBLM for pathological conditions.



3. Urine steroid metabolomic studies by gas chromatography mass spectrometry to aid the diagnosis of disorders of sex development in Vietnamese children (working group chaired by Dr Ronda Greaves)

The National Hospital of Pediatrics (NHP) has progressed well with this difficult project. Dr Mai and her colleagues worked in the first half of 2015 to validate the method. In May 2015, Dr Mai reported that her team was ready to commence participation in the external quality assurance program offered by SKML in the Netherlands and SKML advised that a mid-year enrolment was acceptable. From July 2015 NHP has been enrolled in the SKML programme for urine steroids and the 2015 material supplied has been used for initial evaluation of the method.

The 2016 SKML enrolment will be used as a formal EQA to confirm on-going method performance. Once this has been established the reference interval and ratio studies will be performed. All samples for these studies have been collected and are stored at -20°C awaiting analysis.

4. Vietnam Chemical Pathology Course conducted under APFCB auspices (organized by Dr Ronda Greaves)

The 7th Vietnam Chemical Pathology Course (CPC) was conducted on Saturday 6th June 2015 in Ho Chi Minh City and on Tuesday 9th June 2015 in Hanoi. Speakers were Assoc Prof Graham Jones, Dr. Dinh Thi Thanh Hoa (Clinical Biochemist, Bach Mai hospital, Ha Noi), Pharm. Tran Huu Tam (Director of CSQI of HCMC, Vietnam) and Dr Ronda Greaves. The attendance was as anticipated with around 350 participants in Ho Chi Minh City and 200 participants in Hanoi. Post the CPC re-recordings were also made of the 6th Vietnam CPC; as the original recordings were of poor quality. Discussions have commenced for the 8th Vietnam CPC for 2016. Preliminary discussions are also in place to initiate a similar CPC in Yangon within the next year.

All recordings will be made available online for the APFCB website in dual language and also for the IFCC e-Academy in English.

Acknowledgements:

The APFCB thanks Roche Diagnostics Vietnam, particularly Mr Tien and Mr Rod Ward, for their continued support of professional development in the region.

5. Vietnam Workshops – Point of care testing (organised by Dr Ronda Greaves)

The 3rd Vietnam Point of Care Patient Testing Workshop was conducted in Ho Chi Minh City on 11th June 2015 at the RMIT Vietnam Campus in District 3. Mrs Jo-Ann Northfield (Royal Children's Hospital Melbourne POCT phlebotomy nurse / technician and RMIT POCT Course workshop leader) and Dr Ronda Greaves conducted this workshop. On Friday 12th June 2015 a POCT half-day seminar was conducted in association with Jo-Ann Northfield, Mr Eric Law (Roche Diagnostics Singapore) and Dr Ronda Greaves to present quality management solutions for POCT to senior hospital officials. The eventuation of the potential Six Sigma Workshop did not progress in 2015 and is now planned for 2016. Discussions have commenced to expand the workshop activities to Hanoi.

Acknowledgements:

The APFCB acknowledges the support of Roche Diagnostics Vietnam and Asia for the Workshop and Seminar.

6. Regional project for harmonisation of mass spectrometry-based steroid assays (working group chaired by Dr Ronda Greaves)

The list of scientists / laboratories interested in participating in the APFCB Mass Spectrometry (MS) Harmonisation working group continues to grow, with approximately two thirds encompassing members of the AACB. This APFCB MS Master group list has become quite large and required some time for management.



After some initial discussions with the AACB CEO, Mr Peter Graham, the Master List was transferred to the AACB Office for administration purposes.

The Office has agreed to send out emails on behalf of the APFCB Harmonisation Working Group and will support maintaining the contact list. The first email trial, which informed everyone on the list of this change (with an opt-out option) was successful. This centralised list was also used to invite people to this year's open face to face group meeting conducted on Wednesday 16th September 2015 during the AACB Annual Scientific Meeting. The added advantage of this centralised approach is that there is now a place to record the RSVP and attendance record for these annual face to face meetings.

The work conducted by the group was initially focused on serum testosterone analysis, with the plan to expand this work to other serum steroids in 2015. The establishment of the DHT pilot programme within the RCPAQAP Endocrine program was the primary focus of the 2015 harmonisation initiative.

For this project the working group obtained help from Prof Stefan Wudy (University Giessen Germany) to establish targets for DHT and other steroid analytes using GC-MS. These targets were successfully applied to DHT for the second cycle of 2015. This is the first EQA scheme to offer DHT to our knowledge worldwide and the RCPAQAP have agreed to continue this into 2016.

One of the difficult hurdles to overcome is the establishment of commutability of commercial calibrators and the RCPAQAP material; as it is the base for the harmonisation comparison. As an outcome of the 2015 AACB Annual Scientific Meeting in Sydney, a Commutability Working Party was formed. This group's focus is to establish the commutability of the RCPAQAP Endocrine material; including the serum steroids. The APFCB MS Harmonisation Working Group is represented on this Working Party. To date experimental studies are being developed.

Objectives still in early progress which will be carried forward into 2016:

- Investigation of third party sources of quality control material and support establishment of MS appropriate ranges for package inserts. The implementation of the BioRad MS ranges in the package inserts is still outstanding.
- Provision of longitudinal data for preterm infant steroids using traceable common calibrator. (Note: reference intervals have already been established and published for this group). The longitudinal neonatal hormone data analysis is planned for later in 2016; based on a recent communication with statistician Dr James Baglin.
- Comparison of the common calibrator based MS testosterone method with patient results obtained from immunoassay platforms. The New Zealand Quality Assurance Group has requested support for harmonisation of their immunoassay serum testosterone methods against our groups LC-MS/MS method. The samples have been collected and shipped to Australia and are still awaiting analysis as the LC method is being revamped in order to add additional steroids to the analytical run.
- Travel to Hong Kong to promote harmonisation collaboration.

Publications

Lisa Jolly, Stefan A. Wudy, Michaela F. Hartmann, Chung Shun Ho, Richard KT Kam, John Joseph, Conchita Boyder, Ronda F Greaves. Establishment of an external quality assurance program for serum dihydrotestosterone.



Accepted as a hot topic oral presentation at the 53rd AACB Annual Scientific Meeting. The abstract was published in the Clin Biochem Reviews 2015.

Ronda F Greaves, Janne Pitkin, Chung Shun Ho, James Baglin, Rodney W Hunt, Margaret R Zacharin. Hormone modelling in preterm neonates: Establishment of serum steroid reference intervals by LC-MS/MS. Accepted as an extended oral presentation at the 53rd AACB Annual Scientific Meeting. The abstract was also published in the Clin Biochem Reviews 2015.

A publication developing reference intervals using the “common” calibrator piloted by the APFCB Harmonisation Working Group was published in JCEM in 2015; DOI: <http://dx.doi.org/10.1210/jc.2014-3681>. This work developed mass spectrometry based reference intervals for preterm neonatal serum for testosterone, 17OHP, androstenedione, cortisol and cortisone.

RF Greaves, L Jolly, MF Hartmann, SA Wudy. Should we target set our RCPAQAP material when there are gaps in the traceability chain? Target assignment of 17-OHP, androstenedione, DHEA and DHT by GC-MS/MS. Accepted as a poster presentation at the 53rd AACB Annual Scientific Meeting. The abstract was published in the Clin Biochem Reviews 2015.

Greaves RF, Ho CS, Hoad KE, Joseph J, McWhinney B, Gill JP, Koal T, Fouracre C, Lu Y, Cooke B, Boyder C, Pham H, Jolly L. Achievements and future directions of the APFCB harmonisation project on serum testosterone. Clin Biochem Rev 2015. Manuscript submitted November 2015 and currently under review.

A systematic review of the literature has been conducted to ascertain the published reference intervals for MS based serum steroid assays.

This review, “Systematic review of serum steroid hormone reference intervals for mass spectrometry methods”, has been registered with PROSPERO (CRD42015029637). We are now in the process of collating the data for publication and distribution to the APFCB MS working group in 2016 for further input.

7. APFCB Chronic Kidney Disease (working group chaired by Associate Prof Graham Jones who is also the APFCB Travelling Lecturer for 2015 and 2016)

The key activities have been coupled with the opportunities provided through the APFCB Travelling Lecture Programme. Associate Prof Graham Jones delivered his lectures in Singapore, Vietnam, India, China and Mexico in 2015.

Of the countries Associate Prof Graham Jones has visited there is a great need for action in the area of CKD. In many laboratories, creatinine assays are not standardized, although it seems likely that doctors are calculating the eGFR using smart phones or similar, based on the assumption of standardization. Similarly, while there appears to be excellent co-operation between some laboratories and their local clinical renal colleagues, there does not seem to be as much activity at the national organization level. Associate Prof Graham Jones hopes that some of the presentations and discussions obtained through the APFCB Travelling Lectureship may promote these activities.

A press release from KDIGO on 14th July 2015, KDIGO to Strengthen Implementation Programs in Low and Middle Income Countries, may provide opportunities for collaboration with clinical groups as the organization appears to have representatives from a number of Asia-Pacific nations.



III. Communications Committee (C-Comm)

Chair: Prof Praveen Sharma (India)

1. APFCB website

The APFCB website (www.apfcb.org) was launched on 1st Nov 2011 and is being maintained with regularly updated comprehensive information on the organization and activities of APFCB and its member societies. Access is made available through the site to the on-going scientific, educational and laboratory management programmes of APFCB, to the activities of communication & publications committee and to the photo gallery of these events. It also serves well as a source of information for the APFCB Congress / regional meetings and future events. APFCB e-News and annual reports are conveniently published online on this platform making them readily available to all the members. It also facilitates webinars on different aspects related to clinical biochemistry and laboratory medicine.

The year 2015 witnessed the on-line live telecast of the Vietnam CPC in the month of June (6th June 2015) which was viewed by almost 200 people across the Asia-Pacific Region.

2. APFCB e-News:

The APFCB e-News is published online on the APFCB web-site. This has ensured wide reach of the e-News to all members at no additional cost.

As decided by the EB at its meeting in Singapore on 5th and 6th September 2015, the APFCB e-News shall be published twice a year commencing in 2016. The C-Comm has requested member societies through their National Representatives to contribute annual activities report for publication in the e-News.

3. Public Relations

A power point presentation on the APFCB, its members and its activities was developed by Mr Martin Fuhrer, Corporate Representative to the EB and is now being updated regularly by the new Corporate member, Mr Alexander Wong since Martin Fuhrer's resignation from Siemens. This power point presentation is ready for use at member society conferences and at regional and international meetings to promote the APFCB.

IV. Congress and Conferences Committee (C-CC)

Chair: Joseph Lopez (Malaysia)

1. 14th APFCB Congress

The C-CC Chair has been in close contact with the Chair of the Organising Committee of the 14th APFCB Congress on preparations for the congress. The latest report from the OC is appended below.

The APFCB President and Chair C-CC visited Taipei on 24 Oct 2015 to confer with the COC on preparations for the 14th Congress. A report of this visit has been submitted to EB and the COC. One of the important points noted was that sponsorship from the major vendors of diagnostic products was still not yet forthcoming.

2. APFCB auspices

The following conferences/courses have been granted APFCB auspices:



- i. EFLM-IFCC EuroMedLab, Paris, 21-25 June 2015
 - ii. Chemical Pathology Course 2015 that was held on 06 June 2015 in Ho Chi Minh City and on 09 June 2015 in Ha Noi, Vietnam, upon application received from Dr. Ronda Greaves of the RMIT. The groups organising this meeting were the Vietnam Association of Clinical Biochemists, Ho Chi Minh City Association of Clinical Biochemists, Ho Chi Minh City Association of Medical Laboratory Technologists, Roche Vietnam Co. Ltd. and RMIT, Melbourne.
 - iii. WASPaLM World Congress that was held in Cancun, Mexico from 18-21 November 2015.
 - iv. Cherry Blossom Symposium to be held in Seoul from 20-22 April 2016 in Seoul
3. College of Chemical Pathologists of Sri Lanka Annual Academic Sessions from 4-5 March 2016
3. The Chair of the C-CC has written an article entitled "APFCB Auspices of Meetings" for the 2015 APFCB e-News as a way of informing learned societies in laboratory medicine and APFCB members of the opportunity to apply for auspices

4. Turning Science into Caring (TSIC)

Abbott Laboratories has held TSIC meetings in the Asia-Pacific region over the past few years in conjunction with the IFCC. The purpose of these meetings is to bring laboratory and other healthcare professionals together to exchange information on trends in laboratory medicine.

Following a discussion with a representative from Abbott at the EuroMedLab in Milan in May 2013, the APFCB was invited to become a partner of these meetings. An agreement to this effect was signed between the APFCB and Abbott on 22 July 2013 which enables the APFCB to be a partner and contribute to the planning of the scientific programme of TSIC meetings.

This year's TSIC meeting was initially planned for Bangkok, 2-3 September 2015. However, due to the bombing that occurred in Bangkok the TSIC meeting was held in Bali, Indonesia, 2-3 December 2015. The theme for this years' TSIC meeting was: Elevating the standard of patient care". The APFCB was represented by Dr Elizabeth Frank, Treasurer of APFCB.

5. Asia Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB)-Beckman Coulter (BC) Scientific Symposia

Ho Chi Minh City, Vietnam 8 October 2015

Jakarta, Indonesia 10 October 2015

Bangkok, Thailand 14 October 2015

The APFCB-BC Symposia was an educational series proposed by Beckman for the purpose of raising the standard of laboratory medicine within the region. Beckman had indicated that they were prepared to organise, fund and promote the series of symposia in their selected cities – Ho Chi Minh, Jakarta and Bangkok..This report outlines the activities for 3 events in these three cities within the APFCB region. Planning for the entire event began in May 2015.

Ms Ng Siew Bee from Beckman was the coordinator of the activities and had discussions with Associate Prof Sunil Sethi who represented the APFCB and Beckman Headquarters, particularly Dr Jack Zakowski, Director of Scientific Affairs and Professional Relations at Beckman Coulter. Dr Zakowski also holds appointments within the Board of Directors at Clinical Laboratory Standards Institute (CLSI) and College of American Pathologists (CAP). Dr Zakowski had agreed to participate in all three of the APFCB –BC Symposia as a subject expert in the area of laboratory standards, accreditation and the clinical value of specific biomarkers.

The series of APFCB-BC Symposia were held in hotels within the city centre and the programme was usually a one-day activity with a series of talks from local experts, APFCB representative and BC expert.



The events were generally well received and participation rates were between 70 - 150 participants, who were a mix of laboratory professional and technical staff as well as medical staff. The audience was generally well engaged and there were lively Q&A sessions and panel discussions as part of the planned activities. Overall, the scientific content was tailored in some ways to the needs and interests of the local laboratories which helped maintain the interest. There was also a small exhibition area which featured BC equipment. This gave the event a rather nice conference with exhibition atmosphere.

Each event was opened with formal introductions by the BC senior management team, followed by Associate Prof Sunil Sethi representing the APFCB. The APFCB hopes to continue to work with Beckman and perhaps enshrine the APFCB-BC Symposia as a regular series rather than only for this occasion.

Report prepared by Leslie Lai with contributions from Joseph Lopez, Sunil Sethi, Endang Hoyaranda, Kiyoshi Ichihara, Tony Badrick, Praveen Sharma, Ronda Greaves and Graham Jones.





APFCB WORK PLAN FOR 2015

1. EB, Committee Chairs and Committee Members

- i. Promotion of the APFCB internationally, regionally and nationally, including at workshops, conferences, scientific meetings and during visiting lectureships.
- ii. Recruiting new Full members, Affiliate members and Corporate members.
- iii. Maintaining good and strong relationships with other regional clinical biochemistry organisations, AACC, IFCC and WASPaLM.
- iv. An MoU was signed on 11 December 2014 between APFCB and AACC effective for a period of two years beginning in 2015. AACC will be sponsoring a symposium at the APFCB Congress in Taipei in November 2016 and the APFCB will be sponsoring a symposium at the 2016 AACC Annual Meeting. APFCB and AACC will collaborate to provide education activities to the Asia-Pacific region in the field of Clinical Chemistry and Laboratory Medicine.

2. Education and Laboratory Management Committee (C-ELM)

Chair: Associate Prof Tony Badrick

- i. **IFCC Visiting Lecturer for 2015/2016: Prof Howard Morris (Australia)**
The topic of Prof Howard Morris's visiting lectureship is Vitamin D and bone.
- ii. **APFCB Travelling Lecturer for 2015 and 2016: Dr Graham Jones (Australia)**
The topic of Associate Prof Graham Jones travelling lectureship is Chronic Kidney Disease. Lectures will be delivered at the 14th APFCB Congress in Taipei (Plenary Lecture) and in Hong Kong in 2016.
- iii. **Planning for a Chemical Pathology Course in Malaysia in 2016**
The course will run for 3 days and will involve local and some invited speakers. The content will be developed from a curriculum based on the AACB Course.
- iv. **Pre-Analytical Working Group to work together with EFLM Pre-Analytical Group**
There will be a pre-analytical workshop for the Taipei meeting in 2016. A proposal was submitted for the 2016 AACC in 2015 and has been accepted by the AACC 2016 Organising Committee. The APFCB-sponsored symposium at the AACC 2016 Annual Meeting is as follows:
 1. Driving change in the pre-analytical phase of testing Dra. Endang Hoyaranda
 2. Understanding the impact of race and ethnicity on common tests Prof Kiyoshi Ichihara
 3. Improving Clinical Commenting by a QA program Tony Badrick.
- v. **Development of Material for self-directed learning for QA/QC/Lab Accreditation on the webpage**
The C-ELM webpage has seen some expansion with some material supplied from Randox. It is expected that another two articles will be added in 2016.
- vi. **Awareness of Environmental Impact of Clinical Laboratories**
Mr Joseph Lopez and Dr Tony Badrick are also about to submit a second article on this topic. A Survey of suppliers will be conducted to add further information to this paper.



vii. **14th APFCB Congress, Taipei, 26-29 November 2016**

The C-ELM will be coordinating a session sponsored by Roche entitled the 'Value of Pathology' event at the Taipei meeting in 2016. The format will be a 'hypothetical'.

3. Congresses and Conferences Committee (C-CC)

Chair: Mr Joseph Lopez

i. **14th APFCB Congress, Taipei, 26 – 29 November 2016**

The C-CC Chair has been in close contact with the Chair of the Organising Committee of the 14th APFCB Congress on preparations for the congress.

The APFCB President and Chair C-CC visited Taipei on 24 Oct 2015 to confer with the OC on preparations for the 14th Congress. A report of this visit has been submitted to EB and the Congress OC. One of the important points noted was that sponsorship from the major vendors of diagnostic products was still not yet forthcoming.

The C-CC will continue to liaise with the OC and monitor preparations for the congress.

A report has been prepared by Mr Joseph Lopez together with Prof Woei-Horng Fang, Chair of the 14th APFCB Congress OC (please refer to Appendix I).

ii. **APFCB auspices**

APFCB auspices will continue to be provided upon application after review by the C-CC.

iii. **16th APFCB Congress.**

The C-CC will issue an invitation to members in early 2016 to bid to host the 16th APFCB Congress at the APFCB Council meeting in Taipei.

iv. **Revision of the APFCB Congress Guidelines**

The Chair of C-CC will draft a revised set of Guidelines for the APFCB Congress for presentation to Council before its meetings in November.

4. Communications Committee (C-Comm)

Chair: Prof Praveen Sharma

- i. To publish the APFCB e-News 6 monthly from 2016
- ii. To maintain and further enhance the quality of the APFCB website.
- iii. To ensure that the information on the APFCB website is relevant and up to date.
- iv. Uploading learning materials developed by APFCB members and APFCB Committees on the APFCB website.
- v. To provide more active support for the web-based distance-learning activities like webinars planned by C-ELM.
- vi. Multidisciplinary approach to patient care by obtaining educational material, making it available on the web site and by providing links to other relevant resources.
- vii. Develop a new PR brochure targeted to the general public, governments, industry, etc.
- viii. Publicise and promote APFCB through participation at various National and International congresses and exhibit and promote 'Clinical Biochemist Reviews'.



- ix. To communicate with member societies requesting them to provide their member societies journals weblink on the APFCB website.
- x. Establish a communication process among the committee members and member society representatives to update and work on agreed upon activities and initiatives.

5. Scientific Committee (C-Sci)

Chair: Prof Kiyoshi Ichihara

i. The regional multicentre study on reference values (RVs)

a. Expansion of the study

As of now, 5 countries in the APFCB region, Japan, China, India, the Philippines, and Pakistan, have completed their studies for derivation of country specific reference intervals (RIs) and sources of variation analyses of RVs, which were conducted as a part of the global multicentre project on RVs led by IFCC Committee on Reference Intervals and Decision Limits.

b. More analysis on sources of variation of RVs

Between-country comparison of RVs will be performed to elucidate geographical region and ethnicity-related differences in RVs. The most impressive findings obtained so far are differential effects of BMI on test results depending on ethnicity: i.e., higher sensitivity of HDL-C and ALT to BMI change in Japanese and Chinese, compared with that in Indian, Pakistani, or Caucasian. The findings will be confirmed by the additional results of RVs to be obtained from the three countries.

c. Publication of analytical results for the Asian and global RI studies with international perspective

More papers will be published on analytical results of RVs obtained in the 2008–9 Asian study. The themes of the papers are (1) systematic analyses of sources of variation of RVs for 72 analytes measured, including sex- and age-related changes profiles of major analytes, (2) detailed analysis of sources of variation of thyroid function related tests, and (3) analyses of relationships among test results of iron-related parameters. New papers on country specific reference intervals (RI) will be published by the team scientists in China, India, and Pakistan. The C-Sci will fully support their efforts.

ii. Distribution of computer software for derivation of reference interval (RI-Master)

A beta version of the software was distributed at the pre-congress workshop during 2013 APFCB congress. An updated version with improved user-interface for intuitive use of the software is now available. The new version is not only for deriving the RI more flexibly by coping with various need for secondary exclusion and partition based on sources of variation of RVs. It is also capable of graphical outputs of analytical results including depiction of histogram and probability paper plot of the RV distribution. The new version is to be distributed not only to the members of the C-Sci but also to participants of the Taipei APFCB 2016 during the hands-on statistical educational course.



iii. Development of a clinical case bank and a web-system for the practice of EBLM

Accumulation of a clinical laboratory database, or a clinical case bank, targeting major diagnostic categories, such as common haematological malignancy, autoimmune diseases etc., are being planned in Japan by collaboration of four national universities. The keen interest in joining the project was already expressed by C-Sci members of Bangladesh and Pakistan as well as IFCC C-RIDL members of UK, Turkey and USA. The database is to be used as a source reference data for the practice of evidence-based-laboratory medicine (EBLM). The laboratory test results across the collaborating institutions are to be harmonised by use of serum panel produced for the global multicenter study on RVs.

iv. Hands-on course on statistics for laboratory medicine

As was done at the APFCB Congress 2013 in Bali, an intensive hands-on course on statistics specifically required for conducting scientific research in the field of clinical chemistry and laboratory medicine will be provided as a pre-congress workshop at the 14th APFCB Congress in Taipei. Its objective is to enhance the scientific level of researchers in the APFCB region. The same course is also being planned for the Nepal Association for Medical Laboratory Sciences (NAMLS) for promotion of the scientific research in the country.

v. Regional project for harmonisation of mass spectrometry-based assays (chaired by Dr Ronda Greaves and deputy chaired by Dr CS Ho)

This regional activity originally focused on serum testosterone analysis by LC-MS/MS. With the knowledge built from this activity, work has now expanded to include other steroids. In September 2015 we met face-to-face and via teleconference at the AACB meeting held in Sydney to summarise our current activities and plan for 2016. The resulting work plan for 2016 incorporates:

- a) Ongoing review of EQA performance for steroids analysed by MS and support establishment of MS based targets.
- b) Expansion of the current initiative to focus on serum 17OHP analysis.
- c) Investigate establishment of a pilot EQA program for serum DHEA.
- d) Investigate commutability of the RCPAQAP Endocrine material in conjunction with the AACB Commutability Working Party.
- e) Complete systematic literature review and disseminate information for "*serum steroid hormone reference intervals for mass spectrometry methods*"; PROSPERO registration CRD42015029637.
- f) Comparison of the common calibrator based MS testosterone method with patient results obtained from immunoassay platform.
- g) Complete statistical analysis of longitudinal data for preterm infant steroids using traceable common calibrator. (Note: reference intervals already established and published for this group).
- h) Continue investigation of third party sources of quality control material and support establishment of MS appropriate ranges for package inserts.

vi. Development of regional appropriate methods and reference intervals for complex biochemical tests for children. (coordinated by Dr Ronda Greaves and Dr Tran Mai with supported by a qualified statistician Dr James Baglin)



Disorders of sex development – urine steroids metabolomics project. This project aims to develop a regional method for urine steroid profiles measured in fresh and blotter urine samples. The project is conducted at the National Hospital of Paediatrics (NHP) in Hanoi Viet Nam. From July 2015 NHP has been enrolled in the SKML programme for urine steroids and the 2015 material supplied has been used for initial evaluation of the method. The 2016 SKML enrolment will be used as a formal EQA to confirm on-going method performance. Once this has been established the reference interval and ratio studies will be performed. All samples for these studies have been collected and are stored at -20oC awaiting analysis.

vii. Training (co-ordinated by Dr Ronda Greaves in conjunction with Roche Diagnostics).

Training activities proposed for 2016 to underpin quality scientific research and establish further collaborations for APFCB are:

- a) 2016 Vietnam Chemical Pathology Course conducted in Ho Chi Minh City (HCMC) and Hanoi
- b) Workshop/s to be conducted in Vietnam including the 4th POCT workshop.
- c) 1st Myanmar Chemical Pathology Course.

viii. Paediatric/ Endocrine Symposium at the EFLM-UEMS Conference Warsaw 2016.

This proposed APFCB Symposium will incorporate the following presentations:

- a) Dr Tze Ping Loh - National Hospital Singapore – “*Clinical Utility of Steroid Analysis*”
- b) Dr CS Ho - Prince of Wales Hospital Hong Kong – “*Mass Spectrometry Analysis of Serum Steroids*”
- c) Prof Stefan Wudy – Giessen University Germany – “*Interpreting Mass Spectrometry data for the Diagnosis of Disorders of Sex Development*”
- d) Dr Ronda Greaves - RMIT / Murdoch Children's Research Institute Australia; “*Mass Spectrometry Reference Intervals for Serum Steroids*”.

ix. Addressing chronic kidney disease (CKD) in the Asia-Pacific Region (Chair of CKD working group: Associate Prof Graham Jones)

The overall goal is to support member societies (Ordinary and Affiliate members) in developing policies for laboratory testing in CKD to match the clinical need in their countries. The model is based on the IFCC-WASPALM Task Force on Chronic Kidney Disease.

Proposed actions for the project:

- a. A call for nominations from member societies to submit individuals to be members of this working group. This proposal of an individual should indicate an interest in the area of a national policy on CKD testing. The individual should have an interest in CKD.
- b. Circulation of current recommendations from the TF-CKD for discussion and possible adoption. In general, these are support for the KDIGO 2012 Guidelines for CKD diagnosis and monitoring, a recognition that collaboration with the relevant national nephrology and other clinical organisations is vital and that where possible a national approach is preferred.
- c. A meeting will be planned of nominees and other interested parties to be held at the 14th APFCB congress in Taipei in November 2016.



- d. Nominees and national organisations will identify opportunities for improvements in CKD-related testing and, if possible, the CKD Working Group will provide such advice and assistance as is possible

6. Corporate Representative Report

- i. A new APFCB Promotional Presentation Deck has been developed for the EB's use in raising awareness of the APFCB and its committee activities. The presentation deck will be continuously updated, taking into account new members as well as initiatives.
- ii. Formation of cross-committee Working Groups across the region on select topics for greater integration and impact across meetings, education, speakers, and scientific publications, with Corporate member participation. Key topics include laboratory quality and disease states of interest to the Asia- Pacific region.
- iii. Working with C-CC to understand the various mechanisms for Corporate member participation and development of key metrics to track promotional and branding activities, e.g., number of unique visitors per month, and outreach to member associations. These numbers are useful indicators to justify marketing spending by Corporate Members.
- iv. Convene a Corporate Members' meeting at the 14th APFCB Congress, Taipei, 26 – 29 November 2016, to foster deeper ties between EB and Corporate Members.

*Prepared by Leslie, with contributions from Tony badrick, Ronda Greaves, Kiyoshi Ichihara Graham Jonesh Lopez, Praveen Sharma and Alexander Wong.
17 January 2016*



Progress report of APFCB Congress 2016

APFCB President Leslie Lai and Dr. Joseph Lopez, Chair, APFCB C-CC met the Organising Committee on Saturday 24th October 2015 to discuss the progress of preparations for the 14th APFCB Congress to be held from 26th-29th November 2016, in Taipei. A power point presentation was made by Prof. Woei-horng Fang, Chair of the Congress Organising Committee (COC), Prof. Shu-Chu Shiesh, Chair, Scientific Committee (SC) and other colleagues from the COC. Also present were representatives from the professional conference organiser (PCO). The EB representatives considered that overall preparations appeared to be on course. The following are some key points of the progress:

1. Scientific Programme:

- a. There are 4 plenary lectures and 24 symposia and the speakers and titles are in place.
- b. Dr. Kuo, Director-General of Centres for Disease Control Taiwan, has been invited to be the Keynote speaker with the title of his talk being "Laboratory Medicine in Cloud."
- c. The abstracts submission system was opened in December 2015 and the closing date is 31 May 2016.
- d. APFCB Travelling Lecturer, Dr. Graham Jones is one of the plenary speakers.
- e. Some APFCB national societies have not yet confirmed the themes of their talks and speakers and we are actively tracking them and will reserve some rooms for late additions of symposia.

2. **Taiwan Society of Laboratory Medicine (TSLM)** accepted our invitation to include their annual conference as a satellite meeting of the APFCB Congress. The time frame of this satellite meeting will be on 26th - 27th November with the title "Asia-Pacific Chinese Conference of Clinical Biochemistry and Laboratory Medicine" and Mandarin will be used in this conference. This satellite meeting is expected to attract more participants from China, Hong Kong, Macao, as well as the bulk of local medical technologists. An effort is being made to attract the local clinical pathologists to participate in the congress.

3. **Registration:** USD 550 (same as Bali) for foreign participants; free registration for scholarship holders. Daily registration will be USD 100 and an extra payment is required for the banquet. The registration system will be open in early 2016.

4. Corporate Sponsorship:

- a. There are 2 diamond sponsors – Roche and Siemens.
- b. However, some of the well-known vendors who are APFCB Corporate Members have yet to register their interest in the congress. APFCB will assist the COC in contacting these prospective sponsors.
- c. Local sponsors will be actively contacted in the coming months. Good local vendor support is expected because of the participation of the TSLM.
- d. There are still slots available for industrial workshops and it is expected that these will be taken up in the coming months by the major vendors.

5. **Venue:** the venue of the congress will be the Taiwan International Convention Centre (TICC). The entire building of the TICC is available for the period of the APFCB Congress. The trade exhibition will be held at the Taiwan World Trade Centre which is just across the road from the TICC. TICC, TWTC and the Grand Hyatt are all within the vicinity of the iconic 101 Building and within walking distance of each other and metro stations.



6. Professional Conference Organiser (PCO):

The local Enjoy-PCO will act as the congress's contact point. It will manage everything, including registration, communication with speakers and participants, accommodation arrangements, etc.

7. Social:

- a. The reception for the opening will be held at the TICC.
- b. Packed lunch will be provided to all registered participants on each day of the congress
- c. The congress banquet will be held at the Grand Hyatt hotel and will be open to all registered participants for a fee. This venue can hold 800 guests.

8. Promotions:

- a. The official web-site <http://www.apfcbcongress2016.org/> will be progressively updated.
- b. It will be used for registrations and submission of abstracts.
- c. A major promotional effort will be made at the IFCC General Conference in Madrid.

9. We are ready to provide venues for meetings of the APFCB EB and committees, and the IFCC and its Divisions, Committees, if requested, and other joint meetings (e.g. APFCB-IFCC; APFCB-WASPaLM) that are held in conjunction with the APFCB Congress.

Report prepared by Mr. Joseph Lopez with contributions from Prof Woei-Horng Fang





APFCB Auspices of Meetings

Joseph Lopez

On behalf of the APFCB Congresses and Conferences Committee

One of the functions of the APFCB Congresses and Conferences Committee (C-CC) is the conferment of the APFCB's auspices for scientific meetings within and outside the Asia-Pacific region. The provision of auspices simply means an endorsement by the APFCB and it is mutually beneficial to both the event and the APFCB. In conferring its auspices, the APFCB lends its prestige with the expectation that the meeting will be of a standard acceptable to it and there by attract good participation. The APFCB in turn benefits by raising its profile within the laboratory community.

Every application for APFCB auspices is treated on a case-by-case basis by the APFCB C-CC. Scientific meetings, be they educational courses, seminars and conferences that are held by learned societies of pathology are favourably considered. Meetings by corporate organisations that are not purely sales promotions but are educational and vendor-neutral should consider making an application for auspices. Applications from meetings with a purely commercial bias or which are organised for profit without the backing of any learned society will be closely reviewed to see if they fit into the aims and ideals of the APFCB; in such instances, auspices will only be awarded in exceptional circumstances.

APFCB member societies, in particular, are encouraged to seek auspices for their national and other educational meetings. They may also seek IFCC auspices if they are members of that body. There is no fee for the provision of auspices from either federation. Organisations wishing to apply for it should do so well before meeting materials are prepared. The guidelines and application forms for APFCB auspices are available on the APFCB website within the APFCB C-CC's web-page or may be obtained by writing to the APFCB Secretary.

(JL is APFCB Immediate Past President, Chair of the APFCB C-C and a member of the IFCC C-CC)





IFCC - Task Force Young Scientists (TFYS) at ACBICON-2015, Chandigarh, India, 25-28 November 2015

Association of Clinical Biochemists of India (ACBI) is supporting the IFCC-TFYS educational sessions since 2010. In continuation Organising Committee of 42nd National Conference of ACBICON-2015, PGIMER, Chandigarh, India supported the TFYS sessions 2015, India. The sessions were designed especially for Young Scientists (YS) included Preconference “Medical Writing CME” and first time conducted “ACBI-IFCC TFYS Young Scientist Award 2015” fully supported by Organizing Committee. The conference was held in Postgraduate Institute of Medical Education and Research (PGIMER). PGIMER, Chandigarh was conceived in 1960 as a center of excellence to develop patterns of teaching in postgraduate medical education and attempt to produce specialists in several disciplines of medicine with intensive research in the field of health.

Preconference “Medical Writing CME” Wednesday, 25th November 2015

The CME was a part of continuous efforts of IFCC-TFYS for the education and training of young scientists. “Research” refers to a search for knowledge and “medical writing” involves writing scientific documents of different types which include research-related documents, related to disease or drug-related literature. It includes publication of articles like manuscripts and abstracts for healthcare journals, websites, magazines or news presented to suit the level of understanding of the target audience. This session was led by an experienced academic trainers, with aims to provide structure and motivation through writing a paper for publication.

The session was opened with welcome address by Dr Rajendra Prasad, Chair Organising Committee and Dr Praveen Sharma, President ACBI followed by IFCC-TFYS introduction by Dr Pradeep Kumar Dabla, Chair IFCC-TFYS. The first half of session was Chaired by Prof Praveen Sharma & Dr Pradeep Kumar Dabla and second half by Dr Venkatesh Thuppil, Advisor Quality Council of India and Dr MVR Reddy, Co-Editor IJCB, EB-ACBI. Dr Praveen Sharma opened the first lecture of the programme titled “Understanding the Writing Process: Planning and Productivity” where he summarised the writing process including its various steps & stages which were elaborated by next speakers in row. He gave the idea of importance of planning to make the writing process successful. Planning is most important part of formula called time management. Thus, he advised to keep yourself engaging achieving your goals and objectives.

The next lecture in row was titled “Breaking down the structure of papers to generate writing goals: Manuscript Development” led by Dr Rajiv Erasmus, President Org Committee IFCC-Worldlab Durban 2017. He gave a brief idea of manuscript development and drafts each section of research paper in different headings and subheadings. Getting started is often the most difficult part and for this reason it is best to begin with the easiest sections. These are usually the methods and results, followed by the discussion, conclusion, introduction, references and title, leaving the abstract until last. Dr Pradeep Kumar Dabla delivered first talk of next half session titled “Techniques for being an effective writer”.

He discussed important points to remember while preparing a well-structured and comprehensive manuscript for a publication submission. Long gaps between writing process interrupts the continuity of thought and ensure keeping all the necessary information, e.g. all data, references and tables or figures at hand before start writing. He emphasized on revision process to improve the quality of research manuscript.



Next speaker in row were Dr MVR Reddy for topic titled “Ethics involved in Publication Process: Important to know”. Writing a scientific paper involves a high burden of responsibility on the shoulder of its authors. Thus, he made an effort to elaborate various ethical issues in practice of medicine and punishable by law. He presented the basic principles and standards of Ethics in medical research and publishing so that honesty and integrity can be maintained. Dr Shalmoli Bhattacharyya, Additional Prof, Biophysics, PGIMER, Chandigarh delivered last lecture titled “Publishing your work: Importance of Journal Selection & Submission”. Selecting the best target or good fit journal for your research is a critical step.

It can save you considerable time and effort by avoiding rejection. It will help other researchers in your field to find your work and help in improving visibility. At the end of session, the house was made open for one to one interaction between speakers and participants where efforts were made to solve their queries. The session was closed with remarks by Dr Venkatesh Thuppil and vote of thanks by Dr Thungapathra M, Treasurer ACBICON-2015. IFCC-TFYS is thankful to the Organising Committee, ACBICON-2015 for all their support provided in conducting a successful session while making an effort for closing gaps in the understanding of “Medical Writing” process for students.



Persons in the first row (center), from left to right: Dr Shalmoli Bhattacharyya, Dr Rajiv Erasmus, Dr Venkatesh Thuppil, Dr Praveen Sharma, Dr MVR Reddy, Dr Pradeep Kumar Dabla, Dr Thungapathra M

“ACBI-IFCC TFYS” Young Scientist Award- 2015 Thursday, 26th November 2015

The “ACBI-IFCC TFYS” Young Scientist Award- 2015, a unique session was introduced first time by joint efforts of IFCC-TFYS & Organising Committee ACBICON-2015. The 5 young scientists from pan India covering all zones of ACBI were selected from number of requests on the basis of their research work.

The selected young scientists presented their papers and were awarded with full registration, travel and 3 night accommodation supported by organising committee, ACBICON-2015. The session was chaired by Dr. Alpana Saxena, Dir Prof, Biochemistry, MAMC, Delhi & Dr. Pradeep Kumar Dabla, Chair, IFCC-TFYS. The session was initiated with welcome note of Dr. Sadhna Sharma, Jt Org Secretary, ACBICON-2015 followed by Dr. Alpana Saxena and then brief note on IFCC-TFYS by Dr. Pradeep Kumar Dabla. Selected 5 young scientists presented their research work in row namely: Dr. Surupa Basu (from Kolkata), Dr. Prerna K. Chawla (from Mumbai), Dr. Kritika Krishnamurthy (from Delhi), Dr. Anurag Sankhyan (from Delhi), Prabhat Singh (from Puducherry) and interacted with audience for their queries. The session was ended with award distribution to young scientists by Chairs session and closing remarks by Dr. Sadhna Sharma.



These awards created a good example of advocacy and platform for young scientists to interact and an opportunity of dedicated standalone session. TFYS is thankful to all our senior members Prof. Praveen Sharma, President ACBI; Prof. Rajendra Prasad, Chair Organising Committee, Prof. Graham Beastall, Past President IFCC for their immense support and especially to our young colleague Dr. Arnab Pal, EB-ACBICON 2015 who played an vital role in conducting TFYS sessions successfully.



From Left to Right: Awardees with Chairs Session

Dr Kritika Krishnamurthy, Dr Prerna K Chawla, Dr Alpana Saxena (Dir Prof, Biochemistry, MAMC, Delhi), Dr Pradeep Kumar Dabla (Chair IFCC-TFYS), Dr Surupa Basu, Dr Prabhat Singh, Dr Anurag Sankhyan

The Young Scientists experience of participating in & attending “ACBI-IFCC TFYS” Young Scientist Award- 2015 is enumerated below:



Dr. Surupa Basu
Institute of Child Health, Kolkata, India

I would like to thank IFCC and ACBI for awarding me the coveted IFCC-TFYS Award at ACBICON-2015 and for giving the opportunity to present my ongoing research on vitamin D in primary idiopathic nephrotic syndrome. The title of my paper was **“A Randomised Controlled Trial to assess the effect of Vitamin D supplementation in Steroid Sensitive Nephrotic Syndrome”**. Our research group at Institute of Child Health, Kolkata is trying to establish guidelines for vitamin D supplementation through research in children with the disorder, who have high chances of bone disorders due to losses of vitamin D binding protein in the relapse phase of their disease and prolonged treatment with corticosteroids. Presenting my work and sharing research experiences with fellow biochemists was an enriching experience. I had the opportunity to discuss current trends and newer technologies in laboratory practice with leaders and stalwarts of clinical biochemistry. The platform was a gateway to make new acquaintances; it also enriched my knowledge base and recharged me with great enthusiasm for higher learning. Thank You ACBI & IFCC!





Perna K. Chawla
P. D. Hinduja Hospital & MRC,
Mahim, Mumbai, India

I would like to thank & appreciate the entire team of ACBICON 2015 who successfully conducted a very well organized conference at PGIMER, Chandigarh. This conference has been a real motivation tickling my brains to think newer ideas & approaches that can be implemented in the field of research.

I am thankful to my guide Dr T.F. Ashavaid & the IFCC-TFYS members to allow me to present my data in this incredible conference wherein I was awarded the ACBI-IFCC TFYS Award on my topic **entitled “GENETIC VARIANTS OF ABO BLOOD GROUP & CORONARY ARTERY DISEASE (CAD).”** Our work focused on determining the association of the ABO blood group with CAD in Indians. The conference attendees have appreciated the work done & have encouraged us to further work ahead in future directions. I am happy to inform you, that the topic shall be further presented in an international conference. The entire ACBI-IFCC TFYS Award session was informative nurturing newer ideas & good exchange of knowledge of ongoing research in India. I convey my sincere thanks to you.



Dr. Kritika Krishnamurthy
Final Year, MD Biochemistry, PG Resident
Maulana Azad Medical College, Delhi, India

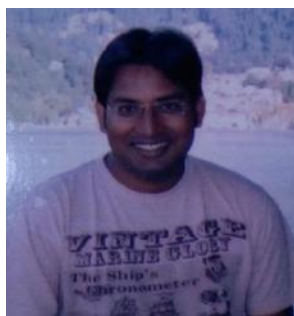
I, Dr Kritika Krishnamurthy, a final year MD Biochemistry student, was awarded the IFCC-TFYS Young scientist award 2015 for my work on **“*NISCH* and *CDHI* promoter hypermethylation in cfDNA of lung cancer patients and its correlation with clinicopathological variables”** It was a really enriching experience for me to be selected & invited as a speaker to the ACBI-IFCC TFYS award session of ACBICON 2015, Chandigarh. I was given the opportunity to present my work to an audience of such senior and eminent researchers. Receiving such an award in recognition of my work so early in my research career, has inspired me to work harder and help further cancer research. In addition, I am grateful for the financial support towards my attendance to this prestigious event. I want to thank ACBI & IFCC for this award. It has really motivated me to advance my research towards better diagnostic and potentially therapeutic modalities for cancer.





Anurag Sankhyan
Innovation Awardee,
Center for Bio-Design, THSTI
Faridabad (Haryana), India

I am grateful to ACBI and IFCC for felicitating me with the prestigious ACBI-IFCC TFYS award-2015 for my work titled **“An array of human recombinant antibodies from naturally recovered individuals for inhibition of preS1-hepatocyte interaction”**. I appreciate ACBI-IFCC for giving me the opportunity to present my work to an august gathering of Scientists and Clinical Biochemists at ACBICON-2015, Chandigarh, India. The work entails generation of neutralizing recombinant human mAbs from individuals naturally recovered from HBV infection and using a combination of such human recombinant antibodies with defined specificities to prevent/manage HBV infections, including those by possible escape mutants. This work provides a new dimension for the development of better immunotherapeutic interventions for hepatitis B. ACBI-IFCC TFYS Award has been an immensely enriching and motivating experience. I congratulate the co-recipients of the award and acknowledge ACBI & IFCC for creating a wonderful platform for providing recognition to young fellows.



Dr. Prabhat
JIPMER, Pondicherry, India

I am writing to express my sincere gratitude to you and the committee for selecting me as a recipient of the ACBI-IFCC TFYS Award at ACBICON-2015, Chandigarh, India.

The title of my paper was **“Luteinizing hormone-Follicle-stimulating hormone ratio as Innovative biochemical predictor of post-partum depression.**

I am so humbled to have been chosen for this award knowing that there were many qualified applicants. Even though the event was a few months ago, the feelings are still present. This experience is something that I will never forget, and I know that the effects of this will reach far beyond the monetary sum of the award. I am doing post-graduation (M.D Biochemistry) at JIPMER Pondicherry, India. My area of interest is meningitis and dengue. I like to come out with innovative idea out of conventional knowledge of science.

Please accept my deepest thanks and appreciation for your philanthropy and for the privilege of being inducted into the prestigious ACBI-IFCC TFYS Award at ACBICON-2015.

Report By: Dr Pradeep Kumar Dabla Chair IFCC-TFYS Email: pradeep_dabla@yahoo.com





Association of Clinical Biochemists of India Annual Report 2015

The year started with the newly elected office bearers elected at the General Body meeting of the Association of Clinical Biochemists of India held in Jodhpur on December 12, 2014, taking up their office. The office bearers elected were:

PRESIDENT:	Dr. Praveen Sharma
VICE PRESIDENT:	Dr. Rajendra Prasad
	Dr. S. V. Rana
ADVISOR:	Prof. K.P. Sinha
IMMEDIATE PAST PRESIDENT:	Dr. Jayashree Bhattacharya
GENERAL SECRETARY:	Dr. Rajiv Ranjan Sinha
IMMEDIATE PAST SECRETARY:	Dr. M.V. R. Reddy
TREASURER :	Dr. Krishna Ranjan Prasad
JOINT SECRETARY:	Dr. Jairam Rawtan
	Dr. Ram Binary Sinha

ZONAL COUNCIL MEMBERS

North Zone:	Dr. Seema Bhargava
South Zone:	Dr. T. Vijayakumar
East Zone:	Dr. Abhijit Pratap
West Zone:	Dr. T. F. Ashavaid
Central Zone:	Dr. Sanjeev Singh

Editor- in Chief, IJCB: Dr. Praveen Sharma

National Representative to APFCB: Dr. Rajiv R. Sinha, General Secretary, ACBI

Regional Meetings:

During this year many scientific activities were organized by State / Regional chapters of ACBI in different parts of the country.

KERALA BRANCH

The Association of Clinical Biochemists of India – Kerala chapter along with Department of Biochemistry, Pushpagiri Institute of Medical Science & Research Centre, Tiruvalla conducted a one-day seminar on “Laboratory Accreditation and Quality Assurance” on 28th February 2015. This program was co-sponsored by Kerala State Council for Science, Technology & Environment (KSCSTE), Govt. of Kerala. Dr. Kannan Vaidyanathan, Prof & Head, Dept of Biochemistry & Organizing Secretary, welcomed over 270 delegates who came from all over Kerala. Speakers covered different topics related to the process of accreditation of Laboratories under NABL & ISO 15189:2012. The 2nd program was conducted by the Kerala Branch in association with the Believers Church Medical College Hospital, Thiruvalla was a 4 day “ISO 15189:2012 Internal Audit and Quality Management” Training course from 30th April to 3rd May 2015. This training programme was attended by 35 delegates.



UTTAR PRADESH STATE BRANCH

Uttar Pradesh ACBI representative Dr. Brijesh Rathore organized a one day meet on the various aspects of Quality Assurance at the Era's Lucknow Medical College & Hospital, Lucknow on 16th March 2015. Speakers covered various topics related to the maintenance of Quality Assurance in the laboratory.

MADHYA PRADESH BRANCH

The Madhya Pradesh ACBI Chapter organized a meet on 6th April 2015 in the Dept. Of Biochemistry at Gajra Raja Medical College Gwalior. Dr. Arun Raizada, Head, Laboratory Medicine, Medanta Hospital Gurgaon was the Key Speaker and he spoke on "Driving transformative changes in clinical laboratory". The meet was presided over by Prof. Dr. Neelima Singh, Head, Dept. of Biochemistry, G R Medical College, Gwalior & Past President, and ACBI.

BIHAR BRANCH

The Bihar branch of ACBI organized a 1 day CME on 28th June 2015 on the topic "Good Laboratory Practices". Past President, Dr Sucheta Dandekar of Seth G S Medical College, Mumbai spoke on "Key Strategies towards improving Laboratory Quality". This was followed by a talk on "Defining Laboratory Quality & Understanding where the error happens" by Dr Seema Bhargava, Sir Garage Ram Hospital, New Delhi. The last speaker was Dr. Adarsh Pal Singh, Director Medical Affairs, Greater Asia, B D Diagnostics, who gave a talk on "Importance of Specimen Quality on overall Laboratory performance".

SOUTH ZONE CONFERENCE

The Association of Clinical Biochemists of India Kerala chapter in association with, Research and Development Department, MES Academy of Medical Sciences, Perinthalmanna and the society of Clinical Chemists of Kerala has organized a two day National conference on Advances in Laboratory practices on 13th and 14th of June 2015 at the MES Medical College Auditorium, Perinthalmanna. The conference was sponsored by Kerala State council for science, technology and environment. Dr. T.Vijayakumar, Joint Secretary of ACBI presided the inaugural function and Dr. V. Ramachandran, Deputy Dean, MES Academy of Medical Sciences inaugurated the function. The proceeding of the conference was released by Dr. George Abraham, Secretary, Society of Clinical Chemists Kerala Chapter. Dr. DM Vasudevan, former president of ACBI delivered the key note address.

The Conference was attended by more than 100 faculty members and 150 researchers, scientists, laboratory personals and Post graduates from South India. The conference gave in depth knowledge in lifestyle and metabolic diseases and advanced laboratory techniques and biomarkers in their diagnosis. The invited speakers gave talks on the recent advances on biomarkers in Kidney function (Dr. DM. Vasudevan), Ethics in Clinical Research and practice (Dr. Rekha Raghavan), Lifestyle Diseases and Management (Dr. V. Jayapal), Carcinoma associate fibrosis (Dr. Antony George), Genetics Testing- points to ponder by (Dr. Divya Pachat) Recent Advances in prenatal Diagnosis (Dr. Dinesh Roy). Around 65 papers were received out of which 50 papers were selected for presentation at the conference and the papers were evaluated by a team of experts. The awards were distributed in the valedictory function by Dr. Vasudevan, former President ACBI.

The GB elected the following as Executive Committee members for the year 2015. Dr. Praveen Sharma as PRESIDENT, Dr. Rajendra Prasad, VICE PRESIDENT (I) & Organizing secretary, ACBICON 2015, Dr. S. V. Rana - VICE PRESIDENT (II), ADVISOR-Prof. K.P. Sinha, GENERAL SECRETARY- Dr. Rajiv Ranjan Sinha, TREASURER- Dr Krishna Ranjan Prasad, JOINT SECRETARY: Dr. Jairam Rawtani (Jodhpur) & Dr. Ram Binay Sinha (Patna). ZONAL COUNCIL MEMBERS-Dr. Seema Bhargava (North Zone), Dr T. Vijayakumar (South Zone), Dr. Abhijit Pratap (East Zone), Dr. T. F. Ashavaid (West Zone) & Dr Sanjeev Singh (Central Zone).



DELHI STATE BRANCH

The Department of Biochemistry, Sir Ganga Ram Hospital (SGRH), under the aegis of North Zone and Delhi Chapter of the Association of Clinical Biochemistry of India (ACBI), conducted a CME titled "Current Health Perspectives" on Friday, the 20th of March, 2015. With the belief that patient care is enhanced when clinicians and laboratorians function synergistically, the scientific session included academicians as well as practicing physicians of Sir Ganga Ram hospital, New Delhi from the Department of Nephrology and Rheumatology & Clinical Immunology. The CME was coordinated & managed by Dr Seema Bhargava, Zonal Representative (North Zone) & Dr Anjali Manocha (Delhi State Representative).

TAMIL NADU BRANCH

The Tamil Nadu branch of ACBI and the Department Of Clinical Biochemistry, Christian Medical College, Vellore conducted a one day CME on 25TH July 2015 on the topic "Vitamin D – its measurement techniques and Clinical Utility". This CME was awarded 10 credit points by the Tamil Nadu Medical University. Dr Victoria Job, Professor & Head of Clinical Biochemistry & the organising secretary welcomed the delegates to the CME. Along with talks on various measurement techniques for Vit D estimation, speakers from the department of Rheumatology, Endocrinology, Neonatology and Clinical Biochemistry spoke on the Vitamin D's clinical role as an immuno modulatory molecule.

The TN Chapter's second CME in 2015 was conducted by The Clinical Biochemistry Department, Cancer Institute, Chennai on 17th October 2015. Dr. R. Arivazhagan, TN Representative and Head of the Department welcomed the gathering with brief introduction about ACBI activities. Dr. A. Rathinavelu, the recipient of 2015 Fulbright Scholarship and the Executive Director, R. Goodwin Institute for Cancer Research, Nova Southeastern University, Florida, USA gave a presentation about "New Horizons and challenges in Cancer Treatment".

JAMMU & KASHMIR STATE BRANCH

A two day State conference "BIOCME- 2015 " was organized by Department of Biochemistry, Govt. Medical college, Srinagar, Kashmir under aegis of North Zone Association of Clinical Biochemists of India (ACBI) & Indian society of Lead Awareness and Research (INSLAR) on the Theme 'Advances in Biochemical & Molecular Diagnostics: Recent Research Trends' on 9th -10th May 2015. The J & K State representative & Head Biochemistry, GMC, Srinagar, Dr Sabhiya Majid was the organizing Secretary of the meet. President ACBI, Dr. Praveen Sharma, Head, Dept of Biochemistry, AIIMS, Jodhpur, General secretary ACBI, Dr. Rajiv R. Sinha, Professor & Head, Department of Biochemistry, Nalanda Medical College, Patna and Dr Seema Bhargava (Professor & Head, Department of Biochemistry, SGRIMS, New Delhi & North Zone representative of ACBI along with Dr L. M. Srivastava were invited speakers and actively participated in academic sessions.

2ndCME The 2nd Programme to be held under the aegis of North Zone ACBI was a 1 day seminar on "Clinical Chemistry Update – 2015" organized by the Department of Biochemistry, SKIMS, Srinagar, Kashmir under the organizing secretary Dr Syed Mudassar, HOD, Biochemistry at SKIMS. The 2nd Programme to be held under the aegis of North Zone ACBI was a 1 day seminar on "Clinical Chemistry Update – 2015" organized by the Department of Biochemistry, SKIMS, Srinagar, Kashmir under the organizing secretary Dr Syed Mudassar, HOD, Biochemistry at SKIMS



The meeting brought together internationally reputed scientists and clinicians whose continuing contributions towards clinical chemistry have advanced the field to a great extent. The topics covered were diverse, from Quality Assurance, Lactose breathing tests, Ion selective electrodes and Biomarkers of Liver fibrosis. This event was a unique opportunity to connect with peers and learn about the latest trends in clinical research.

WEST ZONE MEET

The ACBI West Zone organized the 2nd of the One day lecture series in Clinical Biochemistry on "Applications of Analytical Instruments in Clinical Diagnostics" on 4th July 2015 at P D Hinduja Hospital, Mumbai. The various techniques that were discussed were Capillary Electrophoresis, FTIR, LC Mass Spectrometry, GC Mass Spectrometry, AAS & ICPMS etc. Each techniques was discussed in 2 parts i.e. The basic principles and the techniques followed by clinical applications and case studies. Dr. T.F. Ashavaid was helped in her efforts by Dr. Sucheta Dandekar, Dr. Padma Chavan and Dr. Rohini Bhadre.

WEST BENGAL CHAPTER ACBI

The Department of Biochemistry, College of Medicine & JNM Hospital, Kalyani, West Bengal organized "CliniTech: Workshop on Advances in Technology and Quality Assurance in Clinical Laboratory" in association with ACBI on 3rd & 4th July, 2015. Prof. Praveen Sharma, President of ACBI elaborated about the activities of the Association. The key note address was given by Prof. T. Venkatesh, Past President ACBI. Dr. Subir Kumar Das, Prof & Head, Biochemistry acknowledged contribution of all participants and sponsors.





Award Presentation Ceremony

The General Body elected the following as Executive committee members for the year 2016. Dr. Rajendra Prasad as President. Dr. Poornima Manjrekar as Vice President (I) & Organizing Secretary ACBICON 2016. Dr. Dharamveer Yadav as Vice President (II), Prof. K. P. Sinha as Advisor ACBI and Dr. Rajiv Ranjan Sinha as General Secretary. The Joint secretaries elected were Dr. Thungapathra M & Dr. Ram Binay Sinha. Dr. Krishna Ranjan Prasad was elected as Treasurer. The Zonal Council members elected were Dr. Seema Bhargava (North Zone), Dr T. Vijayakumar (South Zone), Dr. Abhijit Pratap (East Zone), Dr. T. F. Ashavaid (West Zone) & Dr Sanjeev Singh (Central Zone).

This was followed by the valedictory function bringing the curtain down on 4 days of intense, high level scientific sessions. The Organizing Secretary, Prof. Rajendra Prasad thanked all the delegates and volunteers for making the conference a grand success. The Director, PGIMER, Chandigarh, Prof. Y. K. Chawla congratulated Dr. Rajendra Prasad and his team for the successful organization of the conference. After this Awards, Certificates and cash prizes were distributed to all the award winners. The General Secretary, ACBI, Dr. Rajiv Ranjan Sinha in his valedictory address heartily congratulated all the organizing committee members and volunteers for their untiring efforts in making the ACBICON 2015, national conference a great success.



ACBI FELLOWSHIP AWARD (FACBI)

Dr. Jasvinder K. Gambhir, Delhi ACBI- A. J. THAKUR DISTINGUISHED CLINICAL BIOCHEMISTS AWARD Dr. Praveen Sharma, Professor & Head, Department of Biochemistry, All India Institute of Medical Sciences, Jodhpur. **ACBI ORATION AWARDS, 2015: AWADHESH SARAN MEMORIAL ORATION** Dr Tester F. Ashavaid, Consultant Biochemist & Head, Dept. of Lab. Medicine, P.D. Hinduja National Hospital & Medical Research Centre, Mumbai.



"Pharmacogenomics : implementation in medicine." **SETH G. S. MEDICAL COLLEGE & KEM HOSPITAL ORATION** Dr. Harish C. Joshi, Department of Cell Biology & Winship Cancer Institute, Emory University School of Medicine, Atlanta, USA. *"Microtubules, Small Plant derived molecules and uncontrolled cancer cell division."* **DR T. N. PATTABIRAMAN ORATION AWARD** Dr. Shyam S. Chauhan, Professor, Department of Biochemistry, All India Institute of Medical Sciences, New Delhi. *"Transcription factor C/EBP- β mediates down regulation of dipeptidyl-peptidase III expression by interleukin 6 in human glioblastoma cells."* **K. L. GUPTA MEMORIAL ORATION** Dr. Kapil Mehta, Professor of Cancer Medicine (Biochemistry), The University of Texas MD Anderson Cancer Center Houston, Texas, USA *"Circumventing cancer drug resistance in the era of personalized medicine"* **MRS. & DR G. P. TALWAR ORATION AWARD** Dr. B. C. Kabi, Director-Professor and Head, Department of Biochemistry, Vardhaman Mahavir Medical College & Safdarjung Hospital, New Delhi *"Vitamin D: rationalization vs sensationalization,"* **DR. TARANATH SHETTY MEMORIAL ORATION AWARD POPULAR LECTURE SERIES** Dr. Anil Bhansali, Professor and Head, Department of Endocrinology, PGIMER, Chandigarh. *"Emerging concept in pathophysiology of T2DM"*

OTHER AWARDS: K.P. SINHA - P.S. KRISHNAN AWARD FOR BEST PAPER PUBLISHED IN IJCB 2015: Archana Verma, Vibha Singh, Praveen Jaiswal & R. D. Mittal " Genetic Variants in miRNAs Associated with Renal Cell Carcinoma (RCC) Risk: A Pilot Study in North Indian Population" Vol. 30, No 4 (Oct-Dec 2015), Year 2015. **PITABUS – JAMUNA BURMA MEMORIAL AWARD** Dr. Gangadhar Chatterjee, Dept. Of Biochemistry, Grant Med. College & JJ Hospital, Mumbai. "Capture and ligation probe-PCR (CLIP-PCR) for Molecular Screening with application to active Malaria Surveillance for elimination". **DR. P. S. MURTHY AWARD DEVELOPMENT OF DRUG–** Dr. Priyanka S Bhoj (MGIMS, Sewagram) Targeting folate metabolism: A promising therapeutic rationale against *Brugia malayi* infection. **DR SITA DEVI AWARD** Dr. Chiranjit Ghosh, Deenanath S. N. Bose National Centre for Basic Sciences, Kolkata - Insulin sensitivity index (ISI 0, 120) potentially linked to carbon isotopes of breath CO₂ for pre-diabetes. **NIMS BEST POSTER AWARD: CANCER:** Dr. Dhairya H. Patel (Symbiosis School of Biomedical Sciences, Pune).

"To evaluate the Effects of a Polyphenolic Flavonoid Quercetin on the Metastatic Characteristics of SK-MEL-28 Human Melanoma Cells" **NON-CANCER : Ms. Ragini Khajuria (PGIMER, Chandigarh)** Functional Characterisation of Mutations in Congenital Adrenal Hyperplasia Patients (CYP21A2 Gene)" **MGIMS (SEWAGRAM) AWARD:** Dr. Chandresh Sharma, Centre for Bio Design and Diagnostics, Translational Health Science and Technology Institute, New Delhi "Generation of monoclonal antibodies specific to salmonella typhi as a potential candidate for improved typhoid diagnosis **Dr. P. Usha Sharma Best Poster Award in Genomic Proteomic sciences – Clinical Application:** Ms. Jyoti Kundu, PGIMER, Chandigarh "Differential Proteome Analysis of Peripheral Blood Mononuclear Cells from Patients of Concurrent Active Tuberculosis and Type 2 Diabetes Mellitus"



PRESIDENT:

Dr. Praveen Sharma

VICE PRESIDENT

Dr. Rajendra Prasad

Dr. S. V. Rana

ADVISOR

Prof. K.P. Sinha

IMMEDIATE PAST PRESIDENT:

Dr. Jayashree Bhattacharya

GENERAL SECRETARY:

Dr. Rajiv Ranjan Sinha

IMMEDIATE PAST SECRETARY:

Dr. M.V. R. Reddy

TREASURER

Dr. Krishna Ranjan Prasad

JOINT SECRETARY:

Dr. Jairam Rawtan

Dr. Ram Binary Sinha

ZONAL COUNCIL MEMBERS

North Zone:

Dr. Seema Bhargava

South Zone:

Dr. T. Vijayakumar

East Zone:

Dr. Abhijit Pratap

West Zone:

Dr. T. F. Ashavaid

Central Zone:

Dr. Sanjeev Singh

IMMEDIATE PAST PRESIDENT:

Dr. Praveen Sharma (Jodhpur, Rajasthan)





Chinese Association for Clinical Biochemistry (CACB)

This brief report summarizes some of the highlights of activities for CACB during the Year of 2015. CACB held annual conference on March 21st and a new Board of Directors and Board of Supervisors were elected by the General Assembly of CACB. In the regular Board meeting held on June 1st, Dr. Woei-horng Fang was re-elected as the President of CACB with the term from May 2015 to June 2017. Dr. Fang reaffirmed the commitment of CACB to advocate the establishment and education of professional clinical chemistry medical technologist.

The 12th CACB Board of Directors and Supervisors



During the 30th Joint Annual Conference of Biomedical Science (JACBS) held at the National Defense Medical University Campus on March 21-22, 2015, we invited applied IFCC-Abbott VLP for Dr. Howard Arthur Morris, Joint appointment Professor of Medical Sciences, University of South Australia and Senior Medical Scientist, Chemical Pathology Directorate, SA Pathology, to deliver a special lecture on "Vitamin D: Molecular actions across a variety of biological systems". He shared valuable experiences in bridging the basic biomedical research and clinical application with his thorough studies of Vitamin D in osteobiology and physiological homeostasis. CACB also organized a symposium "Current Trend in Clinical Biochemistry" continuing the special lecture. Three speakers shared the experiences and achievement in their research in advancing the field of clinical biochemistry. Dr. Jing-Long.

Huang, MD, Professor of Pediatrics, Chang Gung University, Taiwan, also the Vice Superintendent of Ghang Gung Memorial Hospital, Taiwan, presented "The Prediction of Allergies in Taiwanese Children (PATCH) Study". Sandy Huey-Jen Hsu, Medical Technologist, Department of Laboratory Medicine, National Taiwan University Hospital, presented "Recent Advances in Biochemical Bone Markers," echoing the topic of special lecture from the clinical point of view. Professor Tsan-Zon Liu, Consultant Professor in Translational Research Laboratory, Cancer Center, Taipei Medical University, presented "The potential impact of hydrogen as a preventive and therapeutic medical gas."



" Following the symposium, a student's research poster contest was also held. Overall, the two-day conference was very successful and truly an enjoyable academic gathering for the attending members of CACB.

CACB is actively communicating and collaborating with other scientific societies in Taiwan. On 4 Nov 2015, with support of MSACL, CACB and Department of Laboratory Medicine of Chang-Gung Memorial Hospital jointly host a symposium of 'Application of Mass Spectrometry in Clinical Diagnosis' at Linkou. The symposium was chaired by Dr. David Herold, UCSD. The speakers and titles of the talk include: 'From prediabetes to diabetic complications: what metabolomics can tell' by Dr. Ming-Shi Shiao, Chang-Gung U.; 'Advancing Alzheimer disease diagnostics using mass spectrometry' by Dr. Mari L. DeMarco, U. British Columbia; 'A mass spectrometry toolbox for measuring immunoglobulins' by Dr. John R. Mills, Mayo Clinic; and ' Clinical quality control for multiplex assays' by Dr. Stephen R. Master; Weill Cornell MC. The symposium was attended by more than 50 CACB members and students.



Dr. Fang at welcome dinner with MSACL Board Chair Dr. David Herold and CACB symposium speakers of 'Application of Mass Spectrometry in Clinical Diagnosis' at Linkou, Taiwan (5 Nov 2015). MSACL will sponsor Mass Spec Symposia series containing six symposia and one plenary lecture in APFCB Congress 2016.

Promotion and preparation of APFCB Congress 2016, Taipei, Taiwan 26-29 November 2016.



Dr. Morris, Dr. Zhang, Dr. Koch, Dr. Fang, Dr. Wang, and Dr. Jones at the 12th Chinese Conference of Laboratory Medicine (Nanjing, 9-12 Sep 2015). Dr. Graham Jones (the rightmost) is a plenary lecture speaker in APFCB Congress 2016. Dr. Yan Victoria Zhang is the President of North American Chinese Clinical Chemists Association (NACCCA) and NACCCA will sponsor a symposium in APFCB Congress 2016. Dr. Koch, is the President of American Association for Clinical Chemistry (AACC) and AACC will sponsor a symposium in APFCB Congress 2016.



Dr. Fang with Dr. Pan, BaiShen, the President of Chinese Society of Laboratory Medicine (CLSM), EB members of CLSM and delegates from Taiwan, Hong Kong and Macao at the 12th Chinese Conference of Laboratory Medicine (Nanjing, 9-12 Sep 2015). CLSM will sponsor a symposium in APFCB Congress 2016.



APFCB President Dr. Lai and C-CC Chair Dr. Lopez visit Taipei (24 Oct 2015) for the inspection of APFCB Congress 2016 preparation.

Progress report of APFCB Congress 2016

APFCB President Leslie Lai and Dr. Joseph Lopez, Chair, APFCB C-CC met the Organizing Committee on Saturday 24 Oct to discuss the progress of preparations for the 14th APFCB Congress to be held from 26th-29th November 2016, in Taipei. The meeting was presented by Prof. Woei-horng Fang, Chair of the Congress Organizing Committee (COC), Prof. Shu-Chu Shiesh, Chair, Scientific Organizing Committee (SOC) and other colleagues from the COC. Also present were representatives from the professional conference organizer (PCO). The EB representatives considered overall preparations appear to be on course.



The following are some key points of the progress:

1. Scientific Program:

- a. There are 4 plenary lectures and 24 Symposia have been arranged and the speakers and titles are in place.
- b. We invited Dr. Kuo, Director-General of Centres for Disease Control Taiwan, as Keynote speaker with the talk Title: "Laboratory Medicine in Cloud."
- c. The abstracts submission system was opened in December 2015 and closing date is 31 May 2016.
- d. APFCB Travelling Lecturer Dr. Graham Jones is invited to be one of the plenary speakers.
- e. Some APFCB national societies have not yet confirmed the themes of their talks and speakers and we are actively tracking them and reserve some rooms for last addition of symposium.

- 2. Taiwan Society of Laboratory Medicine (TSLM):** accepted our invitation to include their annual conference as a satellite meeting of the APFCB Congress. The time frame of this satellite meeting will be on 26th-27th, November with a title of "Asia-Pacific Chinese Conference of Clinical Biochemistry and Laboratory Medicine" and mandarin Chinese will be used in this conference. This satellite meeting is expected to attract more participants from China, Hong Kong, Macao, as well as a bulk of local medical technologists. An effort is being made to attract the local clinical pathologists to participate in the congress.

- 3. Centre (TICC):** The entire building of the TICC is available for the period of the APFCB Congress. The trade exhibition will be held at the Taiwan World Trade Centre which is just across the road from the TICC. The TICC, TWTC and the Grand Hyatt are all within the vicinity of the iconic 101 Building and within walking distance of each other and metro stations.

4. Professional Conference Organizer (PCO):

- a. The local Enjoy-PCO will act as the congress's contact point. It manage everything such as registration, communication with speakers and participants, accommodation arrangements, etc.

5. Social:

- a. The reception for the opening will be held at the TICC.
- b. Packed lunch will be provided to all registered participants on each day of the congress
- c. The congress banquet to held at the Grand Hyatt hotel will be open to all registered participants. This venue can hold 800 guests.

6. Promotions:

- a. The official web-site <http://www.apfcbcongress2016.org/> will be progressively updated.
- b. It will be used for registrations and submission of abstracts.
- c. A major promotional effort will be made at the IFCC General Conference in Madrid.

We are ready to provide venues for meetings of the APFCB EB and committees, and the IFCC and its Divisions, Committees if requested and other joint meetings (e.g. APFCB-IFCC; APFCB-WASPaLM) that are held in conjunction with the APFCB Congress.





Indonesian Association of Clinical Chemistry (IACC)

Laboratory Management & Quality Control Department

Preanalytical Seminar: Improving Preanalytical Quality in Patient with Specific Condition

Quality is a very fundamental element in a laboratory management system. In order to improve the quality and to ensure the accuracy of laboratory results, a comprehensive process of laboratory testing must be monitored and evaluated continuously.

A laboratory should be able to identify the source of error, whether the source was in pre analytical, analytical, or post analytical phase, the errors could be corrected and prevented accordingly.

General opinion assumed that the errors in a laboratory mostly happened in the analytical phase, which is considered as the most complex phase in a laboratory process. Therefore special approach has been focused on this phase, for example by the involvement in several quality assurance programmes. In addition to this approach, an evolution in the technology of laboratory instrumentation and automation also has resulted in a significant improvement in accuracy, precision, and overall laboratory performance.

On the other hand, it is difficult to detect and correct error in the pre analytical phase. The corrective action is focused by doing some preventive measures. In order to improve the quality of pre analytical phase, Indonesian Association of Clinical Chemistry (IACC) has collaborated with Becton Dickinson to perform a pre analytical survey program which is known as "May I Help You Campaign" (MIHYC) since 2011. This program has involved participants from 39 hospitals and laboratories from several areas in Indonesia and with more than 32 laboratories in waiting list due the lack of surveyor number.

Realizing the importance of pre analytical phase, IACC proudly organized a pre analytical seminar. In this event we discussed about several pre analytical issues which are often found in daily practice, such as specimen collection of neonates, pediatric, geriatric and cancer patients; pre analytical phase for blood gas and electrolytes analysis and special handling of sample from patients with diseases which causing abnormality to sample. We promoted MIHYC program and shared participants' testimonies in a mini presentation to give a better image of the benefits of this programme to all participants. More than 180 participants coming from more than 12 cities in Indonesia attended this seminar discussing the importance of preanalytical phase in Laboratory Medicine. The responses from the audience were beyond our expectation. Based on the feedback from the participants, they found the information very valuable and expected IACC to conduct this kind of seminar in several cities in their provinces in order to raise up the awareness of Laboratory Medicine stakeholders in the marketplace.



Session I (Moderator: dr. July Kumalawati, SpPK(K)) Specimen collection and sample handling in special cases	
Specimen collection in neonates and pediatric patients (dr. Nuri Dyah I, SpPK)	Specimen collection in neonates, pediatric, geriatric and cancer patients.
Specimen collection in geriatric and cancer patient (dr. Lyana Setiawan, SpPK)	
Session II (Moderator: dr. July Kumalawati, Sp PK(K)) Pre-analytical for electrolyte and blood gas test	
Update of pre-analytical for electrolyte and blood gas analysis (dr. Stefanus Lembar, SpPK)	<ul style="list-style-type: none">- Anticoagulant for electrolyte and blood gas analysis- Specimen collection (arterial, vein, mix-vein)- Transportation of sample- The effect of sample type (plasma vs serum) on the result of electrolytes test, especially potassium
Session III May I Help You Campaign Program: for better Preanalytical phase QC	
MIHYC program and implementation - dr. Tjan Sian Hwa, M.Sc, SpPK - dr. Samiha Salida Hamedan MARS	<ul style="list-style-type: none">- Introduction of program- The implementation of MIHYC, the advantages and the problems
Testimony from MIHYC participants - Dr. Ninik Sukartini SpPK the head of Laboratory Medicine of Ciptomangunkusumo Hospital Jakarta - Hendra Apt Head of Pramita Laboratory Jakarta	<i>Sharing the benefit of MIHYC</i>
Session IV (Moderator: dr. July Kumalawati, SpPK(K)) Handling of problematic samples due to patient's disease	
Special handling of problematic samples due to preanalytical factors and patient's disease for hematology and coagulation test (dr. Anggraini I. Winardi, SpPK)	<ul style="list-style-type: none">- Preanalytical factors that influence the quality of the sample- Patient condition/ disease that can influence the quality of the sample- How to handle problematic samples for hematology and coagulation testing, such as sample with hemagglutination, platelet clumping, lipemic, icteric, hemolysis, and easily clotting citrate plasma, etc
Special handling of samples with problem due to preanalytical factors and patient's disease for chemistry and immunology analysis (dr. Anita Singh, MD, Pathology –India)	<ul style="list-style-type: none">- Preanalytical factors that influence the quality of the sample- Patient condition/ disease that can influence the quality of the sample- How to handle problematic samples for chemistry and immunology testing, such as serum which easily clots, serum which appear icteric, lipemic or haemolysis, etc



Dr. Tjan Sian Hwa SpPK., as Chairperson of Laboratory Management and Quality Control of IACC presenting the MIHYC Programme



a. SCIENTIFIC SEMINAR: CHALLENGES FOR QUALITY IMPROVEMENT

Due to address the feedback from our participants during preanalytic seminar which held in Jakarta, it was decided to have same topics in our scientific seminar in Makassar in 28-29 August 2015. As complementary, we have some topics for hemostasis and coagulation. Almost 400 participants were attended this event.

We opened the scientific seminar with the plenary lecture by dr. July Kumalawati SpPK (K), DMM., the president of IACC who presented her lecture topic "Increasing Quality Process and Result in Laboratory Medicine". She highlighted the importance of communication between internal and external laboratory people for better quality process and results in Laboratory Medicine. This It was followed by the panel discussion on hemostasis. Prof. Dr. Mansyur Arief SpPK., Clinical Pathologist from Hasanuddin University Makassar was spoke about the importance of preanalytic variables in hemostasis interpretation and followed by dr. Tutik Harijanti SpPD., KHOM., Internist and Hematology - Oncology Medic Specialist from Hasanuddin University Makassar who spoke on Diagnosis and Management of Deep Vein Thrombosis and Pulmonary Embolism.

The president of IACC dr. July Kumalawati SpPK(K), DMM., lead the meeting discussion during 13th Working Congress of IACC





President of IACC opened 13th Work Conference and Scientific Seminar accompanied by dr. Darwati Muhadi SpPK the Chairman of Organizing Committee, Prof. Mansyur Arief, SpPK the Head of Clinical Pathology Department of Hasanuddin University Makassar and dr. Agus. A. Abdullah SpPK as the Head of Indonesian Association for Clinical Pathologist and Laboratory Medicine (IACP) Chapter Makassar.



Participants of 13th Work Conference and Scientific Seminar IACC

Right after panel discussion, two parallel workshops on Lean Management and Workflow Analysis sponsored by Roche Diagnostic and Six Sigma-metric laboratory quality management sponsored by Abbott Diagnostic were held.



Participants cheerfully taken a picture together after Workshop on Lean Management and Work flow Analysis.

On the second day, we had same topics for preanalytic seminar which held in Jakarta previously. We also keep promote MIHYC programme for all participants which come from eastern part of Indonesia.



Dr. Yenny Surjawan SpPK PhD., Dr. Noventy Febrina Msi, dr. Samiha S., MARS, Dr. Tjan Sian Hwa SpPK and Dr. MI.Dyah SpPK during MIHYC Symposium during 13th Work Conference & Scientific Seminar IACC.

In order to support Young Scientist Community in Indonesia in this event, IACC delightfully granted award for three participants for Oral Poster Presentation as follow:

1. Dr. Sheilla Febriana, Hasanuddin University Makassar
2. Miftakh Nur Rahman, Prodia Laboratory Jakarta
3. Dr. Yesi, Andalas University Padang

During the 13th Work Conference and Scientific Seminar IACC, we had trade exhibition from some diagnostics companies and their distributors in Indonesia.



Dr. Darwati Muhadi SpPK as the chairwoman of 13th Work Conference and Scientific Seminar together with dr. July Kumalawati SpPK (K), DMM., opened the trade exhibition.

3. IACC co-hosted APFCB Beckman Coulter Scientific Symposium

The new collaborative initiative between APFCB and Beckman Coulter, the scientific symposium held in Double Tree Hotel Jakarta in October 10th, 2015 and attended by around 100 IACC members.



Dra. Endang Hoyaranda lead the panel discussion on Laboratory Management for Tomorrow with Associate Professor Sunil Sethi (Singapore), Dr. July Kumalawati Sp PK(K), DMM (Indonesia) and Jack Zawoski PhD FACB (USA).



Japan Society of Clinical Chemistry (JSCC)

The 55th Conference of the Japan Society of Clinical Chemistry

Yoshinori Iwatani, MD, PhD
Professor of Biomedical Informatics (Preventive Medicine),
Division of Health Sciences,
Osaka University Graduate School of Medicine

We held the 55th Annual Academic Conference of the Japan Society of Clinical Chemistry (JSCC) in the Convention Center of Osaka University, Suita City, Osaka Prefecture from October 30th to November 1st, 2015. We made “Opening the way to the future of Clinical Chemistry” the main theme of the Conference.



The distinctive feature of the Conference was to promote young fellows to the chairs of research presentations in order to increase the admission of young researchers and to rejuvenate JSCC. To select them, we asked the councilors of the Society to recommend the young fellows who will be expected to become the central figures of JSCC. After all that, more than 630 people participated in the Conference, and above all, young participants increased considerably. Furthermore, the number of oral presentations by participants was 114 and reached a record high. We prepared 2 special lectures, 4 educational lectures, 6 symposiums, 1 workshop, 7 project reports, 10 sponsored luncheon and evening seminars, and 1 presidential address. One of special lectures was about the future of laboratory diagnostics and was presented by Prof. Kiyoshi Ichihara, Yamaguchi University, and another was about omics sciences and was given by Dr. Yoshihide Hayashizaki, Advisor to the President of RIKEN. Four educational lectures were pertaining to metabolomics (by Prof. Eiichiro Fukuzaki), microRNA (Prof. Yukio Kawahara), big data analysis (Dr. Jun Sese), and lipid metabolism (Prof. Shinji Kihara).

The symposium's six themes were the future of clinical chemistry, the safety evaluation of drugs, preventive healthcare and bio bank, young researchers, mass spectrometry, and the development of human resources in genomic medicine.

A workshop of the Clinical Chemistry Academy was held on the analysis of routine laboratory test abnormalities. Project reports were conducted by 7 expert committees for quality management, nutrition, lipoprotein test, POCT, plasma protein, laboratory system, and test reagent.



The contents of sponsored luncheon and evening seminars were about an index of blood sugar control, early diagnostics of pancreatic cancer, zinc signaling, KL-6: diagnostic marker for interstitial pneumonia, *Helicobacter Pylori* infection and gastric cancer, the significance of laboratory tests, reference interval, diagnostics of hepatoma, urine NGAL, and cardio-renal syndromes. Lastly, I presented about preventive diagnostics, which is the genome and epigenome diagnostics for predicting and preventing the development of diseases, in presidential address.

During the Conference, we were able to feel great potential of clinical chemistry and JSCC in medicine and health sciences in the 21st century. Finally, we would like to express our sincere appreciation to all of the members who offered cooperation in the planning and management of the events, as well as to the sponsors for their understanding the concept of the Conference.





Korean Society of Clinical Chemistry Annual Report Of 2015 (KSCC)

National Meetings		
Name of the Meeting	Date	Topic
Annual Meeting of KSCC (I)	2015. 5.14.	Symposium 1; Comparisons and suggestions about procedure manuals of clinical chemistry laboratory
		Symposium 2; Research highlights
		Symposium 3; Recent advances in hormonal testings
		Symposium 4; Industry workshop (New tests in the field of clinical chemistry)
Quality Assurance Workshop	2015. 10. 30.	Quality Assurance workshop for neonatal screening tests
Annual Meeting of KSCC (II)	2015. 10. 30.	Symposium 1; The basic requirements of accredited laboratory
		Symposium 2; Health insurance benefit standard – about clinical chemistry tests
		Symposium 3; Introductions for updated homepage of KSCC
		Symposium 4; Industry workshop (New tests in the field of clinical chemistry)
		Symposium 5; CLSI guidelines applied to clinical chemistry

- Procedure manuals of clinical chemistry laboratory
- Hormonal testings
- Neonatal screening tests
- The basic requirements of accredited laboratory
- Health insurance benefit standard – about clinical chemistry tests
- New tests in clinical chemistry
- CLSI guidelines applied to clinical chemistry

International Relations

- Attended 'Euromed Lab Paris 2015' and promoted the 'IFCC World Lab Seoul 2020' to the participants of the Congress
- Working APFCB committee members (2016)
 - Pf. Yong Hwa Lee for the education and laboratory management committee
 - Pf. Hwan Sub Lim for the communications committee
- IFCC Network Laboratory for HbA1c in Korea (2012 - present)
- Pf. Junghan Song was working as a member of the 'International Scientific Advisory Board of IFCC World Lab Durban 2017'
- Pf. Hyung-Doo Park was working as a member of the 'IFCC C-STFT (Standardization of FT4 and Harmonization of TSH Measurement)'
- Dr. Eun-Hee Lee participated the 'AACC ICHCLR Council meeting and HOG of 2015'



Additional Information

- IFCC Network Laboratory for HbA1c in Korea (2012-present)

Current Officer Bearer of KSCC (2015-2016)

- **President:** Pf. Gye Cheol Kwon (Chungnam National University College of Medicine)
- **New Secretary General :** Pf. Sang-Hoon Song (Seoul University College of Medicine)
- **Treasurer:** Pf. Hwan Sub Lim (Yonsei University College of Medicine)
- **International Committee:** Dr. Sung Eun Cho (Lab Genomics Clinical Laboratories)



Macao Laboratory Medicine Association (MLMA)

The AGM of Macao Laboratory Medicine Association was held on March 21st with scientific seminars. Four well-known speakers from Mainland China and Hong Kong were invited to deliver different seminar topics in clinical laboratory sciences. Their presentations cover wide variety topics in molecular biology “molecular diagnostic in different age population and personalized medical care”, biochemistry “The usage of 2 serum protein markers for bone metastasis—total PINP and Beta CTx ”, “Effective Blood Center and hospital blood bank inventory system” of blood banking and “Ebola virus nucleic acid testing in Africa wildlife condition” for virology. Over a hundred colleagues from laboratory medicine participated for seminars and discussions.



In May 21st to 24th, MLMA has travelled to Seoul, Korea for exchange visiting trip. We have visited Korean Red Cross Blood Service for their general blood donation service, blood preparation, supply division and the lab. Besides, the tour visit EONE reference laboratory for their lab automation system. MLMA also visited Shinchon Severance Hospital and RDK office.



Community Activity Day was held on October 24th in order to promote residence attention on personnel health issues and the importance of lab medicine. There were booths of point-of-care for blood pressure, blood glucose monitoring. Moreover, blood donation service was introduced to encourage residence to donate blood. Parasite specimens were shown to promote personnel hygiene practice. Allergy testing and liquid base cytology for gynecology were also presented to raise residence health awareness.



Mongolian Association of Health Laboratorians (MAHL)

1. The Mongolian Association of Health Laboratorians held its first convention on March 12th, 2015 in Ulaanbaatar city. 166 lab doctors and lab technicians participated the convention during which the following activities were carried-out:
 - Presentation of past activities of MAHL, followed by Q&A.
 - Presentation, discussion and approval of planned medium-term activities of MAHL.
 - Election of the Governing board and President of the Association. (Prof. Ts. Enkhjargal was re-elected as President of MAHL).



2. MAHL organized the 1st Scientific Conference of lab technicians which took place on May 15, 2015. Sixty eight lab technicians participated the conference, and 14 papers were presented out of which three papers were selected for the Excellence award.



3. The professional journal “Health laboratory” published by MAHL was accepted as a member of the Western Pacific Region Index Medicus (WPRIM).
4. The following trainings were organized by MAHL in 2015:
 - One-day training on laboratory quality (May 22, 69 participants).
 - One-day training for lab technicians on pre-analytical quality (September 09, 61 participants).
 - One-day training for lab doctors and technologists on reference values (September 24, 37 participants).
 - One-day training for lab doctors and technologists on clinical lab standardization (October 09, 170 participants).
 - One-day training for lab technicians on best practices for laboratory procedures (November 27, 72 participants).
5. MAHL assisted the Joint health reference laboratory of the Ministry of Health, Mongolia, in developing its plan of actions for 2016-2020.





Singapore Association of Clinical Biochemists (SACB)

Singapore Association of Clinical Biochemists (SACB) started 2015 activities with their Annual Scientific Meeting (ASM) on Saturday 28th March 2015 at Hotel Jen Tanglin, Singapore. It coincided the mourning week of the late Mr. Lee Kuan Yew, Founding father of Singapore.

The one-day ASM was packed with 9 lectures supported by the diagnostic industry and well attended by 143 participants and speakers. Associate Professor Sunil Sethi, President of SACB, welcomed the attendees and led a one minute silence in memory of Mr Lee Kuan Yew.

The first lecture was given by Dr Graham Jones, Sydpath St. Vincents Pathology, Australia, speaking on "Chronic Kidney Disease - the Role of the Routine Laboratory" describing 5 stages of chronic kidney disease which range from Stage 1 normal with GFR ≥ 90 ml/min/1.73m² to stage 5 kidney failure with GFR at < 15 ml/min/1.73m². Chronic kidney disease being defined as either kidney damage or GFR < 60 ml/min/1.73m² for ≥ 3 months. Low eGFR (calculated from MRD equation) and raised urine albumin values are markers for death, cardiovascular disease, end-stage kidney disease and acute kidney injury.

Dr Jones also spoke on "Getting the Right Answer to Manage the Patient - the Importance of Traceability" that emphasized calibration hierarchy or the traceability chain of reference materials, reference methods and reference laboratories. Laboratories should choose methods which are traceable to good references (JCTLM listed), have low uncertainties for calibrators, minimize changes over time, select and promote unbiased comparators (eg. common decision points, reference intervals), and confirm performance with EQA and standards.

Raising the Laboratory's Standard of Quality, was presented by Dr Raja Elina Raja Aziddin, President Malaysian Association of Clinical Biochemists sharing her laboratory experience with internal QC practices. Using a combination of Westgard multi-rules and Sigma metric, 63.6 % of all analytes achieved ≥ 3.0 sigma. This attainment was translated into an annual cost saving of 58% from reducing waste and re-work. From the diagnostic market, Mrs. Jolanda Pelloli, International Product Manager from Roche Diagnostics spoke on LDL-C Direct Measurement – Don't Guess. Measure It! She shared the analytical performance of the assay and how LDL-C, Homocysteine, Lipoprotein (a) and hs CRP could form a risk prediction model. The Dr Lincoln Tan, Urology Consultant, Singapore, introduced Emerging Biomarkers in the Detection and Prognosis of Prostate Cancer by showing how the use of sensitivity and specificity of PSA is not a strong predictor of prostate cancer. However the rate of detection could be improved by using panels such as prostate health index (ϕ) = $\frac{[-2) \text{proPSA} \times \sqrt{t\text{PSA}/f\text{PSA}}]}$.

Lung Cancers Biomarkers by Dr Carlum Shiu, from Abbott Diagnostics Division, Singapore was our next presenter. He shared that tumour markers play three key roles in lung cancer: they can aid in the differential diagnosis between lung cancer and benign lung conditions; they can help differential between small cell (SCLC) and non-small cell lung cancer (NSCLC); and they can be used to determine efficiency of treatment or outcome. Useful tumour markers in lung cancer are CYFRA 21-I, CEA and SCC for NSCLC and ProGRP and NSE for SCLC.

Professor Dr Rosmawati Mohamed, Consultant Hepatologist from Malaysia shared her experience on the clinical application of enhanced liver fibrosis test (ELFTM) in the assessment of liver fibrosis discussing the clinical utility of the ELF test component assays, hyaluronic acid, procollagen III amino terminal peptide and tissue inhibitor of metalloproteinase I.



Together they generate an algorithm with an ELF score of <7.7 = no fibrosis and an ELF score >9.8 = fibrosis with recommendation of a liver work-up for further assessment of fibrosis. ELF Score has received AI recommendation from EASL 2015 guidelines on the management of chronic hepatitis.

Mr. Kevin Davies from Ortho-Clinical Diagnostics, Singapore spoke on Total Lab Automation, introducing concepts, streamline processes and enhance safety in laboratory practices.

Final lecture of the day was presented by Dr Irakli Jaliashvili Radiometer Medical, Denmark on acute care testing – clinical relevance of parameters. In addition to measurement of arterial blood gases, the Radiometer analyser is now able to measure whole blood bilirubin and foetal haemoglobin in an acute care environment for intrauterine haemolysis.

The Annual General Meeting was held at the end of the scientific programme. Members had a rewarding day with scientific updates and lots of catching up with friends. September saw the start of our popular Education Programme conducted by SACB which is now into its seventeenth year. Topics for this module included liver function tests, emerging global pandemic threats-how can the laboratory respond faster, thyroid function tests, renal function tests, reference intervals, ABO and Rh(D) testing and LIS and beyond. Early in October we jointly hosted with Bio-Rad Laboratories (Singapore) Pte Ltd, Mr. Sten Westgard from Westgard QC, USA on Setting new standards in the laboratory. This was a well attended dinner session highlighting six sigma metrics across the testing spectrum: achieving world class quality from A (lbumin) to V(iral load).



President, Prof Sethi, presenting our speakers with a token of our appreciation.



A Renaissance Man Shares His Life Experiences

By Joseph Lopez, Immediate Past President, APFCB and past IFCC Executive Board Member

Most successful people achieve recognition in one field of endeavour. Fewer achieve it in two. Rare, however, is the individual who has received success and recognition in three.

Such person is Dr. Tan It Koon, founder and past president of both the Singapore Association of Clinical Biochemists (SACB) and the APFCB. He was also an active council member of the Singapore Society of Pathology (SSP), Singapore National Institute of Chemistry and Federation of Asian & Oceanian Biochemistry (FAOB). Besides his pioneering contribution to the advancement of the practice of clinical biochemistry in Singapore and the Asia-Pacific region, he is an accomplished musician and a painter of international renown. He can truly be described as a renaissance man without any sense of hyperbole. Dr. Tan graduated with the BSc Honours (First Class) and PhD degrees from the University of Singapore (now known as the National University of Singapore, NUS). He was the first person in Singapore to receive formal training in Clinical Biochemistry.

He obtained the Mastership in Clinical Biochemistry (MCB) professional qualification in a newly introduced examination during his postdoctoral studies in the UK. Subsequently he also obtained Fellowship of the Royal College of Pathologists (FRCPath, London) and became a Fellow of the Academy of Clinical Biochemistry (FACB) in the USA. He then embarked on a long career at the Singapore General Hospital that spanned over 40 years. He has authored or co-authored more than 140 scientific papers on many aspects of clinical biochemistry and sat on the editorial boards of the profession's more renowned international journals. Dr. Tan has also taught in both the Science and Medical Faculties of the NUS and served as an examiner for MSc, PhD and MD candidates. During this time he was appointed to board and management positions in many local, regional and international professional bodies, including the Singapore Professional Centre and the Singapore National Science Council. Dr. Tan was elected a Member of the IFCC Executive Board. He was also appointed by the World Health Organization (WHO) as a Member of its Expert Panel on Health Laboratory, and a Member of its Committee on Biological Standardisation.

Dr. Tan was conferred two distinguished National Day Awards by the Government of Singapore, one for excellence in public administration and provision of a highly proficient clinical laboratory service, and another for his significant contributions to cultural and community development in Singapore. He received the SACB-Boehringer Mannheim and SSP-Becton Dickinson awards for significant contributions to the advancement of clinical biochemistry and pathology respectively. For initiating the series of APFCB Congresses, the APFCB News, education and collaborative research programs over more than 20 years, he received the inaugural Distinguished Service Award from the APFCB. A special distinguished service award was conferred by Becton Dickinson in recognition of his pioneering and continued efforts in raising the awareness of pre-analytical problems affecting the correctness and quality of patient testing results, through educational lectures and publications for countries in the Asian-Pacific region. Dr. Tan has been a practitioner and advocate of the arts since his school days.

He is an accomplished pianist, who has won several performance and composition competitions in Singapore and Malaysia. He championed the advancement of the arts in Singapore and has time and again sat on or helmed many national bodies, such as the National Theatre Trust, Singapore Cultural Foundation, Singapore Festival of Arts, Singapore Dance Theatre, Forum of Fine Art and the South-East Asia Art Association.





In addition to all this, Dr. Tan is an accomplished Chinese brush painter of renown. His talent has seen his works featured in major local and international exhibitions since 1971. His works have appeared on the covers of the APFCB News and featured in Clinical Chemistry. In February of this year Dr. Tan was invited by the alumni of the NUS to share his multi-dimensional life experiences in science, art and music with members of the alumni, the teaching staff, postgraduates and undergraduates. The objective of the event was to stimulate interest in the early development of interest, knowledge, skills or hobbies other that required for a specific profession or desired work, in order to enjoy a more interesting and fulfilling life, particularly after retirement from formal work. Undergraduates were encouraged to prepare for retirement even as they are just preparing to enter working life. Dr. Tan's presentation took just over 2 hours. He gave a lecture of one and a half hours using Power-Point slides to illustrate the oral presentation of his experience and show his works of art. This was followed by a piano recital by him that featured the works of renowned music composers such as Bach, Elgar, Schubert, Chopin, Grieg, Field, Joplin, among others. The recital was followed by a dinner. The NUS Museum is currently holding an exhibition of his works of art from March to August this year. July 2015



The Clinical Value of Assay Standardization and Traceability

Howard A. Morris

Howard A. Morris, School of Pharmacy and Medical Sciences, University of South Australia and Chemical Pathology Directorate, SA Pathology, Adelaide South Australia 5000 Australia

Why is traceability of clinical laboratory measurements important for the community?

The interpretation of clinical laboratory reports is increasingly dependent on guidance from internationally agreed clinical guidelines. An important example of this strategy is the diagnosis of hypercholesterolemia for estimating risk of coronary heart disease (CHD). The international application of these clinical guidelines provides important lessons for the current practice of laboratory medicine. CHD remains the leading cause of death worldwide with an estimated 17.5 million deaths in 2012 representing 31% of all global deaths. Evidence from population studies and randomized, controlled clinical trials demonstrate that lowering blood cholesterol reduces the risk of CHD (1). This knowledge prompted the establishment in 1985 of the National Cholesterol Education Program (NCEP) to reduce the prevalence of elevated blood cholesterol (1). Importantly the clinical data provided the foundation for the definition of critical target levels for blood cholesterol based on risk of CHD. A blood cholesterol level less than 200 mg/dL (5.2 mmol/L) was considered Desirable, between 200 to 239 mg/dL (5.2 to 6.2 mmol/L) was considered Borderline and levels greater than 240 mg/dL (6.2 mmol/L) were considered High.

The definition of these limits was accompanied by a widespread public health campaign for people to know their blood cholesterol level and to take action to lower their cholesterol if required. It immediately generated unprecedented attention on the performance and reliability of clinical laboratory testing indicating inadequate precision and accuracy of blood cholesterol assays. The NCEP adopted performance goals for assay precision of less than 3% and a bias within 3%. To meet these criteria it was necessary to develop a reference measurement system for the assay of blood cholesterol such that its measurement in each clinical laboratory was traceable to an international reference cholesterol standard. The establishment of important clinical outcomes including disease severity or even death at specific levels of an analyte is necessary for the use of biomarkers in clinical guidelines. The implementation of clinical guidelines requires clinical assays traceable to international reference materials such that every laboratory can obtain the same result on the same patient.

Development of a Reference Measurement System

The development of a reference measurement procedure for any analyte requires at least three components: a primary reference material, a primary reference method and a network of reference laboratories (2). For clinical measurements the analyte is most often in blood or a fraction of blood such as serum or plasma. This is a complex matrix and very often this matrix interferes with the assay. This interference is known as a lack of commutability. The commutability of all reference materials must be established by demonstrating that the values of the reference material and human serum/ plasma specimens for an analyte demonstrate an identical relationship across at least two assay methods (3). An effective method to overcome a commutability problem is to develop a secondary reference material in which the analyte is present in the matrix used for clinical assays such as serum.

For cholesterol the USA national metrology institute, National Institute of Science and Technology (NIST) has played a leading international role providing both primary and secondary reference materials and developing and performing a secondary reference method for cholesterol.

The primary reference material is purified cholesterol and secondary reference material is serum-based cholesterol while the primary reference method is isotope-dilution liquid chromatography-tandem mass spectrometry assay for cholesterol. As well the US Centers for Disease Control and Disease Prevention (CDC) in Atlanta, USA provide an alternative secondary reference method for cholesterol, the Abell-Kendall method and coordinates the network of reference laboratories (4).



Clearly it is not practical for each clinical laboratory to adopt a reference measurement system for each of their assays. The current strategy is to interact with the manufacturers of reagents and instruments to ensure that the calibrators provided to routine laboratories are traceable to a recognized international reference material. To assist the manufacturers to access recognised reference materials, reference procedures and networks of reference laboratories, the laboratory medicine profession through the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the metrology profession through the International Bureau of Weights and Measures (BIPM) formed the Joint Committee on Traceability in Laboratory Medicine (JCTLM). The JCTLM supervises three working groups, one to assess the suitability of candidate reference materials, a second to assess the suitability of candidate reference procedures and a third to assess the performance of reference laboratory networks. The JCTLM maintains databases for each of these activities providing an international source of information of materials and services for manufacturers or laboratories.

Initially this strategy was very successful as the limited number of major manufacturers collaborated strongly with the metrology institutes and professional bodies. However over the last 20 years a very large number of new manufacturers have entered the market particularly in China, India and South America. It is unclear whether they are adopting the principles of assay traceability to the level required for high quality laboratory medicine practice. The principles of metrology, accepted in so many other aspects of our life such as any purchase by its weight, have now been extended to laboratory medicine along with the resources for their international application. Clearly not all analytes are currently covered by these developments and most are chemical tests. Work is being undertaken to continuously expand the coverage and extend the application of metrology to hematology, microbiology and molecular pathology where appropriate. However it is a responsibility of everyone working in laboratory medicine to understand the traceability of their assays and to demand from their suppliers' information such as the international reference material to which their assays are traceable.

We also need to ensure that the reference material is appropriate for the clinical care of our patients. Consultation with the clinicians using their service regarding the clinical use of their testing and its application to international clinical guidelines is very useful here.



Therapeutic Drug Monitoring of Rifampicin & Isoniazid

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Rifampicin (Rif) and Isoniazid (Inh) are two most crucial drugs in the treatment of first line tuberculosis (TB) [1]. India ranks second in the world with about total 11% TB cases worldwide and being one of the major causes of mortality [2]. Therapeutic Drug Monitoring (TDM) is a routinely practiced clinical laboratory technique which aids the clinicians with a clear clinical judgment of the drug therapy and optimize the doses if necessary. Bioavailability and pharmacokinetics of drugs alter their plasma levels in the body. Several factors like age, weight, gender, doses and formulations, gastro-intestinal disorders, ethnicity etc alter the absorption and bioavailability of rifampicin thus altering the drug levels [1,3,4]. Low plasma levels of rifampicin may play a plausible role in slow response to therapy, treatment failure or relapse or acquired drug resistance.

Mechanism of action and Pharmacokinetics of both the drugs

Rifampicin: Rifampicin is a critical and potent component of first-line TB therapy having unique properties of a rapid onset action once in contact with *M. tuberculosis* [5]. Rifampicin inhibits bacterial DNA-dependent RNA synthesis by inhibiting bacterial DNA-dependent RNA polymerase. RNA synthesis is blocked due to inability of the phosphodiester bond formation in the RNA backbone, preventing extension of RNA products beyond a length of 2-3 nucleotides ("steric-occlusion" mechanism). Resistance to rifampicin arises from mutations that alter residues of the rifampicin binding site on RNA polymerase, resulting in decreased affinity for rifampicin. Resistant mutations map to the *rpoB* gene, encoding RNA polymerase beta subunit [6]. It is absorbed from the gastro-intestinal (GI) tract in an acidic condition and the rate of absorption is most variable amongst all TB drugs. Following an oral dose, the peak levels (time to attain maximum concentration – t_{max}) are attained within 2 hours however in cases of delayed absorption, t_{max} may be attained in 6 hours post dose. [1,4] The peak levels (C_{max}) and t_{max} are delayed in presence of high-fat meals, so the drug should be given on empty stomach whenever possible. Its absorption is fairly reduced in fixed dose combinations with isoniazid and pyrazinamide[3,7].

The half-life of rifampicin is 2- 3 hours [8]. Rifampicin induces its own hepatic metabolism and hence the C_{max} and t_{1/2} of rifampicin decrease over the first two weeks of therapy [5,7]. Therefore, patients on longer than 3 weeks of rifampicin levels tend to have lower rifampicin levels than their initial baseline values.

Isoniazid: Isoniazid is approved for latent and active tuberculosis infections. In active TB treatment, it is used in combination with other anti-TB medications to limit drug resistance. Isoniazid is a prodrug and must be activated by a bacterial catalase- peroxidase enzyme – KatG in the *Mycobacterium tuberculosis*. [9] KatG couples the isonicotinic acyl with NADH to form isonicotinic acyl-NADH complex. This complex inhibits the synthesis of mycolic acid, required for the mycobacterial cell wall via the InhA, an enoyl acyl carrier protein reductase. Isoniazid is bactericidal to rapidly dividing mycobacteria, but is bacteriostatic if the mycobacteria are slow-growing.

It is rapidly and completely absorbed from the GI tract after oral administration with a t_{max} within 1-2 hours [4]. It is widely distributed in the body and reaches therapeutic concentrations in serum, cerebrospinal fluid, and within caseous granulomas. Plasma half-life in adults is 1 to 4 hours, depending on metabolic rate. It is metabolized by a hepatic enzyme N-acetyl transferase (NAT2) via acetylation. Two forms of the enzyme are responsible for acetylation to form a major metabolite AcINH which has no anti-tubercular activity and is far less toxic than INH.



Formation and elimination of AclNH is genetically controlled, and hence its elimination profile is dependent on phenotype of acetylation i.e rapid, intermediate or slow acetylation [10]. The NAT2 acetylator phenotype can be inferred from NAT2 genotype (a combination of SNPs observed in a given individual) into rapid, intermediate, and slow acetylator phenotypes. Polymorphisms in NAT2 are also associated with higher incidences of cancer and drug toxicity [4]. Slow acetylation, which is transmitted as an auto somal recessive trait, increases the risk for peripheral neurotoxicity and hepatotoxicity in INH users. Study reports have shown the prevalence of NAT2 polymorphisms amongst Indians with ~ 55% slow acetylators, 32% intermediate & 13% rapid acetylators [11]. Also a high prevalence of slow acetylators is seen amongst Indian Muslims while fast acetylators amongst South Indians [12]. There are numerous reports available which show the influence of NAT2 genotype on isoniazid levels explaining the variability in plasma isoniazid levels seen in different populations [10-14]. The metabolites are excreted in the urine. Doses do not usually have to be adjusted in case of renal failure.

Drug – drug interactions play an important role in treatment regimen and hence need close monitoring. Isoniazid and rifampicin also exhibit a drug-drug interaction thus reducing rifampicin exposure / bioavailability in extended presence of isoniazid. Rifampicin on hydrolysis forms 3-formyl rifamycin which actively binds to isoniazid in a second order reaction to form isonicotinyl hydrazine. This hydrazine is an inactive compound thus reducing the bioavailability of rifampicin [15]. Thus dosing formulations should be closely monitored in patients on combinations doses.

Singh N, Dubey S, Chinnaraj S, Golani A, Maitra A. Study of NAT2 Gene Polymorphisms in an Indian Population. *Mol Diag Ther*. 2009;13(1):49-58

1. Lakkakula S, Mohan Pathapati R, Chaubey G, Munirajan A, Lakkakula B, Maram R. NAT2 genetic variations among South Indian populations. *Hum Gen Variation*. 2014;1:14014
2. Zabost A, Brzezińska S, Kozińska M, Błachnio M, Jagodziński J, Zwolska Z et al. Correlation of N-Acetyltransferase 2 Genotype with Isoniazid Acetylation in Polish Tuberculosis Patients. *BioMed Research International*. 2013;2013:1-5.
3. Kinzig-Schippers M, Tomalik-Scharte D, Jetter A, Scheidel B, Jakob V, Rodamer M et al. Should We Use N-Acetyltransferase Type 2 Genotyping To Personalize Isoniazid Doses?. *Antimicrobial Agents and Chemotherapy*. 2005;49(5):1733-1738.
4. Singh S, Marriapan T.T, Sharda N, Kumar S, Chakraborti A. The Reason for an increase in Decomposition of Rifampicin in the presence of isoniazid under acid conditions. *Pharm Pharmacol Commun* 2000, 6, 405-410.
5. Van Crevel R, Alisjahbana B, de Lange WC, Borst F, Danusantoso H, van der Meer JW, Burger D, Nelwan RH. Low plasma concentrations of rifampicin in tuberculosis patients in Indonesia. *Int J Tuberc Lung Dis*. 2002;6(6):497-502.
6. Fahimi F, Tabarsi P, Kobarfard F, Bozorg B, Goodarzi A, Dastan F et al. Isoniazid, rifampicin and pyrazinamide plasma concentrations 2 and 6 h post dose in patients with pulmonary tuberculosis. *Int J Tuberc Lung Dis*. 2013;17(12):1602-1606.
7. Abou-Auda HS (2014) Possible Interethnic Differences in Rifampin Pharmacokinetics: Comparison of Middle Eastern Arabs With Other Populations. *Adv Tech Biol Med* 2014; 1:112. doi: 10.4172/atbm.1000112
8. Prahl J, Johansen I, Cohen A, Frimodt-Moller N, Andersen A. Clinical significance of 2 h plasma concentrations of first-line anti-tuberculosis drugs: a prospective observational study. *Journal of Antimicrobial Chemotherapy*. 2014; 69(10):2841-7.
9. Um S-W, Lee S-W, Kwon S.Y, Yoon H.I., Park K.U, Song J et al. Low serum concentrations of anti-tuberculosis drugs and determinants of their serum levels. *Int J Tuber Lung Dis* 2011;11(9):972-978



10. Babalik A, Ulus I, Bakirci N, Kuyucu T, Arpag H, Dagylidiz L et al. Pharmacokinetics and serum concentrations of antimycobacterial drugs in adult Turkish patients. *The International Journal of Tuberculosis and Lung Disease*. 2013;17(11):1442-1447.
11. P. K. Chawla, R. V. Lokhande, P. R. Naik, A. J. Dherai, R. A. Amale, Z. F. Udwadia, A. A. Mahashur, R. Soman, T. F. Ashavaid. Therapeutic Drug Monitoring of Rifampicin and Isoniazid: An Indian Perspective. *Ind J Clin Biochem* 2015;30 (Suppl 1): S114-S115
12. Gurumurthy P, Ramachandran G, Hemanth Kumar A, Rajasekaran S, Padmapriyadarsini C, Swaminathan S et al. Decreased Bioavailability of Rifampin and Other Antituberculosis Drugs in Patients with Advanced Human Immunodeficiency Virus Disease. *Antimicrobial Agents and Chemotherapy*. 2004;48(11):4473-4475.
13. Arya A, Roy V, Lomash A, Kapoor S, Khanna A, Rangari G. Rifampicin pharmacokinetics in children under the Revised National Tuberculosis Control Programme, India, 2009. *Int J Tuberc Lung Dis*. 2015;19(4):440-445.
14. Mukherjee A, Velpandian T, Singla M, Kanhiya K, Kabra S, Lodha R. Pharmacokinetics of isoniazid, rifampicin, pyrazinamide and ethambutol in Indian children. *BMC Infect Dis*. 2015;15(1).



BOOK REVIEW

CLINICAL CASES IN LABORATORY MEDICINE

Jane French, Beverly Harris and William Marshall

Published by ACB Venture Publications, Oct 2014 (a publication of the Association of Clinical Biochemists, UK), 194 pages, ISBN 978-0-902429-56-7, EAN 9780902429567

Traditionally, the laboratory has produced results with reference intervals to guide interpretation. The pathophysiological interpretation has been mostly left to the attending doctor and there is no mandatory requirement for comments on results, even for the abnormal ones. Increasingly, however, the laboratories now append a comment to results when it is felt that this would help. This practice adds value to the result. While there is some evidence that comments have an impact on patient-care (1, 2), there have been very few studies of its value and clearly more are required.

It is important that comments should reflect accepted practice and current knowledge and guidelines. Often, they do not. Indeed, there is a perception that there is much room for improvement as seen from the responses in QA programmes on result commentary. It has been of concern that a large proportion of comments seen in these in QAPs were considered to be inappropriate and even misleading (3).

Therefore, CLINICAL CASES IN LABORATORY MEDICINE is a book whose time has come since there are hardly any books purely dedicated to the interpretative commentary of results in clinical chemistry. It contains 80 cases largely drawn from the UKNEQAS for Interpretative Comments. A list of reference intervals for the common analytes (intervals for the uncommon analytes are given where appropriate in the individual cases) and references for each scenario are provided in the appendices.

While many of the cases are straightforward, some of them have esoteric diagnoses. The format of the book consists of a short scenario for each case, followed by a set of laboratory data. There follows a question or questions designed to encourage the reader to consider the information from the perspective of the requesting clinician and then provide comment on the appropriate course of action to take. One of the authors has previously said that a good comment, should aim to answer the enquiring doctor's stated or implied question, indicate the possible significance of the results and perhaps suggest a response such as further investigation or referral (4).

While each case in the book begins on a fresh page, it is often much less than a page in length. This format has meant that a lot of space is wasted on the page containing the case description. The case commentary is given on the reverse page. Presumably this is to discourage the reader from falling to the temptation of reading the discussion before trying to figure it out. The commentary contains issues raised by the case together with options for further investigations and management of the patient and key learning points, all squeezed into a single page. The need to cram the commentary into a single page has resulted in a smaller sized font being used to accommodate it into a single page. It would have been better if the same font size was used throughout the book and the commentary simply followed the case presentation without any waste of space.

This book is yet again another contribution from that excellent series of publications of the ACB. Besides the practicing clinical biochemist, it will be useful to anyone involved with clinical biochemistry, including undergraduate or postgraduate students.



While a wide range of cases is presented, almost all are based on clinical problems. However, unusual results can sometimes occur due to problems in the pre-analytical phase of testing. It is hoped that the authors will present in future editions scenarios that address problems in this important part of laboratory investigation.

Joseph Lopez
Kuala Lumpur, Malaysia.

References

1. Kilpatrick ES. Can the addition of interpretative comments to laboratory reports influence outcome? An example involving patients taking thyroxine. *Ann ClinBiochem* 2004; 41: 227–229.
2. Bell DA, Bender R, Hooper AJ, McMahon J, et al. Impact of interpretative commenting on lipid profiles in people at high risk of familial hypercholesterolaemia. *ClinChimActa* 2013; 422: 21–25.
3. Lim EM, Sikaris KA, Gill J, Calleja J, et al. Quality Assessment of Interpretative Commenting in Clinical Chemistry. *ClinChem* 2004; 50:3 632– 637.
4. Marshall W. Read the Question Carefully Before You Write Your Answer! *ACB News* Issue 576. April 2011

(The above book review was first published in the November 2015 issue of the eJIFCC and is reproduced here with the kind permission of its Editor-in-Chief Professor GL Kovacs)



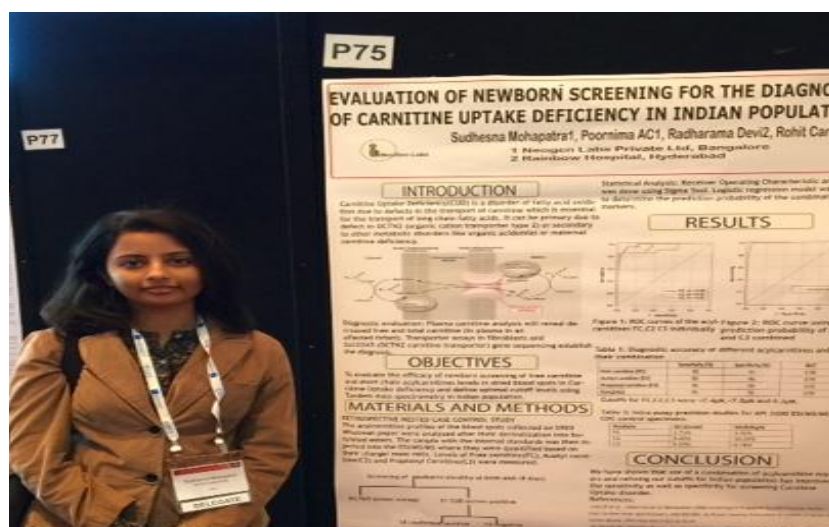
APFCB Travel Award- 53rd Annual Scientific AACB Conference

Travel Award Report

It's with great pleasure that I write this letter to thank the committee members of APFCB for bestowing the 'APFCB Travel Award', which enabled me to attend the Annual AACB conference in Sydney.



Personally, it was an enriching experience to meet fellow biochemists, and witness the repertoire of work in the field of Clinical Biochemistry. I enjoyed every aspect of the conference. All the symposiums were engaging. I was literally rushing from one room to the other in order to attend the best of the concurrent sessions. Core biochemical concepts like diabetic hyper lipidemia, metabolic bone disease and pheochromocytomas were reviewed and refreshed. The debate between A/Prof Graham Jones and Prof Richard MacLissac was a refreshing change in the normal proceedings. The focus on upcoming topics as evidenced by the good selection of 'hot topics' from the poster presentations and molecular advances was very enlightening. The QAP Clinical Cases discussion was an engrossing cheerful session for young biochemists like us, which I thoroughly enjoyed.

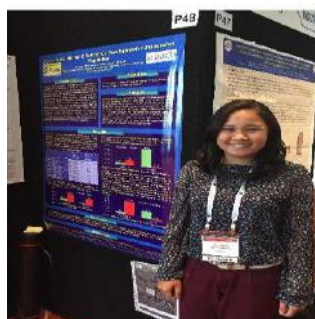


Socially, apart from the delicious cuisine and drinks, the friendliness of the delegates and professors was much appreciated. I made some new friends and caught up with old ones. We compared notes on prevailing laboratory conditions in different countries. These interactions have provided me with ideas to implement international best practices in local setups.

Finally, I thank AACB for the opportunity to showcase my work in the poster session. Looking forward to meeting everyone next time round.

By: Sudhesna Mohapatra

As my first travel grant, this opportunity is really important to me. Not only because I have to bring my poster here, but also this will be my chance to make my laboratory more well known in other country and to widen my networking as well. Since my laboratory is developing mass spectrometry recently, I learn much about mass spectrometry application in this conference and I met many experts in this field which are very welcome and with generously share their experience. Besides the presentation, I enjoyed the passport games and gala dinner as well. The committee knew really well how to be serious and have fun in the same time. I really had a good time in Sydney and would like to thank for APFCB, AACB and all the participants for this wonderful experiences. As Dr. Tina said in closing ceremony, I hope more scientists will encourage to join this program in the future and have good experiences like I did.



By: Jinia Lilianty



The Value of a Standardized and Certified Vitamin D Total Assay for Clinical Confidence

by Spears R, Parker N, Freeman J, Wilson K, Sibley P, Molinaro R. Siemens Healthcare Diagnostics Inc., Tarrytown, New York, USA

Abstract

Background: Vitamin D is a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. Standardization of vitamin D assays in laboratory medicine has become increasingly important. Apart from being able to assess the vitamin D status of an individual, standardization is necessary to accurately determine the concentration of vitamin D in patients on supplementation. The Siemens ADVIA Centaur® Vitamin D Total assay has been standardized to the University of Ghent ID-LC/MS/MS reference measurement procedure (RMP) and has achieved the Centres for Disease Control (CDC) Vitamin D Standardization Certification (VDSCP). Assay performance has been assessed in patient samples and compared to a VDSCP-certified LC-MS/MS assay. In addition, samples containing 25(OH)vitamin D2 and 25(OH)vitamin D3 were included in the study to demonstrate the ability of the assay to measure both forms of 25(OH)vitamin D and also to demonstrate the equimolarity of the test.

Method: A comparison between the ADVIA Centaur Vitamin D Total assay and the Endocrine Sciences Laboratory (LabCorp, Calabasas Hills, CA) VDSCP-certified 25(OH) vitamin D LC/MS/MS method was achieved by running 149 samples across the range of both methods. The samples were tested using the ADVIA Centaur Vitamin D Total assay and subsequently run on Lab Corp's VDSCP certified method. These data were analyzed with a Deming fit comparison plot as well as a Bland-Altman plot comparing the total vitamin D dose data between the two methods. both 25(OH)vitamin D2 and D3 and for samples containing 25(OH) vitamin D3 only in order to assess the assay's equimolarity.

Results: The data obtained showed good correlation between the ADVIA Centaur Vitamin D Total assay and the VDSCP-certified 25(OH) vitamin D LC/MS/MS method. The Deming fit comparison between the two methods yielded a Deming slope of 0.97, an intercept of 2.22 ng/mL, and a Pearson's coefficient of 0.95. When focusing specifically on the 55 samples containing 25(OH) vitamin D2, the Deming slope was 1.02, with an intercept of 1.92 ng/mL and a Pearson's coefficient of 0.93. When analyzing the 94 samples that contain only 25(OH) vitamin D3, the Deming slope was 0.95, with an intercept of 2.13 ng/mL and a Pearson's coefficient of 0.97.

Conclusions: In comparison to a VDSCP-certified 25(OH) vitamin D LC/MS/MS method, the ADVIA Centaur Vitamin D Total assay produced comparable results across the full range of the assay and was able to accurately measure both forms of 25(OH) vitamin D. These data indicate the importance of standardization to improve clinical confidence in the comparability of vitamin D measurement.

Method and Results

The ADVIA Centaur Vitamin D Total assay successfully passed the performance criterion for total 25(OH) vitamin D VDSCP certification. The performance specified for total 25(OH) vitamin D VDSCP includes a $\pm 5\%$ bias to the CDC and University of Ghent Vitamin D2 and D3 RMP and an overall imprecision of $\leq 10\%$ between 8.8 and 110 ng/mL. The Endocrine Sciences Laboratory (Esoterix, Endocrine Sciences, Calabasas Hills, CA) LC/MS/MS method has also been certified. It is important to evaluate patient samples similarly across platforms and locations, so in order to further evaluate the harmonization between different certified methods; a method comparison was performed between the ADVIA Centaur Vitamin D Total assay and the Endocrine Sciences Laboratory LC/MS/MS method.



Unknown patient samples were tested in singleton with one lot of reagent on the Siemens ADVIA Centaur Vitamin D Total assay. After testing, samples were selected across the range of the assay and sent to Lab Corp for further testing on their 25(OH)vitamin D LC/MS/MS method. The comparison of total vitamin D values between both methods is shown in Figure 1; the residual plot is shown in Figure 2. The Deming fit shows good alignment between the two methods, with a Deming slope of 0.97, intercept of 2.22 ng/mL, and a Pearson's coefficient of 0.95, as shown in Table 1. An Altman Bland bias plot that shows minimal bias was also generated for all samples tested across the range to demonstrate the correlation between methods, as shown in Figure 3.

Figure 1. Deming fit for the ADVIA Centaur Vitamin D Total assay dose versus the corresponding Endocrine Sciences Laboratory dose.

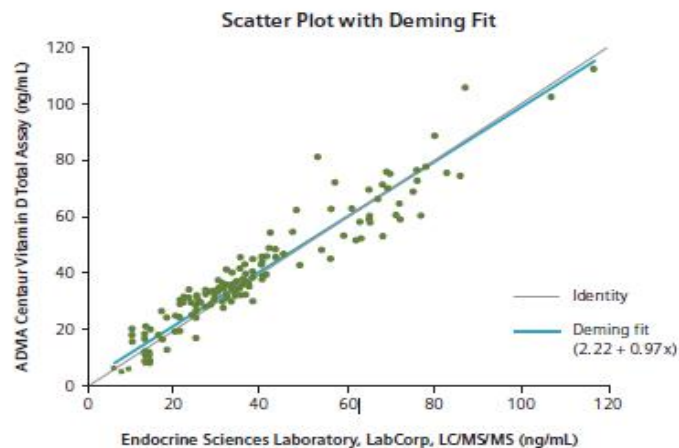


Figure 2. Residual plot between ADVIA Centaur Vitamin D Total assay versus the corresponding Endocrine Sciences Laboratory LC/MS/MS method.

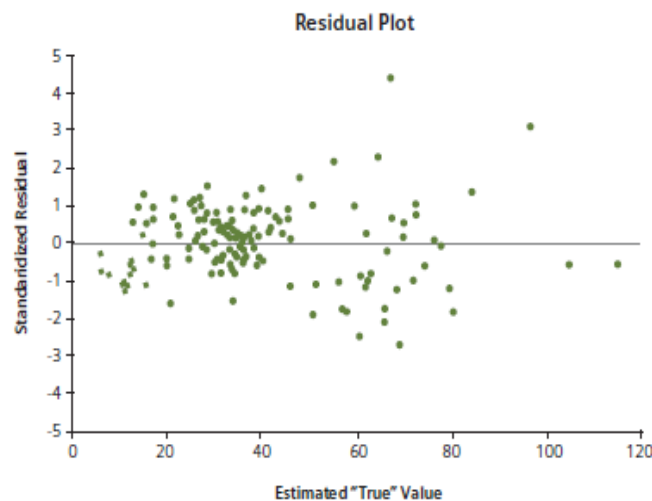
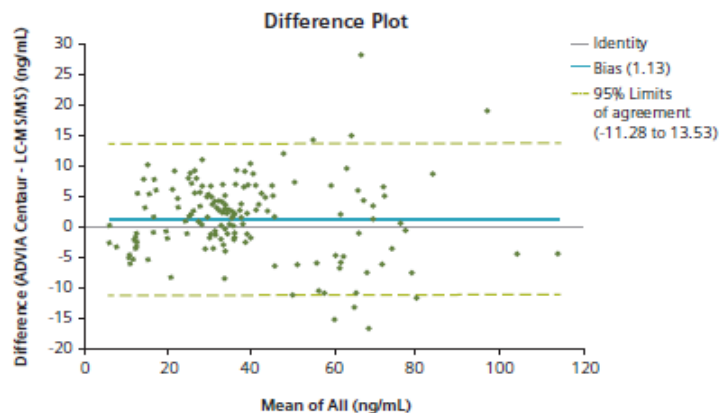


Figure 3. Altman Bland bias plot between all samples run on the ADVIA Centaur Vitamin D Total assay and Endocrine Sciences Laboratory LC/MS/MS method.



Two forms of vitamin D are metabolized in the body. Vitamin D₃ is found naturally in the body, derived from the irradiation of pro vitamin 7-dehydrocholesterol in the skin. Vitamin D₂ can be obtained through diet from sources such as fish and plants. These two forms of vitamin D are metabolized by the body to produce 25(OH)vitamin D₂ and 25(OH)vitamin D₃, both of which have similar biological activity. Since vitamin D₃ is the form that occurs naturally in the body, the normal population has more 25(OH) vitamin D₃ than 25(OH)vitamin D₂. However, patients who test low for vitamin D are advised to add a supplemental source of vitamin D to their diet, which can elevate either 25(OH) vitamin D₂ or 25(OH) vitamin D₃ levels. Since the two metabolite forms are biologically similar, it is important for an assay to detect both forms equally. The Endocrine Sciences Laboratory 25(OH) vitamin D method employs LC/MS/MS and can determine separate values for 25(OH) vitamin D₂ and 25(OH) vitamin D₃. Samples that contained 25(OH) vitamin D₂ when tested by the Endocrine Sciences Laboratory method were plotted against the ADVIA Centaur Vitamin D Total assay to ensure the assay's equimolarity and that there was no bias between the two forms. The comparison of samples containing vitamin D₂ between the two methods is shown in Figures 4 and 5, and the comparison of samples only containing vitamin D₃ is shown in Figures 7 and 8. An Altman Bland bias plot for the two forms can be seen in Figures 6 and 9, respectively.

Figure 4. Deming fit for the ADVIA Centaur Vitamin D Total Assay dose versus the corresponding Endocrine Sciences Laboratory dose for samples containing vitamin D₂.

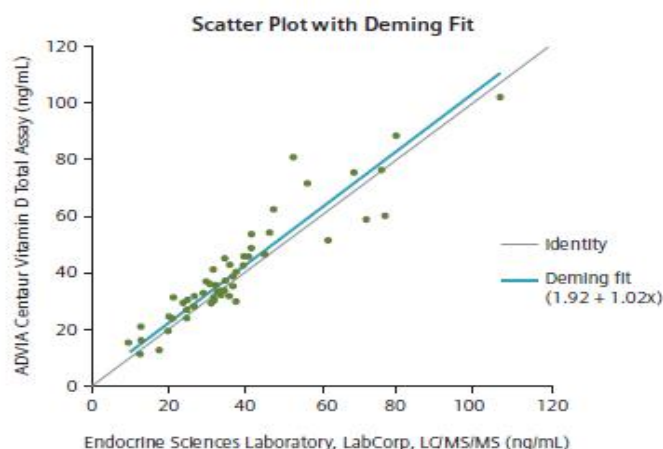


Figure 5. Residual plot for the ADVIA Centaur Vitamin D Total assay dose versus the corresponding Endocrine Sciences Laboratory dose for samples containing vitamin D2.

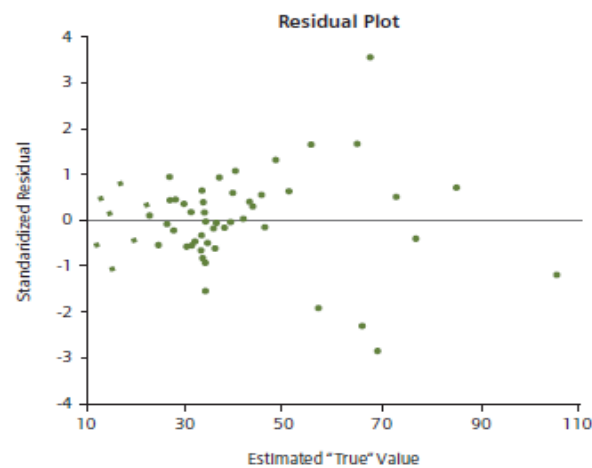


Figure 6. Altman Bland bias plot between vitamin D2 samples run on the ADVIA Centaur Vitamin D Total assay and Endocrine Sciences Laboratory 25(OH)vitamin D assay.

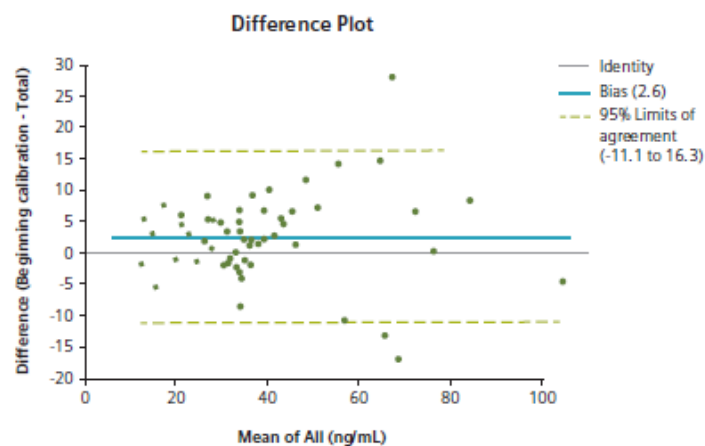


Figure 7. Deming fit for the ADVIA Centaur Vitamin D Total assay dose versus the corresponding Endocrine Sciences Laboratory dose for samples containing vitamin D3.

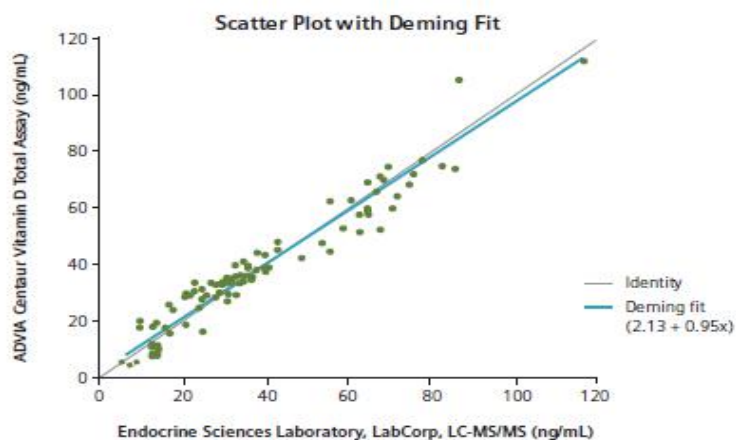


Figure 8. Residual plot for the ADVIA Centaur Vitamin D Total assay dose versus the corresponding Endocrine Sciences Laboratory dose for samples containing vitamin D3.

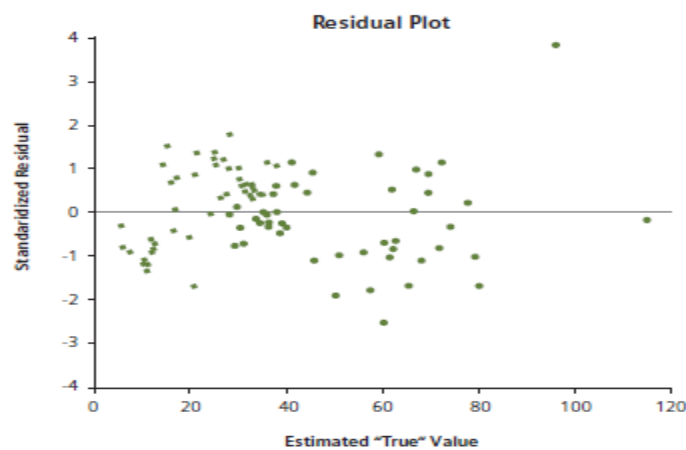
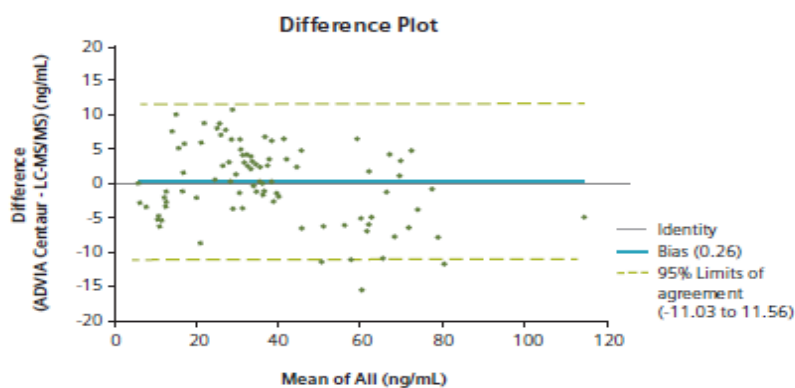


Figure 9. Altman Bland bias plot between vitamin D3 samples run on the ADVIA Centaur Vitamin D Total assay and Endocrine Sciences Laboratory 25(OH)vitamin D assay.



As shown in Table I, the methods are harmonized regardless of whether the sample contains vitamin D3 only or both vitamin D3 and vitamin D2.

Table I. Deming line equation and Pearson's coefficient statistic summary for ADVIA Centaur Vitamin D Total assay dose versus Endocrine Sciences Laboratory dose.

Sample Set	Slope	Intercept (ng/mL)	Pearson's Coefficient
All	0.97	2.22	0.95
D ₃ only	0.95	2.13	0.97
Containing D ₂	1.02	1.92	0.96



Conclusion: The alignment of the Siemens ADVIA Centaur Vitamin D Total assay to the CDC and University of Ghent Vitamin D2 and D3 RMP provides laboratories with a standardized method to tests patients for total 25(OH) vitamin D levels. In this study, the method comparison of the Siemens ADVIA Centaur Vitamin D Total assay to another method that is also traceable to the CDC and University of Ghent Vitamin D2 and D3 RMP demonstrates that having assay methods align to a single standard leads to accurate and reliable results for patients, regardless of the test performed. The data in this study shows clinical confidence in the comparability of vitamin D measurements between methods and that the automated Siemens ADVIA Centaur Vitamin D Total assay measures both forms of 25(OH) vitamin D equally and provides laboratories with a high through put, standardized assay.



Performance and Certification of the ADVIA Centaur Vitamin D Total Assay

by Spears R, Parker N, Freeman J, Wilson K, Sibley P. Siemens Healthcare Diagnostics Inc., Tarrytown, New York, USA

Abstract

Background: Vitamin D helps regulate calcium in the development and maintenance of healthy bones. The National Institutes of Health Office of Dietary Supplements created the Vitamin D Standardization Program (VDSP) to establish a standard for accurate and comparable results for the detection of 25(OH)D across laboratories. Siemens Healthcare Diagnostics enrolled in the VDSP to produce a harmonized industry standard for 25(OH)D testing.

Method: Between January and December 2013, the Centers for Disease Controls (CDC) provided 40 blinded 25(OH)D samples to the Vitamin D Standardization- Certification Program (VDSCP), in which a set of 10 samples with Reference Measurement Procedure (RMP) values was evaluated each quarter. Samples were tested blindly in replicates of four over 2 days, two replicates per day. Additional supplemental samples were also evaluated, including the four standards from the National Institute of Standards and Technology (NIST).

Results: The ADVIA Centaur R Vitamin D Total assay met the criteria for VDSCP certification. The mean bias to the reference method was 0.3%, within the acceptable bias of $\pm 5.0\%$. The assays imprecision of 5.5% was also within the acceptable range of $\leq 10.0\%$. A linear regression of the blinded samples demonstrates a slope of 1.01 and an intercept of -1.89 nmol/L. The ADVIA Centaur Vitamin D Total assay also shows an acceptable bias with the NIST Standard Reference Material (SRM) 972a vitamin D metabolite samples.

Conclusions: The VDSCP certification for the ADVIA Centaur Vitamin D Total assay establishes an acceptable alignment to a harmonized testing standard for 25(OH)D. The ADVIA Centaur Vitamin D Total assay provides laboratories with a standardized and automated means for quickly and efficiently testing patients' 25(OH)D levels.

Introduction

The Vitamin D Standardization Program (VDSP) is an initiative to standardize 25(OH)vitamin D measurements using a Reference Measurements Procedure. There are two RMPs approved as part of the VDSP: (1) NIST and (2) Ghent University. These values are treated as "true" values to which 25(OH)vitamin D assay manufacturers can harmonize their assays^{1,2}. 25(OH)vitamin D methods are challenged by the DC's Vitamin D Standardization Certification Program (VDSCP) to obtain a yearly certification as well as monitored by performance testing surveys and external quality assessments, such as CAP and DEQAS.

The CAP survey samples have the values assigned by the CDC laboratory, which is traceable to the NIST RMP, and the DEQAS survey samples have the values assigned directly by NIST RMP. The RMP is also the primary method employed for use with vitamin D reference materials, such as NIST Standard Reference Materials® (SRM) 972a⁴.

Figure 1. Linear regression analysis of the reference value(nmol/L) versus the sample value (nmol/L) by the ADVIA Centaur Vitamin D Total assay. Data was analyzed using CLSI EP9-A2 section 4.2 B1.



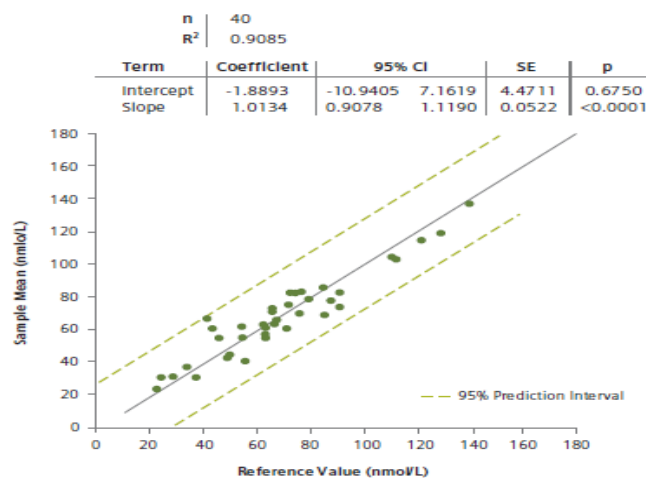
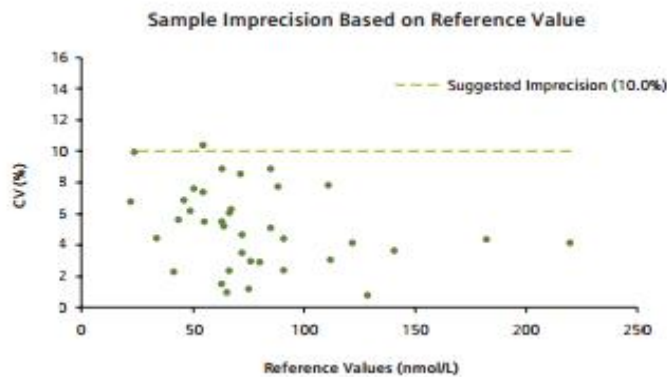


Figure 2. Precision of the ADVIA Centaur Vitamin D Total assay based on the reference value (nmol/L).



In order to assure consistency across assays, the VDSP program ties these true values to proficiency testing, such as CAP and DEQAS, as well as the NIST SRM. Siemens Healthcare Diagnostics tested the ADVIA Centaur Vitamin D Total assay with SRM 972a control materials and demonstrated similar results to the RMP, as seen in Table 3.

Table 3. Comparison of 25(OH)Vitamin D reference values (nmol/L) versus ADVIA Centaur XP (nmol/L). Yellow cells indicate reference values, and the other cells represent certified values, which are values for which NIST has the highest confidence in accuracy.

	Reference Values (nmol/L)				Centaur XP (nmol/L)
NIST SRM 972a	D ₂	D ₃	3-epi	D ₂ +D ₃	Vitamin D Total
Level 1	1.35	72	4.6	73.35	69.43
Level 2	2.025	45.25	3.225	47.275	47.07
Level 3	33.25	49.5	2.95	82.75	79.66
Level 4	1.375	73.5	66	74.875	70.26

Table 4 shows the ADVIA Centaur Vitamin D Total assay results from a recent DEQAS survey in comparison to the target value. The DEQAS survey provides five samples that are shipped quarterly. The samples are unprocessed human serum and value-assigned by the NIST Reference Measurement Procedure. These data clearly show that the assay is performing acceptably in laboratories worldwide, as each sample is within at most 6% of the target.



Table 4. January 2015 DEQAS Survey samples comparing the reference method, NIST, to the average of all Siemens ADVIA Centaur Vitamin D Total assay participant values in the survey.

Sample	DEQAS January 2015	
	NIST Target (nmol/L)	All Siemens Values (nmol/L)
466	64.5	65.8
467	44.4	46.9
468	68.3	65.7
469	69.3	65.2
470	118.4	118.6

The ADVIA Centaur® Vitamin D Total assay shows good alignment to the “true” reference method, as seen in Figure 1. The method comparison demonstrated a slope of 1.01 and an intercept of -1.89 nmol/L. Also, the samples showed good correlation between methods, with an R of 0.95.

Table 1. Bias assessment of each sample in comparison to the reference value. Mean bias was derived from the individual sample bias for each of the 40 samples.

Mean % Bias	95% Confidence Interval	
0.3	-5.0	5.6

Table 1 shows the overall bias (0.3%) and 95% confidence interval for that bias, which is -5.0% and 5.6%. As demonstrated through the certification process, it is clear that the ADVIA Centaur Vitamin D Total assay is within the acceptable specifications.

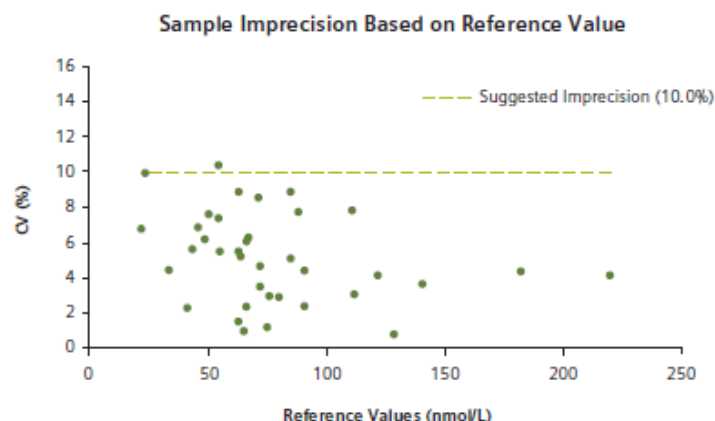
As seen in Table 2 and Figure 2, the ADVIA Centaur Vitamin D Total assay passed the CV requirements, demonstrating a mean CV of 5.5%, which was below the acceptance criteria of 10%.

Table 2. Summary of precision data from the 40 individual serum samples tested by Siemens Healthcare Diagnostics.

Imprecision (%CV)					
Mean	SD	10th and 90th Percentile		Min	Max
5.5	3.2	1.6	9.8	0.8	15.1

Figure 2. Precision of the ADVIA Centaur Vitamin D Total assay based on the reference value (nmol/L).





Conclusion

Having passed the acceptance criteria for the Vitamin D Standardization Certification Program, and demonstrating good alignment and correlation with the industry standard Reference Method Procedures, the Siemens Healthcare Diagnostics Vitamin D Total assay provides laboratories with a quick and efficient method to accurately measure patients' 25(OH)vitamin D levels.

References

1. Sempos CT, Vesper HW, Phinney KW, Thienpont LM, Coates PM, Vitamin D Standardization Program (VDSP). Vitamin D status as an international issue: National surveys and the problem of standardization. *Scandinavian Journal of Clinical & Laboratory Investigation*, 2012; 72(Suppl 243): 32–40
2. Thienpont L, Stepman HCM, Vesper HW. Standardization of measurements of 25-Hydroxyvitamin D3 and D2. *Scandinavian Journal of Clinical & Laboratory Investigation*, 2012; 72 (Suppl 243): 41–49
3. Vitamin D Standardization Program (VDSP). (n.d.). Retrieved 2015, from <http://ods.od.nih.gov/Research/vdsp.aspx>
4. NIST Material Measurement Laboratory Standard Reference Materials CoA 972a. (2013, February 20). Retrieved 2015, from https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=972a
5. Vesper, H., & Botelho, J. (2014, March 27). Vitamin D Standardization Program. Standardization of the total serum 25-hydroxyvitamin D measurements. Retrieved 2015 from http://www.cdc.gov/labstandards/pdf/hs/Vitamin_D_Protocol.pdf

Background

The Vitamin D Standardization Program (VDSP) is an initiative to standardize 25(OH)vitamin D measurements using a Reference Measurements Procedure. There are two RMPs approved as part of the VDSP: (1) NIST and (2) Ghent University. These values are treated as “true” values to which 25(OH)vitamin D assay manufacturers harmonize their assays, allowing more trust in the 25(OH)vitamin D values from laboratories worldwide. 5(OH) vitamin D methods are challenged by the CDC’s Vitamin D Standardization Certification Program (VDSCP) to obtain a yearly certification as well as monitored by performance testing surveys and external quality assessments, such as CAP and DEQAS. CAP survey samples have the values assigned by the CDC laboratory, which is traceable to the NIST RMP and DEQAS samples are value assigned directly by NIST. The RMP is also the primary method employed for use with vitamin D reference materials, such as NIST SRM 972a. The CDC has provided single-donor serum samples that have value-assigned concentrations by the Ghent University RMP.



With these samples, Siemens Healthcare Diagnostics performed a method comparison between the ADVIA Centaur Vitamin D Total assay and the RMP. In order to demonstrate harmonization, Siemens has performed a method comparison between the ADVIA Centaur Vitamin D Total assay and another assay that has also been aligned to the Ghent University RMP.

Methods and Results

118 samples with true RMP values were assessed by Siemens with a method comparison to demonstrate alignment between the RMP values and the ADVIA Centaur Vitamin D Total assay. These data were analyzed with a Deming fit, residual plot, and Altman Bland difference plot to show the alignment between the two methods.

Figure 1 shows good correlation between the reference method and the ADVIA Centaur Vitamin D Total assay. The Deming fit has a slope of 0.95 and an intercept of 1.62 ng/mL. The residual and Bland Altman bias plots of the data in Figures 2 and 3, respectively, show minimal bias between the sample values for the two methods.

A method comparison was also performed with another CDC VDSCP-certified assay containing samples that span a range from 4.2 to 152 ng/mL. As seen in Figure 4, this method comparison results in a Deming slope of 0.99 with an intercept of 1.17 ng/mL, evidence that the two assays are harmonized and aligned to the true assigned values. The residual plot (Figure 5) and the Altman Bland bias plot (Figure 6) also support the alignment of these two assays by demonstrating minimal bias. If all vitamin D methods were aligned to the RMP, as these two assays are, it would allow uniform decisions based on the patient's 25(OH)vitamin D level, since patients will receive similar values regardless of where and which laboratory tested their blood sample.

The data compiled in Table 1 as well as the corresponding figures shows good correlation to the true RMP values and to another CDC VDSCP-certified assay. Clinicians can have confidence in the values reported by assays that have been CDC VDSCP-certified, such as the ADVIA Centaur Vitamin D Total assay.

Figure 1. Deming fit for the ADVIA Centaur Vitamin D Total assay versus the corresponding CDC-RMP-assigned values.

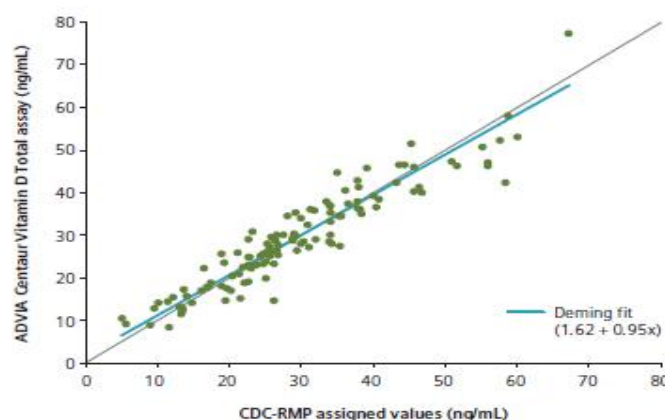


Figure 2. Residual plot between the ADVIA Centaur Vitamin D Total assay dose and the corresponding CDC-RMP dose.

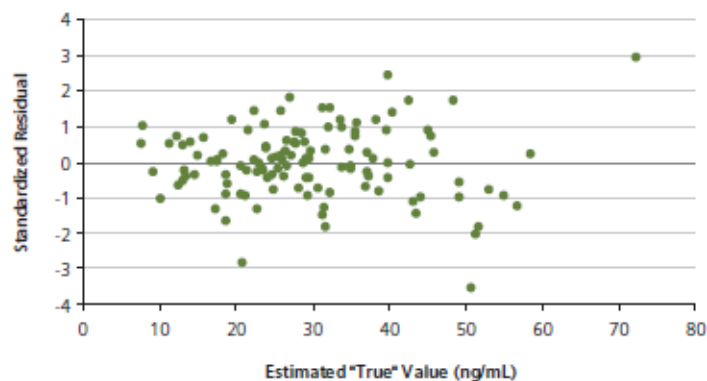


Figure 3. Altman Bland bias plot between all samples run on the ADVIA Centaur Vitamin D Total assay and CDC-RMP.

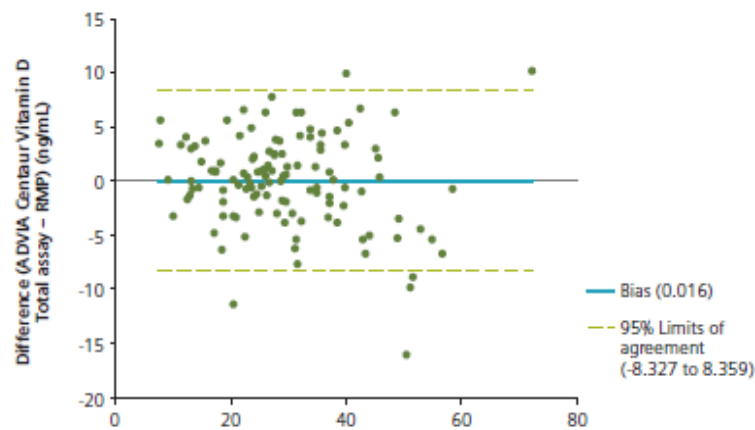


Table 1. Summary of method comparison

X-axis	Y-axis	Slope	Intercept	R*	Sample Range
CDC-RMP–assigned value	ADVIA Centaur Vitamin D Total assay	0.95	+1.62	0.94	5.04–67.2 ng/mL
IDS 25-Hydroxy Vitamin D EIA assay (k021163)	ADVIA Centaur Vitamin D Total assay	0.99	+1.17	0.98	4.2–152 ng/mL

Figure 4. Deming fit for the ADVIA Centaur Vitamin D Total assay versus the corresponding IDS 25-Hydroxy Vitamin D EIA values.

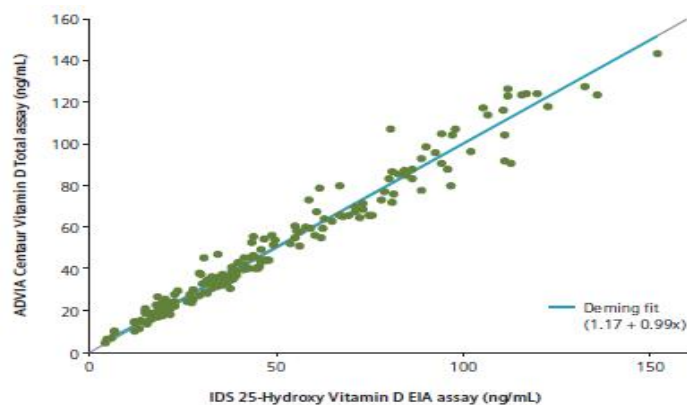


Figure 5. Residual plot for the ADVIA Centaur Vitamin D Total assay dose and the corresponding IDS 25-Hydroxy Vitamin D EIA assay dose.

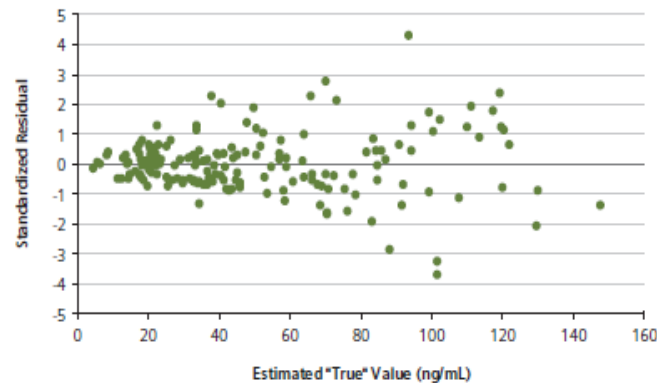
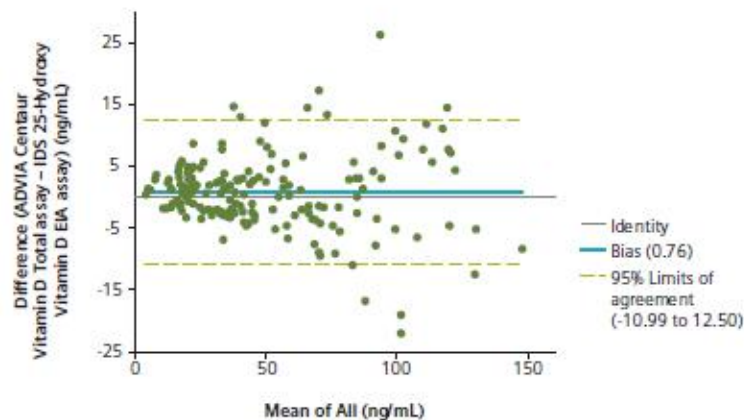


Figure 6. Altman Bland bias plot between all samples run on the ADVIA Centaur Vitamin D Total assay and IDS 25-Hydroxy Vitamin D EIA assay.



Conclusion

The Siemens ADVIA Centaur Vitamin D Total assay is a CDC VDSCP-certified assay that demonstrates good alignment to both the RMP method and another CDC VDSCP-certified assay. At the time of publication, both assays had received their second year of certification. The harmonization between the ADVIA Centaur Vitamin D Total assay and the true RMP values for 25(OH) vitamin D ensures accurate and reliable results.

