



# APFCB News

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

古卷春榮  
丁巳年春  
李國強



2013



## Publication Team, 2013 Issue

Chief Editor	Prof. Praveen Sharma Jodhpur, India praveensharma55@gmail.com
Immediate past Chief Editor	Joseph B Lopez Kuala Lumpur, Malaysia jblopez@streamyx.com
General and Case Studies Editors	Leslie Lai Kuala Lumpur, Malaysia lesliecharleslai@gmail.com
	Tester Ashavaid Mumbai, India dr_tashavaid@hindujahospital.com
	Aysha Habib Karachi, Pakistan aysha.habib@aku.edu

## APFCB Membership

### 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)  
Singapore Association of Clinical Biochemistry (SACB)  
Association for Clinical Biochemistry, Sri Lanka (ACBSL)  
Chinese Association for Clinical Biochemistry, Taiwan (CACB)  
Thailand Association of Clinical Biochemists (TACB)  
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Technidata Medical Software

### Affiliate Members

Association of Medical Biochemists of India (AMBL)  
Chinese Association of Clinical Laboratory Management (CACLM)  
Macau Laboratory Medicine Association (MLMA)

## APFCB Executive Board and Chairmen of Committees, Elected October, 2010

President	Dr Leslie C Lai Consultant Chemical Pathologist, Kuala Lumpur, Malaysia lesliecharleslai@gmail.com
Immediate Past President	Mr Joseph B Lopez MAHSA University College, Kuala Lumpur, Malaysia jblopez2611@gmail.com
Vice-President	Dr Sunil K Sethi National University Hospital, Singapore patsks@nus.edu.sg
Secretary	Dra Endang Hoyaranda Prodia, Jakarta, Indonesia endang.hoyaranda@prodia.co.id
Treasurer	Dr Elizabeth Frank BioChem Diagnostic Laboratory, Mysore, India anet21frank@yahoo.com
Corporate Representative	Mr Martin Fuhrer Siemens Healthcare Diagnostics Holding GmbH, Germany martin.fuhrer@siemens.com

## Chairman of Committees

Communications	Prof. Praveen Sharma Jodhpur, India praveensharma55@gmail.com
Education and Laboratory Management	Dr Tony Badrick Brisbane, Australia tony_badrick@snp.com.au
Scientific	Prof. Kiyoshi Ichihara Yamaguchi University, Japan ichihara@yamaguchi-u.ac.jp
Congress and Conference	Mr Joseph B Lopez MAHSA University College Kuala Lumpur, Malaysia jblopez2611@gmail.com
Hon. Auditors	Dr Woei Horng Fang whfang@ntu.edu.tw
	Mr Romeo Joseph Ignacio 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.

**The cover page "Cherry Blossom time in Japan" has been graciously provided by Prof Tan It Koon from its precious art collection. He is the Founding and Past President APFCB.**

## Address

The registered address of APFCB is as follows:  
APFCB, c/o Solid Track Management Pte Ltd.  
150 Cecil Street, #10-06, Singapore 069543  
Tel: 6223 9118 Fax: 6223 9131



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## From the desk of Chief Editor...



Dear Colleagues,

Greetings!

At the outset I would like to thank the executive of APFCB for reposing their faith in me and electing me as the Chair, APFCB Communication Committee for 2014 - 2016. I present to you the fourth Annual issue of APFCB news with great sense of gratification.

This is a special issue, coming just after the 13th APFCB Congress 2013, Bali and shall give you a glimpse of the successful organization of the event, along-with updating you on the member societies' activities and share with you some useful articles both from Corporates and from the members.

I take this opportunity to thank those member societies and national representatives who have contributed by sending their respective societies' timely reports for the APFCB news 2013. However not every member society has contributed and this creates a lacunae in this issue. I request all the member societies to send their activity reports for the future APFCB news editions and make it a useful platform for all to share their work and views. I regret the delay in publishing of this issue of APFCB news 2013.

I am very grateful to our corporate partners Randox and Beckman and Coulter for their continued support and contribution to the APFCB news in form of valuable scientific article. We hope to have their sustained support in future also.

The attractive painting on the cover page of the current issue of APFCB News "Cherry Blossom Time in Japan", has been graciously contributed by Prof. Tan It Koon from his precious art work. Prof. Tan It Koon the founding and the past president of APFCB has been an active contributor to the progress and development of APFCB. I'm thankful to him for providing beautiful paintings from his art treasure for the fourth consecutive issue of APFCB news.

Prof Praveen Sharma  
Chief Editor





## Message from APFCB President

It gives me great pleasure to write a short message for the APFCB e-News. The 3-year report of the APFCB is available on the APFCB website ([www.apfcb.org](http://www.apfcb.org)) and I would encourage you to read this report as it highlights the many activities and achievements of the APFCB from October 2010 till September 2013.

I would like to thank the Executive Board (EB) members and all our Committee Chairs, Committee members and Corresponding members as well as the Corporate members for contributing to the many activities of the APFCB over the last three-year term of the APFCB EB, thus helping contribute to the development and growth of clinical biochemistry and laboratory medicine in the Asia-Pacific region.

For those of you who participated in the 13th APFCB Congress in Bali in October 2013, I am certain that you will agree with me that the congress was a resounding success. The scientific programme was excellent, the social programme resulted in us making melodious music together on the angklung, and the ability to network with colleagues and make new friends in such an idyllic setting will forever linger in our memories. Congratulations to Dr Jyoti Kumalawati and her Organising Committee for a job well done!

The results of the recent elections for the IFCC EB 2015-2017 have been announced and it is indeed most unfortunate that there will not be a representative from the Asia-Pacific region on the next IFCC EB. However, there has been a motion put forward by AACB and seconded by IACC for regional representation on the IFCC EB. This will be discussed at the IFCC Council meeting on June 22nd 2014 in Istanbul before the commencement of the IFCC World Lab congress. There will be electronic voting on this issue after the IFCC Council meeting and I would encourage all IFCC Council members from the Asia-Pacific region to vote in favour of regional representation on the IFCC EB. Having regional representation on the IFCC EB will ensure that the interests of each region are well represented and not overlooked.

The previous APFCB EB members were re-elected for a second three year term, January 2014 till December 2016 at the APFCB Council meeting in Bali on October 27th 2013:

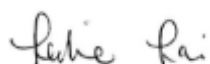


President	Dr Leslie Lai, Malaysia
Immediate	Past President Associate Prof Joseph Lopez, Malaysia
Vice President	Associate Prof Sunil Sethi, Singapore
Secretary	Dra Endang Hoyaranda, Indonesia
Treasurer	Dr Elizabeth Frank, India
Corporate	Representative Mr Martin Fuhrer, Siemens

**The Chairs of the four Standing Committees of the APFCB from January 2014 till December 2016 are:**

Communication	Prof Praveen Sharma, India
Congress and Conferences	Associate Prof Joseph Lopez, Malaysia
Education and Laboratory Management Committee (C- ELM)	Associate Prof Tony Badrick, Australia
Scientific Committee(C-Sci)	Prof Kiyoshi Ichihara, Japan

I would like to wish all of you a fruitful and peaceful year ahead.



Dr Leslie Lai, APFCB President





## ASIA-PACIFIC FEDERATION FOR CLINICAL BIOCHEMISTRY AND LABORATORY MEDICINE

### Annual Report for 2013

#### I. 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)

##### Corporate Members

1. Abbott Diagnostics
2. Agappe Diagnostics Ltd
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4. Beckman Coulter
5. Bio-Rad
6. Diasorin Ltd
7. Diasys Diagnostic Systems, GmbH
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. Sukraa Software Solution Pvt Ltd
17. Sysmex
18. 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)

**Office Bearers (October 2010 till 31st December 2013)****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 (November 2010 till 31st December 2013)**

Communications (C-Comm)	Praveen Sharma (India)
Congress and conferences(C-CC)	Joseph Lopez (Malaysia)
Education (C-Edu)	Samuel Vasikaran (Australia)
Laboratory Management(C-LM)	Tony Badrick (Australia)
Scientific (C-Sci)	Kiyoshi Ichihara (Japan)
Honorary Executive Officer	Dr Johnson Wijaya (Indonesia)

**New EB (Term of office: 1 Jan 2014 till 31 December 2016)**

Elections for the new EB were held at the Council Meeting in Bali on 27th October 2013. The results of the elections are as follows:

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

This means that Joseph Lopez from Malaysia remains as the Immediate Past President.





### Appointment of Chairs of Standing Committees (Term of office: 1 Jan 2014 till 31 December 2016)

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

### Memorandum of Understanding (MoU) between APFCB and World Association of Pathology and Laboratory Medicine (WASPaLM)

An MoU between APFCB and WASPaLM was signed on 17 May 2011 during the IFCC WorldLab in Berlin by the Presidents of APFCB (Dr Leslie Lai) and WASPaLM (Prof Michael Oellerich). As an initial co-operation between APFCB and WASPaLM, WASPaLM granted its auspices to the 13th APFCB Congress in Bali and sponsored four speakers at the 13th APFCB Congress in Bali. A meeting was held between APFCB EB and WASPaLM EB at the APFCB Congress in Bali and it was agreed to have joint projects on laboratory accreditation and Chronic Kidney Disease (CKD) in the Asia-Pacific Region. The CKD project Chair is Graham Jones (Australia). This MoU will be renewed for a three year term in May 2014.

### Golden Jubilee Celebration

VACB celebrated its Golden Jubilee in September 2013. Associate Prof Sunil Sethi, Vice President of APFCB represented the President of APFCB at this auspicious event where he handed the President of VACB, Prof Hoang Thi Bich Ngoc a memento from the APFCB.



VACB Golden Jubilee celebrations.

## **APFCB Activities**

### **I. APFCB Education Committee (C-Edu)**

*Chair: Prof Samuel Vasikaran (Australia)*

#### **1. APFCB Travelling Lectureships**

The APFCB TL for 2013/14 is Prof Sunil Sethi of Singapore. Prof Sethi gave lectures on Managing Laboratory Informatics, Middleware and Process Control at the MACB Annual Scientific Meeting in June 2013, in Vietnam in September 2013 and at the APFCB Congress in Bali in October 2013. Other lectures are being planned in 2014.

#### **2. IFCC-Abbott Visiting Lecturer**

Prof Howard Morris, (Vice President of IFCC) of the University of South Australia and South Australia Pathology has been nominated to be the IFCC-Abbott Visiting Lecturer for 2014. His topic is Vitamin D and Bone Metabolism. Those interested to host Prof Morris should contact the Chair of the Education and Laboratory Management Committee, Associate Prof Tony Badrick.

#### **3. APFCB Scholarships**

Two APFCB scholarships of up to SGD 3,500 each were awarded for attendance at the APFCB Congress in Bali, October 2013. The recipients were Chi Mai of Vietnam and Surupa Basu of India. In addition, Saswati Das of India was awarded the APFCB-Abbott Travel Scholarship to the value of up to SGD 5000, and Apilak Worachartcheewan, Wanvisa Treebuphachatsakul and Walanphorn Ungsawat of Thailand, Kisundeo Mehta of Nepal and Mu Yu of China were awarded APFCB-Siemens Travel Scholarships each to the value of up to SGD 3500 to attend the APFCB Congress in Bali in October 2013.

#### **4. Workshop at the APFCB Congress in Bali**

The Education Committee also organised the APFCB-sponsored workshop "Interpretation and commenting on laboratory results" at the APFCB Congress in Bali in October 2013. The speakers were Drs Gordon Challand, Ken Sikaris and Sam Vasikaran.

### **II. Scientific Committee (C-Sc)**

*Chair: Prof Kiyoshi Ichihara (Japan)*

#### **1. Publication of papers on the 2009 Asian study for collaborative derivation of reference intervals.**

The Asian study conducted as a collaborative work of APFCB and the IFCC Committee on the Reference Intervals and Decision Limits (C-RIDL) was completed in 2009. The publication of two papers reporting the study results took a long time because of controversies over the new approaches employed in the study (The use of parametric method, latent abnormal value exclusion



Method, transference of centrally derived RIs by cross-comparison of common specimens, etc). With acceptance of a review supporting the study methodologies (Ichihara K, Boyd J. An appraisal of statistical procedures used . the papers were finally accepted in 2013 as listed below. The Asian study in fact revealed evidence regarding the regional, age-, sex-, BMI related differences in a very conclusive way. The study also predicted the feasibility of expanding the study on a global scale by use of a panel of sera. The Asian study then led to the launch of the IFCC global study using the same methodologies coordinated by the C-RIDL .

1) Ichihara K, Ceriotti F, Tam TH, Sueyoshi S, Poon PM, Thong ML, et al. The Asian project for collaborative derivation of reference intervals: (1) strategy and major results of standardized analytes. Clin Chem Lab Med 2013; 51(7):1429–42.

2) Ichihara K, Ceriotti F, Mori K, Huang YY, Shimizu Y, et al. The Asian project for collaborative derivation of reference intervals: (2) results of non-standardized analytes and transference of reference intervals to the participating laboratories on the basis of cross-comparison of test results. Clin Chem Lab Med 2013; 51(7):1443–57.

## 2. Collaboration on the global study on reference values

The study, planned and coordinated by C-RIDL (IFCC) was launched in December of 2011 after nearly two years of discussion by the committee, and a pilot study conducted in April of 2011. The objectives of the global study are 1) to establish country specific RIs in a harmonised way using the common C-RIDL protocol, and 2) to explore sources of variations of major analytes across the countries after alignment of test results through common measurement of a panel of sera prepared by C-RIDL. A total of 14 countries in five continents collaborate in the study. The following four Asian countries (members of the APFCB) are taking part in the global study.

### ***The activity of each collaborating country from Asia as of August 2013 is as follows:***

Japan: Leading the study with provision of data analytical service. 760 volunteers were recruited between 2012 and 2013 from Yamaguchi, Hiroshima and Osaka Universities. The measurement of 55 analytes was supported by Beckman-Coulter (BC) Japan.

China: In the first phase of the study, 480 volunteers were recruited in 2012 from Beijing National Hospital, coordinated by Dr. Jian Guo. The measurement of 35 analytes was supported by BC China. The second phase of the study was launched in March 2013, led by Dr. Ling Qiu of the Beijing Union Hospital, involving 7 provinces throughout mainland China. Recruitment of 2,800 (400×7) volunteers are to be completed by September 2013. The target analytes for the second phase were increased to 56.



**India:** Recruitment from 500 volunteers and the measurement will be completed by September of 2013 in P.D.Hinduja National Hospital and Medical Research Center, Mumbai, headed by Dr. Tester Ashavaid. BC, Abbott and Johnson & Johnson support the assay reagents for total of 55 analytes.

**Philippines:** 1,200 volunteers are being recruited by a team of 9 medical technologists in Iloilo city. The study is conducted under the auspices of the Philippine Association of Medical Technologists (PAMET), San Agustin University and the city municipal government. **Siemens analysers are to be adopted** for the measurement of 22 major biochemical analytes.

**Meetings regarding the global study, including the Asian collaborators, were held over the past three years as listed below:**

- 1) 15-16 May 2011 during the World Med Lab in Berlin, Germany as the IFCC C-RIDL
- 2) 26 July 2011 during the 2011 AACC in Atlanta, USA as the IFCC C- RIDL meeting
- 3) 4- 6 December 2011 in Beijing National Hospital in Beijing, China
- 4) 16 to 17 July 2012 during the 2012 AACC in Los Angeles as the IFCC C-RIDL meeting
- 5) 20-21 August 2012 in Hinduja National Hospital in Mumbai, India
- 6) 21-22 October 2012 in Iloilo city of the Philippines with a team of laboratory technicians
- 7) 25-26 February 2013 in Beijing with the team from the Beijing Union Hospital,
- 8) 19-20 May 2013 in Milan, Italy, as the IFCC C-RIDL meeting.
- 9) 28 July 2013 in Houston, USA, during the 2013 AACC as the IFCC C- RIDL meeting.

The results will be combined with those from the 2009 Asia study comprising test results of 72 analytes from 3,500 volunteers. The objective of the combined analysis is to obtain a comprehensive picture of evidence on sources of variations for commonly tested analytes (such as regionality, ethnicity, age, sex, BMI, smoking, alcohol, blood type related changes). An interactive web site viewing the study results is being built. The entire results from the last Asia study and the global study are to be presented and discussed during the 2013 Bali APFCB Congress scheduled on 29 October 2013.

**Papers published as keynote papers on the global study are as follow:**

- 1) Ichihara K, Ozarda Y, Klee G, Straseski J, Baumann N, Ishikura K. Utility of a panel of sera for the alignment of test results in the worldwide multicenter study on reference values. Clin Chem Lab Med 2013; 51(5):1007–25. 10.1515/cclm-2013-0248





2) Ozarda Y, Ichihara K, Barth J, Klee G. Protocol and standard operating procedures for common use in the worldwide multicenter study on reference values. Clin Chem Lab Med 2013; 51(5): 1027–40.

### **3. Project on reference values (Project Lead: Dr Ronda Greaves)**

1) A joint project is under way on the standardisation of assays for testosterone and related analytes by use of mass spectrometry among the researchers in the APFCB region. In the RCPA Chemical Pathology QAP survey conducted in 2012 with participation of 130 labs, laboratories in the harmonisation working group attained very good results, all within the target ranges, thanks to the use of common calibrators and assay procedures.

2) A project on establishment of a mass-spectrometry based assay system for paediatric screening of neuroblastoma in Vietnam is also under way using the support fund provided by the APFCB in 2012.

The results of both projects were presented during the APFCB Congress in Bali.

## **III. Laboratory Management Committee (C-LM)**

*Chair: Associate Prof Tony Badrick (Australia)*

### **1. Quality Assurance/Quality Control Workshops**

A workshop on pre-analytical errors was held in Hanoi (see Speciality Meeting under C-CC), Vietnam in March 2013. This was a day and a half workshop which attracted some 100 attendees from Vietnam, Thailand, the Philippines and Indonesia. The Workshop was planned and prepared by the APFCB and Becton Dickinson and was also very generously supported by Becton Dickinson.

### **2. Environmental Initiative**

One of the goals of the C-LM was to begin raising awareness amongst members of the APFCB of the importance of lessening the environmental impact of clinical laboratories. The aim would be to produce some detailed content for the new APFCB website and some planning has begun on this project.

Joseph Lopez and Tony Badrick have written a document "PROPOSALS FOR THE MITIGATION OF THE ENVIRONMENTAL IMPACT OF CLINICAL LABORATORIES" which will be the basis for further educational activities in the area of Environmental Awareness. A symposium on this topic was held at the Bali Congress in 2013.

### **3. Needs Survey of Members for Quality/Accreditation Activities**

This activity involved a Survey of the APFCB membership to determine their needs. The key findings are below.



Answer Options	Response Percent	Response Count
Webinar	71.4%	5
Workshop	42.9%	3
Travelling Lecturer	57.1%	4
Specialty meeting	28.6%	2
Online activity	85.7%	6
Other (please specify)		0
answered question		7
skipped question		0

### APFCB Member Survey

What are the major topics you would to see covered in these activities?

Answer Options	Response Percent	Response Count
QA/QC	71.4%	5
Management	71.4%	5
Pre-analytical processes	28.6%	2
Laboratory Workflow	42.9%	3
Result interpretation and commenting	85.7%	6
Troponin	14.3%	1
HbA1c	42.9%	3
Quality management/ISO 15189	57.1%	4
Measurement of Uncertainty	71.4%	5
Accreditation and Certification	28.6%	2
Resource management	28.6%	2
Quality improvement	85.7%	6
Training and competence	42.9%	3
Quality indicators	85.7%	6
Safety	0.0%	0
Environmental impact	0.0%	0
Renal markers	57.1%	4
eGFR equations	42.9%	3
Other (please specify)		1
answered question		7
skipped question		0



#### 4. QA/QC Self-directed learning material for the APFCB Website

The committee is anxious to further develop the website and we are seeking material for the Committee website pages.

1. Quality management systems and ISO 15189
2. Leadership roles
3. Accreditation and certification issues
4. Resource management
5. Quality Improvement
6. Training and Competence
7. QC and QAP
8. Quality Indicators
9. Safety

### IV. Communications Committee (C-Comm)

*Chair: Prof Praveen Sharma (India)*

#### 1. APFCB e-News

The Chair of the Communications Committee is also the Editor of the APFCB e-News. As it was agreed by the Council, the committee started publishing the APFCB News as an online pdf copy from the 2010 issue. This has ensured wide reach of the APFCB e-News to all the members at no additional cost. The APFCB e-News 2010, 2011 and 2012 issues are available on the APFCB website. The 2013 issue will be out in the first quarter of 2014.

#### 2. APFCB Website

The Chair of the Communications Committee was charged with the responsibility of launching the APFCB website and its coordination, maintenance and improvement ([www.apfcb.org](http://www.apfcb.org)). Dr MVR Reddy (India) has been assigned the responsibility of being the web editor. The site was successfully launched on 1 Nov 2011. Since then, it is regularly updated with comprehensive information on the organisation and activities of APFCB and its member societies. Access is made available through the website to the ongoing Scientific, Education and Laboratory Management Committee programmes of APFCB as well as the activities of the Communications and Congress Committee. There is also a photo gallery of relevant events. The website is also a source of information on the APFCB Congress and regional meetings as well as the APFCB Travelling Lecturer programme as well as future events. The APFCB e-News and annual reports are conveniently published online on this platform, making them readily available to all members. It also gives access to the APFCB webinars.

#### 3. Public Relations

A power point presentation on the APFCB, its members and its activities has been developed by Mr Martin Fuhrer, Corporate Representative to the EB and is ready for use at member society conferences and at regional and international meetings to promote the APFCB. This presentation is being regularly updated by Mr Martin Fuhrer.



## V. Congress and Conferences Committee (C-CC)

*Chair: Joseph Lopez (Malaysia)*

### 1. 13th APFCB Congress

The 13th APFCB Congress, held from 27th till 30th October 2013 at the Bali Nusa Dua Convention Center, was a huge success and feedback from participants has been very positive. There were 943 participants from 49 countries and 400 registrants from the corporate sector with 80 booths. IFCC, WASPaLM, EFLM, APFCB and several APFCB member societies sponsored symposia and plenary speakers. Participants and accompanying persons from 49 countries played the angklung beautifully and melodiously in unison at the cultural night. The next APFCB congress will be in Taipei in 2016.



Opening Ceremony, 27th October 2013.



Cultural Night, Garuda Wisnu Kencana Cultural Park, 29th October 2013.

### 2. APFCB Speciality meeting

In conjunction with the APFCB Committee for Laboratory Management and BD Diagnostics, the first APFCB Speciality Meeting was held in Hanoi from 18-19 March at the Melia Hotel in Hanoi. The theme of the meeting was "Quality Improvement in Laboratory Medicine through Pre-analytical Process Control".



There were approximately 80 participants in all with representation from Indonesia, the Philippines and Thailand, besides Vietnam. Despite the language difficulties faced by local participants, the real-time translation services organised by the sponsor appeared to have worked well. We thank BD for its sponsorship and excellent organisation of this meeting. They brought in participants from Thailand, the Philippines and Indonesia, besides the participants from Vietnam who formed the majority.

### 3. APFCB Auspices

APFCB auspices were provided for the following meetings

- i. Research Workshop on "Inborn Errors of Metabolism & Metabolic Disorders" organised by the Department of Biochemistry, College of Medicine & JNM Hospital, India, March 7-8, 2013
- ii. EUROMEDLAB 2013, Milano, 19-23, May, 2013
- iii. 5th Vietnam Chemical Pathology Course. 2nd July 2013 (Melia Hotel, Hanoi) and 6th July 2013 (Intercontinental Hotel, Ho Chi Minh City)

### 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 Euro MedLab 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 will enable the APFCB to contribute to the planning of the scientific programme future TSIC meetings.

A TSIC meeting was held in Taipei, Taiwan on 23 and 24 September 2013. The APFCB Immediate Past President represented the APFCB at the opening of this meeting.

## VI. Report by the Corporate Representative:

*Chair: Mr Martin Fuhrer, Siemens*

### 1. APFCB Specialty Meetings Opportunity

APFCB Corporate members have become eligible to apply for APFCB auspices with the Congresses and Conferences Committee to promote meetings and attract a large professional participation. The guidelines and procedures for application can be accessed on the APFCB website under <http://apfcb.org/apfcb-guidelines.pdf>. The first Specialty meeting in this programme was organised by Becton Dickinson on 18-19 March 2013 in Hanoi, Vietnam covering the area of pre-analytical sample treatment.

### 2. IVD industry Management Information System

APFCB Corporate members have become eligible to apply for APFCB auspices with the Congresses and Conferences Committee to promote meetings and attract a large professional participation. The guidelines and procedures for application can be accessed on the APFCB website under <http://apfcb.org/apfcb-guidelines.pdf>. The first Specialty meeting in this programme was organised by Becton Dickinson on 18-19 March 2013 in Hanoi, Vietnam covering the area of pre-analytical sample treatment.



EDMA (European Diagnostics Manufacturers Association) is cooperating with the APFCB to expand their very successful Management Information System (MIS) from Europe to Asia Pacific. This system will provide IVD companies with market data from the region. A first introduction of this system was held at the Corporate members meeting on 29 October 2013.

*Report prepared by Dr Leslie Lai with contributions from Associate Prof Joseph Lopez, Dra Endang Hoyaranda, Mr Martin Fuhrer; Prof Kiyoshi Ichihara, Prof Sam Vasikaran, Associate Prof Tony Badrick, Prof Praveen Sharma and Dr July Kumalawati (Chair of the 13th APFCB Congress Organising Committee), 12 January 2014.*

## Appendix 1. APFCB Speciality Meeting, Hanoi, Vietnam, 18-19 Mar 2013

### Scientific Programme Item

#### Day1/Time /18 Mar 2013

8.00-9.30	Opening – brief speeches by APFCB Vice- President, BD, VACB representative, Ministry of Health representative	
9.00-9.30	Introduction - laboratory errors and their impact on overall healthcare delivery system – new perspectives Choosing the right test and ordering tests: electronic versus paper	
10.30-11.00	Coffee break	BD speaker
11.00-11.30	Laboratory errors in the preanalytical phase where and when do they occur?	
11.30-12.00	Informatics and automation in the preanalytical phase of clinical testing	Sunil Sethi
12.00-2.45	Pre-analytical issues affecting clinical chemistry	Joseph Lopez
12.45-2.00	Lunch	
2.00-2.30	Pre-analytical issues affecting: <ul style="list-style-type: none"> <li>• Microbiology</li> <li>• Haematology</li> <li>• Transfusion medicine</li> </ul>	BD Speaker
2.30-3.30	The ISO standard for the pre-analytical phase of testing	Tony Badrick



3.30-4.00	Coffee break	
4.00-5.00	Standardization and new trends in preanalytical error prevention, detection, reporting and management – An interactive session	BD Speaker

**Day2/Time /19 Mar 2013**

9.00-9.30	Quality Improvement in pre-analytical processes	Tony Badrick
9.30-10.00	Key Incident Management and Monitoring (KIMM) in the pre-analytical phase	Tony Badrick
10.00-10.30	Coffee break	
10.30-12.30	Interactive Workshop: Case studies of QI (using QI where participants work	Facilitators: T Badrick, J Lopez, S Sethi
12.30-2.00	Lunch Break	
2.00-2.30	Special lecture: Laboratory waste management	Tony Badrick
2.30-3.30	Capability building opportunities in Vietnam and launch of new initiatives	BD and local facilitator
3.30	Closing followed by coffee	





## APFCB Work Plan for 2014

### I. EB, Committee Chairs and Committee Members

1. Promotion of the APFCB internationally, regionally and nationally, including at workshops, conferences, scientific meetings and during visiting lectureships.
2. Renewal of Memorandum of Understanding with WASPaLM in May 2014.
3. Recruiting new Full members, Affiliate members and Corporate members.
4. Maintaining good and strong relationships with other regional clinical biochemistry organizations, IFCC and WASPaLM

### II. Education and Laboratory Management Committee (C-ELM)

#### 1. IFCC-Abbott Visiting Lecturer for 2014 and 2015: Prof Howard Morris (Australia)

The topic of Prof Howard Morris's visiting lectureship is Vitamin D and bone disease. Expressions of interest to host the IFCC-Abbott Visiting Lecturer are invited to the Chair of the C-ELM.

#### 2. APFCB Travelling Lecturer for 2013 and 2014: Prof Sunil Sethi (Singapore)

The three topics on offer are:

- i. Managing Laboratory Informatics, Middleware and Process control.
- ii. The Clinical and technical demands of Laboratory Cardiac Biomarkers Resulting
- iii. Developments in laboratory diagnostics and diagnosis and monitoring of Diabetes and related metabolic disorders

Planned lectures for 2014: HongKong on 11th Jan 2014 and Taiwan on 15th Mar 2014

The selection of the APFCB travelling lecturer for 2015 and 2016 will be made later this year.

#### 3. APFCB Symposium on Awareness of Environmental Impact of Clinical Laboratories at the IFCC World Lab Congress in Istanbul in June 2014.

The program for the symposium is as follows:

Chair: T. Badrick (Australia)

- Environmental guidelines in laboratories  
J. Lopez (Malaysia)
- Adopting environmental guidelines and cost savings  
T. Badrick (Australia)
- Environmental laboratory facilities management  
D. Jackson (USA)

#### 4. Planning for a Chemical Pathology Course in 2015. Country to be decided.





### **5. Form a Pre-Analytical Working Group to work together with EFLM Pre-Analytical Group.**

- I. Validated questionnaires for assessing the key challenges that laboratories face in managing the pre-analytical phase.
- II. Surveys to assess the current pre-analytical challenges in laboratories and their importance in order to define how best the working group can support laboratories in the Asia-Pacific region.
- III. Solutions/guidance for laboratories to address the top pre-analytical challenges.

- Active web page with pre-analytical tools

### **6. Development of Material for self-directed learning for QA/QC/Lab Accreditation on the web page**

This material will be developed as an online assessed program of basic QA/QC.

### **7. Awareness of Environmental Impact of Clinical Laboratories**

- Survey of Suppliers on Environmental awareness
- Survey of senior lab staff in SE Asia region about environmental awareness
- Travel to Philippines and Indonesia to establish test labs and base power/water/waste measurements

### **8. Scholarships**

Selection of four (4) APFCB-Abbott Travel Awardees to IFCC WorldLab in Istanbul, 22-26 June 2014 and two (2) APFCB Travel Awardees to AACB Scientific Meeting in Adelaide, 27-29 Oct 2014.

### **9. Interpretative comments program to involve APFCB and AFCC**

The interpretative comments program will be run with four (4) cases in 2014. The AFCC have been invited to be involved.

## **III. Scientific Committee (C-Sci)**

### **I. Expansion of the regional multicenter study on reference values.**

China, India and Japan have completed the study as a part of the global multicenter study by 2013.

- I. The Chinese study, headed by Dr. Ling Qiu of Beijing Union University Hospital, has just completed a nationwide study with total recruitment of 3200 healthy subjects from six provinces. Regional differences within China were observed in some analytes.
- II. The Indian study, headed by Dr. Tester Ashavaid of Hinduja National Hospital was completed with recruitment of 512 volunteers by November 2013. They involved multiple platforms (Abbott, Beckman Coulter and J&J) and analyses are to be made to explore platform-dependent differences in immunological assay results in early 2014.
- III. Nepal Association of Medical Laboratory Sciences (NAPLS) has just joined the study to conduct a nationwide study, being led by Mr. Binod Yadav. They are planning to complete the study by April 2014.



- IV. The Philippines study, being conducted by a group of laboratory technicians headed by Mr. Reynan Rolle in Iloilo city under the auspices of PAMET, has a delay in completing the study due to analytical problems, and thus, technical support will be provided for smooth progression of the study in early 2014.
- V. Additional collaboration: Malaysia and other laboratories in India have expressed their interest in joining the study and negotiation will be made for smooth launch of the study in 2014.

## **2. Provision of statistical knowledge and skills required for laboratory medicine.**

Two or more international seminars are being planned in 2014 in Yamaguchi University in Japan, inviting researchers from national societies belonging to the APFCB.

## **3. Provision of web-based EBLM system.**

The prototype of an interactive website was built in 2013 to provide evidence on biological sources of variation (BSOV) for commonly tested laboratory tests. It allows dynamic access to the reference values gathered by the 2009 Asian projects for derivation of common reference values. To visualize evidence on BSOV, the user can specify an arbitrary test item and its possible sources of variation, such as sex, age, BMI, levels of drinking or smoking, ABO blood type, etc. The website requires improvements in user-interfaces in 2014. Its portal can be posted in the APFCB web-site.

## **4. Regional project for harmonization of mass spectrometry-based steroid assays (chaired by Dr Ronda Greaves).**

This regional activity currently includes members from Australia, Austria, Hong Kong, New Zealand, Singapore and Vietnam. Laboratories in Malaysia and Korea have also expressed their interest to participate in the future. Significant engagement with industry partners (Agilent Technologies, Biocrates, National Measurement Institute of Australia, PM Separations and the RCPAQAP) has ensured the successful completion of the common calibrator pilot study in 2013.

The work outlined below for 2014 stems directly from this study.

- Write up of the common calibrator study for peer review publication.
- Continue to review RCPAQAP performance post common calibrator study
- Develop protocol and establish traceability of common calibrator for testosterone in the first instance.
- Examine associated costs and hence feasibility to establish traceability for other steroids in calibrator mix
- Establish pre term neonatal reference intervals for testosterone using traceable common calibrator
- With the common calibrator base established, investigations in comparative performance with immuno assay platforms has been proposed.

**5. Studies to establish 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*



i. Expansion of the Vietnam method and reference interval project for the biochemical diagnosis and monitoring of neuroblastoma to other interested APFCB countries. To start, a laboratory in Malaysia has expressed interest in joining this study.

Objectives:

- Support the dissemination and establishment of the analytical method by other laboratories in the APFCB region.
- Once method has been established, support the transference of reference intervals, or if required the establishment of local specific intervals.

ii. New project for 2014: Using the model established in the Neuroblastoma project the next local reference interval study will commence in 2014. This study is fully supported statistically by RMIT University Urine steroid metabolomic studies by gas chromatography mass spectrometry to aid the diagnosis of disorders of sexual development in Vietnamese children (National Hospital of Pediatrics, Hanoi, Vietnam, in collaboration with investigators from RMIT University and Box Hill Hospital, Melbourne, Australia).

Objectives:

- To develop and validate the urinary steroids profiling analysis using gas chromatography-mass spectrometry (GCMS).
- To establish the urinary steroids reference values for Vietnamese newborns.
- To investigate age-related changes in steroid ratios across childhood, with emphasis on the timing and significance of change at adrenarche and puberty.
- To apply the GCMS urinary steroids profile in diagnosis of inborn errors of steroid synthesis at National Hospital of Pediatrics for Vietnam.

iii. Additional collaboration: Once established, it is anticipated that the laboratory will act as a regional centre for the metabolomics studies of steroids collected on filter paper. (Current discussions with clinicians/laboratories in India and Africa in progress). This project also aims to foster APFCB links with the regional organisation CLAN.

## **6. Vietnam Chemical Pathology Course and POCT workshop (co-ordinated by Dr Ronda Greaves).**

This educational activity will be conducted both in Ho Chi Minh City and Hanoi in early June 2014 once again under the APFCB auspices. In addition, Jan Gill and Ronda Greaves would like to continue to follow up on some discussions held at the APFCB Congress in Bali regarding opportunities in Malaysia for the POCT workshop.

Objectives:

- Present APFCB Vietnam Neuroblastoma project results
- Discuss ethical considerations for research in clinical biochemistry
- Disseminate strategies for publishing research findings
- Present current concepts in diagnostic clinical biochemistry
- Network to establish further local collaboration with APFCB.



### **7. Regional Chronic kidney disease project (chaired by A/Prof Graham Jones)**

This regional project is Chaired by Dr Graham Jones (Australia) representing the APFCB and Dr Leslie Lai representing WASPaLM is the Vice Chair. The other APFCB representative is Prof Sunil Sethi (Singapore) and one further WASPaLM representative is being sought to be a member of this working group. The Asian Pacific Society of nephrology (APSN) and the Asian Forum for CKD Initiative (AFCKDI) have been approached by Dr Graham Jones to join this project and it is hoped that one of members of the clinical associations will be Co-Chair of this working group. Please refer to Appendix I.

### **8. Developing scientific research strategies in the APFCB region. (Dr Ronda Greaves)**

In a number of the resource poor laboratories / countries of the APFCB region the development of appropriate standards of testing to achieve ISO15189 accreditation is still in progress. To support the scientific activities and foster research on a regional level it is imperative that the laboratories are working to this testing standard for the measurands of interest in the research project; otherwise the project results may be undermined by poorer than acceptable quality. Hence this section of work of the Scientific Committee is aimed at supporting quality scientific research activities through an education and training mentoring model (developed by Ronda Greaves in Vietnam in 2008 - 2011).

- Key laboratories identified in the APFCB region that express an interest may participate and a mentor will then need to be identified to support the laboratory. Effectively this support should include but not be limited to: 1) development of appropriate internal quality control practices; 2) establishment of external quality assurance participation and ongoing review; and 3) supporting implementation of ISO15189 or equivalent; and then 4) developing research activities where practical. It is hoped that this laboratory(s) in the country will then be able to locally and regionally support the development of others longer term. With the establishment of this support the laboratory can develop to participate fully in the research activities of the APFCB.

- Activities for 2014:

- Medical Testing Laboratories at Dhulikel Hospital Nepal. A meet and greet site visit was conducted in late 2013 by Mr Christian Rantzau, from the Bio21 Institute University of Melbourne. Discussions are now in progress to offer longer term mentoring support.
- National Hospital of Pediatrics Vietnam. Mentoring of for the biochemistry staff has been conducted since 2008. Scientific research activities commenced in 2011. The new activities are for 2014 are highlighted in under point 5 above.
- Other laboratories will be considered as mentors are identified.

### **9. Seeking proposal of new collaborative scientific researched in APFCB region.**

After new regular/corresponding members of the Scientific Committee are appointed, active efforts will be made to ask for proposal of a possible regional collaborative study by making close communication with the newly selected members.





## IV. Congress and Conferences Committee (C-CC)

### 1. 14<sup>th</sup> APFCB Congress, Taipei, 2016

To establish contact with the CACB and the Organising Committee of the 14<sup>th</sup> APFCB Congress and to assist in their preparations for this congress.

### 2. 13<sup>th</sup> APFCB Congress, Bali, October 2013

To receive and review the report of the 13<sup>th</sup> APFCB Congress from the organizing committee

### 3. APFCB Speciality Meetings

To organize one speciality meeting within the APFCB region.

### 4. Provision of Auspices

To consider applications for the provision of APFCB auspices for scientific meetings as per guidelines

## V. Communications Committee (C-Comm)

### 1. APFCB website ([www.apfcb.org](http://www.apfcb.org))

To maintain and further enhance the quality of APFCB website and to ensure that the information on the website is relevant and up to date

### 2. Uploading learning materials onto the website

Learning materials developed by APFCB members and APFCB Committees will be uploaded onto the APFCB website.

### 3. Supporting web-based learning activities

To provide more active support for the web-based distance-learning activities like webinars planned by the C-ELM.

### 4. Multidisciplinary approach to patient care

Obtaining educational material and making it available on the APFCB website as well as by providing links to other relevant resources.

### 5. PR brochure

Develop a new PR brochure targeted to the general public, governments, industry, etc.

### 6. Establish a communication process

Improve communication amongst committee members and member society representatives to update and work on agreed activities and initiatives.

### 7. Publicize and promote APFCB

This will be done through participation at various National, Regional and International congresses and booth exhibits. The official journal of the APFCB is Clinical Biochemist Reviews and C-Comm will promote this journal at conferences regionally and internationally.

*Prepared by Dr Leslie Lai with the help of Associate Prof Tony Badrick, Prof Kiyoshi Ichihara, Prof Praveen Sharma, Associate Prof Joseph Lopez, Dr Ronda Greaves and Associate Prof Graham Jones. 18 January 2014*



## Appendix I

### CKD testing in the Asia pacific Region (Prepared by Dr Graham Jones)

Dr Graham Jones, Staff Specialist in Chemical Pathology, St Vincent's Hospital, Sydney, Australia (gjones@stvincents.com.au) has been appointed as Chair of the Asia-Pacific Working Group on CKD

#### Invitation Summary

The Asian Pacific Society of nephrology (APSN) and the Asian Forum for CKD Initiative (AFCKDI) are invited to join a joint working group with the aim of supporting the development and implementation of integrated programs for the laboratory testing of Chronic Kidney Disease (CKD) in the Asia-Pacific region. The working group would aim to combine expertise from both clinical nephrology and laboratory medicine. The working group would aim to identify and support countries, groups of countries or regions within countries with developing and implementing such programs.

The proposal is based on the belief that an optimal CKD program requires collaboration between laboratory medicine, nephrology and other medical groups.

This proposal has the official executive support of the Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) and the World Association of Societies of Pathology and Laboratory Medicine (WASPaLM).

Our invitation is for an agreement to work together in this working group, and for two representatives of APS and/or AFCKDI to join the working group, with one to take a role as co-chair to ensure open collaboration.

#### Background

There are a number of initiatives that are under way either globally or in the Asia-Pacific Region related to CKD. These initiatives have been developed by a range of global or regional organizations and are based on the knowledge that CKD is clinically important, present in a significant proportion of the population and clinically silent in the early phases. These initiatives include:

#### 1. Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for CKD

KDIGO have recently published the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease which provides global advice on CKD definition, staging and monitoring. The previous version of this document, produced by KDOQI, provided the global basis for diagnosis and classification of CKD and this update provides the guidance in this area for future developments.

#### 2. The Asian Forum of Chronic Kidney Disease Initiative (AFCKDI).

The AFCKDI was formed in 2007 by delegates from 16 countries in the Asia-Pacific region.



This forum serves as a consensus meeting for Chronic Kidney Disease (CKD) initiative in the Asia-Pacific. The mission of this forum is to promote collaboration and coordination of CKD initiative in our area. The Forum has now held 7 conferences related to CKD, the most recent in Thailand in 2013.

The AFCKD has recently published an important guideline: Asian chronic kidney disease best practice recommendations: Positional statements for early detection of chronic kidney disease from Asian Forum for Chronic Kidney Disease Initiatives (AFCKDI) Nephrology 16 (2011) 633–641.

Countries with representation on the AFCKDI include: Australia, Bangladesh, Brunei, China, Hong Kong (China), India, Indonesia, Japan, Laos, Macau (China), Malaysia, Mongolia, Nepal, Pakistan, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam

### **3. International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and World Association of Societies of Pathology and Laboratory Medicine (WASPaLM) Task Force on Chronic Kidney Disease (TF-CKD).**

In many countries there are now established CKD programs formed by collaboration between clinical and laboratory groups. Specific examples include activities in Australia and New Zealand, the UK and Germany where well established national programs are in place. The leadership of the National Kidney Disease Education Program (MKDEP) in the USA has also been vital in supporting development of traceable assays for serum creatinine and urine albumin. The TF-CKD has not produced these results but is a group of laboratory scientists and pathologists with experience in different countries with the strong belief that collaboration between laboratories and clinicians is vital for provision of a successful CKD program. The goal of the TF-CKD is to assist national or regional groups to develop appropriate local testing programs.

The IFCC represents over 87 national laboratory medicine organizations and WASPaLM represents over 30 national pathology organizations. Many members of each organization are in the Asia-Pacific Region.

Further information regarding inviting organizations:

#### **1. Asia Pacific Federation of Clinical Biochemistry (APFCB)**

The APFCB is a federation comprising the national clinical chemistry or laboratory medicine organizations in the Asia-Pacific region. The aim of the organization is to support and co-ordinate activities in laboratory medicine in the Asia-Pacific Region and has been involved in multinational scientific projects. The APFCB is a partner organization of the IFCC and WASPaLM.

Represented organizations include: Australia, China, Hong Kong (China), India, Indonesia, Japan, Macau (China), Malaysia, Nepal, Pakistan, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam.

Further information is available at <http://www.apfcb.org/index.html>



## 2. World Association of Pathology and Laboratory Medicine (WASPaLM)

WASPaLM is a global organization representing societies of pathology and/or laboratory medicine, specifically with a majority of medically trained members. WASPaLM includes member organizations within the Asia Pacific region and has a key goal in sharing information amongst member organizations.

Further information is available at <http://www.waspalm.org/>

### Proposal – Expanded information

There is great interest in development of high quality CKD programs globally, including in the Asia Pacific region. These programs rely on laboratory results for the correct diagnosis, classification and monitoring of CKD. Laboratories can also be agents for implementation of programs, both by advising on test selection and especially by reporting in an agreed manner (eg routine reporting of eGFR using standardized creatinine assays, an agreed eGFR formula and clinical decision points for various tests linked to clinical actions).

The proposal is that a Working Group is formed jointly between the APFCB and WASPaLM representing laboratory medicine and APSN and AFCKDI, representing nephrology, to foster collaboration between laboratories and nephrologists for the provision of agreed, best-practice tests and supporting interpretation. A joint meeting of the APFCB and WASPaLM executives has formally endorsed this proposal.

The working group will assess the most appropriate method of coordinating activities. These activities may be at the national level (e.g. collaboration between national laboratory medicine and nephrology organizations), or at the supra-national level (e.g. several national laboratory medicine and nephrology organizations), or in intra-national level (for example the Canadian health system is organized at the provincial level rather than the national level).

While an overview of goals is provided by documents such as the KDIGO 2012 guidelines and the AFCKDI best practice recommendations, it may be preferred to plan implementation at the national, supra-national or intra-national level to allow local variations based on laboratory and nephrology resources, training and educational support, reagent and instrument suppliers, funding mechanisms and political boundaries.

A proposed plan is for the working group to identify countries and regions that may be ready to plan and implement integrated CKD programs, and then provide support as these plans are developed and brought into fruition. The success of any such program depends on local leadership and we believe this is best organized through local organizations representing laboratory medicine and nephrology and other organizations such as are considered relevant in the local environment. Support for local organizations may be through provision of visiting lecturers; mentors from countries with successful programs; support for achievement of standardized assays; review of proposed implementation plans or other ways. Countries with the fewest barriers to implementation may be those with well-established laboratory and clinical professional organizations, high uptake of standardized assays and awareness of the importance of CKD management.



- A local plan is likely to involve consideration of at least the following factors:
  - Standardization of creatinine assays
  - Managing change in results and reference intervals for any laboratories changing to standardized creatinine assays
  - A quality assurance program to confirm assay quality
  - Agreement on which patients to report an eGFR
  - Agreement on the most appropriate eGFR formula
  - Agreement on units for serum creatinine and eGFR
  - eGFR decision points for reporting
  - Standardization of measurement and reporting of urine albumin or protein
  - Guidelines to primary care doctors on when to request creatinine/ eGFR/ urine albumin
  - CKD diagnosis and management guidelines for doctors
  - Promotion of agreed best practice in laboratories and amongst doctors.

As noted in the AFCKDI best practice guidelines several of these steps may be beyond the resources of many countries. The initial step is for the parent organizations to agree in principle to the joint activity and identify a number of key people to develop the proposal and take it forward.

Success for the project would be development and implementation of integrated CKD testing and management programs in different locations in the Asia-Pacific.







## Report of the APFCB Congresses and Conferences Committee (C-CC) - 2011 – 2013

The following report on the activities of the APFCB C-CC from 2011 was presented to the APFCB Council in Bali on 27 October 2013.

### C-CC Members

Assoc. Professor Joseph Lopez - Chair (MACB, Malaysia)

Dr Leslie Lai – APFCB President and ex officio member

Mr Eric Martoyo (IACC, Indonesia)

Ms Marian Tantungco (PAMET, Philippines)

### 13th APFCB Congress Bali

The C-CC maintained close communication with the Organising Committee on the preparations leading to the 13th APFCB Congress. The APFCB President and the C-CC Chair visited Bali from 14-16 October 2012 to inspect the congress venue and meet members of the congress organising committee. The Congress Organising Committee presented a detailed progress report on the preparations for the congress. Include in the presentation was a detailed budget. In addition The COC also provided a report for presentation to the meeting of the IFCC Congresses and Congresses Committee (IFCC C-CC) held on 19th May 2013 in Milan. This report was presented by the C-CC Chair .

### First APFCB Speciality Meeting

In keeping with the APFCB Strategic Plan of 2010, the first APFCB Speciality Meeting was held at Melia Hotel, Hanoi from 18-19 March 2013. It was organised in conjunction with APFCB Committee on Laboratory Management (C-LM) and BD Diagnostics. The theme: "Quality Improvement in Laboratory Medicine through Pre-analytical Process Control". There were approximately 80 participants most of whom were from Vietnam with a small number from Indonesia, the Philippines and Thailand. The APFCB wishes to place record it thanks BD for its sponsorship and excellent organisation of this meeting.

### Auspices

One of the activities of the C-CC is the provision of the APFCB's auspices, upon request, to meetings within the region and elsewhere. In order to facilitate this activity, a set of guidelines was prepared in January 2011 for adoption by the APFCB Executive Board. These guidelines were based, with permission, on the IFCC guidelines for the provision of auspices.

The following auspices have been provided since the adoption of the guidelines:

- "International Conference on Free Radicals, Antioxidants and Neutraceuticals in Health Disease & Radiation Biology" & 11th Annual Meeting of the Society for Free Radical Research-India (SFRR-India) held at Swabhumi, The Heritage Plaza, Kolkata, India, on January 12-14, 2012.



- ✍ Research Workshop on "Inborn Errors of Metabolism & Metabolic Disorders" organised by the Department of Biochemistry, College of Medicine & JNM Hospital, India, March 7-8, 2013.
- ✍ EUROMEDLAB 2013, Milano, 19-23, May, 2013.
- ✍ 5th Vietnam Chemical Pathology Course. 2nd July 2013 (Melia Hotel, Hanoi) and 6th July 2013 (Intercontinental Hotel, HCMC).

### Turning Science Into Caring (TSIC)

Abbot has held TSIC meetings in the Asia-Pacific region over the past few years. More recently these meetings have been held in conjunction with the IFCC. Purpose of these meetings: 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 the TSIC meetings. Agreement on APFCB's participation subsequently signed with Abbott. The agreement calls for the APFCB, inter alia, to contribute to the planning of the scientific programme of future TSIC meetings.

The 6<sup>th</sup> TSIC 2013 was held in Taipei on the 23<sup>rd</sup> and 24<sup>th</sup> September, 2013. The C-CC Chair represented the APFCB at the opening. The meeting consisted of 6 plenaries and 4 workshops with the following themes:

### Plenaries

- The Global Diabetes Epidemic: diagnosis, monitoring and disease management
- The Evolution of Cardiovascular Disease, from Definition to Patient Care
- Hepatitis Prevention, Screening, Diagnosis and Patient Care
- Revolutionizing Laboratory Medicine with Hospital and Laboratory Information Systems (HIS/LIS)
- The Global Harmonization Initiative
- Clinical and Health Economic Implications of HCV Viral Load Precision in an era of New Direct Acting Antivirals

### Workshops

- Implementation of hsTnI in Acute Setting, Cardiology and Laboratory Medicine
- Three Pillars of Patient Care: Universal Reference Intervals, Assay Standardization, Assay Quality
- Impact of Laboratory Medicine on Patient Outcomes and Management
- Current Trends in Infectious Diseases Diagnosis and Patient
- As the agreement with Abbott was signed after all preparations for
- Taipei meeting had been made the APFCB could not contribute to the scientific programme but will do so for future meetings.

*Report Prepared and Submitted by Joe Lopez -Chair - C-CC*





## 13th APFCB CONGRESS 2013, BALI

**Interim Report on 13th APFCB Congress, Nusa Dua, Bali, Indonesia,  
27-30 October 2013**

1. **Venue: Bali Nusa Dua Convention Center**
2. **Attendees:**
  - a. Participants + accompanying persons: 943 from 49 countries  
(one participant each from Algeria and Sudan did not attend)

No	Country	Participants
1	Australia	28
2	Austria	3
3	Belgium	4
4	Brunei	3
5	Canada	13
6	China	42
7	Cyprus	1
8	Czech Republic	3
9	Denmark	3
10	Egypt	4
11	France	1
12	Germany	3
13	Hong Kong	12
14	Hungary	1
15	India	41
16	Indonesia	412
17	Italy	2
18	Iran	2
19	Japan	46
20	Kazakhstan	1



No	Country	Participants
21	Kenya	1
22	Korea, South	36
23	Malaysia	28
24	Macau	1
25	Mexico	1
26	Netherland	10
27	Nepal	4
28	New Zealand	4
29	Nigeria	1
30	Norway	1
31	Pakistan	2
32	Philippines	22
33	Russia	1
34	Saudi Arabia	10
35	Singapore	55
36	South Africa	5
37	Sri Lanka	10
38	Slovakia	3
39	Spain	1
40	Sweden	2
41	Switzerland	1
42	Taiwan	20



No	Country	Participants
43	Thailand	28
44	Turkey	19
45	UK	14
46	UEA (United Arab Emirates)	1
47	USA	15
48	Vietnam	21
49	Zambia	1
<b>TOTAL</b>		<b>943</b>

b.Exhibition: 400 exhibitors

### 3.Workshop Attendees:

a. 5 Pre-congress workshops:

	Indonesian	Overseas
- Workshop 1	10	7
- Workshop 2	17	5
- Workshop 3	2	2
- Workshop 4	6	7
- Workshop 5	45	7

- - Workshop 1: IFCC Workshop: Allowable Errors for Traceable Results
- - Workshop 2: Quality Tools for patient safety (Healthcare Quality Society of Singapore)
- - Workshop 3: IACC Workshop: Conducting mini research in your own laboratory





- Workshop 4: Hands-on: Statistical knowledge and skills required for conducting a study on reference values.
- Workshop 5: APFCB Education Committee: Interpretation and commenting on laboratory results
- b. 4 Plenary lectures
  - Predictive, personalized, preventive and participatory laboratory medicine
  - Managing laboratory informatics, middleware and process control
  - Non-Invasive prenatal diagnosis: from science to clinical applications
  - Future Laboratory Medicine: LC/MS vs Immunoassay
- c. 26 Symposia
- d. Free papers:
  - 29 oral presentations
  - 201 posters
- e. Invited speakers: 94 for plenary lectures and symposia (Dr. Wei Lai from CSLM, who was supposed to talk at symposium 16, didn't come because of health issue. He informed the committee by email at the time of congress and Dr. Sun Fei from CSLM presented the lecture in place of him), 1 facilitator for workshop 2, 2 facilitators for workshop 4, and 1 speaker for the publisher workshop (Elsevier).
- f. From total of 153 presentation slides:
  - 57 speakers agree to upload their slides to the websites
  - 48 speakers didn't agree
  - 48 speaker didn't fill in the agreement form
- g. Awards:
 

Poster Presentations:

1st : PP014 (Winny Djiu – Indonesia)

2nd : PP008 (Johanis Chan – Indonesia)

3rd : PP004 (Thyrza Laudamy Darmadi – Indonesia) and PP001 (Shanti Naidu Kamatham – India)

Oral Presentations:

  1. Jean Claude Forest – Canada (Op2)
  2. Shanmugapriya Chandrasekaran – India (Op3)
  3. Manhar Vanessa Lo – Hongkong SAR, China (Op4)
  4. Limei Luo – China (Op5)
  5. Phey Liana – Indonesia (Op6)

#### 4. Scholarships:

- a. APFCB: 8 delegates
  - 2 from APFCB
  - 1 from APFCB-Abbott
  - 5 from APFCB-Siemens
- b. IFCC: 10 delegates



## 5. Trade and exhibition:

A. 97 booths (per 3x3 meter square booth) consist of 40 companies and 6 associations namely IACC, APFCB, IFCC, AACC, WASPaLM, and ASCPaLM.

List of participating companies:

ABBOTT DIAGNOSTICS	RCPA
ALERE HEALTH	ROBONIK
BD DIAGNOSTICS	ROCHE DIAGNOSTICS
BECKMAN COULTER	SAMSUNG ELECTRONICS
BINDING SITE	SEBIA
BIO-RAD	SEKISUI
BIOSINO BIOTECHNOLOGY	SETIA GUNA MEDIKA
DIALAB	SHANGHAI KINBIO TECH
DIASORIN	SIEMENS HEALTHCARE DIAGNOSTICS
DIASYS DIAGNOSTIC SYSTEM	SNIBE
DIRUI INDUSTRIAL	SUKRAA SOFTWARE SOLUTION
HORIBA	SUMMIT
INTI MAKMUR MEDITAMA	SYSMEX
JASEM	TAMARA OVERSEAS CORPORINDO
MAYO MEDICAL LABORATORIES	TECHNIDATA
MINDRAY	THERMO FISHER SCIENTIFIC
MITRA BAHAGIA	TOKYO BOEKI
ORTHO CLINICAL DIAGNOSTICS	TRANSMEDIC INDONESIA
PROLINE	WIDYA MITRA PERSADA
RANDOX LABORATORIES	WYNACOM

B. 7 industry symposia: Becton-Dickinson, Roche, Mindray, Abbott, Siemens, Sysmex, and Beckman-Coulter.

## 6. Social events:

- a. Opening ceremony on 27 October 2013: the congress was opened by DR. Dr. Trihono, Head of Health Research and Development Agency, Ministry of Health (Kepala Badan Penelitian dan Pengembangan Kesehatan) on behalf of Dr. Nafsiah Mboi, SpA, MPH, Minister of Health of Indonesia, who had given her opening address in video recording.
- b. Cultural night at Garuda Wisnu Kencana on 29 October 2013 with the theme of Indonesian culture which included cultural dances from Bali, West Sumatera, Madura, Aceh, and interactive “Angklung” performance from West Java.
- c. Closing by Dr. Leslie Lai, President of APFCB and hand-over ceremony to the next host (Taiwan) on 30 October 2013.





Executive and council members of APFCB at 13th APFCB Congress on 27th October 2013, Bali

**7. Event Organizer:**

IACC as the host signed an agreement with Pactoconvex Ltd ,in Jakarta on 25th Jan 2012 on a profit / loss sharing basis.

*Report prepared and submitted by July Kumalawati, Chairman - OC*



## 4<sup>th</sup> "ACBI-IFCC Task Force for Young Scientists" Educational Symposium At 40<sup>th</sup> ACBI CONFERENCE, 5<sup>th</sup> Dec 2013, Delhi, India



*Left to Right: Dr. Pradeep Kumar Dabla, Dr. Pankaj Sharma, Dr. Bernard Gouget, Dr. Michael Oellerich, Dr. Praveen Sharma, Prof. Howard Morris, Dr. MVR Reddy*

### Theme: Promising Pathways for Young Scientists-Today & Tomorrow

**IFCC-Task Force Young Scientists (IFCC-TF YS) and Association of Clinical Biochemists of India (ACBI)** organised 4th Educational Session at Annual ACBI Conference (ACBICON) 2013 held at Delhi on 5 Dec 2013.

This symposium aimed at creating awareness about the new changing environment of medical laboratories and the role of laboratory scientists in the field of research and industry. The event was successfully conducted and attended by more than 100 delegates from across the country to know about the emerging trends in Laboratory Medicine and the current and future developments related to technological advancements and testing profile. It helped to describe the role of research training to improve research services. It was held at the National Agriculture Science Centre (NASC) Complex, Pusa, Delhi. The conference was organised by the Vardhaman Mahavir Medical College & Safdarjung Hospital in association with ACBI Delhi Chapter under the leadership of Dr. Jayashree Bhattacharjee, Principal, VMMC & Organising Secretary ACBICON-2013, Delhi.

Devoted to prepare young scientists, IFCC-TF YS was built in 2010 with the objectives of Networking, Training, Participation & Multidisciplinary exchanges of different fields & different ideas. Three workshops have been conducted in row at India with the collaborative efforts of ACBI & IFCC since 2010. First IFCC-TF YS workshop was organized in ACBICON-2010, 12Dec2010 at Mumbai under the theme of "Mapping Future of Laboratory Scientists" stressing on good Lab practices and Accreditation.



Second workshop was organised in ACBICON-2011, 3 Dec 2011 at Gwalior themed as “Think The Unthinkable” stressing on Various Job Opportunities present in Lab Industry and other health related sectors.

Third workshop was organised in ACBICON-2012, 11 Dec 2012 at Ranchi under the theme of “Clinical Chemistry to Clinical Laboratory Science” to embrace new technologies & learn the challenges related to laboratory management.

The opening ceremony was initiated by Dr. Pradeep Kumar Dabla, then Member Core Committee IFCC-TF YS & Convener session. He gave a brief note about the objectives of Task Force & previous sessions organised at annual ACBI Conferences, India & worldwide throughout the year 2013. He welcomed delegates & senior members of ACBI, IFCC & WASPaLM fraternity on behalf of Dr. Gabriel Ko, Chairperson, IFCC-TF YS. Dr. Abhay Pratap, President ACBI welcomed & addressed the young scientists for upcoming activities.

The first session was chaired by Dr. Praveen Sharma, Past President-ACBI, Chief Editor-IJCB & Chair Communication Committee-APFCB. Dr. Bernard Gouget, Treasurer-IFCC opened the talk by briefing the technological development of Laboratory Medicine and opened new avenues. He explained how the rapid progress of science and technology is improving the expertise and professionalism of laboratory medicine specialists. He advised to join forces and work together outside our national borders to have access to this knowledge & to maximize the influence of laboratory results on to the patient welfare. Dr. Michael Oellerich, Director Europe WASPaLM described the advantage of Tandem Mass Spectrometry for monitoring specific analytes such as immunosuppressants, antiretroviral drugs whereas automated Immunoassays as a leading technology for routine determinations. He explained the role of proteome analysis by mass spectrometry as a tool for discovery of biomarkers. Emphasizing lab professionals as being central to safe & effective patient care, he stressed onto the raising profile of lab medicine as an attractive career choice. Dr. Pradeep Kumar Dabla, Assistant Prof. Biochemistry & Lab Incharge, CNBC, Pediatric Super speciality Hospital, Delhi said “children are not little adults, so we need to have unique approach for pediatric lab testing” and described how pediatric patients are different from adults both in physiological & pathological state.

He advocated for total automated instrumentation and the need of special instrument designs to handle smaller pediatric sample volumes & tubes. Need to perform more correlative laboratory studies based on specific age and diagnostic subsets of children.

The second session was chaired by Dr. Howard Morris, Vice-President IFCC. Dr. MVR Reddy, EB-ACBI, Web Editor-APFCB News, Prof. & Head Biochemistry, MGIMS Sevagram initiated on promising note for Research environment & hopes for young scientists. He explained the various career options for budding medical biochemists & why to choose a research as a career with detailed insight. He summarised skills needed for research, raising research profile and opportunities in India & abroad.





Dr. Pankaj Sharma, Head Quality Control & Biophysics, Dr Lal Path Labs Pvt Ltd, India explained the point of view of Industry as a career option for young scientists. He said “the world has become a local market. Industry is facing domestic as well as international competition where distance is dead. He gave a real time data for booming Healthcare Industry and stressed onto the need of “Techno Commercial Scientist” with the technical knowledge & business skills. He explained the concept of Right Place at the Right Time in view of Industry.

The session was ended by Dr Pradeep Kumar Dabla vote of thanks and souvenir distribution by senior members of ACBI, IFCC & WASPaLM fraternity. To conclude, this session provided a unique platform to the healthcare professionals to exchange ideas and to build stronger bridges between our professional societies. Lab medicine contribution has become an essential to our healthcare services, which not only impact clinical outcomes but quality, satisfaction and cost.

*Report prepared and submitted by Dr Pradeep Kumar Dabla*





## Report of Association of Clinical Biochemistry of India 2013

The year 2013 started with a large number of scientific meetings & workshops which were arranged by the different State/Regional Chapter of the Association. The major ones were:

**(1) The EAST ZONE Unit of ACBI** organized a four day training course on Quality Management System & Internal Auditors, from 15th to 18th of January, 2013. The program was coordinated by QCI coordinator for West Bengal, Prof. Krishnajyoti Goswami, Former President of ACBI.



*The training course was attended by 46 participants from the state of Odissa, Jharkhand, Assam & West Bengal, all of whom completed it successfully under the training & guidance of Dr P D Sawant, Technical Committee member of NABL, and Prof. T. Venkatesh, Principal Advisor of QCI & Director, NRCLPI. A Final evaluation of the candidates along with the results of the mock audit was conducted on the fourth & final day of the training. This was followed by a closing speech by*

**2) A "Research Workshop on Inborn Errors of Metabolism & Metabolic Disorders"** was organized by the Department of Biochemistry, College of Medicine & NM Hospital, West Bengal University of Health Sciences,, Kalyani on March 7-8, 2013, in association with International Union of Biochemistry & Molecular Biology (IUBMB) and under auspices of Association of Clinical Biochemists of India (ACBI).





*Releasing of Abstract by Dir Prof Amit Banerjee, Hon'ble Vice Chancellor, WBUHS. In dias: Prof D.M. Vasudevan, Prof D. Bhattacharyya, Principal, COMJNMH & Prof. Subir Kr Das*

The workshop was officially opened by Prof Amit Banerjee, Hon'ble Vice Chancellor, West Bengal University of Health Sciences. Various scientists from India and abroad addressed the august gathering. Amongst them were Prof. D.M. Vasudevan – Kochi, Prof Robert Aquaron, France , Dr. Ashwin Dalal, Hyderabad, Dr. Rita Christopher from NIMHANS, Bangalore, Dr. Noah Weisleder from the Ohio State University, USA, Dr. K. Nandagopal, Calcutta University, Dr. Purnima Prabhu from the PD Hinduja Hospital, Mumbai, Prof John E Baker, Wisconsin, USA , Dr N. Maulik, Connecticut Medical Center, USA, Travis Gurney, Columbus, USA; Dr. T.Vijayakumar, Dr. J. Bhattacharyya, University of Missouri, Columbia, USA.





**(3) A National Seminar on Biomarkers was organised by the ACBI Kerala chapter in connection with the first south zone meeting of the ACBI at MES Academy of Medical Sciences, Perinthalmanna on 8 & 9 June 2013.**



It was inaugurated by Dr. K Mohandas, the honourable Vice Chancellor of Kerala University of Health Sciences. Dr. D M Vasudevan, chairman of the organising committee and the past president of ACBI chaired the function and also delivered his keynote address on Markers of Diabetics and Diabetic complication. Amongst the other topics that were covered were Cardiac Markers, Tumor Markers, Markers of Chronic Kidney Disease Acute Kidney Injury, etc. More than 350 delegates participated in the seminar which included participants from Kerala, Tamil Nadu, Pondicherry, Karnataka and Andhra Pradesh. The Medical Council of India had sanctioned 6 credit hours for medical practitioners participating in the conference.



**(4) A National Symposium on Biomarkers in Health and Disease: Bench to Bedside** was organized by Department of Biochemistry, Shri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun on July 3-4, 2013, under the auspices of Shri Guru Ram Rai Education Mission, Dehradun, Medical Council of India and Indian Council of Medical Research, New Delhi. Dr RK Singh, Acting Principal and HOD of Biochemistry Department, Shri Guru Ram Rai Institute of Medical and Health Sciences was the Organizing Secretary.

The Symposium was inaugurated by Dr VM Katoch, Secretary, Department of Health Research, Government of India and Director General, Indian Council of Medical Research, New Delhi. The symposium was attended by more than 200 delegates from India and abroad.

**(5) The Uttarakhand Branch of Association of Clinical Biochemists of India** and Shri Guru Ram Rai Education Mission, Dehradun jointly organized the First International Lead Poisoning Awareness Week at the Department of Biochemistry Shri Guru Ram Rai Institute of Medical and Health Sciences, Dehradun from 20-26 October 2013. This function was addressed by Prof R K Singh, Head, Biochemistry Department who presented an overall view of Lead Poisoning as per World Health Organization Report in developing countries and particularly in India. Prof S K Rana, Head, Pediatrics Department delivered a Lecture on IMPACT OF LEAD EXPOSURE ON NEONATAL AND CHILDHOOD MORBIDITY. Students from different schools of Shri Guru Ram Rai Education Mission were invited to the Department on this occasion and were explained the importance of Lead Poisoning through Posters and oral Presentations.

**(6) A Seminar on Advances in Laboratory Medicine** was conducted under the auspices of Association of Clinical Biochemists of India (ACBI), Kerala Chapter, in collaboration with the Association with the Society of Clinical Chemists of Kerala (SCCK), on the 6th October 2013 at Alappuzha (Alleppey), Kerala and was organized by Dr. T. Vijayakumar, Kerala State representative of ACBI. About 200 delegates were registered for the Seminar, which included practicing doctors, medical students, MSc Biochemistry students, MLT students, Laboratory managers and Technicians, coming from all over Kerala. The Keynote address was delivered by Dr. D.M. Vasudevan, Principal (Retd), Amrita Institute of Medical Sciences, Kochi and Past-President, ACBI, on "Laboratory Medicine, yesterday today and tomorrow". Eminent speakers from different medical colleges of Kerala delivered their talk on different advances that took place in laboratory medicine.

### **13<sup>th</sup> ASIAN PACIFIC CONGRESS OF CLINICAL BIOCHEMISTRY & LABORATORY MEDICINE**

About 35 delegates from India attended the 13<sup>th</sup> APFCB Congress which was held in Bali, Indonesia from 28 to 30<sup>th</sup> October 2013. ACBI sponsored a symposia on "Endocrine and Metabolic Abnormalities" in which Dr. Praveen Sharma, Dr M.V.R Reddy and Dr Rajiv R Sinha spoke on various aspects of Metabolic syndrome and Type I DM.





Three young ACBI members Dr. Saswati Das, Dr Surupa Basu and Dr Namita P. Mahalle, were awarded Scholarships to attend the Bali congress by APFCB as well as IFCC. During the APFCB council meeting on 27<sup>th</sup>. October, ACBI had submitted and won its bid for hosting the 2019, 15<sup>th</sup>. APFCB Congress in Jaipur.

**The "ACBI-CMC External Quality Assurance Programme"** - is being run smoothly by Dr. R . Selvakumar and his team at Christian Medical College, Vellore, Tamil Nadu. A total of 2810 labs participated in this years EQAS programme with 282 new labs joining this year. ACBI-CMC EQAS crossed another mile stone with the introduction of an immunoassay programme having Thyroid hormone & cortisol. The HbA1C prograzmme was added in 2012 and nearly 350 labs are participating in its QC programme. As had been mentioned last year, The application for accreditation of the programme by NABL has been submitted under ISO 17043:2010. The preliminary assessment is over and the final assessment is due in December 2013.

During the year newer programs namely Special hormones which include mainly the reproductive hormones, Biochemical Markers for Down's screening and Urine chemistry were introduced. In its efforts on adding more value to the EQAS sample, reference materials were purchased from Welsh EQAS and a new assessment tool was introduced in April 2013, termed 'VCRM' the Value Corrected to Reference Mean. During the coming years, the EQAS team looks forward to improve the assessment pattern, to introduce more programs and to cater to a larger population. Thanks to Dr Selvakumar, his team & the management of CMC Vellore for keeping this flagship project of ACBI moving smoothly.

### **40<sup>th</sup> Annual National Conference – ACBICON 2014**

The year ended with the highly successful 40<sup>th</sup> ACBICON 2014, the 40<sup>th</sup>. Annual National Conference of Association of Clinical Biochemists of India was hosted by VMCC & Safdarjung Hospital and Delhi Chapter of ACBI from 3<sup>rd</sup> December to 6<sup>th</sup> December 2014 at National Agricultural Science Convention Centre, Pusa Road, New Delhi.. It was a four days event, beautifully segregated into Orations, Plenary, key notes, oral and poster presentations, quiz and Industrial symposia.

The conference commenced with the Awadesh Saran Memorial Oration delivered by Dr Praveen Sharma, AIIMS, Jodhpur, Rajasthan. This was followed by Seth G.S Medical College & KEM Hospital Oration delivered by Dr. Subrata Sinha, Director, National Brain Research Centre, Gurgaon, Haryana. This was followed by parallel session which had a Plenary talk by Dr. Steven Wong, President Elect, AACC, USA and Special Talks by Dr K Kannan, Dr.S.K Jain, Dr Kalyan Goswami & Dr Arun Raizada. There was also a Corporate sponsored symposia by Beckman. This was followed by the Poster session. After this, all the delegates enjoyed their lunch in the lovely winter sunshine.

Inauguration of the 37<sup>th</sup> ACBICON 2010 was done in presence of many eminent personalities. The chief guest was the Honorable Vice-chancellor of Jamia Hamdard University, Dr G. N Qazi and the Guests of Honor was Dr. B. D. Athani. The year ended with the highly successful 40<sup>th</sup> ACBICON 2014, the 40<sup>th</sup>. Annual National Conference of Association of Clinical Biochemists of India was hosted by VMCC & Safdarjung Hospital and Delhi Chapter of ACBI from 3<sup>rd</sup> December to 6<sup>th</sup> December 2014 at National Agricultural Science Convention Centre, Pusa Road, New Delhi.. It was a four days event, beautifully segregated into Orations, Plenary, key notes, oral and poster presentations, quiz and Industrial symposia.



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During the function, Dr Neelima Singh (Gwalior) and Dr Suman Bala Sharma (Delhi) were conferred with the Fellowship of ACBI (FACBI) by the chief Guest. He also presented a Shawl & Silver plate to Dr. T. Venkatesh (Bangalore) who was conferred with the ACBI-A.J. Thakur Award for Distinguished Services to Clinical Biochemistry and Laboratory Medicine.

December 4<sup>th</sup> commenced with the Taranath Shetty Memorial Oration given by Dr. S. K. Sarin, Director, Institute of Liver & Biliary Disease, Delhi and the Mrs. & Dr G P Talwar Oration by Dr Rajendra Prasad, PGIMER, Chandigarh. Thereafter, the Plenary Session was delivered by Dr. N. K. Mehra. Special Talks were held in parallel with Corporate sponsored symposia by Merck Millipore. After lunch, Poster & various Parallel session were held. Before the close of the day's proceedings Oral Free paper presentations were held, after which the General Body Meeting of Association was held. The GB elected the following as Executive Committee members for the year 2014. Dr. Jayashree Bhattacharya as PRESIDENT, Dr. Praveen Sharma, Organizing secretary, ACBICON 2014, Dr. Monika Gupta - VICE PRESIDENT (II), ADVISOR- Prof. K.P. Sinha, GENERAL-SECRETARY- Dr. Rajiv Ranjan Sinha, TREASURER- Dr Krishna Ranjan Prasad, JOINT SECRETARY: Dr. H. V. Singh (Delhi) & 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). Mr. Upendra Singh, Kopran Limited was elected as CONVENOR, ACBI CORPORATE WING.

Morning of Day 3 started with the T. N. Pattabiraman Oration being delivered by Dr. S. V. Rana, PGIMER, Chandigarh and the K. L. Gupta Memorial Oration, which was delivered by Dr. Lalit Kumar, Prof of Medical Oncology, AIIMS, Delhi. Dr Howard Morris (Australia) delivered the Plenary lecture on Vitamin D: clinical & laboratory perspective. Thereafter, Parallel sessions and as well Corporate symposia sponsored by Transasia, Meril and Abbott took place. The Poster Discussion and Lunch was followed by Parallel symposia's and the IFCC sponsored IFCC Task Force for Young Scientists symposia. The day's scientific session ended with the much awaited and ever popular AFMC Quiz Session which was successfully conducted by Dr. T. Malati and Dr R Chawla. Day 3 ended on a grand note with a lively cultural programme and Banquet which was sponsored by Transasia Biomedicals.



The penultimate day of the conference started with a plenary lecture by Dr Brain Gouget (France) on Lab Management and Patient safety. This was followed by parallel sessions. One session was the Award Paper Presentation, which saw young delegates vying for the different ACBI Awards. There were two corporate session side by side, by Siemens & Nicholas Piramal. Following the Tea break, we had three parallel symposia's by Dr Subir Das, Dr B. C. Harinath & Dr S. B. Sharma. This was followed by the Valedictory Function bringing the curtain down on 3 ½ days of intense, high level scientific sessions. The organizing Secretary, Dr Jayashree Bhattacharya thanked all the delegates and volunteers for making the conference a grand success. The advisor ACBI, Dr K. P. Sinha congratulated Dr Bhattacharya & her team for the successful organization of the conference. After this he distributed the award certificate & cash prizes to all the award winners. The General Secretary, ACBI, Dr Rajiv R. Sinha in his valedictory address heartily congratulated all the organizing committee members and volunteers for their untiring effort in making the 2014 National conference a great success.

*Report prepared and submitted by Association of Clinical Biochemists of India*



## Report from Association of Clinical Biochemistry Sri Lanka (ACBSL) 2013

ACBSL is an incorporated association under the Companies Act, Sri Lanka. The total membership, including associate members is 25 and both Chemical Pathologists and Clinical Biochemists attached to state sector hospitals, universities and private sector hospitals who are involved in the provision of Clinical Biochemistry Diagnostic services are eligible to apply for the membership. ACBSL is a full member of APFCB and IFCC.

### Office Bearers:

Mr. H. Weerawarna	President
Dr. B. K. T. P. Dayanath	Secretary
Ms Sriyani Amarasinghe	Treasurer
Dr. Saroja Siriwardane	Past President

ACBSL has conducted three Executive committee meetings during the year. All the members were informed of the important notices and messages received from IFCC and APFCB.

Seven ACBSL members participated in the 13th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress in Bali, 27-30 October 2013. This was a very rare and valuable opportunity for our members, especially for young members to exchange ideas about the practices of clinical chemistry in other regions and update their knowledge by listening to eminent speakers. In addition the exposure to this regional event will be helpful for our members to organize similar regional events in future.

Dr B K T P Dayanath, Secretary, ACBSL has participated in EUROMEDLAB which was held in Milan from 19th - 23rd May 2013 as he was fortunate to win Roche Travel Scholarship. Detailed report on this participation appeared in IFCC e-NewsLetter, July – August, 2013 issue. In his report he has specifically mentioned that he was amazed by the organizational skills of IFCC and its member associations in organizing such a highly advanced event. He has learned essential components to be applied when organizing a scientific congress back in Sri Lanka, by participating in this event.

ACBSL has provided two resource persons to deliver lectures on two topics namely, Measurement Uncertainty and Traceability and Potential Errors in Laboratory Testing, for a workshop on "Quality Improvement of Laboratory Testing: Some Important Aspects" conducted by the Sri Lanka Association for the Advancement of Science (SLAAS) which has been held at the Faculty of Medicine, Colombo on 02nd November, 2013.

ACBSL has been entered in to an AGREEMENT FOR MUTUAL COLLABORATION with M/s. OMICS Group Inc., 2360 Corporate Circle, Suite 400, Henderson, NV 89074-7722, USA (journals, Medicinal Chemistry and Chemical Sciences Journal) with effect from the 12th August, 2013. A considerable number of ACBSL members have participated in Interpretative



Comments Educational Program conducted by APFCB and they will be continued their participation once this program is re-launched for the year 2014. At the executive committee meetings ACBSL has taken the following decisions to implement as future plans.

- ACBSL to offer the assistance to Cosmetics, Devices & Drugs Regulatory Authority, Sri Lanka to streamline the registration process of IV Devices. Presently some of ACBSL members are involved in the process of registration by evaluating new laboratory devices for diagnostic purpose.
- To work in association with Sri Lanka Accreditation Board (SLAB) to promote ISO 15189 accreditation, especially in state sector hospital laboratories. Presently some of our ACBSL members are working as quality consultants and Assessors for the SLAB.
- To organize training programs on subjects related to accreditation for the private sector and state sector laboratory staff. Training programs will be conducted for Phlebotomy staff on Pre Analytical Errors which is a neglected area in laboratory diagnosis.
- To support the idea of accreditation and to give necessary support to the committee appointed by the Ministry of Health, Sri Lanka to implement the accreditation in state sector hospital laboratories.
- Next Annual General Meeting of the ACBSL will be held in March 2014.

*Report prepared and submitted by Association for Clinical  
Biochemistry, Sri Lanka*





## Report from Chinese Association of Clinical Biochemistry (Taiwan) 2013

### I. CACB annual conference and scientific symposium, conjunction with 28<sup>th</sup> JACBS

This brief report summarizes some of the highlights of activities for CACB during the Year of 2013. CACB held annual conference on March 23<sup>rd</sup>, and its constitution was amended. CACB will be also devoted to advocate the establishment and education of professional clinical chemistry medical technologist, which is aimed at promoting research studies in the field of clinical chemistry, its development and application, to improve quality of medical service, and to upgrade the citizen's health. This amendment was approved by the Ministry of the Interior, Taiwan.

During the 28<sup>th</sup> Joint Annual Conference of Biomedical Science (JACBS) held at the National Defense Medical University Campus on March 23-24, 2013, we invited Dr. David G. Grenache, Associate Professor of Pathology at University of Utah School of Medicine and Medical Director of ARUP Laboratories in Salt Lake City, U. S. A., to deliver a special lecture on "Macroprolactin: what laboratorians need to know". He also shared valuable experiences in detecting macroprolactin with us. CACB also organized a symposium "Current Trend in Clinical Biochemistry" regarding to the recent findings in hepatocellular carcinoma, colorectal cancer, lung cancer, and diabetes. Four respected speakers shared their new knowledge and insights with students and professionals. Prof. Tsan-Zon Liu presented "Serum ferritin-to-iron (FIR) ratio as a hepatocellular carcinoma marker complementary to alpha-fetoprotein and as a prognostic predictor of metastasis". Dr. Chih-Pei Lin addressed "Simvastatin have artery calcification inhibitory effects in type II DM Ldlr<sup>-/-</sup> mice". Dr. Ya-Chien Yang spoke on "Molecular diagnostics for chromosomal and epigenetic instability in colorectal cancer". Dr. Kang-Yi Su talked about "Molecular diagnostics for lung cancer multiplex gene testing by MALDI-TOF MS with high sensitivity and flexibility".

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.





2. CACB members participated in 13<sup>th</sup> APFCB Congress in Bali, Indonesia on Oct. 27-30, 2013, and also exhibited for the promotion of the next 2016 Congress in Taipei.

President Woei-horng Fang, together with 4 executive board members and secretary general, attended 13<sup>th</sup> APFCB Congress in Bali. CACB also sponsored Symposium 24 on "Trends in laboratory medicine technology" of the Congress. Dr. Kang-Yi Su was invited to speak on "Molecular diagnostics for lung cancer multiplex gene testing by MALDI-TOF MS with high sensitivity and flexibility".

Dr. Tjin-Shing Jap addressed "Genetic study of disorders of mineral metabolism in Taiwan". Prof. Shu-Chu Shiesh talked about "Assessment of metabolic alterations by tandem mass spectrometry". A comprehensive discussion and communication of these issues arose from the presentation. In addition, it is a great honor for CACB to have the opportunity to host the 14<sup>th</sup> APFCB Congress 2016 in Taipei, Taiwan. Currently, the organizing committee has been established in charge of conference organization.

We also exhibited a Taiwanese-style booth to promote the next Congress. More than five hundred participants dropped by and received the 2016 Congress announcements, traveling information, and small warm welcome gifts. President Fang also performed an impressive slide show with singing a Taiwanese folk song in the closing ceremony. We sincerely invite you to participate in the 14<sup>th</sup> APFCB Congress in Taipei on Nov. 5-8, 2016, and also visit our beautiful island.



*28th Joint Annual Conference of Biomedical Science: Members of organizing committee and special lecturer*



*APFCB President Dr. Leslie C. Lai and CACB members in front of our 14th APFCB Congress booth.*

*Contributed by Dr. Woei-horng Fang, National Taiwan University, President,  
Chinese Association for Clinical Biochemistry*



## Report of Hong Kong Society of Clinical Chemistry 2013

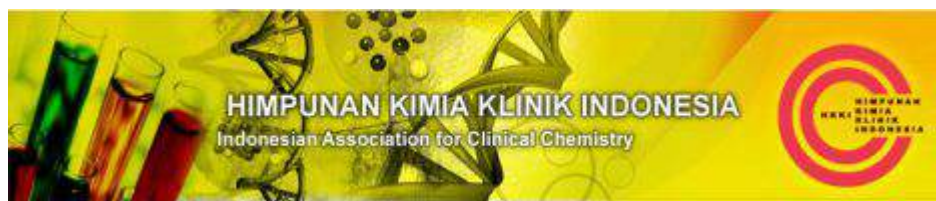
The year 2013 began with the Society's Annual Scientific Meeting and Annual General Meeting held in January. Being the 30th Anniversary for the Society, the event was attended by over 200 members who enjoyed two exciting presentations on non-invasive prenatal diagnosis, and public health dimension of chemical pathology delivered by two veteran members – Prof Rossa Chiu and Dr Tony Mak.

Education activities for the year carried on with presentations by distinguished scientists: Prof Ann Gronowski on laboratory testing during pregnancy in April; Prof Chris Florkowski delivering two lectures on porphyria and vitamin D respectively in May; Dr Alan McNeil on use and misuse of tumor markers in September; Dr James Nicols on laboratory QCs based on risk management in November; Dr Peter Veraart and practical approach to QC rules and frequency in November as well. All these educational events were attended by over 150 members and guests.

In support to regional clinical biochemistry development, HKSCC afforded a strong delegation to the 13th Asian Pacific Congress of Clinical Biochemistry held in Bali, Indonesia in October. The effort was lead by Prof Dennis Lo as a plenary speaker on non-invasive prenatal diagnosis, and the hosting of an HKSCC Symposium in the Congress. Three distinguished members: Dr CS Ho, Dr Robert Cheung, and Dr Doris Ching presented on clinical chemistry topics of diverse interests: steroid analysis by mass spectrometry, organization of trace element analytical service, and emerging drugs of abuse.

Future educational and training events will continue in 2014: Society's Annual Scientific Meeting and Annual General Meeting held in January; Dr Michael Meisner on procalcitonin biochemistry & clinical diagnosis in February; Prof Greg Miller on harmonization and traceability of results and Dr Steve Wong on pharmacogenomics and pharmcometabolomics for transplant, pain management and toxicology in April. Further training on clinical cases interpretation will be scheduled in October.

*Report prepared and submitted by Hong Kong Society of Clinical Chemistry*



## Report from Indonesian Association of Clinical Chemistry 2013

### I ORGANIZATION

Indonesian Association for Clinical Chemistry (IACC) National Congress held in Santika Hotel Nusa Dua Bali, October 26, 2013. Beside for the Accountability Report of IACC Organization Committee 2009-2013 and the National Congress participants had elected Dr. July Kumalawati for the new president and appointed by the association to lead the formation of the new organization committee of IACC for period 2013 to 2016. The formation the new organization committee of IACC 2013-2016 is as follows:

#### Past president:

Dr . Dra. Dewi Muliaty, M.Sc.

#### President:

Dr . July Kumalawati, DMM, SpPK (K)

#### Secretary:

Krist Haksa

#### Secretariat:

Sri Paulani, Ssi

#### Treasurer:

Dr . Augustine Matatula, SpPK and Sri Paulani, Ssi

### LABORATORY MANAGEMENT and QUALITY CONTROL

#### Improving Preanalytical Practice in Indonesia by "May I Help Campaign" (MIHC)

More than 70% of the medical decisions in the modern healthcare system are influenced by the results obtained from the clinical laboratory. While analytical automation in laboratory testing has resulted in reduction in a large number of analysis related errors; unless specimen quality is improved, increasing the reliability of laboratory results is difficult to achieve. There are several published reports in multiple, reputed peer reviewed scientific journals indicating that up to 75% of laboratory errors are caused by the processes carried out – including blood collection – before the analysis is performed. The 'Garbage in Garbage out' analogy that has been so well accepted and understood in the IT industry is equally relevant to the modern clinical laboratories.





The Indonesian Association of Clinical Chemistry (IACC) and Becton Dickinson (BD) share a common goal of improving preanalytical specimen collection, handling practices with an intention of improving overall patient care in the country. The current processes used for specimen collection throughout the country vary considerably and may be responsible for a large number of preanalytical specimen quality compromises leading to errors in laboratory results and hence sub-optimal patient care. Also, use of improper practices in the preanalytical phase could pose risks to the healthcare workers via exposure to infectious body fluids through potential needle stick injury or through other routes. Both organizations recognize the need to strengthen preanalytical practices in Indonesia and would like to promote awareness for safer and improved specimen collection and handling practices. The partnership aims at improving preanalytical practices and will be referred to as the "May I Help You Campaign".

BD has the capability and expertise to conduct these audits in Asia Pacific region and would deploy personnel to conduct these audits in Indonesia and also later would build capability within BD Indonesia team to conduct such audits.

BD also has deep expertise in providing training to health care workers on occupational safety and key clinical and laboratory procedures, which are vital components of healthcare capacity building and sustainability. The specific goals of the May I Help Campaign are:

1. Conduct mini-audits in selected healthcare facilities in Indonesia with an objective of identifying gaps in preanalytical practices with reference to various international guidelines / recommendations. This work would be conducted over the course over an initial period of 12 months. Audits to be conducted by BD and IACC free of charge.
2. Present the identified gaps to the respective laboratory and institution leadership and make recommendations for improvement that could help the facility in improving practices and patient outcome.
3. Conduct a revised mini-audit at the facilities after they have confirmed having taken actions based on the recommendations from the first audit



4. Utilize the data obtained from the above for furthering advocacy and policy deployment for addressing preanalytical practices and also for publishing with joint agreement of both organizations.

Implementation activities will be driven by work plans developed by IACC and BD with requesting facilities. BD will dedicate a program liaison / project manager to this effort for ease of coordination with IACC and other implementing partners. BD program liaison will work directly with IACC to:

- Develop work plans
- Generate quarterly progress reports
- Coordinate activities across facilities

The project has been starting from January 2012 and IACC has been reached an agreement with BD to continue this project until 2017.

### 3. Project of Indonesian Pediatric Reference Interval (PIPER Study)

Diagnosis and monitoring of almost all pediatric diseases require the measurement of a wide range of disease biomarkers. These biomarkers are commonly measured in clinical laboratories and the results interpreted based on established reference (or normal) intervals.

In children, physiological changes associated with growth and development may require separate reference intervals for different ages. In addition, physiological changes of growth and development may be different for male and female children. Biomarkers may also be affected by ethnicity. As a result, age, sex and ethnic group-specific reference intervals may be necessary for different biomarkers. This allows comparison of individual results with the correct reference interval, i.e. the interval derived from correct reference group. ([http://www.caliperdatabase.com/cdb/controller?op=menu\\_about\\_refer](http://www.caliperdatabase.com/cdb/controller?op=menu_about_refer)).







IACC has been reached eliminary agreement with Indonesian Association of Pediatric (IDAI) to conduct Project of Indonesian Pediatric Reference Interval (PIPER study) to set biomarkers reference range for children as follow: Routine hematology, TSHs, FT4, G6PD, Bilirubin Direct, Bilirubin Total, AST, ALT, GGT, Glucose, Albumin, Fe, TIBC, Ferritin, Tchol, HDL-C, LDL-C, TG, PT/APTT, Ureum, Creatinine, Na, K, Cl, Ca, Mg, Phospate, hsCRP and Uric Acid.



*Report prepared & submitted by Indonesian Association of Clinical Chemistry*



## Report of Korean Society of Clinical Chemistry (KSCC) 2013

National Meetings		
Name of the Meeting	Date	Topic
Annual Meeting of KSCC (I)	2013. 5. 3.	Plenary Lecture; Standardization & Harmonization of Clinical Laboratory Results
		Symposium 1; Accreditation Requirements for Laboratory Management of Clinical Chemistry
		Symposium 2; Principles and Practices of Laboratory Tests for Clinical Chemistry I
		Symposium 3; Principles and Practices of Laboratory Tests for Clinical Chemistry II
Quality Assurance Workshop	2013.6.26.	Quality Assurance Workshop for Neonatal Screening Tests
Annual Meeting of KSCC (II)	2013.11.22	Plenary Lecture; Clinical Application of Mass Spectrometry
		Symposium 1; Overview of Quality Control Procedures and Proficiency Testing
		Symposium 2; Traceability of In Vitro Diagnostic Tests for Clinical Chemistry
		Symposium 3; Understanding and Applying of Tests for Tumor Markers
		Symposium 4; Basic Principles of Urinalysis

## 2. Education

1. Principles and Practices of Laboratory Tests for Clinical Chemistry  
Protein, Enzyme, Lipid, Liver function
2. Tumor markers
3. Urinalysis



### 3. International Relations

1. APFCB : 13th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress (Oct 27-30, 2013) in Bali, Indonesia

KSCC Symposium : Molecular Diagnostics

Speaker : Woochang Lee, Yong Wha Lee, Jong-Won Kim, Chang-Ho Jeon

2. The International Conference on the Standardization in Clinical Chemistry 2013

(Oct 10th, 2013) in Seoul, Korea

Speaker : Patric A. Clapshaw, Junghan Song, Anja Kessler, Robert Ian Wielgosz, Hae Kyoung Park

### 4. Additional Information

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

### 5. Current Officer Bearer of KSCC (2013-2014)

President : Professor Gye Cheol Kwon (Chungnam National University College of Medicine)

Immediate Past President : Professor Kyung Dong Kim (Yeungnam University College of Medicine)

Secretary General : Professor Yeo Min Yun (Konkuk University College of Medicine)

Treasurer : Professor Hwan Sub Lim (Kwandong University College of Medicine)

*Report prepared & submitted by Korean Society of Clinical Chemistry*





## Report from Malaysian Association of Clinical Biochemists (MACB) 2013

### MACB Council 2013-2014

President:	Dr. Raja Elina Raja Aziddin (rajaelina@yahoo.com)
Vice President:	Tunku Marinah Ashraf (tmarinah@yahoo.com)
Secretary:	Dr. Norlida Harun (ida5044@yahoo.com)
Treasurer:	Miss Jaleezah Idris (jaleezah@hotmail.com)

### Activities for 2013

#### Scientific Sub-committee

##### 1) 23<sup>rd</sup> MACB Conference

The MACB 23<sup>rd</sup> Conference was held successfully on 17-18th June 2013 at Seri Pacific Hotel, Kuala Lumpur. The conference was attended by 230 delegates from Malaysia and from Brunei, Singapore and Indonesia. Scientific program included the APFCB Travelling Lecture, which was delivered by Assoc. Prof. Sunil Sethi from National University Hospital, Singapore on the topic of "Managing Laboratory Informatics, Middleware and Process Control". Plenary lectures were presented by Assoc. Prof. Graham White, president of AACB on "Uncertainty of Measurement (MU) In Clinical Laboratories", Mdm Fariza Wan Abdullah from Standards Malaysia on "What's New on ISO 15189:2012?", Dr. Ngu Lock Hock, Consultant Metabolic and Geneticist, Hospital Kuala Lumpur on "An Insight into the Biochemistry of Inborn Errors of Metabolism For A Clinical Biochemist."

The scientific program also included two symposia on topics of Pediatric Pathology and Evidence Based Medicine, oral and poster presentations.

A total of six industrial workshops were also held during the conference, which included:

- i) Troponin I sponsored by Abbott Diagnostics,
- ii) Introduction to Sysmex's Clinical Chemistry Analyzers by Sysmex Malaysia
- iii) Making the Leap to LC/MS/MS: Enhancing and Accelerating Clinical Research and Forensic Toxicology Applications by Mr Tan Chor Teck, Field Application Specialist, AB SCIEX,
- iv) Recent Developments of LC/MS/MS Techniques for High Sensitivity Measurements of Steroid Hormones in Human Plasma by Mr Jeremy Dietrich Netto, Waters Corporation, Singapore.
- v) Towards Rapid and Precise HbA1c Assay Using HPLC Method and
- vi) Rapid and Multi-Analyte Assay Using Compact Immunoassay Analyzer delivered by Mr Hisao Tsukamoto, Tosoh Corporation, Tokyo, Japan.



**Awards presented at the conference**

- Best Quality Control Practice Award which was awarded to Sunway Medical Centre
- Best Poster Award which was awarded to Institute for Medical Research.

**2) Pre-Conference Workshop**

Two pre-conference workshops were conducted on 16th June 2013 in conjunction with MACB 23rd Conference:

Workshop 1 - How to write and submit a scientific paper

Workshop 2 - A practical approach to method verification

**3) A seminar on "Quality Control & Risk Management"** was held on 25th October 2013 at Medical Academies of Malaysia with Mr Sten Westgard as the invited speaker. This event was supported by Abbott Laboratories.

**Education Subcommittee**

Four (4) workshops were conducted in 2013.

Participants were laboratory scientists, chemical pathologists and medical laboratory technologists. Trainers were local senior biochemists and Chemical Pathologists.

**Workshop topics:**

- ✍ Liver and Hepatology Workshop: 1-2 April 2013
- ✍ Basic Quality Control Workshop: 6-7 May 2013
- ✍ Advanced Quality Control Workshop: 13-14 May 2013
- ✍ Endocrinology Workshop: 7-8 October 2013

**Publicity and Publication**

The sub-committee members began work on upgrading the MACB website which will be launched in 2014.

**Other activities****Annual General Meeting**

The MACB AGM was held on 17th June 2013. There was no change of office bearers except for the post of treasurer where Miss Jaleezah Idris replaced Mr



### Meeting with Universities

A meeting was held with local universities on 12th June 2013 to discuss the possibility of conducting professional certification program for clinical scientists.

13th APFCB and Laboratory Medicine Congress Bali, Indonesia on October 27-30, 2013.

The president, Dr Raja Elina represented MACB at the APFCB Annual General meeting which was held on the 27th October 2013 at Nusa Dua Convention Centre, Bali.

MACB also took part in the APFCB Congress by sponsoring a symposium on Patient Safety. Three speakers for the MACB symposia were Assoc. Prof Dr. T. Malathi (Malaysia), Prof Trefor Higgins (Canada) and Dr. Raja Elina (Malaysia)

MACB committee members also attended the other APFCB and IFCC sub committee meetings:

### APFCB Scientific Committee meeting on 28 October 2013 was attended by Dr Raja Elina

- APFCB Education and Laboratory Management Committee meeting on 28 October 2013 attended by Mr Mohd Jokha
- AFFCB Congress and Conference Committee meeting on 29 Oct 2013 was attended by Mdm Chen Bee Chin
- 9th National Society Journal Editors & Publishers Meeting organized by Communications and Publications Division of the IFCC was attended by Miss Jaleezae Idris
- IFCC Young Scientists committee meeting was attended by Miss Nor Shuhadah

### Awards

MACB Travel Grant was awarded to Mr Mohd Izani to attend the 24th Great Wall International Congress of Cardiology and Asia Pacific Heart Congress 2013 in Beijing and Mdm Chen Bee Chin to attend ICIEM, 2013 in Barcelona, Spain.

### Training and Consultancy

MACB also provided training and consultancy on ISO 15189 accreditation requirements to one private laboratory





## Activities for 2014

### Annual Conference and AGM

24th MACB Conference will be held on 28-29 May 2014 in Kuala Lumpur Convention Centre in conjunction with MLab 2014.

A pre-conference workshop focusing on Application of Risk Management in Clinical Diagnostic Laboratory will be held on 27th May 2014 at the same venue.

The AGM will be held on 28th May 2014 also at the same venue.

### Tentative Training workshops

- Laboratory Safety
- Method Validation
- Fundamentals of Drugs of Abuse Testing
- Pathology of Endocrine Disorders
- Requirements of ISO 15189: 2012
- Quality Control Practice in Clinical Diagnostic Laboratory (In collaboration with Department of Standards Malaysia)

*Report prepared & submitted by Malaysian Association of Clinical Biochemists*



## Report from Pakistan Society of Clinical Pathologists (PSCP) 2013

### Distance Learning Programme (DLP) in Chemical Pathology

#### First Edition of Distance Learning Programme (DLP) in Chemical Pathology

First Edition of Distance Learning Programme (DLP) in chemical pathology was conducted under the auspices of PSCP in collaboration with all the senior Chemical Pathologists of the country.

Ninety five participants were registered in DLP which included trainees of chemical pathology FCPS Part II, students of masters of philosophy Chemical Pathology, rotational Trainees in Chemical Pathology, medical laboratory technologist and junior consultant chemical pathologists.

All these participants were sent 20 lessons on weekly basis from March 2013 to Aug 2013. A competition was simultaneously held for selection of the best trainee participant called *Chemical Pathology Laureate* and other high performers. Major Qurat-ul-Ain topped the First Distance Learning Programme and won the title of "Chemical Pathology Laureate".

Electronic methods were successfully used during the course e.g. e-mails, Facebook to provide inter-participant discussion forum and Skype for live discussion with the facilitators.

A program for participants of DLP from all over the country was held at PNS Shifa Karachi on 24 Aug 2013. The meeting provided a useful platform for all the trainees and residents of Chemical Pathology to interact with each other. During the meeting various key topics related to the specialty of Chemical Pathology were discussed and valuable suggestions and feedback from the participants were documented.



### Workshops conducted in 2013

Following workshops were conducted under the umbrella of PSCP in the year 2013:

#### Workshop on 'Interpretation of ABG Reports'

Workshop on 'Interpretation of ABG Reports' took place at Bahria University Medical and College Karachi in April 2013.



#### Workshop on "Laboratory automation"

Workshop on "Laboratory automation" was conducted at Quaid-e-Azam Medical College, Bahawalpur in May 2013.



### Pathology week

"National pathology week" organized by College of Pathologists, Pakistan, was celebrated from 13th to 18th May 2013 nationwide. The theme was "Standardization of laboratories". All major departments organized events during the week. Banners and flex signs were displayed in pathology departments. There was overwhelming response from participants and the week turned out to be a success.



*A glimpse of Pathology week held at Quaid-e-Azam Medical College, Bahawalpur*

### 6th National conference of PSCP

6th National conference of PSCP, which is now part of the Joint Conference of Societies of Pathologists, which was held in Lahore from 20th to 22nd December 2013. The theme of the conference was **"Young Pathologists – Our Future."** The conference excelled in presenting exciting developments in the field of pathology and laboratory medicine. Pathologists, trainees and laboratory personnel from all over the country and abroad attended the conference.

The first day began with inauguration ceremony on 20th December followed by the "Razi lecture", given by Dr. Mohammad Akhtar from King Faisal Specialist Hospital Riyadh KSA on 'Breast Cancer'. It was followed by four scientific sessions in which different researches and studies were presented. A plenary session was also organized in which senior Chemical pathologists delivered talks on various aspects of "Laboratory Management".

Second day started with meet the experts' session, a great learning opportunity for budding pathologists for learning from experts in their respective fields. It was followed by scientific sessions. A general body meeting was also held during the day. Several selected abstracts were also displayed as posters which portrayed research advances in the field of chemical pathology.

On the third day of the conference two scientific sessions were held. The conference closing ceremony was held in afternoon and best oral and poster presentations were announced. Dr. Sehar Iqbal won the best oral award, while the best poster was awarded to Dr. Samia Fatima.

The conference was successful in bringing together delegates from the different disciplines of pathology and laboratory medicine and allowed opportunity for a healthy debate.





### Workshop on "Dynamic function tests in endocrinology"

The closing of the third of PAP conference was marked by the Workshop on "Dynamic function tests in endocrinology". It was facilitated by Brig. Waqar Azeem and Dr. Javaid Subzwari. Attending participants were pre-registered and it provided an excellent learning opportunity.

### Seminar organized by Randox Laboratories Ltd

A seminar was organized by Randox Laboratories Ltd. in association with UK Trade and Investment Pakistan in May 2013. Dr. Adnan Zuberi, a Consultant Chemical Pathologist at Ziauddin University Hospital, also was one of the speaker's during the seminars who discussed the cost saving benefits of early errors detection and correct patient diagnosis.



### APFCB meeting

The 13th APFCB Congress was held in Bali, Indonesia from 27th till 30th October 2013. The local Organizing Committee had produced an excellent scientific program with many renowned speakers from all over the globe. Dr. Imran Siddiqui represented PSCP at the meeting.





### Inductions of new members of PSCP

**The following new fellows joined PSCP as consultant chemical pathologists:**

- Dr. Lubna Sarfraz (QAMC),
- Dr. Saleha Zafar (QAMC),
- Dr. Usman Munir (AFIP Rawalpindi),
- Dr. Ghazanfar Abbas (Zia-Ud-Din University, Karachi),
- Dr. Maliha Akhtar Zubairy (Zia-Ud-Din University, Karachi),
- Dr. Noreen Sherazi (Aga Khan University, Karachi)
- Dr. Muhammad Anwar (AFIP Rawalpindi)



### Office bearers of PSCP 2013-2014

- **The Patron:** Maj Gen Prof Farooq Ahmad Khan, HI(M), (retired)
- **President:** Brig Dilshad Ahmed Khan
- **Vice President:** Dr Sameena Ghayyur
- **Secretary:** Brig Rizwan Hashim
- **Counsellor:** Dr Sami Saeed
- **Counsellor:** Prof Asim Mumtaz
- **Counsellor:** Dr Munawar H Muree
- **Counsellor:** Prof Asma Shaukat
- **Counsellor:** Prof Ejaz Hassan Khan
- **Counsellor:** Dr Adnan M Zuberi

*Report prepared & submitted by Pakistan Society of Clinical Pathologists (PSCP)*

## Report from Singapore Association of Clinical Biochemists (SACB) 2013

Singapore Association of Clinical Biochemists (SACB) started their year's activities with the Annual Scientific Meeting held in Orchard Hotel on 23rd March 2013. The sessions were a combination of Diagnostic company sponsored speakers as well as prominent overseas and local speakers. Our company sessions included "Advancements in Monitoring Chronic Hepatitis B Patients" by Dr Benjamin Lillienfeld from Roche Diagnostics; "Recent Trends in Syphilis Testing – Improving Detection and Diagnosis" by Dr Katherine Soreng of Siemens Healthcare Diagnostics; "The Role of AMH and Other Novel Markers in Fertility Testing" by Mr Bernard Cook of Beckman Coulter Pte Ltd and "High Sensitive Troponin-I" by Dr Jaganathan Sikan of Abbott Diagnostics Pte Ltd. Our invited overseas speakers were Dr Andrew St John (Australia) presenting on the "Demonstrating the Value of Medical Tests" and Dr Graham Jones (Australia) presenting on "HbA1c – Factors affecting the Result and the Interpretation". Our local speaker was A/Prof Ponnuduri Kuperan sharing on "Tumour Lysis Syndrome".

In September we jointly organized a Quality Control Education Workshop with Bio-Rad Laboratories. The speakers were Mr Peter Lim and Ms Ong Siew Kim, both SACB members.

The 15th module of our SACB Education Programme was held between August and October 2013 for ten weeks duration. The lectures comprised: Updates on laboratory automation. Quality indications as a useful tool in the quality control procedures. Updates in vitamin D testing. Molecular tests for inherited genetic diseases. Research and the clinical laboratory. Principles of biochemical tests. Screening for aneuploidy and anti-mullerian hormone. Therapeutic drug monitoring. The role of laboratory in the diagnosis and management of diabetes mellitus. Acute coronary syndrome: the present and future role of biomarkers. This programme is well received by our members and the Association will continue to support the education of our members.

Singapore was well represented at the APFCB Congress in Bali with at least twenty speakers and registrants. SACB offered three travel scholarships to its members to attend the congress. The recipients were Mr Andrew Goh of Alexandra Hospital with his abstract "a case study to estimate the indices of biological variation and its implication in clinical measurement"; Dr Ong Lizhen from National University Hospital with her abstract "intra-individual variation of insulin-like growth factor I levels in patients with chronic kidney disease and Mr Hisyam Adnan from National University Hospital with his abstract "postprandial drop in glucose (PPDG): Is it associated with impaired glucose tolerance?"



Members of SACB Council attending APFCB Congress in Bali.  
Reported by: Dr Sharon Saw, Secretary, SACB



## Importance of Warfarin Genotyping in Asians

*N. Sripriya<sup>1</sup>, CK. Ponde<sup>2</sup>, RM. Rajani<sup>2</sup>, TF. Ashavaid<sup>1</sup>  
1Research Laboratories, 2Department of Cardiology,  
P.D. Hinduja Hospital & MRC, Veer Savarkar Marg,  
Mumbai – 400 016, India.*

Warfarin has been in commercial use for medical purpose since six decades, and till date it is the most popular oral anticoagulant in use. It is used for prophylaxis of thromboembolic episodes in Deep Vein Thrombosis (DVT), Pulmonary Embolism, Mechanical Valve Replacement and Stroke due to Atrial Fibrillation [1-3].

### Mechanism of action of warfarin

Warfarin exerts its anticoagulant activity by inhibiting the C I subunit of Vitamin K epoxide reductase enzyme (encoded by VKORC I gene) and interfering with cyclic interconversion of vitamin K and its 2, 3 epoxide. This decreases the available Vitamin K epoxide in liver that is required for carboxylation of glutamate residues of vitamin K dependent proteins like coagulation factors II, VII, IX and X. These proteins require carboxylation by vitamin K epoxide for their biological activity and thus warfarin induces hepatic production of partially decarboxylated proteins with reduced coagulant activity.[1-3]

### Pharmacokinetics and Pharmacodynamics of warfarin

Warfarin is a racemic mixture of two optically active isomers, R- and S-warfarin, in roughly equal proportion. It is rapidly absorbed from the gastrointestinal tract, circulates bound to plasma proteins and accumulates in the liver, where the two isomers are metabolically transformed by different pathways. Both the isomers differ in their potency and metabolism. S-warfarin is 5 times more potent than R-warfarin and metabolized majorily by CYP2C9 enzyme in liver to S-7-Hydroxywarfarin whereas R-warfarin is metabolized to minor end products like R-6,8,10-Hydroxywarfarin by CYP1A1, CYP1A2 and CYP3A4 [1-3].

Currently, the anticoagulation status of an individual is monitored by blood prothrombin time using International Normalized Ratio (INR). For patients who are on warfarin therapy, an INR of 2.0 to 3.0 is generally recommended for most indications. The exceptions are for those who have undergone mechanical prosthetic heart valve replacements (where the recommended INR is 2.5 to 3.5) or certain patients with thrombosis and antiphospholipid syndrome (APS) who may require a higher than the targeted INR of 2.0 to 3.0. [3].

Maintaining the therapeutic range of warfarin is very important as a sub therapeutic INR caused due to under dosing, leads to thrombosis and a supra therapeutic INR due to overdosing increases the risk of bleeding. Physicians find it extremely problematic to adjust warfarin dosage as this treatment shows a large inter and intra individual variability.



The cause of this has been mainly attributed to numerous factors like complexity of coagulation cascade, clinical factors like age, gender, BMI, vitamin K intake and concomitant drugs [4-5].

However, based on the increasing evidence in the last decade, almost 40% variability in warfarin dosage is now being attributed to genetic variants in genes involved in warfarin metabolism and activity.

Aithal and his associates were the first to report direct associations between warfarin dosage and CYP2C9 gene variants in 1999 [6]. Following this, numerous studies have been performed to study the variants in this gene and its effect on warfarin dosage in many ethnic groups. The most reported variants of this gene are CYP2C9\*2 (430 C>T) and CYP2C9\*3 (1075 A>C). Both \*2 and \*3 alleles have impaired hydroxylation of S-warfarin with 12% and less than 5% of wild type activity respectively, causing a decrease in degradation and clearance of warfarin. Therefore a low warfarin dosage is needed for patients harboring these variations to maintain therapeutic INR [2].

African-Americans require the highest doses of warfarin followed by Caucasians, and Asians are found to be most sensitive to warfarin. Amongst Asians too, Indians require higher doses than Chinese, Japanese and Malays. It is widely believed that the variability in warfarin dosage is due to differences in frequency and effect of the above mentioned genetic variations.

In Caucasians, VKORC1 variants are found in 20% of population whereas CYP2C9\*2 variation is found in 16% and CYP2C9\*3 variation in 6.5% of the population. All these variants are reported to be affecting warfarin dosage in Caucasians [4-7]. CYP2C9 variants are very rare or absent in Chinese and Japanese population but found in 3-8 % in specific Indian cohorts [4-11]. Infact these variants do not have any major effect on warfarin dosage in Indians as reported by many [8-11]. The VKORC1 variants are seen in 90% of the Chinese population and it is thought that the warfarin sensitivity observed in them is only because of large effects of VKORC1 variants [4-11]. In Indians, VKORC1 variant allele is present in 12 -14% of population as given by earlier published articles [8-11] and these variants make an individual sensitive to warfarin therapy.

Infact, our recent study conducted at our hospital has also shown that patients harbouring VKORC1 variant allele (even as a single copy), required lower than standard warfarin doses to maintain their INR in the therapeutic range. Majority of them developed supra therapeutic INR (>4) within four standard warfarin doses of 5mg/day. Their INR was however brought down to therapeutic range and was maintained within it when their warfarin dose was decreased to 2 to 3mg/day. [8]

According to literature, an individual, carrying the \*3 allele of CYP2C9 gene is more important than carrying VKORC1 variant allele, since VKORC1 variant allele only contributes to 25-30 % reduction in warfarin dosage as opposed to almost 95% reduction explained by CYP2C9 \*3 variant. Also CYP2C9\*3 variation increases the risk of supra therapeutic INR and bleeding complications within 3 months of start of warfarin therapy [12]. But on a population level, VKORC1 is more important in Asians simply because it is found in higher frequency in our populations.



FDA has also approved genetic tests to identify warfarin sensitivity in individuals undergoing warfarin therapy in 2007 and also updated labeling for Coumadin, the brand name version of warfarin, explaining that people with variations of the genes, CYP2C9 and VKORC1 may respond differently to the drug. Manufacturers of generic warfarin are adding similar information to their products' labeling. Thus along with clinical parameters, a prior knowledge of the patient's genotype can be used to decide initial warfarin dose required by an individual to maintain therapeutic INR and can thereby help in reducing the risk of developing supra therapeutic INR and bleeding complications in patients undergoing warfarin therapy.

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## **What Laboratory Hematology Is, or Should Be, About Analyzing White Blood Cell Morphology with Automated Cell Counters**

*by Fernando Chaves, Director of Scientific Affairs, Beckman Coulter*

Blood analysis, at increasing degrees of complexity, has played a crucial role in the history of medicine for over a century. Traditionally, laboratory hematology was composed of two main aspects: quantity and morphology.

Early laboratorians began evaluating the quantity of the various cell types in the blood (or “cell counts”), and at the same time soon recognized the value of also evaluating their morphology. These early evaluations allowed laboratorians to recognize various important changes in blood that have provided valuable information in the diagnostic process of various medical conditions, such as bacterial infection (toxic granules; left shift), myelodysplasia (hypogranular and hypolobated neutrophils) and vitamin B12 and folate deficiencies (hypersegmented neutrophils).

However, with the advent of automated cell counters and the increased economical pressures in healthcare systems, today only a small minority of blood samples actually come under the review of a human eye (typically when samples are flagged by the analyzer, which most often occurs in samples with significant changes in cell counts).

It's been well recognized in literature that many medical conditions may be present without any significant changes in cell counts. In some studies as many as 45 percent of septic patients have been found to have completely normal CBC with white cell differentials (CBC-diffs). Myelodysplastic patients with dysplasia of the myeloid cells can have cell counts on the lower range of normal and consequently their results might not trigger a microscopic review that could pinpoint the correct diagnosis.

The current reality is that millions of CBC-diffs are performed worldwide each day and laboratorians may be missing critical diagnostic opportunities for patients simply because they aren't routinely reviewing blood morphology at the time the test is performed.

### **Digital Morphology in Today's Cell Counters: How it Works**

Cell counters vary significantly in their technologies, and most of them rely on both morphologic features and chemical reactions of cells in order to recognize the various cell types and generate a differential count.

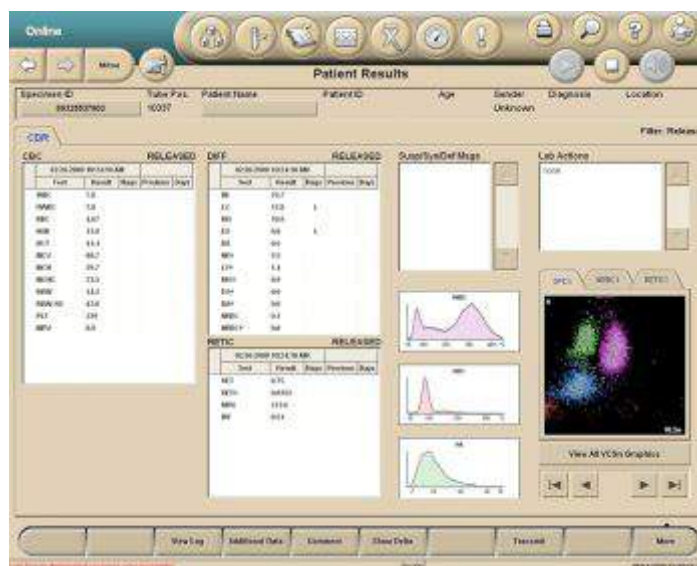
There is, however, technology available today that relies solely upon morphologic features to recognize cells. In much the same way a human looks at multiple features of cells with the eye and processes the information with the brain before deciding which cell type they're viewing, hematology analyzers that use this technology have various set of “eyes” each meant to “look” at specific morphologic features of cells in order to process information and determine the cell type.



Analyzers with this type of technology use these “eyes,” which are actually multiple parameters obtained directly from the cell morphology, to determine cell type. These parameters include:

- **Cell Size** Measured by direct current impedance (based on the Coulter Principle), whereby cells passing through the aperture block an electric current and thus generate a voltage differential, and the larger the cell the higher the impedance of this pulse.
- **Cytoplasmic Granularity / Nuclear Lobularity:** These two features are analyzed by laser light scatter. The more complex the nucleus of a cell, and the more granulated the cytoplasm, the more light is scattered when a laser beam hits the cell being analyzed.
- **Internal Density of Cells:** Radio frequency waves are thrown at the cell, and a receptor on the other side of the analysis chamber measures how many waves are transmitted through the cell (conductivity). Cells that have denser cellular contents (i.e. basophils) will transmit more waves.

For each of these parameters, each cell analyzed receives points. Based on these points, cells are plotted in multi-dimensional histograms, and since leucocytes of the same type have similar morphologic features, they cluster together forming cell populations. The instrument then counts the number of events in each population to generate a differential count. In addition to generating this differential count, the mean and standard deviation of the points from each parameter, for each of the WBC populations, are also calculated by the instrument, and are collectively called cell population data (CPD)\*. (Fig. 1)



**Figure 1: Screenshot of the Differential Count.** This image shows the WBC sub-populations clearly separated and defined by different colors, in a histogram with cell size (volume) in the y axis and light scatter in the x axis. By clicking on the “Additional Data” tab, users can view the CPD values. Note how these values correspond to both the position of the population in the histogram and to the morphology of the WBCs under the microscope. Decision rules can be written based on these values to flag the sample and alert the user to the presence of significant morphologic changes.\*

\* For Research Use Only.



CPD is a numerical quantification of the morphologic features of all WBC types. Since CPD is directly related to cell morphology, these parameters are also affected by changes in the morphology of individual cell types as they occur in certain clinically relevant conditions. For instance, if larger granulocytes are present, the mean neutrophil volume increases, as does the standard deviation of neutrophil volume. If there are neutrophils with less cytoplasmic granulation (thus scattering less light), the mean neutrophil scatter decreases accordingly, and so forth for all the various morphologic changes that can affect WBCs.

### Using Automated Hematology Analyzers for Morphologic Analysis of Leucocyte Morphology

Over the years, numerous papers have been published showing how cellular morphological changes from various disease states can be observed with automated technology in certain cell counters, such as changes in cellular size, cytoplasmic granularity and nuclear complexity. Examples include, but are not limited to:

- Granulocytic macrocytosis and anisocytosis, demonstrated by increased mean and standard deviation values for cellular volume - study population included patients with bacterial infection. (Fig. 2)
- Hypogranular and hypolobated neutrophils, measured by decreased mean value for light scatter - study population included patients with myelodysplasia (MDS). (Fig. 3)
- Lymphocyte microcytosis, demonstrated decreased mean value for cellular volume - study population included patients with Chronic Lymphocytic Leukemia.
- Megaloblastic changes in WBCs, demonstrated increased values for cell volumes in more than one sub-population - study population included patients with vitamin B12 and folate deficiencies.

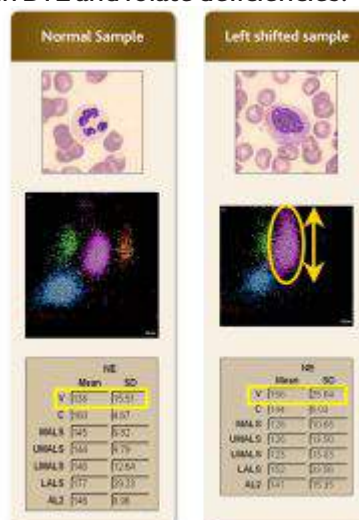


Figure 2: Traditional Microscopy, Histogram and CPD Changes in Bacterial Infection: The morphologic changes in a sample from a patient with bacterial infection, with larger activated mature neutrophils and increased numbers of immature granulocytes, can be observed in the histogram by the varying position and shape of the purple population (granulocytes). These changes are also reflected numerically by increased values for mean and standard deviation of the neutrophil volume, parameters of the CPD. Decision rules based on these parameters can be written by the user to flag the presence of these morphologic abnormalities even in the absence of leucocytosis, the traditional expected CBC finding in infection.

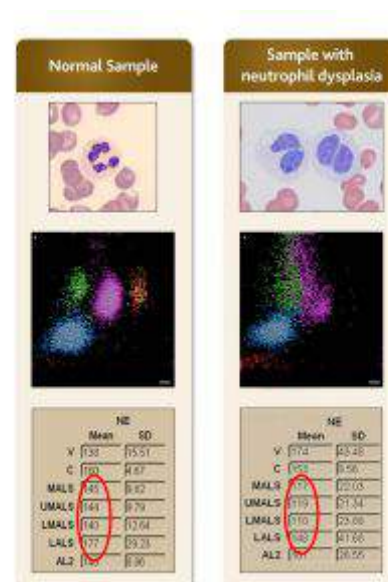


Figure 3: Traditional Microscopy, Histogram and CPD Changes in Myelodysplasia: The morphologic changes in a sample from a patient with myelodysplasia, with hypolobated and hypogranulated neutrophils, can be observed in the histogram by the varying position and shape of the purple population, which stretches to the left and blends with the green monocyte population. These changes are also reflected numerically by decreased values for mean light scatter of the neutrophils measured at four different angles, parameters of the CPD. Decision rules based on these parameters can be written by the user to flag the presence of these morphologic abnormalities even in the absence of cytopenias, the traditional expected CBC finding in myelodysplasia.

### The Benefits of Morphologic Decision Rules

Beyond academic findings, CPD parameters can offer immediate, practical, real-life benefits for laboratories. CPD parameters can be used to set automated morphologic flags that can alert the laboratorian when morphologic abnormalities (like those mentioned above) are present, so that a microscopic review can be performed.

Today, the vast majority of CBC-diff samples are reported without a microscopic review. Microscopic reviews typically occur only when significant changes in the cell counts are present or when one of the other traditional flags is activated. However, many important medical conditions can occur in the absence of significant changes in CBC-diff counts. In these samples, a significant delay in results can occur because a microscopic review wasn't performed.

Thanks to modern technology, however, today's hematology analyzers can improve diagnoses by not only counting cells, but also by screening for the presence of diagnostically important morphologic changes.

The benefits of this new era in laboratory hematology are very easy to understand. By turning every CBC-diff, the most ordered test in medicine, into a screening opportunity for various significant morphologic changes, laboratorians can recognize abnormalities sooner via the reflex microscopic review, and reap the benefits of an earlier result.



Individual laboratories can benefit, too. By using morphologic decision rules, samples with clinically significant morphologic abnormalities can, and should be, referred to pathologist review, resulting in a higher reimbursement rate than a regular CBC-diff.

For healthcare systems, the approach brings tremendous benefits. Since morphologic decision rules are not separate laboratory tests, there's no need for extensive clinician education, the generation of additional billing codes or for actual payment of these parameters.

### **The Solution: Modern Technology Applied to Traditional Testing**

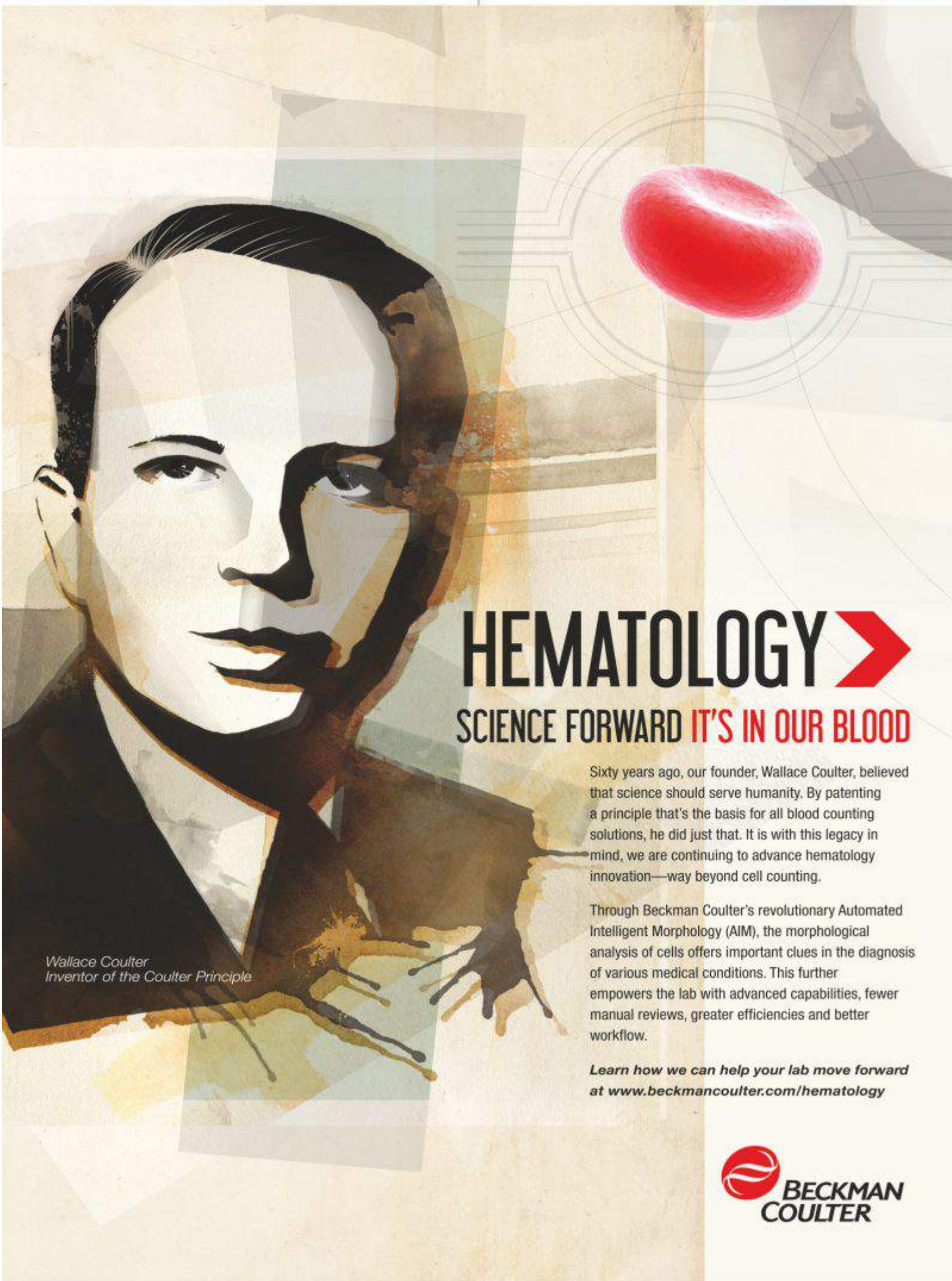
Given the current economic state of the healthcare environment worldwide, it's more important than ever to optimize the use of resources and technology that already exist, rather than relying on newer technologies that often come with additional costs, aren't readily available to all patients and may offer questionable performance improvements.

The use of the CPD is a prime example of how the laboratory can effortlessly use modern technology to significantly improve the value and utilization of one of the most traditional tests in medicine the CBC-diff.

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Wallace Coulter  
Inventor of the Coulter Principle

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## Utility of Biochip Arrays for the Multiplex Detection of Sexually Transmitted Infections and respiratory pathogens

*Randox Laboratories Limited, Molecular Diagnostics, Diamond Road, Crumlin, Co Antrim BT29 4QY, United Kingdom*

### Abstract

Biochip array technology provides a platform that enables multiplex measurement of markers in a clinical patient sample both in the fields of proteomics and genomics using miniaturized assay procedures with implications in the reduction of sample/reagent consumption and cost-effectiveness of the tests. Multiplex detection on biochip arrays provides more information from a single sample than single tests, improving diagnosis and encouraging more tailored therapy. The biochip represents not only the platform in which tKeywords: Multiplex, Biochip Array technology, STIs, Respiratory pathogens

### Introduction

STIs present a major public health concern worldwide.<sup>1</sup> Most STIs are easily treated, however many infections are asymptomatic<sup>2</sup> and remain undiagnosed, potentially leading to significant health problems including infertility. Undiagnosed STIs also increase the risk of unhindered spread. In this context, the need for more efficient means of detecting these infections has become increasingly important. Most commercially available STI tests are uniplex or duplex assays, whereas a multiplex approach would improve patient outcomes by ensuring that co-infections are identified. Multiplex assays have the added benefit of promoting more appropriate antibiotic use, which will reduce the potential for antibiotic resistance.

Respiratory pathogens are a diverse group responsible for some of the most common human infections worldwide.<sup>3</sup> They can cause diseases including mild self-limiting upper respiratory tract infections, such as sore throats and the common cold and more serious infections like influenza, bronchiolitis and pneumonia.<sup>4,5</sup> Early and specific detection is critical to improve individual patient outcomes and prevent spread of disease. However, respiratory infections he capture molecules are immobilized and stabilized, defining arrays of discrete test regions but is also the vessel were the reactions take place. This study reports two multiplex assays, one applied to the simultaneous screening of up to ten causal agents of sexually transmitted infections (STI) and the other applied to the multiplex detection of twenty two respiratory pathogens from a single sample produce variable clinical symptoms that cannot easily identify the etiologic agent. Availability of effective antiviral and antibiotic therapeutic agents has prompted development of molecular techniques for direct detection of viruses and other respiratory pathogens.

This study reports analytical evaluations of two multiplex assays, one applied to the simultaneous screening of up to ten causal agents of sexually transmitted infections (STI) including viruses, bacteria and protozoa (Fig 1) and the other applied to the multiplex detection of twenty two respiratory pathogens (Fig 2) from a single sample.





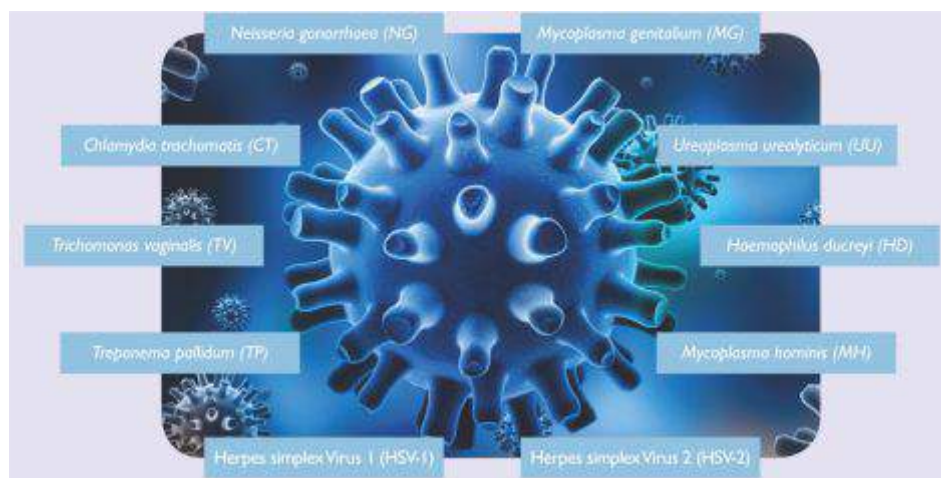


Fig 1 Causal agents of STI detected with the Sexually Transmitted Infections Array

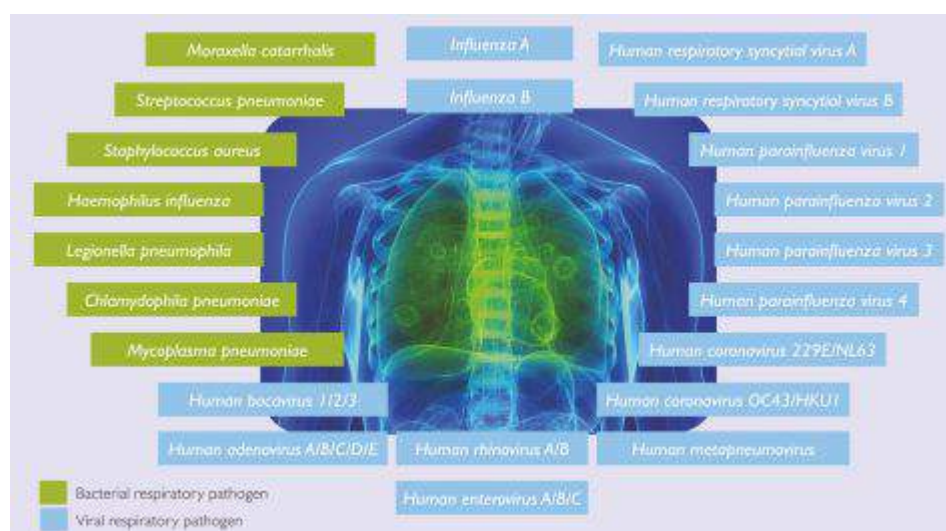


Fig 2 Respiratory pathogens detected with the Respiratory Pathogen Multiplex Array

## Materials and Methods

### Sexually Transmitted Infection Multiplex Array

Assay clinical sensitivity and specificity was determined for all commonly tested STIs when compared to routinely performed uniplex qPCR assays from an NHS hospital (Table 1). In addition, several panels of Chlamydia Quality Control Material for Molecular Diagnostics panels (QCMD, Qnostics, Glasgow UK) were tested.

DNA extraction from clinical samples was performed using the Qiagen Symphony Instrument (Qiagen, Crawley, UK) following the manufacturers' instructions. An aliquot of extracted nucleic acid was then subjected to Multiplex PCR, incorporating all target-specific, highly sensitive primers in a single reaction. Amplified pathogen sequences were spatially separated and detected using biochip array technology, which involves hybridisation, conjugation and chemiluminescent detection. The biochips were analysed using the Evidence Investigator analyser and dedicated software (Randox Laboratories Limited, Crumlin, UK) (Fig 3). The assay includes controls for extraction, amplification and biochip steps to ensure confidence in the results. From extracted nucleic acid, analysis time to result takes <6 hours for up to 10 samples.



### Respiratory Pathogen Multiplex Array

Total nucleic acid extracted from human respiratory specimens ( $n=399$ ) from a wide range of matrices to include nasopharyngeal swabs and secretions, sputum and bronchiolar lavage (BAL) were provided by the Regional Viral Laboratory (RVL, Royal Victoria Hospital, Belfast). Extraction was performed using Qiagen Symphony®, Qiagen QIAmp (Qiagen Crawley, UK) or Roche MagnaPure® systems (Roche Diagnostics Limited, Burgess Hill, UK). These specimens were pre-screened using routine single-target Quantitative Real Time Polymerase Chain Reaction (qPCR) by the RVL. Since the qPCR used in this screening/diagnostic process only detects one pathogen per qPCR reaction, pathogens are tested for based on specific consultant request. The residual extracts were subsequently tested using the Randox Respiratory Multiplex Array, for the presence of 15 viral and 7 bacterial pathogens. This process involved an initial reverse transcription step using RevertAid™ H Minus First Strand cDNA Synthesis Kit (Thermo Fisher Scientific UK Ltd., Loughborough, UK). The Respiratory Multiplex Array (EV3801A, EV3801B, Randox Laboratories Limited, Crumlin, UK) was then used to amplify template DNA/cDNA with subsequent hybridisation of amplified targets to the biochip according to manufacturer's instructions. Image capture and analysis was performed on the Evidence Investigator analyser (EV3602, Randox Laboratories Limited, Crumlin, UK) allowing pathogen detection (Fig 3).



Fig 3 Molecular Arrays workflow outline

## Results

### Sexually Transmitted Infection Multiplex Array

Of the samples which tested positive for an infection, 20% harboured at least one additional infection (Table 1), highlighting the need to screen for multiple pathogens to ensure all infections are detected and treated. The Randox STI Multiplex Array consistently identified all results correctly in swab and urine samples over a broad range of copies/ml. The panels included the Swedish variant and negative samples (Table 2).

**Table 1. Co-infections detected using Randox STI Multiplex array in**

Pathogen	Total infections	Single infections	Two infections	Three infections	Four infections	Total co-infections	% co-infections
CT	105	81	21	3	0	24	23
HSV2	24	19	3	2	0	5	21
TP	5	5	0	0	0	0	0
NG	17	13	4	0	0	4	24
TV	3	3	0	0	0	0	0
HSV1	44	28	10	5	1	16	36
MH	28	7	12	8	1	21	75
MG	3	0	2	0	1	3	100
HD	0	0	0	0	0	0	-
UU	25	6	12	6	1	19	76

**Table 2. Randox STI Multiplex Array: correct identification in urine and swab samples**

Sample	Type	copies/vial	copies/ml	Correct Result
CTB10-01	Urine	280	233	3/3
CTB10-02	Urine	57	47.5	3/3
CTB10-03	Urine	5700	4750	3/3
CTB10-04	Urine	Negative	Negative	3/3
CTB10-05	Urine	1:45 Dilution (SV)	-	3/3
CTB10-06	Urine	280	233	3/3
CTB10-07	Swab	5700	5700	3/3
CTB10-08	Swab	Negative	Negative	3/3
CTB10-09	Swab	57	57	3/3
CTB10-10	Swab	28	28	2/3

### Respiratory Pathogen Array

A very high level of agreement was found between the two methodologies. In addition to pathogens identified by the RVL, the Respiratory Multiplex Array detected further pathogens (n=69) in samples not previously reported by qPCR. These samples were sent for confirmatory testing, where it was found that 94% of re-tested for co-infections were positive (Table 3)





**Table 3. Randox Respiratory Multiplex Array: correct identification of co-infections**

Sample	Target	Additional Target	RLU	Confirmed	Ct
388	S. pneumoniae	81	21	3	0
M. catarrhalis	H. influenza	8158	POS	16.99	0
389	M. catarrhalis	H. influenza	6373	POS	15
392	H. influenza	M. catarrhalis	21935	POS	23
396	M. catarrhalis	S. pneumoniae	13185	POS	19
406	M. catarrhalis	H. influenza	5561	POS	19
477	Bocavirus	S. pneumoniae	14408	POS	29
484	MPV	Enterovirus	505	POS	31
556	Adenovirus	Enterovirus	552	POS	32
560	Enterovirus	Enterovirus	1714	POS	26
576	M. pneumoniae	C. pneumoniae	12167	POS	24
615	OC43	H. influenza	8120	POS	32
616	OC43	M. pneumoniae	1080	POS	30.55
670	PIV 3	M. pneumoniae	1526	POS	26.8
672	Adenovirus	H. influenza	752	POS	24
674	PIV 4	M. catarrhalis	4368	POS	29
675	Bocavirus	H. influenza	336	POS	29
676	Bocavirus	S. pneumoniae	6954	POS	27
679	PIV 2	M. catarrhalis	3454	POS	21
680	PIV 1	H. influenza	1162	POS	22
681	Bocavirus	M. catarrhalis	6281	POS	23
683	PIV 4	S. pneumoniae	12481	POS	24
685	PIV 2	H. influenza	1218	POS	16
687	Adenovirus	M. pneumoniae		POS	Culture
688	PIV 4	M. catarrhalis	3362	POS	23
689	PIV 1	S. pneumoniae	996	POS	33
691	PIV 1	H. influenza	1111	POS	15
692	RSV A	M. catarrhalis	4077	POS	21
		S. aureus	670	POS	32
		M. catarrhalis	6823	POS	26
		S. pneumoniae	7523	POS	30
		H. influenza	1448	POS	22
		M. catarrhalis	1497	POS	29
		S. aureus	3235	POS	26



## Conclusions

The results of these evaluations indicate applicability of biochip array technology to the multiplex detection of causal agents of STIs and respiratory pathogens by using two sensitive and specific assays. Straightforward protocols allow ease of use in any molecular or pathology laboratory, using routine sampling and PCR equipment in conjunction with the Evidence Investigator analyser. The assays combine multiplex PCR and biochip hybridisation allowing rapid and specific amplification followed by spatially discrete detection on biochips, providing sensitive assays for detection of multiple targets and simultaneous identification of co-infections. This, in turn, facilitates improved patient care pathways and a reduction in antibiotic misuse.

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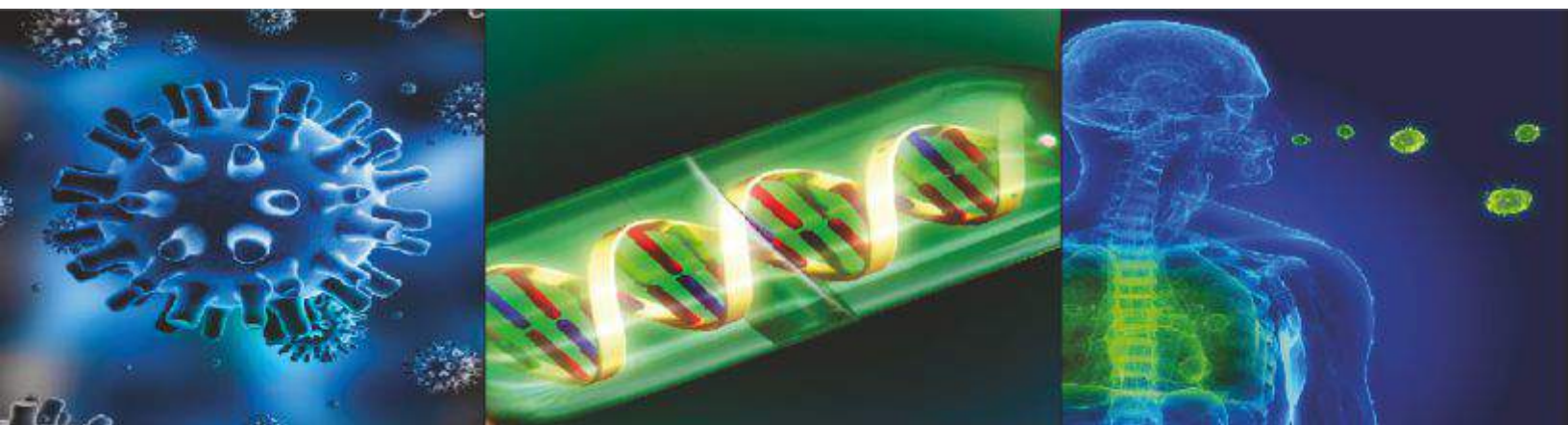


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