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

# 2012

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#### **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) Vietnamese Association of Clinical Biochemistry (VACB)

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#### **Submissions**

The APFCB News welcomes suitable contributions for publication. These should be sent electronically to the Chief Editor. Statements of opinions are those of the contributors and are not to be construed as official statements, evaluations or endorsements by the APFCB or its official bodies. **cover page :** courtesy Dr Tan It Koon, Founding and Past President of APFCB

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## From the desk of Chief Editor...

Dear Colleagues,

Greetings! It is with a deep sense of gratitude and satisfaction that I am before you with the third annual issue of APFCB news. At this hour of joy and pride I take this opportunity to thank APFCB Executive for their continued support and faith in me to carry forward the core objective of APFCB news.

It is a pleasure to include reports from the various APFCB member societies for which I'm thankful to the respective national representatives for their efforts in presenting detail annual activity report.

I 'm also grateful to Randox and Beckman Coulter, for contributing scientific article and advertisement thus financial support to this publication.

My apologies to the readers and contributors for delay in publication of this issue, primarily due to work pressure after change in my affiliation as Professor and Head Department of Biochemistry, AIIMS, Jodhpur an upcoming national level institution of this country and partly also the delay in receiving reports from members of APFCB family. However as we are all aware, the world does not stand still and we very much look forward to your sustained support in future to maintain the APFCB site as a very interactive and well updated site representing the active picture of APFCB and reflecting its activities. So friends, please use this forum effectively to share your progress, achievements and your thoughts and contributions on different issues related to the clinical biochemistry and laboratory medicine disciplines, as knowledge shared is knowledge gained.

The attractive painting on the cover page of the current issue of APFCB News was graciously contributed by Tan It Koon from his precious art work. Further it will not be out of place to mention that Tan It Koon is founding and the past president of APFCB and active contributor to the progress and development of APFCB. I'm thankful to Tan It Koon for providing two beautiful paintings from his art treasure, of which one has been picked up for the cover page of the current issue.

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

**Prof Praveen Sharma** 

**Chief Editor** 





## **Message from APFCB President**



Greetings to all members of the APFCB.

This is my third year as President of the APFCB. I would like to thank all the Executive Board members, Chairs, members and corresponding members of the five standing committees of the APFCB for a job well done. With all your hard work and dedication we have achieved all that we have stated in our three year strategic plan well ahead of time.

A new Executive Board will be elected at the APFCB Congress in Bali in October 2013 and the new Executive Board will take up office in January 2014 for a three year term.

I would like to invite you to attend the APFCB Congress this year which will be held from 27 till 30 October 2013 in the idyllic island of Bali in Indonesia. The scientific programme is excellent and I assure you that the social programme will be most memorable. I would like to thank the Organising Committee for the excellent work they have done in planning for the APFCB Congress 2013.

There will be eight (8) scholarships on offer to attend the APFCB Congress in Bali: Five are sponsored by Siemens, one by Abbott and the other two are from the APFCB Philanthropic Fund. You are eligible to apply for these scholarships if you intend to present a poster at the APFCB Congress in Bali and have less than 20 years of laboratory experience. The IFCC will also be offering IFCC-Roche Travel Awards to participate in this APFCB Congress.

I would like to thank Professor Praveen Sharma for the excellent work he has done as Editor of the APFCB eNews and for getting our APFCB website off the ground and for overseeing the development of the website.

My very best wishes to all of you.

Dr Leslie Lai President, APFCB





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

## Annual Report for 2012

The APFCB has 16 Member Societies, 18 Corporate members and 2 Affiliate members.

#### **Ordinary Members**

- I.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)
- II.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**

- I.Abbott Diagnostics
- 2. Agappe Diagnostics
- 3.BD Diagnostics
- 4.Beckman Coulter
- 5.Beijing Wantai
- 6.Bio-Rad
- 7.Diasorin Ltd
- 8. DiaSys Diagnostic Systems GmbH
- 9.Kopran Laboratories Ltd
- 10.Mindray Bio-Medical Electronics Co Ltd
- II.Ortho-Clinical Diagnostics
- **12.PM** Separations
- 13.Randox Laboratories
- 14.Roche Diagnostics
- 15.Sekisui Chemical Co (Japan)
- 16.Siemens Healthcare Diagnostics



#### 17. Sysmex

18. Technidata Medical Software

We would like to welcome Diasorin Ltd, DiaSys Diagnostics Systems GmbH, Kopran Laboratories Ltd, Mindray Bio-Medical Electronics Co. Ltd and Technidata Medical Software, our new APFCB Corporate members admitted in 2012.

#### **Affiliate Members**

I.Chinese Association of Clinical Laboratory Management (CACLM) 2.Macao Laboratory Medicine Association (MLMA)

#### **Office Bearers**

The Executive Board of the APFCB was elected at the Council Meeting in Seoul on 3rd October 2010 while the chairs were appointed in November 2010 based on nominations by APFCB member associations. The office-bearers will serve until the 31st of December 2013.

#### **Executive Board**

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	
Chairs of Committees Communications (C-Comm)	Praveen Sharma (India)
-	Praveen Sharma (India)
Communications (C-Comm)	Praveen Sharma (India) Joseph Lopez (Malaysia)
Communications (C-Comm) Congress and conferences	
Communications (C-Comm) Congress and conferences (C-CC)	Joseph Lopez (Malaysia)
Communications (C-Comm) Congress and conferences (C-CC)	Joseph Lopez (Malaysia) Samuel Vasikaran
Communications (C-Comm) Congress and conferences (C-CC) Education (C-Edu)	Joseph Lopez (Malaysia) Samuel Vasikaran (Australia)
Communications (C-Comm) Congress and conferences (C-CC) Education (C-Edu) Laboratory Management	Joseph Lopez (Malaysia) Samuel Vasikaran (Australia)

#### Honorary Executive Officer: Dr Johnson Wijaya (Indonesia) Executive Board meetings

The Executive Board has held three meetings since taking office. These were held on: 16 May 2011 during the EuroMed Lab meeting in Berlin 7 February2012 in Singapore 17 November 2012 in Kuala Lumpur prior to the IFCC General Conference 2012 Only the meeting on 7 February 2012 in Singapore wasfunded by the APFCB (travel and accommodation).



#### **APFCB EB** members' participation in National Society meetings

I.Dr Elizabeth Frank, Treasurer of the APFCB, represented the APFCB at the Annual Scientific Meeting of the South African Association for Clinical Biochemistry on 29th September 2012. The title of her talk was "A new paradigm shift in the direction of HDL research, Are we ready for it?"

2.Dr Endang Hoyaranda was the Keynote Speaker at the ACBICON in December 2012, Ranchi, India, where she represented the President of the APFCB who was unable to attend the ACBICON 2012 due to a prior engagement. The title of her talk was "Managing Risk Beyond Patient Safety".



From left to right: Dr Elizabeth Frank, Treasurer of APFCB; Dr Endang Hoyaranda, Secretary of APFCB and Keynote Speaker at ACBICON 2012;Mr S.M.Thakur, Manager, Quality Assurance, Occupational Disease Centre, Bokaro and Treasurer of ACBICON 2012 held at Ranchi in December 2012.

#### APFCB Rule Book

The APFCB Rule Book has been completed and will be available on the APFCB website.With this rulebook finalised, all items in the Strategic Plan have been completed.

#### Report from the Education Committee (C-Edu)

(Chaired by Professor Samuel Vasikaran, Australia)

I. APFCB Travelling Lecturer

Dr Angela Wang from Hong Kong delivered her lecture "Inflammatory markers in renal disease" to the MACB in Kuala Lumpur, Malaysia in July 2012 and in Kunming, China in August 2012. The APFCB Travelling Lecturer for 2013/14 is Prof Sunil Sethi of Singapore.



#### 2. IFCC-Abbott Visiting Lecturer

Dr Gary Myers was the IFCC-Abbott Visiting Lecturer to the APFCB region in 2012. His topic was "Current Markers of Cardiovascular Disease". Dr Myers visited China and Hong Kong in May 2012. In China he presented a plenary lecture in Nanjing at the 7th National Youth Congress of Laboratory Medicine that was attended by nearly 1000 scientists and in Hong Kong to a meeting of the Hong Kong Society of Clinical Chemistry attended by about 190 members. He presented a plenary lecture at the AACB ASC in Melbourne on the 15th of November 2012 followed by further lectures at the MACB conference in KL on November 21st, IACC special seminar in Jakarta on the 24th of November, and the PAMET conference in Manila on the 28th of November.

3. An APFCB Webinar that was sponsored by Siemens Diagnostics was delivered on April 4th 2012 by Dr Elizabeth Frank of India. The topic was "How to prepare your lab for accreditation".

4. The APFCB Interpretative Comments Education Program for 2012 continued to be coordinated by Dr Gordon Challand of UK. There were 43 registrants. Four cases were sent to participants in 2012. However, the participation rate is well below 50%.

5. Two scholarships of up to SGD 3500.00 each have been awarded for attendance at the AACB ASM in Melbourne in November 2012. The recipients were Prabin Gyawali of Nepal and Deepani Siriwardena of Sri Lanka. Prabin gave an oral presentation "Evaluation of Using Interpretative Cut-off Value as Decision Limit Amongst Practising Clinicians in Nepal" and Deepani presented a poster entitled "Is there Harmony in Reporting Units of Biochemistry and Haematology in Accredited Laboratories of Sri Lanka?".

6. The Education Committee organised the APFCB-sponsored symposium "Osteoporosis: Investigations, fracture risk assessment and monitoring of treatment" at the EFLM-UEMS Conference, in Dubrovnik, 10-13 October 2012. The speakers were:

I. Prof Vladimir Palicka: Diagnostics of osteoporosis and fracture risk assessment

2. Dr Devika Thomas: Bone turnover markers in management of osteoporosis

3. Prof Howard Morris: Vitamin D status and osteoporosis: evidence for a role in hip and non-vertebral fractures, optimal levels and treatment targets.

#### Report from the Scientific Committee (C-Sci)

(Chaired by Professor Kiyoshi Ichihara, Japan)

I Collaboration by countries in the APFCB region in the worldwide study on reference values



The study, planned and coordinated by the Committee on Reference Intervals and Decision Limits (C-RIDL), IFCC, was launched in December 2011. Its objectives 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 12 countries worldwide are collaborating in the study. The following four countries are from the APFCB.

**Japan:** 760 volunteers were recruited from Yamaguchi, Hiroshima and Osaka Universities. The measurement of 55 analytes was supported by Beckman-Coulter (BC) Japan.

**China:** 480 volunteers were recruited from Beijing National Hospital, coordinated by Dr. Jian Guo and Dr. Luyan Xiao. The measurement of 35 analytes is being supported by BC China. Additional recruitment of 800 from other cities is being planned.

**India:** 500 volunteers are being recruited 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:** 1200 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. Dyasis' autoanalyser will be used for the measurement of 22 biochemical analytes.

The results will be combined with those from the 2009 Asia study consisting of test results of 72 analytes from 3500 volunteers. The objective of combined analysis is to obtain the comprehensible picture of evidence on sources of variations for commonly tested analytes (such as regionality, ethnicity, age, sex, BMI, smoking, alcohol, blood type related changes). A web site showing the results is being built. The entire results from Asia are to be presented and discussed during the 2013 APFCB Congress in Bali.

2. A joint project is under way on the standardisation of testosterone and related analytes assays by use of mass spectrometry among researchers in the APFCB region, coordinated by Dr Ronda Greaves. In the RCPA Chemical Pathology QAP survey conducted in 2012 with participation of 130 laboratories, the laboratories in the harmonisation working group attained very good results, all within the allowable limits of performance. Participants are currently involved in assessing the utility of a traceable matrix matched common secondary calibrator. It is anticipated that the initial results of this project will be presented at the APFCB Congress in Bali in October 2013.



3. A project on establishment of a mass spectrometry-based assay system or paediatric screening of neuroblastoma in Vietnam is also under way, coordinated by Dr Ronda Greaves. This project was awarded a research grant from the APFCB. It is anticipated that the results of this project will be presented at the APFCB Congress in Bali in October 2013.

#### Report from the Laboratory Management Committee(C-LM)

(Chaired by Associate Professor Tony Badrick, Australia)

1. The major activity of the CLM is the organisation and delivery of the QA/QC Workshops. Planning is well underway for a workshop in Hanoi to be conducted in March 2013. The Workshop has been prepared with the generous support of Becton Dickinson.

2.A needs survey amongst member societies has been undertaken. We are waiting feedback from member societies/associations to inform the Executive Committee on the preferred future activities of the APFCB.

3.One of the goals of the CLM was to begin raising awareness amongst members of the APFCB of the importance of lessening the environmental impact of clinical laboratories. This continues with relevant material on the website.

4. 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

Report from Communications Committee (C-Comm)

(Chaired by Professor Praveen Sharma, India)

#### I. APFCB Website

Our APFCB website (<u>www.apfcb.org</u>) was launched on 1st Nov 2011 and 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 CommunicationsCommittee and to the photo gallery of these events. The website is also a source of information on the APFCB Congress and regional meetings 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 the members. It also gives access to the APFCB webinars.

2.APFCB e-News:

The APFCB e-News 2010 and 2011 were published online on the APFCB website. This has ensured wide reach of the APFCB News to all the members at no additional cost. The APFCB News 2012 is being compiled and will be published by the end of February 2013

#### **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.

#### Report from the Congress and Conferences Committee (C-CC)

(Chaired by Mr Joseph B. Lopez, Malaysia)

I.I3th APFCB Congress (27-30 October 2013)

The APFCB President, Dr Leslie Lai and the C-CC Chair paid a visit to Bali from 14-16 October 2012. The report of the visit may be found in Appendix I below. The C-CC and President also received a Progress Report from the Chair of the Organising Committee on 7th October 2012.



Venue of the APFCB Congress 2013: Bali Nusa Dua Convention Centre





Lobby in Bali Nusa Dua Convention Centre

2.Speciality Meeting

Following a joint letter dated 28 February 2012 to Corporate Members by the President and C-CC Chair inviting expressions of interest to sponsor an APFCB speciality meeting only one response was received and it was from BD Diagnostics to sponsor a meeting on Pre-Analytical issues. This offer of sponsorship resulted in a telephone conference among 3 representatives from BD and the Chair on 18th September 2012. Essentially, it was decided that the meeting will be held in Vietnam (as requested by BD). Sunil Sethi and Tony Badrick will be the APFCB main speakers while BD will also provide speakers. The C-CC Chair will also be present at the meeting as speaker and to ensure the smooth running of the meeting.

#### **Corporate Members Report** (Mr Martin Fuhrer, Corporate Representative)

At the end of 2012 the APFCB has 18 Corporate members. This is an incr-ease of three (3) from 2011. Five (5) new members joined in 2012:

- Diasorin Ltd.
- DiaSys Diagnostic Systems GmbH
- Kopran Laboratories Ltd.
- Mindray Bio-Medical Electronics Co. Ltd.
- Technidata Medical Software

Piramal Healthcare Limited and Osmetech decided to discontinue their APFCB Corporate membership in 2011.

APFCB Corporate members are eligible to apply for APFCB auspices from the Congress 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 <a href="http://apfcb.org/apfcb-guidelines.pdf">http://apfcb.org/apfcb-guidelines.pdf</a>.

As part of the preparation for the 13th APFCB Congress the Corporate sponsors' meeting was held on 7 February 2012 at the National University Hospital in Singapore. Almost all Corporate members sent their representatives and the organising committee presented the scientific program, the venue and sponsorship opportunities. Most up-to-date information about this important congress is available under http://www.apfcbcongress2013.org/home.



The APFCB EB wishes to thank all Corporate members for their ongoing collaboration and continuous support of the APFCB.

Report prepared by Dr Leslie Lai with contributions from Samuel Vasikaran, Kiyoshi Ichihara, Ronda Greaves, Tony Badrick, Praveen Sharma, Joseph Lopez, Martin Fuhrer and Endang Hoyaranda.

#### Appendix I

## Report to APFBC EB on the visit to Bali to meet the Organising Committee of 13 APFCB Congress

#### Present

#### Organising Committee:

Dr July Kumalawati, Chair Dr Dewi Muliaty, (President, IACC; Chair of Scientific Committee) Dra Endang Hoyaranda Mr Eric Martoyo, Mr Aferza Reviansha, PACTO (Conference organiser)

#### **APFCB:**

Dr Leslie Lai, APFCB President Mr Joseph Lopez, Past President and Chair APFCB C-CC

#### REPORT

Friday, 14 September 2012: visit to site of Gala dinner Saturday, 15 September 2012: visit to and meeting at Bali Nusa Dua Convention Centre (BNDCC)

#### General

Dates of the congress have been changed to 27-30 October 2013. This change has been necessitated due to the annual APEC summit of Heads of States which will be held in early October 2013 at the same convention centre. The OC was reminded that the full name of the APFCB included Laboratory Medicine following the decision at the last Council meeting.

#### **Congress Venue and Hotel**

I. The venue is the BNDCC. It is the location where the next APEC summit will be held. Main lectures have good acoustics and seating space. The meeting rooms are also very good. All in all this is a modern convention centre and should serve us well. It is located within a 5 minutes' walking distance from the main congress hotel

2. The main congress hotel will cost about USD230 per room per night. Nusa Dua is an expensive area and the hotels in the vicinity are all 4 or 5 stars.



3.Most of the main programme symposia will be sponsored by national or international societies. The OC was reminded that we need to provide good science. Some of APFCB member societies who had offered to sponsor symposia have not as yet submitted their titles or speakers' names.

4. The organisations outside of the region which will sponsor symposia are the IFCC (three), EFLM, WASPaLM and NACCCA (one each). It was suggested that the OC also invite the AACC and ACB (UK) to sponsor symposia.

5.1t was suggested that a symposium on biomarkers be considered by the Scientific OC.

6.Some overlap in symposium topics (e.g. osteoporosis) were identified and suggestions to rectify this overlap were made

7.Corporate workshops/symposia: these will be held during lunch breaks and to date two have been taken up.

8. There will be 5 pre-congress workshops that will be held on the morning of 27 October 2013. It was noted that these would overlap with the Council meeting that would be held the same morning.

9. Posters:

a)About 400 posters are expected to be presented.

b)They will be on display on 28 and 29 October 2013.

c)It was decided that presenters had to provide a 5 minute oral presentation of their posters at times that would be scheduled.

d)The best posters will be chosen for an oral presentation. It would be mandatory for all holders of travel awards/scholarships to present their posters. Otherwise they will not be given their award.

e)All posters will have to be original and not previously presented (although it was agreed that this provision would be difficult to enforce)



#### Finances

I. The OC was urged to budget for and appoint a public auditor who will audit the congress accounts, as mentioned in the APFCB Strategic Plan.

2.Most of the main booth areas (diamond and platinum) have been sold. There are still 2 booth areas that have yet to be sold. A number of booths along the sides (Gold) have yet to be taken. OC was urged to work closely with Martin Fuhrer to secure greater support of our Corporate members.

3.Siemens has agreed to sponsor congress badges. However, a sponsor has yet to be found for the congress bags.

#### Social

1. Opening: In keeping with tradition, the opening will be held on the evening of 27 October 2013. Speeches will be the following sequence:

- Welcome by the Chair, OC
- APFCB President
- IFCC president
- · Speech by Minister of Health and official opening
- Distinguished Service Award presentation:
- Citation by Chair of DSA Committee
- Presentation by APFCB President

The Opening ceremony reception will be held after these events. There will be an open-air cocktail with cultural shows as entertainment. Should it rain the venue will be moved inside the convention centre

2. **Gala Dinner:** The gala dinner will be an open air event at GWK, a location some 30 minutes away from the conference centre. The OC was advised to provide contingency plans in the event of rain. There will be cultural dances and performances show-casing Balinese and Indonesian culture.

3. Accompanying persons and tours: The OC was urged to have pre and postcongress tours A social programme for accompanying person will be arranged



#### **Congress Promotions**

I. There have been promotions at various meetings and OC was urged to ramp up promotions with about I2 months to go. It was suggested that the OC focus on APFCB member associations in their promotions. It was suggested that some kind of promotion be done at the IFCC General Conference in Kuala Lumpur.

2. The OC promised to get the congress website up and running as soon as possible. Website will enable payments to be made online.

Prepared by Joe Lopez, 17 September 2012



## REPORT ON 13TH APFCB CONGRESS PREPARATION AND PROGRESS



The Indonesian Association of Clinical Chemistry (IACC) is appointed to host the I3th Asia-Pacific Federation of Clinical Biochemistry and Laboratory Medicine (APFCB) Congress in 2013, which will be held on 27-30 October 2013. This Congress is under the auspice of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and World Association of Societies of Pathology and Laboratory Medicine (WASPaLM).

The Organising Committee has chosen a Professional Convention Organiser (PCO) as a partner to organise the Congress. IACC has signed agreement with Pactoconvex Ltd., in Jakarta on 25 January 2012 on a profit/loss sharing basis. The company is a reputable professional convention organizer which has vast experience of organising international conferences, including health and intergovernmental meetings.

The venue for this congress is Bali Nusa Dua Convention Centre, located in an enclosed area of Nusa Dua, Bali, Indonesia. As the newest and biggest convention centre in Bali, this venue has good meeting facilities and has been appointed as the venue of APEC Summit Meeting on 1-9 October 2013. Many 4-5 star hotels are available in the enclosed area of Nusa Dua and several 3 star and budget hotels are available nearby to the enclosed area.Shuttle buses will be provided to and from the hotels designated by the committee during the congress period.



Bali Nusa Dua Convention Centre (BNDCC) (http://www.baliconventioncenter.com/)



A website (www.apfcbcongress2013.org) has been developed and published to promote and provide the latest information on the congress. This website is also used as the registration method for participants of the congress.

Scientific events consist of 5 pre-congress workshops, 4 plenary lectures, 26 symposia, oral free paper presentations, and poster presentations. As per 12 March 2013, 86 speakers have been invited and confirmed. Speakers come from 11 countries from Asia-Pacific region, Europe, and America.

Sponsorship and exhibition have been offered in the forms of exhibition packages, lunch industry symposia, industry workshops, coffee break sponsorships, conference kit, and publication in the programme book, inserts, and the website. For the exhibition, 70 of 100 booths have been booked by 34 international and local companies, 5 of 9 lunch symposia have been booked, and none of 9 industry workshops have been taken (as per 12 March 2013).

Travel scholarships that have been offered are:

- Two APFCB Travel Scholarships each to the value of up to SGD 3500
- Five APFCB-Siemens Travel Scholarships each to the value of up to SGD 3500
- One APFCB-Abbott Travel Scholarship to the value of up to SGD 5000

Application of scholarship is directed to APFCB Education Committee and winners will be nominated by APFCB Education Committee.

Social activities include the opening ceremony, welcome reception, cultural night, and closing ceremony. The cultural night will be held in Garuda Wisnu Kencana, an area carved out of a lime stone hill with huge Balinese statues and unique environment, in which the Indonesian culture will be introduced to the participants.



Garuda Wisnu Kencana (http://gwk-culturalpark.com/)



#### Important dates:

- Scholarship application deadline is 12 April 2013
- Abstract submission deadline is 15 April 2013
- Early bird registration deadline is 15 May 2013
- Full rate registration is from 16 May 2013 to 23 October 2013, after which will be considered as on-site registration.

Registration has been opened via the website from 10 February 2013.

Report received from IACC



## 3rd IFCC-Task Force Young Scientists Workshop At 39th ACBICON 11th Dec, 2012,

## Ranchi, India

Theme: Clinical Chemistry to Clinical Laboratory Science

**Dr Pradeep Kumar Dabla** National Representative IFCC-TF YS;Email: Pradeep\_dabla@yahoo.com

The IFCC-TF YS was built in 2010 and is devoted to prepare young scientists with ongoing changes in laboratory medicine and healthcare practices. The specific objectives were identified as Networking, Training, Participation & Multidisciplinary exchanges of different fields & different ideas. Thus, IFCC-TF YS has organised Workshops in different Congresses of IFCC & Member Societies to learn perspectives & principles of Laboratory Management & Leadership. In India with collaborative efforts of ACBI & IFCC, the first IFCC-TF YS workshop was organized on 12th Dec 2010 in ACBICON-2010 at Mumbai under the theme of "Mapping Future of Laboratory Scientists" stressing on good Lab practices and Accreditation. As a part of efforts, the second workshop themed as "Think The Unthinkable" was organised on 3rd Dec 2011 in ACBICON-2011, Gwalior. For the first time, this workshop brings the laboratory medicine and Industry together, stressing on Various Job Opportunities present in Industry and other sectors related to Laboratory Medicine.



Dr. Bernard Gouget delivering his lecture

Continuing the efforts, the 3rd workshop was organised at Rajendra Institute of Medical Science (RIMS), Ranchi during the pre-conference day of ACBICON-2012. **The theme of the workshop was "Clinical Chemistry to Clinical Laboratory Science".** This visionary process engages young scientists actively to embrace new technologies & learn the working practices of different disciplines. To know challenges related to laboratory management and principles of leadership for scientists at various sites. It helped to describe role of research training to improve research services and enhance communication within the profession.





Participants of 3rd IFCC Task force Workshop

During the opening ceremony, welcome address was initiated by Dr. Pradeep Kumar Dabla, National Representative & Convener IFCC-TF YS. He summarised the previous networking and activities organised at ACBICON-2010 & 2011 in India and the current workshop motives and objectives remembering Dr. Gruson Damien, Chairperson, IFCC-TF YS. He thanked Dr Leslie Charles Lai (Chair, IFCC-Abbott Visiting Lectureship Programme Committee) for providing financial support to call Dr. Bernard Gouget (EB-IFCC). Dr. Neelima Singh, President ACBI addressed and conveyed the ACBI activities for young scientists and its upcoming programmes. Dr. K. P. Sinha, Advisor ACBI welcome all and stressed on to the need of networking at larger scale adopting advanced technologies.

The first session was chaired by Senior ACBI members, Dr. Arun Raizada, Dr. T. Malati and Dr. Sucheta Dandekar. Speaking on occasion, Dr Pradeep K Dabla briefed the technological development of Laboratory Medicine and opened new avenues. He explained the need and gave suggestions for more integration between clinical information and laboratory data to maintain highest quality data and to maximize influence of laboratory results on to the management of patients. Dr Bernard Gouget (EB-IFCC) described thebiosensors and new technologies for patient-proximal diagnostic products and the new attitudes of patients and healthcare providers. He explained how the POCT will transform the organization and the practice of laboratory medicine for more efficient medical service and economic perspective. Dr Guillaume Galpy (Head of AQT Clinical & Scientific Affairs department, Radiometer) said POCT encompasses a large variety of IVD products ranging from moderate to single-use, disposable tests. It has the potential to enhance clinical outcome and impact on rapid diagnosis including existing new technology areas such as protein sequencing, DNA sequencing.



Dr. Pradeep Kumar Dabla conducting the IFCC task force



The second session was chaired by Dr. D. M. Vasudevan, Dr. Neelima Singh, Dr. Praveen Sharma, past and current ACBI presidents. Dr. Hariom Sharma (Head of Biochemistry & Lab. Director, Govt. Medical College, Gujrat) initiated and gave brief note on Core Laboratory Concept. He said "In current scenario as much as 90 percent of science relies on core capabilities and, in many fields, experiments and analyses cannot be done without them." Dr. Bernard Gouget explained the research as an increasingly important criterion to create opportunities into health-related professionals at different levels. Then he told how IFCC being an International Organisation is working towards raising scholarship and other funds for the international exposure of YS and briefed various scholarship programmes and available grants. Dr. Jayashree Bhattacharjee (Principal, VM Medical College, Delhi) described the increasing emphasis on research in medical research centres, medical colleges and other professional programs in Indian health care. In medicine, clinical research facilitates the optimization of medical practice and assessment of new procedures. This was followed by Round table discussion between speakers and young scientists. YS cleared doubts and queries related to subjects. Dr. Abhay Pratap (Organising Secretary, ACBICON-2012) ended the session delivering concluding remarks and vote of thanks.



Dr. Pradeep Kumar Dabla, concluding the session and giving vote of thanks

To summarize, this exceptional experience has shaped how each of these students interprets medicine within their profession. This new generation of health professionals will be shifting the paradigm of medical research to encompass fully the great variety and experience of doctoral programmes and research training schemes, including both the opportunities and barriers. So this workshop provided useful information and insight into the challenges of research and new technologies.



## IFCC-ABBOTT VISITING LECTURE PROGRAMME "BIOMARKERS IN CARDIOVASCULAR DISEASE" Jakarta, November 24, 2012

The IFCC-Abbott Visiting Lecture with the theme of Biomarkers in Cardiovascular Diseases, was held in Jakarta on November 24, at Sari Pan Pacific Hotel.

The speakers were Gary L Myers, PhD, FACB from AACC and Prof. Marzuki Suryaatmadja, SpPK (K) from IACC



Prof Gary L Myers talked about Biomarkers for Assessing Cardiovascular Disease Risk

The event was well-attended with 106 participants from clinical laboratories and hospitals, coming from Jakarta and its neighbourhood.



Discussion session (left to right : Prof Gary L Myers, Prof Marzuki Suryaatmadja, dr. Tjan Sian Hwa)

The first speaker, Prof. Marzuki talked about Non-lipid Biochemical Markers for Cardiovascular Risk Factor. The talk focused on non lipid biomarkers such as pro oxidant and oxidant marker; hs-CRP as a marker of inflammation and endothelial dysfunction; LpPLA2 as a marker of plaque inflammation; adiponectin as an anti atherogenic and anti inflammatory molecule; MPO as a marker for plaque destabilization and IL-18 as a marker of plaque rupture.

The second speaker, Gary L Myers started his presentation with an introduction to the IFCC (member, mission, structure and organization, EB, Divisions) and continued with his talk about Biomarkers for Assessing Cardiovascular Disease Risk. Gary informed about US guidelines for CVD risk prediction, LDL-C direct assay performance, and the role of other markers of CVD risk such Apolipoprotein B, Creactive Protein, renal markers such as cystatin C.

In general, the visiting lecture was very well accepted, and very useful for the Indonesian laboratories.



#### The Participants



Apart from the formal seminar, the lecturers had the chance to taste a little bit of the Indonesian cuisine, the committee took them to Bunga Rampai, an indigenous Indonesian restaurant with "Europe" decorations. Gary L Myers also had the chance to see Indonesian handicrafts, and a miniature of Indonesia at the Taman Mini Indonesia Indah the day before leaving back home.



Discussion session

The IACC wishes to thank the speakers, especially to Gary L Myers for coming to Indonesia, and for their time and expertise shared to the audience.



Dr. Endang Hoyaranda (APFCB's secretary and m e m b e r o f I A C C Organizational Committee), Prof. Gary L Myers and Prof. Marzuki Suryaatmadja as speakers, dr. Tjan Sian Hwa as Moderator, Dr. Dewi Muliaty (IACC's President)

The IACC is grateful to the IFCC for making it possible to conduct this Visiting Lecture Programme.



## Report on the activities of Association of Clinical Biochemists of India (ACBI) in 2012

The year started with the newly elected office bearer selected at the General Body meeting of the Association of Clinical Biochemists of India held in Mumbai on December 5, 2011, taking up their office. The office bearers elected were :

Our Golden Jubilee was celebrated throughout the year with special events held.

President	Dr. Neelima Singh Professor & Head, Department of Biochemistry, G. R. Medical College, Gwalior, Madhya Pradesh India.
Advisor Vice President	Dr. K. P. Sinha I . Dr. Abhay Pratap, Bokaro, Jharkand 2. Dr. Jayashree Bhattacharya, New Delhi
Immediate Past President	Dr. Sucheta Dandekar, Mumbai, Maharashtra
General Secretary	Dr. Rajiv R. Sinha Associate Professor Department of Biochemistry Nalanda Medical College Patna-800001. Bihar. India Tel: +91-9835067630 <u>E-mail:kpsacbi@yahoo.co.in</u>
Joint secretary Treasurer Editor, IJCB	Dr. Monika Gupta, Jaipur, Rajasthan Dr. Sanjeev Singh, Gwalior, M.P. Dr. K. R. Prasad, Patna, Bihar Dr. Praveen Sharma, Jodhpur, Rajasthan

National Representative to IFCC Dr T. Malati, Hyderabad, A.P.



## Activities in 2012 Regional Meetings:

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

• The Delhi State branch & Department of Biochemistry, Sir Ganga Ram Hospital, New Delhi organized a symposium on 21st. January 2012 titled :Opening New Horizon in Clinical Biochemistry" with Prof. L.M. Srivastav & Dr Anjali Manocha being the lead persons for the symposia.

• Dr. Shyamali Pal and Dr.JayantaDey, under the aegis of The West Bengal State Chapter organized a one day CME on 12th February, 2011 in Kolkata on "Quality Assessment as per ISO 15189". Dr. P. D. Sawant, Lead Assessor NABL and CAP Inspector was the Guest speaker of this CME.

• Department of Biochemistry, Kasturba Medical College, Mangalore, Karnataka in association with the local chapter of ACBI conducted a CME on "Glycomics" on October 8th 2011 at KMC, Mangalore. Over 150 delegates from different Medical Colleges in Karnataka attended the CME. The CME was followed by ACBI Mangalore chapter meeting where Dr. Poornima Manjrekar was elected President of the Mangalore Chapter.

• A CME on "Current Trends in Laboratory Practices" was conducted by the Department of Biochemistry, MGM Medical College, Navi Mumbai on 25th. November 2011 under the auspices of ACBI Maharashtra state chapter. Around 110 delegates from all over Maharashtra had registered for the programme. Dr. Padma Chavan was the organizing Secretary.

 The Department of Biochemistry & Immunology of KokilabenDhirubhaiAmbani Hospital & Medical Research Institute, Mumbai in collaboration with the Association of Clinical Biochemists of India, Maharashtra Branch, hosted the 'Total Quality Management Seminar' on January 7, 2012. The Department of Biochemistry & Immunology of Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai in collaboration with the Association of Clinical Biochemists of India, Maharashtra Branch, hosted the 'Total Quality Management Seminar', which was an attempt in reviving quality awareness. The event took place in the convention centre of Kokilaben Hospital on January 7, 2012. Dr. Barnali Das, organizing secretary of this seminar, started the scientific session by outlining the background and motivation behind this event. The technical programme included 7 presentations by distinguished national & international speakers from Quality Council of India (QCI), College of American Pathologists (CAP), NABH and NABL. Dr. Girdhar J Gyani, Secretary General, QCI & CEO, NABH elaborated the role of accreditation in improving patient safety and quality of care in his keynote address. Dr. Bharati Jhaveri, CAP Governor, delivered her keynote address on CAP accreditation overview. Dr. Ronald B Lepoff, CAP inspector, spoke about physical space & safety requirements from the view point of accreditation. Ms. Adrienne Malta, CAP inspector, detailed the methods for fulfilling CAP's competency assessment requirements.



- A Seminar cum Workshop was organized by the Association of Clinical Biochemists of India (Kerala Chapter) on 29th of July 2012, at Hotel Casino, Trissur. The function was Presided by Dr T Vijayakumar, Former Dean and Director at School of Health Sciences, University of Calicut and was formally inaugurated by Dr D.M. Vasudevan, Former Dean of Amrita Institute of Medical Sciences and and Past President of ACBI. A special session on was a Hands on training and Workshop on "Equipment Calibration in Laboratory" by M/s Medical Engineering & Services, Trissur.
- A half a day CME-III meeting was conducted by **DR. R. Arivazhagan**, Associate Prof. & Head of the Clinical Bio Chemistry Dept., Cancer Institute ,Adayar, Chennai, Tamil Nadu on **15th September 2012.**
- Haryana Chapter of the ACBI organized a Conference & CME under the guidance of Dr. Harbans Lal, Sr. Prof & Head, Department of Biochemistry, Maharaja Agrasen Medical College Agroha (Hisar), on 29th Sept 2012. Thirty seven research papers were presented in the poster session. Five papers were given best paper awards.

## 39th. ANNUAL NATIONAL CONFERENCE OF ACBI (ACBICON 2012)

The year 2012 ended with the 39th Annual National conference of the Association, ACBICON 2012, at Ranchi, the capital of the lush green state of Jharkhand, which was successfully conducted during December I I to 14, 2011 at Rajendra Institute of Medical Sciences and KhelGaon Sports Complex, Ranchi with Dr. AbhayPratap as Organizing Secretary. The conference was attended by about 650 delegates from India and abroad. Two Pre-conference CME's were held on 11th December on " New approaches to Medical Education in Biochemistry" & "Implementation of good laboratory practice". In the post-lunch session, the IFCC Task Force for Young Scientist held its session with the theme of "Clinical Chemistry to Clinical laboratory science". It was addressed amongst others, by Dr. Bernard Gouget, representing the IFCC on the panel. The main scientific session started on 12th. December 2012 with Revered Swami Sarvalokanandaji Maharaj, Ramakrishna Mission Hospital Kolkata, giving his blessings for the success of the conference and exhorting biochemists to do their best for the upliftment of society. This was followed by a plenary lecture on "Risk management beyond patient safety" which was delivered by DrEndang Hoyaranda, Secretary, APFCB. The K. L. Gupta Memorial Oration was delivered by Dr. Raghunadharao, Professor of Medical Oncology at Nizam's Institute of Medical Sciences, Hyderabad, This was followed by the Taranath Memorial Popular lecture series Oration which was delivered by Dr. T. Venkatesh, Professor emeritus, St. Johns Medical College, Bangalore.

The Inaugural function was held in the evening and was inaugurated by Dr. TulsiMahato, Director, Rajendra Institute of Medical Sciences, Ranchi. During the inaugural function, ACBI-A.J. Thakur award, K.P.Sinha-P.S.Krishnan Award and Fellowship of ACBI were conferred. Also, Dr. Abhay Pratap was installed as the new President of the Association of Clinical Biochemists of India. The inaugural function also saw the felicitation of Dr. P. S. Murthy, Abhay Pratap of the association and also former editor of Indian Journal of Clinical Biochemistry, for his immense contribution to the ACBI. This was followed by a beautiful cultural programme showcasing the different dance forms of Jharkhand, especially Chhau Dance.



Scientific programme of the conference comprised of 6 oration lectures, 3 Industrial workshops,46 symposia on various aspects of clinical biochemistry and laboratory medicine, 12 invited lectures, award paper presentation sessions, free paper sessions and a special session on "Lunch with Experts".

Dr. M. V. Kodliwadmath, Professor & Head,, Department of Biochemistry, Navodaya Medical College, Raichur, Karnataka, delivered the **Dr. T. N. Pattabiraman Oration.**Dr. Suman Bala Sharma, Professor of Biochemistry University College of Medical Sciences & GTB Hospital, Delhi delivered the **Seth G.S. Medical College & KEM Hospital Oration**.Dr. Nibhriti Das, Professor, Department of Biochemistry, All India Institute of Medical Sciences, New Delhidelivered the **Mrs. & Dr. G. P. Talwar Oration**.

Four Industrial workshop were held during the conference. The first was held on 12th December which was sponsored by Johnson & Johnson-OCD Division where Dr. P. D. Sawant spoke on "Lean Labs". The second workshop, which was sponsored by Nicholas Piramal, was on the topic of "Monitoring of Acute & Chronic Kidney dysfunction with CystatinC, was delivered by Dr. Hektor. Dr. Barnali Das, of Kokilaben Dhirubahi Ambani Hospital, Mumbai delivered talk on "Essentials in prenatal Screening" which was sponsored by Roche. The "Lunch with Experts" session was quite successfully conducted by Dr. A. S. Kanagasabapathy with Dr. EndangHoyaranda, Dr Bernard Gouget as experts. The symposia were held on various topics namely cardiovascular system related disorders, Free Radicals & antioxidants, Diabeted, endocrine & Haematologic disorders, Insrumenmtation in Lab practices & Animal experiments, Maladies of Reproductive system & Topics associated with pregnancy and Functional Disordersand as many as 46 invited speakers of eminence in their respective fields delivered lectures in these symposia. Eight young scientists were awarded with different ACBI Best Paper awards & Travel Award.

The AFMC Quiz was a hotly contested event with Dr. Rajni Dawar of Lady Harding Medical College, New Delhi walking away with the First prize trophy & cash of Rs. 10,000/- . 14th December saw the curtain coming down on the 4 days of academic feast with the valedictory function where all the award winners were felicitated and delegates congratulated Dr Abhay Pratap and his team for organizing a great conference.

#### **AWARDS**:

(1) Sri A. J. Thakur Distinguished Clinical Biochemist Award for the 2012 was given to Dr, R. Selvakumar, Professor & Head, Department of Clinical Biochemistry, Christian Medical College, vellore, Tamil Nadu

(2) Fellowship of ACBI (FACBI) was awarded to Dr. Shyamali Pal from Kolkata.

(3) Awadhesh Saran Memorial Oration Award was bestowed on Professor H. R. Nagendra, Vice-Chancellor, YogaUniversity, Bangalore

(4) K. L. Gupta Memorial Oration Award was bestowed on Dr. D. Raghunadharao, Professor of Medical Oncology, Nizam'sInstutute of Medical Sciences, Hyderabad.



(5) Seth G.S. Medical College & KEM Hospital Oration Award was bestowed on Dr. SumanBala Sharma, Professor of Biochemistry University College of Medical Sciences & GTB Hospital, Delhi.

(6) Mrs. & Dr. G. P. Talwar Oration Award was bestowed on Dr. Nibhriti Das, Professor, Department of Biochemistry, All India Institute of Medical Sciences, New Delhi

(7). Dr. T. N. Pattabiraman Oration Award was bestowed on Dr. M. V. Kodliwadmath, Professor & Head,, Department of Biochemistry, Navodaya Medical College, Raichur, Karnataka

(8). Taranath Memorial Popular Lecture Oration Award was bestowed on Dr. ThuppilVenkatesh, Emeritus Professor, Department of Biochemistry & Biophysics, National Referral Centre for Lead poisoning in India, St. John's National Academy of Health Sciences, Bangalore & Principal Advisor, Quality Council of India.

The next Annual conference of Association of Clinical Biochemists of India will be held at New Delhi (India) in November-December 2013 with Dr. Jayashree Bhattacharya, Principal, Vardhaman Medical College & Safdarjung Hospital, New Delhi as the Organizing secretary. More news would appear on website : www.acbindia.org.

The Office Bearers elected for the year 2013 are : PRESIDENT: Dr. Abhay Pratap (Bokaro, Jharkhand) Immediate Past President : Dr Neelima Singh, Gwalior, Madhya Pradesh. Vice President : (1) Dr. Jayshree Bhattacharya (New Delhi) (2) Dr. Ulhas Tendulkar (Mumbai, Maharashtra)

GENERAL SECRETARY: Dr. Rajiv R. Sinha (Patna, Bihar) ADVISOR: Dr. K P. Sinha (Patna, Bihar) TREASURER: Dr. K R. Prasad (Patna, Bihar) JOINT SECRETARY: (1) Dr. S. V. Rana (Chandigarh)



(2)Dr. AbhijitPratap (Bokaro, India)

#### **COUNCIL MEMBERS :**

- (I) Dr. H.V. Singh, (New Delhi)
- (2) Dr. D. G. Dastidar(Kolkata, West Bengal)
- (3)Dr. Sukesh Mukherjee, (Srinagar, Uttarakhand)
- (4) Dr. Monika Gupta, (Jaipur, Rajasthan)
- (5) Dr. Sanjeev Singh (Gwalior, Madhya Pradesh)
- (6) Dr. Sadanand S. Naik (Pune, Maharashtra)

#### PHOTOGRAPHS OF 2012 NATIONAL CONFERENCE.



Inaugural ceremony of 39th ACBICON 2012 at Ranchi: Lighting the Lamp





Chhau dance being performed during cultural evening



Valedictory Function of 39th ACBICON 2012



Dr Venkatesh Thuppil delivering Taranath Shetty popular lecture



Pleanary Lecture – DrEndangHayoranda, Indonesia



Revered Swami Sarvalokanandji Maharaj addressing the delegates in opening ceremony.

Report prepared by Dr Rajiv Sinha, Secretary, ACBI





## **HKSCC Annual Report of 2012**

Office Bearers 2012-2013 President Prof Allen KC CHAN Vice President Ms Judy PS LAI Immediate Past President Dr Eric LK LAW Secretary Dr Lydia CW LIT Treasurer Mr Yun Chuen LO

The year's educational activities began with the 12th Annual Scientific Meeting (ASM) held on 7th January 2012. The theme of the scientific meeting was "Nuclear Magnetic Resonance for Clinical Chemists: Principles and Applications" with Prof Hector Keun of the Imperial College, London University addressing members. The meeting was well-attended by 160 participants plus 12 exhibitors. Over 150 members and guests attended the dinner banquet

Following the 12th ASM, a dinner lecture by Dr Andrew St John on "Contemporary Challenges and Opportunities in Laboratory Medicine" was held at the Inter Continental Grand Standford Hotel on 6th March 2012. Over 130 members and guests attended the event which was sponsored by Ortho Clinical Diagnostics (HK) Ltd.

On 11th April 2012 at the Inter Continental Grand Standford Hotel, Dr Fred Apple delivered a lecture on "What information do we need to implement high sensitivity cardiac troponin assays into clinical practice". The event was well attended by over 150 members and was partially sponsored by Beckman (HK) and Siemens (HK).

IFCC-Abbott Visiting Lecture entitled "Biomarkers for assessing cardiovascular disease risk" was delivered by Dr Gary Myers on 7th May 2012. This lectureship was supported by Abbott Laboratories (HK) and was well received by over 140 members and guests.



A joint symposium with three industrial partners under the Danaher Group (Beckman Coulter, Radiometer, AB Sciex) was held on 11th August 2012 at the Langham Place Hotel. The full day symposium provided a forum for in-depth and informal discussions of the most recent developments in the practical applications in the Clinical Chemistry. Three lectures were delivered. The topic of presentations were "Principles and Roles of Anti-Mullerian Hormone (AMH) in Managing Reproductive Disease States addressed by Dr Linda Rogers of Beckman Coulter; "Pushing the Limits of Sensitivity and Selectivity of Mass Spectrometry in Clinical Research Applications" by Dr Liu Hua-Fen of AB Sciex and "How Blood Gas Analyzer QA Management Helps to Meet Overseas Accreditations" by Ms Lyn Bourke of Radiometer. The event was attended by over 110 members and guests. The successful scientific meeting was followed by a dinner banquet.

Prepared by Dr Lydia Lit, Hon Secretary, HKSCC



## Japan Society of Clinical Chemistry JSCC 2012 Activities Report



Akira Suwabe

Professor, Department of Laboratory Medicine, School of Medicine Iwate Medical University 19-1 Morioka, 020-8505, Japan

Fifty-second (52nd) Annual Academic Conference of the Japanese Society of Clinical Chemistry was held at Aiina in Morioka, Iwate, Japan, from September 6 through 8, 2012. More than 500 people participated in this meeting.

Morioka is the capital city of Iwate prefecture, which was attacked by the Japan Earthquake and Tsunami (2011) and many people and constructions in the coastal areas were catastrophically damaged. One of the important idea behind holding this meeting in Morioka was to make participants understand the reality & severity of the damages caused because of earthquake & Tsunami

The special lecture entitled as 'Prospects of Lipid Biology' was presented by Professor Takao Shimizu in the Department of Advanced Lipidomics Research in Graduate School of Medicine and Faculty of Medicine, University of Tokyo.

Seven Symposiums and five educational lectures were organised & more than 80 papers were presented & topics of symposium essentially focussed on role & approach of the medical team during earthquake & Tsunami in 2011.

Further as no medical laboratory facilities were totally disrupted & this meeting was fruitful as many creative suggestions from different experts came forth which could be of help in similar events in future.



Picture showing the damage done by Earthquake & Tsunami in 2011



Recently in Japan, the approaches by medical teams, nutrition support team & diabetes patient education team have received attention & role of clinical chemist and their association in medical disaster control was also highlighted during the symposium.

More than 200 peoples participated in by on the reception party held in September 7. Participants enjoyed many kinds of sake of local brew in lwate, sea foods from the Sanriku coastal area and a so-called 'Wanko- Soba' ceremony (photo), which was the famous local ceremony to compete how many cups of soba noodle can be ate within the constant time.



Wanko - Soba Ceremony

Report of JSCC 2012 was prepared by - Professor Akira Suwabe.



## Korean Society of Clinical Chemistry KSCC 2012 Activities Report

Following is the executive committee of KSCC:

• President; Professor Kyoung-Dong Kim (Yeungnam University College of Medicine)

• President Elected; Professor Gye-Cheol Kwon (Chungnam National University College of Medicine)

• Immediate Past President; Professor Ki-Sook Hong (Ewah University College of Medicine)

- Executive Secretary; Professor Sail Chun (University of Ulsan College of Medicine)
- Treasurer; Dr Sung-Eun Cho (Eown Foundation)

Following national & various scientific meetings were organized during 2012, program is as under:

National meetings				
Name of the meeting	Date	Торіс		
Annual Meeting of KSCC		Plenary Lecture; Next-Generation Sequencing, Biomarker Discovery & Future Medicine		
		Symposium 1; Clinical Utility of Laboratory		
	0040 0 4 0	Testing: Techniques & Case Studies		
	2012. 6. 1.~2.	Symposium 2; Point-of-Care Testing:		
		Implemnetation & Quality Assurance		
		Poster Presentation		
		Education Sessions		
Quality Assurance Workshop	2012. 9.7.	Biochemical & Genetic Test Quality Assurance		
Standardization	2012, 11, 9,	Workplace Drug Testing Standardizsion		
Workshop	2012. 11. 9.	Workplace Drug Testing Standardizaion		
Education				

Electrochemistry & Chemical sensors

Preanalytical Variables & Analytical Performance Criteria based on Biological Variation

Lipids & other Cardiovascular Risk Factors

**Kidney Function Tests** 

Laboratory Evaluation of Pregnancy

Carbohydrate Metabolism & Diabetes



## Nepal Association for Medical Laboratory Sciences NAMLS 2012 Activities Report

OFFICE BEARERS 2009-2012:

#### President

Binod Kumar Yadav Imed. Past president Birendra Tiwari **Vice President** K.P singh **General Secretary:** Rajan Dahal Secretary **Rojeet Shrestha Treasurer** Sardha Bajracharya **Members** Puspa Raj Khanal Hem Tamang Rajendra Karmacharya Rajesh Gupta lyotsana Khadaki



Binod Kumar Yadav President, NAMLS

1. NAMLS is a non political medical laboratory professional association in Nepal which is registered under the Govt of Nepal and working for the betterment of the laboratory profession and professional in Nepal. This association has a very good number of members who have sound background in medical laboratory profession. Most of the member are medical technologist having bachelor degree in medical laboratory sciences followed by Biochemist, microbiologist, cytopathologist who have masteres and Ph. D. degree in respective subjects. The Kathmandu University, Nepal advertized the notice to take admission in master program in basic medical science for which only B.Sc in Human biology were eligible. NAMLS called central committee meeting and discussed on this issue as KU were not ready to take the Bachelor degree in Laboratory science for its master program and decided to talk with KU official and we made a very good discussion with them and finally they agreed with us and postponed that advertisement.

2. Nepal Public health Laboratory (NPHL), a Govt authority for the medical Laboratory services in Nepal appoint NAMLS as one of the member in the Laboratory policy management committee in which NAMLS participated actively and made some very good decision for the betterment of the medical laboratory profession and professionals like their promotion with the academic degree and work experience, appropriate designation/post with the relevant degree like consultant Biochemist/microbiologist/cytotechnologist/hematologist which were not included the previous policy. NAMLS also raised the voice to start the regional laboratory services in the each development region of Nepal.



3. NAMLS also actively participated in the quality control training program of NPHL which is running in every 3 months for the laboratory professional in Nepal.

4. NAMLS is actively associated with the Nepal Health professional council (NHPC), responsible for the monitoring and evaluation of laboratory services, and teaching institutions providing laboratory education and also registers health professional.

#### 5. IFCC Visiting Lecture Program: IFCC-NAMLS-APFCB

#### "International Workshop on Clinical Laboratory Quality Management"

Aim: To make participants aware of quality management in medical laboratories Venue/Date: Hotel Park Village, Bansbari, Kathmandu, Nepal, 22 – 24 November 2011

Participant: 200 persons (from clinical laboratory and hospital)

Details of the Program were as below:

#### 22 November 2011

VLP to visit 2-3 laboratories

23 November 2011

VLP to visit 2-3 laboratorizes         23 November 2011         0       W elcome         VLP team introduce themselves and the program         Participants introduce themselves         0 - 10:40         The N eed for Quality         0 - 11:00         Laboratory Errors         Internal Quality Control         0 - 11:10         The Current Practice of Using IQC in Nepal         0 - 12:00	Who Binod
0       W elcome         VLP team introduce themselves and the program         Partic ipants introduce themselves         0 - 10:40         The N eed for Quality         0 - 11:00         Laboratory Errors         Internal Quality Control         0 - 11:10         The Current Practice of Using IQC in Nepal	
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Participants introduce themselves         0 - 10:40         The N eed for Quality         0 - 11:00         Laboratory Errors         Internal Quality Control         0 - 11:10         The Current Practice of Using IQC in Nepal	Binod
0 - 10:40       The N eed for Quality         0 - 11:00       Laboratory Errors         Internal Quality Control         0 - 11:10       The Current Practice of Using IQC in Nepal	
0 - 11:00     Laboratory Errors       Internal Quality Control       0 - 11:10     The Current Practice of Using IQC in Nepal	
0 - 11:10Internal Quality ControlThe Current Practice of Using IQC in Nepal	Janice Gill
0 – 11:10 The Current Practice of Using IQC in Nepal	Elizabeth Frank
0 12:00 The Drineinles of Internal Quality Control	From Nepal
0 – 12.00 The Principles of Internal Quality Control	Clare Murphy
0 – 12:15 IQC Products Available	B io Rad
5 – 13:15 Lunch	
5 – 13:45 Setting IQC Acceptance Limits	Clare Murphy
5 – 15:00 IQC Small Group Exercises	
0 – 15 :15 Break	
Pre-Analytical Errors	
5 – 15:45 Sample Collection – Artefacts & Improving Quality	A darshpal Singh (BD)
5 – 16:15 Pre-analytical Errors Small Group Exercises - cases	
5 – 16:30 Questions	Panel
0 Close	
November 2011	
0 – 10:20 Recap from Day 2	
External Quality Assurance	
0 – 10:30 The Current Practice of EQA in Nepal	From Nepal
0 – 11:15 The Principles of External Quality Assurance	Janice Gill
5 – 11 :30 Break	
0 – 12:00 How to Run E QA & Interpret Reports	Sally Picton
0 – 13:00 EQA Small Group Exercise – report interpretation	Sally Picton
0 – 14:00 Lunch	
Post-analytical Factors	
0 – 14:20 Reference Intervals	Janice Gill
0 - 14:40 Critical Limits and Patient Report Comments	Janice Gill
0-15:10 Discussion - Reporting Results - Current Practice in Nepal &	Chair Elizab eth Fran k
How to Improve	
0 – 15:30 Laboratory Documentation	Elizabeth Frank
0 – 16:00 Discussion – Implementation of QC/EQA in Nepal	
0 Close	



6. NPHL made an expert team which includes the NAMLS also for the survey of the baseline for the quality system of laboratory in Nepal and NAMLS actively involved in this survey through the Nepal and final reports were submitted to NPHL/WHO for the implementation in the laboratory policy in Nepal.



IFCC - VLP workshop



IFCC-VLP workshop-Lab visit 7. NAMLS raised the voices against the NHPC to stop the registration of non medical Laboratory professional in this council.





NAMLS protest against the NHPC

#### Annual General Meeting 2012

The annual general meeting of NAMLS was held on December 8, 2012 at Norling Resort, Godawari ,Kathmandu. There were 300 participant registered for the meeting from different countries. There were seven IVD companies and distributors participated for clinical laboratory expo. The conference was divided into different sessions, namely the inaugural, plenary, scientific, business and election sessions.

#### **Inaugural Session**

The meeting was preceded under chairmanship of Mr Binod Kumar Yadav, President of NAMLS. Prof Dr. Bharat Mani Pokharel, senior Life member of NAMLS and Asst Dean –Institute of Medicine, opened the inaugural Session as chief guest. Guests were high level dignitaries from Ministry of Health and Population, chairman of Health Professional council, presidents of different professional associations, representative from National Public Health Laboratory, prestigious professionals, professors and scientists of laboratory medicine and former presidents of NAMLS. The session started with the lighting of the traditional lamp by the Chief Guest.Prof Bharat Jha , founder president of NAMLS and ex-chairman of Nepal Health Professional Council (NHPC) highlighted some of the remarkable achievement we have made since 27 years in the field of laboratory medicine. Representatives from different professional associations have expressed their view about role of quality health laboratory and its importance in better patient care. Prof Dr. Bharat Mani Pokhrel, chief guest and Mr. Binod Kumar Yadav together released the official publication of NAMLSJournal of JNAMLS, VOL. 11, NO. 1, DECEMBER, 2012 on the occasion. Inaugural Session was completed after the work done by NAMLS was highlighted by the general secretary Rajan Dahal. The vote of thanks was delivered by vice-president Puspa Raj Khanal to all supporting teams, the journal publication committee, IVD companies and distributer and organizing Committee of annual meeting 2012.





President Binod Kumar yadav delivering his talk on the activities and achievement of NAMLS



Chief Guest Asst. Dean Prof (Dr) Bharat Mani Pokharel delivering his few words on NAMLS activities

#### **Plenary and Scientific Session**

The plenary session was chaired by Prof Bharat Jha, Ex-Asst dean, IOM and Head of Department of Biochemistry, TU Teaching Hospital. Mr Binod Kumar Yadav, President of NAMLS presented on **"ISO 15189: 2007 AWARENESS and NABL,** India laboratory accreditation system where he lighted the points on workforces which differs in these and emphasized that laboratory accreditation is one of the very important factor for the better laboratory services and shared his international exposure to audience. Mr. Prasant Regmi presented on "ESTIMATING GFR: WHICH FORMULA IS BETTER?", where he discussed some of the important facts about GFR in the prediction of future kidney disease. Mr Uddhab Timilsina highlighted on **"Single Nucleotide Polymorphism (rs1468384) In The Human Niemann-Pick C1-Like I Gene in Nepalese population?"** There were altogether 7 scientific paper scheduled to be presented from different parts of country. Time allocated for each paper was 6 minutes for presentation and 2 minute for discussion. The plenary session ended with lunch break.

#### **Business session**

The business session was started at 4:00 PM. All central committee members, regional members, Past presidents, organizing committee, editorial board, life members and general members participated in the session. President Binod Kumar Yadav presented a briefing on the work and activities of the NAMLS .Mr Rajan Kumar Dahal, general secretary, then presented his report followed by the financial report by Rajesh Gupta, acting Treasurer. There was active discussion among members to improve laboratory service in Nepal.

#### **Election session**

Election session started with the nomination of candidates, followed by election. Eighth Executive committee was formed with the election. Mr Binod Yadav and his team were elected as executive of the 8th central committee.

Report prepared by Mr Binod K Yada & Rojeet Shreshtha



# Pakistan Society of Chemical Pathologists (PSCP) PSCP Activities during 2012

# 1. Workshops on "Good Professional Practices in Chemical Pathology"

Series of workshops were conducted by Brig Dr. Amir Aijaz, Dr Adnan Zubairi and Brig Dr. Rizwan Hashimin PNS SHIFA Naval Hospital, Karachi, Pakistan on 16 Dec 2011 and at Armed Forces Institute of Pathology (AFIP), Rawalpindi, Pakistan on 17th March 2012. In these workshops young pathologists and Post-Graduate students of Chemical Pathology were trained on various routine professional activities they are supposed to carry out during their professional life including communicational skills. They were also trained for laboratory safety and good laboratory practices.

#### 2. 4th CME Biennial Course in Chemical Pathology

Fourth CME Biennial Course was held for young Consultants and Post-Graduate Students of Chemical Pathology, Internal Medicine and other related specialties. A large number of them from all training institutes of Pakistan attended the course. This two day course was organized by Armed Forces Institute of Pathology (AFIP), Rawalpindi, Pakistan on 16th and 17th March 2012. Major General Farooq Ahmed Khan, Patron Pakistan Society of Chemical Pathologist and Commandant AFIP appraised the participants about updates in management of Diabetes Mellitus. Eminent specialist in Chemical Pathology and related specialties gave updates on various aspects of Metabolic and Endocrine diseases, Novel markers, Point of Care Testing, management of critically ill patients, molecular diagnostics, Laboratory Management and Quality Control.

#### 3. Workshop on Method Evaluation

A workshop on Method Evaluation was held in Department of Chemical Pathology, PNS SHIFA Naval Hospital, Karachi Pakistan, on 06 Nov 2012. Brig Dr Amir Aijaz and Dr Adnan Zubairi were facilitator of this workshop. It was attended by 12 junior Pathologists and post-graduate students of Chemical Pathology (Clinical Chemistry). Participants learnt by Hands-on Exercises the procedures adopted for Analytical Method Validations in Laboratory Medicine as per CLIA and ISO 15189 requirements according to CLSI guidelines.

#### 4. Workshop on In-Born Errors of Metabolism

This workshop was held in the College of Physicians and Surgeons, Karachi, Pakistan,in collaboration with Aga Khan University, Karachi, Pakistan, on 07 November 2012. Dr Ayesha Habib, Dr Farooq Ghani and Brig Dr Amir Aijaz were facilitators of this workshop. Participants were mostly post-graduate students of Chemical Pathology (Clinical Chemistry) and senior Laboratory Technologists. Inborn errors of metabolism were discussed in detail, pathophysiology, clinical presentation, and the clinical laboratory support in diagnosis and management, sample collection andvarious analytical techniques used for the screening diagnosis of IEM were discussed alongwith some practices of data interpretat higher cognitive domains were practiced by the participants.

#### 5. Workshop on Clinical Toxicology

This workshop was conducted in Department of Forensic Toxicology, AFIP, Rawalpindi, Pakistan on 7th Dec 2012. Brig Dr Dilshad Ahmed Khan, Brig Dr Rizwan Hashim and Col Dr Muhammad Amir were facilitators of workshop. This workshop was largely attended by chemical pathologists, post graduate trainees senior technologists of different clinical laboratories from all over Pakistan. Various aspects of clinical toxicology including, therapeutic drug monitoring, grouping of toxins, clinical presentation, choice of clinical samples, sample preparation in department, Screening methods and confirmation of screened toxins along with analytical techniques especially CO-oxymetry, osmometry, immunoassays, HPLC and GCMS were discussed and demonstrated.

#### 6. Fifth PSCP Conference

The fifth PSCP conference was held with First Joint conference of all societies of Pakistan Association of Pathologists (PAP) at Convention Centre, Islamabad, Pakistan on 7th to 9th Dec 2012. Most of the practicing clinical pathologists and post graduate trainees of Pakistan attended this conference. The conference was also attended by diagnostic companies with their stalls in exhibition areas for demonstration of their instruments and other support for clinical laboratories. Prof Aw Tar Choon (Singapore) and Dr D P Mikhailidis (United Kingdom) delivered lectures on Circulating tumor cells & CVD risk assessment respectively, in plenary session. The scientific sessions followed, which were well attended by personnel from clinical laboratories from all over the Pakistan. Apart from various presentations by Chemical Pathologists, free papers were presented by the post graduate trainees and laboratory technologists.



Participants at the post conference workshop of 5th PSCP Conference

Inaugural function of the 1st Joint Conference of PAP/ Societies of Pathologists

#### 7. Miscellaneous Activities

President, PSCP Dr. Imran Siddiqui and Secretary, Dr Adnan Zubairi attended IFCC conference in Malaysia. Executive Council met at regular intervals to overlook the technical, professional and administrative affairs of the society, recommendation for the new memberships of IFCC and nominations for the various committees of IFCC. The general body meeting was held with conference in convention hall Islamabad in Dec 2012 where Election commission was formally communicated to hold the election of next executive council in March 2013.



## Philippines Association of Medical Technologists (PAMET) Activities for 2012



#### **REPORT OF ACTIVITIES FOR 2012**

The organizational planning session was held at the Summit Ridge Hotel in Tagaytay City on January 28-29, 2012. The session, which was attended by the PAMET officers and board of directors, regional directors, Mid Year host President, former PAMET presidents and organizing committee chairs strengthened the objectives of the association as planned in 2011.



Planning Session of the officers and board of directors with the advisory council and regional directors held at Summit Ridge, Tagaytay City.

Early part of the year, the board of directors gathered during the planning session and revisited the five major thrusts we set for this term.

- I. Enhance Professional Growth and Competency
- 2. Address the needs and concerns of the members

3. Strengthen linkages and bonding between and among its members and with other professions

- 4. Review Constitution and by-Laws and the amendment to R.A. 5527
- 5. Maintain viability of PAMET organization

#### **PROFESSIONAL DEVELOPMENT**

A Leadership and Teambuilding seminar was conducted for three groups, North and South Luzon, Visayas and Mindanao and the NCR groups. Confluent Learning team facilitated the Teambuilding program. The goal of the seminar was to gather the key leaders of the organization and build an effective and excellent team in facing the challenges ahead.



The first activity was held at Corregidor Island for the North and South Luzon Chapter presidents together with the National Board of Directors and Advisory Council last April 21 and 22, 2012. The second activity was held on June 21 and 22, 2012 at Chali Resort in Cagayan de Oro for the Visayas and Mindanao group and the last activity for the NCR group was held at Loreland Resort in Antipolo, Rizal on July 6 and 7, 2012.

#### AWARDS

Yearly, PAMET recommends nominees for Most Outstanding Professional Award for Medical Technology to Professional Regulation Commission through the Committee on Awards. The prestigious PRC Most Outstanding Medical Technologist Award for 2012 was given to Ms. Josephine Culaton-Milan of Baguio-CAR Chapter last June 22, 2012 at the Manila Hotel.

Through the Committee on Awards, the four PAMET's major awardees were honored during the Annual Convention: the Most Outstanding Medical Technologist, Distinguished Service Award, Crisanto Almario Research Award and the Most Outstanding Chapter's Award. The PAMET's 2012 Most Outstanding Medical Technologist is Ms. Josephine Culaton-Milan of Baguio-CAR Chapter, the Distinguished Service awardee is a posthumous award for the late Ms. Lily M. Alquiza, the Crisanto Almario Research awardee is Ms. Jasmen Pasia from San Pedro College of Davao and the Most Outstanding Chapter is Camarines Sur Chapter.

#### **EDUCATION**

Dagdag Karunungan, Kinabukasan ng Kalusugan is a post-graduate scholarship program supported by Safeguard (Procter and Gamble) for active members of the Philippine Association of Medical Technologists, Inc. (PAMET). The purpose of this program is to assist Medical Technologists in completing their higher education goals and achieve higher level of competency in the professional practice. This year, scholarship was granted to two PhD students and one MS student.

Handog ng Safeguard, Med Techs ng Kinabukasan is a scholarship for undergraduate students of BS Medical Technology/Medical Laboratory Science. The Safeguard Scholarship awarding was held at the Manila Peninsula on October 29, 2012 with Mr. Tom Araullo as the emcee. The best essay was awarded to Mr. John Datoy of Adventist University of the Philippines. The 15 scholars who recently graduated were also present and were given certificate of recognition. All the 15 scholars of the batch 2009 completed their scholarship. Some graduated with honors and some already took the exam and passed successfully.

#### RESEARCH

A Research Forum was conducted during the Med Tech Week Celebration. The event was headed by Ms. Teresa Rodriguez of Trinity University of Asia. It was held at Arellano University in Legarda, Manila last September 19, 2012. Students from San Pedro College of Davao City bagged the 1st place, San Juan de Dios Educational Foundation got the 2nd place and the 3rd place went to Our Lady of Fatima University.



The latest edition of the Philippine Journal of Medical Technology has been released.

#### **CONTINUING PROFESSIONAL EDUCATION**

The National PAMET and each chapter have their own set of activities for the continuing professional education program. The PAMET CPE committee screens all programs and endorses to CPE council of PRC for approval. The following are list of CPE programs of the national. Separate listing of activities of the chapters is posted in their own newsletter and in the PAMETLINK.

First Med. Tech Consortium 2012. A back to back symposium for Laboratory Management and Scientific Updates was held on April 17, 2012 at the Abbott Training Center, Mandaluyong. The 1st topic, "Ethics in the Workplace", was discussed by Ms. Donna Golpeo Pangcog, the Abbott Laboratories Compliance Officer, Office of the Ethics and Compliance Policies, Code of Business Conduct and Law. The 2nd topic was about "Optimizing Efficiency in Hematology through Optical Technology", which was delivered by Mr. Victor Lumboy, RMT, MBM, Hematology Product Specialist of Abbott Laboratories. This scientific activity was sponsored by Abbott Laboratories.

**Updates on Diabetes Care.** This scientific session was conducted in Celebration of the Med. Tech Week. It was held at the National Kidney and Transplant Institute last September 21, 2012. The first speaker was Dr. Ronaldo Toledo, an advocate in Diabetes Care and Management. Another topic discussed was about the association of **MDR-TB and Diabetes Mellitus.** The 2nd speaker was Dr. Leilani Baldeviso. PAMET also recognized MEDTEK for their utmost support and collaboration to make this event successful.

#### **Phlebotomy Training**

The module for Phlebotomy training has been completed. Materials are all set and ready. Training of trainers is postponed to a later date due to busy schedule for ASEAN preparation but part of the module has been cascaded to the different chapters.

#### LABORATORY MANAGEMENT & PRACTITIONERS

The 1st Laboratory Management Meeting and Continuing Med. Tech. Education Seminar were held last April 17, 2012 at the Training Room of Abbott Laboratories. There was a "**CPE and Ethics Public Consultation**" given by Ms. Marian Tantingco, RMT, MT(ASCP) and Ms. Marilyn Atienza, RMT – members, PRC Board of Medical Technology. They reiterated the need to follow the Code of Ethics of the Medical Technologists, the importance to continuously have programs and activities that will address the professionals' need for continuing education.

The 2nd meeting was held last August 6, 2012 with the first topic, **"New Trends in the Serological ANA Diagnostics and Connective Tissue Disease Diagnostics"**, which was discussed by Ms. Cecilia Lim, the General Manager and Technical Manager of the EuroImmun Singapore. This was followed by the 2nd topic entitled, **"Competency Standards of Medical Technologists"**, which was delivered by Mr. Ronaldo Puno, RMT, MBA, Vice President of PAMET National. This seminar held at the Catrina Room of the Hotel Rembrandt was sponsored by Eliasaph Company.



#### MEMBERSHIP

The firmware integration software has been used successfully for the ID system of all members. For three years, the database has been stable and reliable. The next step in the improvement process is the upgrading of database in which seminars and conventions attended by all members, including the corresponding CPE units, are stored.

#### **CHAPTERS**

The year was filled with different activities covering various regions and islands all over the country. There had been a close communication between the members and PAMET National through the Committee on Chapters. The local chapters had been constantly updated on the affairs of the association through the Regional Directors.

**CHAPTERS VISITATION:** Throughout the year, a good number of chapters were visited by the committee, either to participate in scientific seminars, conduct election and induction, give PAMET Updates and hold membership fora, conduct ocular inspection for conference venues, reactivate some chapters or confer with officers and members with urgent and special concerns.

**MID-YEAR CONVENTION:** Close to 600 Medical Technologists from different chapters of the Philippine Association of Medical Technologists, Inc. (PAMET) nationwide converged to attend the 17th Mid-Year Convention in Sison, Pangasinan on May 16-19, 2012. This annual event which took place at the historic Sison Auditorium was anchored on the theme **A Hundred-fold Commitment for A Greener Laboratory Environment**", which underscored the profession's intense desire to contribute in environmental protection and in preserving Mother Earth.

**REGIONAL CONFERENCES and REGIONAL CHAPTER PRESIDENTS' MEETINGS:** Continuing the accomplishment of year 2011 as a banner year for the committee in terms of Regional Conferences, the committee was able to have another 100% conduct of regional conferences in 4 PAMET regional divisions. All Regional Directors exerted much efforts to come up with their respective regional activities Amidst several challenges encountered along the way,

3rd Visayas Regional Conference – Harold's Hotel, Cebu City – June 15-16, 2012 Theme : **"PAMET: Redefining the Practice, Re-aligning Competence"** Regional Chapter Presidents' Meeting: Visayas - Cebu City - June 16, 2012

6th North Luzon Regional Conference - Acropolis North, Cabanatuan City, Nueva Ecija - Aug. 9-11, 2012 Theme: **"PAMET North Luzon: Strengthening Regional Linkages"** Regional Chapter Presidents' Meeting: North Luzon - Cabanatuan City, Nueva Ecija August 10, 2012

9th South Luzon Regional Conference - Batis Aramin, Lucban, Quezon – September 8-9, 2012 Theme: **"PAMET: Trending Towards Competency** Regional Chapter Presidents' Meeting: South Luzon - Lucban, Quezon-September 7, 2012



6th Mindanao Regional Conference – Dottie's Hotel and Convention Center, Butuan City, Agusan del Norte – September 28-30, 2012

Theme: "Excellence in the New Perspective with Integrity and Passion"

Regional Chapter Presidents' Meeting: Mindanao - Butuan City, Agusan Del Norte – September 29, 2012

**CHAPTER GUIDELINES/CHAPTERS CODE:** The Chapter Guidelines which was adopted in 2011 had the pilot implementation beginning 2012. The Committee released the PAMET **CHAPTERS' CODE** which contains all important documents, guidelines, protocols and information pertinent to effective operations of different chapters. This landmark publication will serve as the backbone of all chapters from formation to accreditation to hosting of various chapter activities

#### **AFFILIATE MEMBERS**

During the 17th Mid-Year Convention in Pangasinan, a constitutional amendment creating Special Category of Membership was ratified on May 17, 2012. It aimed to legalize and formalize the establishment of PAMET groups in different countries where Filipino Medical Technologists are working.

**Saudi-Arabia:** PAMET-Eastern Region Saudi Arabia was formed last October 5, 2012. Subsequently, Medical Technologists in Western Region Saudi Arabia also organized their group last November 9, 2012 and formed PAMET-Western Region Saudi Arabia.

**Singapore:** PAMET-Singapore updated their activities and other plans for PAMET-Singapore members. In their recent meetings, they talked about matters concerning membership, participation in ASEAN Conference and other relevant issues.

#### WELFARE AND BENEFITS

The committee sponsored job fairs for the year. These were held during the Oath taking activities at the Manila Hotel. In lieu of Bayanihan program, PAMET enrolled all active members in an Insurance Company, wherein after careful consideration was found out to be more beneficial for all the members.

#### PUBLICATION AND DOCUMENTATION

The aim of the Committee is to make sure that we provide all our colleagues with the latest happenings in the organization. The whole year round activities of PAMET were documented and published at the PAMETLINK.

#### MEDICAL TECHNOLOGY WEEK

PAMET celebrated its 40th Medical Technology Week through a series of activities which ran from September 16-22, 2012. It was supported by Procter and Gamble, some diagnostic companies and schools of Medical Technology. The activities were chaired by different committees of the association. Each chapter also had their own celebration of Med Tech Week.



- WAYS AND MEANS: A Fun Walk for A Cause kicked off the weeklong activities last September 16, 2012 at the Mall of Asia ground parking area. SPORTSFEST: The sportsfest was held at San Juan de Dios Educational Foundation, Inc. gymnasium after the Fun Walk for a Cause last September 16, 2012.
- **THANKSGIVING MASS:** A Thanksgiving Mass was held on the September 17, 2012 at the chapel of Delos Santos Medical Center.
- **RESEARCH FORUM:** A Research Forum for students was held at Arellano University in Legarda, Manila last September 19, 2012.
- ADVOCACY: Advocacy program and career orientation were given in different schools. Programs were implemented at Manila Science High School and Global City Innovative College.
- QUIZ SHOW: The PAMET-PASMETH Interschool Quiz Show Manila Central University, Caloocan City on September 20, 2012. This annual brain twisting event was participated by the best students of 30 schools all over the country. Participants from Calayan Educational Foundation, Inc. of Quezon Province bagged the first place, St. Paul College of Tuguegarao City, Cagayan for the 2nd place and University of Santo Tomas for the 3rd place.
- **CONTINUING PROFESSIONAL EDUCATION:** A seminar about "Diabetes" was held at the National Kidney and Tranplant Institute, Quezon City during the Med Tech Week last September 18, 2012.
- **COMMUNITY OUTREACH:** A community outreach was held last September 22, 2012 at Mother of Divine Providence Parish, Payatas, Quezon City, as part of The Med.-Tech Week celebration.

#### **CONSTITUTION AND BY-LAWS**

The ratification of the amendment was held during the 17th Mid Year Conference in Lingayen, Pangasinan. The committee also completed the implementing rules and regulations for the by-laws.

#### LINKAGES:

PAMET is a member of the Council of Professional Health Associations (COPHA), the Council of Health Agencies (CHAP) and the Philippine Federation of Professional Associations (PFPA).

#### **PROFESSIONAL REGULATION COMMISSION (PRC)**

**PRC Awards:** The awarding ceremony was held last June 22, 2012 at Fiesta Pavillion of The Manila Hotel during the PRC Week Celebration.

**PRC week medical mission for the employees during the PRC week celebration:** PAMET participated in the celebration by giving free laboratory services such CBC, urinalysis and Blood Chemistry.

**CPEC** (Continuing Program for Education Council): To date, since PAMET started as provider of CPE in 2009, 109 CPE programs have been approved. For the year 2012, there were 35 CPE programs approved.



**PRC Summit:** Last October 18-19, 2012, The Philippine Association of Professional Regulatory Board Members, Inc. (PAPRB) in cooperation with the Professional Regulation Commission (PRC), spearheaded the first Professional summit entitled "Convergence of Professionals for Nation Building and Global Competitiveness". The convergence of all professionals of the state regulated professions will fulfill nation building and global competitivess in line with the Phillipine commitment to international agreements, the free mobility of professional services which will be implemented starting 2015.

**Competitiveness Roadmapping for Med Techs:** PRC, PAPRB and DTI conducted seminars on Doing Business in Free Trade Areas – Strengthening the Competitiveness for Nation-Building and Global Mobility of Philippine Professions. PAMET was represented in the meeting. The Competitiveness Roadmap is envisioned to give the profession the handle and strategic guidance in navigating towards international agreements with respect to trade in services of professionals.

#### **COMMISSION ON HIGHER EDUCATION (CHED)**

The CHED Technical Committee for Med. Tech Education (TCMTE) is composed of Dr. Leila Florento (chairman.), and Hon. Marian Tantingco (Member, PRC Board of Medical Technology, Prof. Magdalena Natividad (Dean, FEU-NRMH), Dr. Jurel Nuevo (Dean, Our Lady of Fatima University) and Dr. Soledad Bautista (Dean, EAC) as members.

The activities of the committee were:

- Accreditation of Clinical Laboratories utilized for Medical Technology / Medical Laboratory Science Internship Training Program.
- Finalization of Policies and Standards for Graduate Program for Medical Technology/Medical Laboratory Science.
- Resolutions passed by the committee and submitted to Technical Panel for Health Profession's Education for approval.
  - a. Moratorium on Opening of New Med Tech/MLS Schools in the country
  - b. Opening of San Pedro College' Med Tech Graduate Program
  - c. PSG for Graduate Program
- A memo for implementation of a standardized affiliation fee has been passed for signature of Dr. Patricia Licuanan, the chairperson of CHED.
- The template draft for the evaluation of performance of MT/MLS interns to be
- · Used by accredited laboratory training has been formulated.
- Draft of new curriculum aligned to K+12 were formulated.



#### **DEPARTMENT OF HEALTH (DOH) ACTIVITIES**

**National Health Laboratory Network:** The launching of the National Framework and Strategic Plan for National Health Laboratory Network was held last Nov. 9, 2012 at Bay Lagoon Function room of Ocean H2O Hotel. PAMET is one of the members of the National Advisory Council to the National Unit for Health Laboratories (NUHL) of the National Center for Health Facilities Development (NCHFD), the unit which shall implement the National Strategic Plan for the National Health Laboratory Network.

**DSSM Project:** The DSSM (Direct Sputum Microscopy) Competencybased Learning Module for undergraduate students of Medical Technology/Medical Laboratory Science Program has been prepared for distribution to different stakeholders.

#### **INTERNATIONAL LINKAGES**

# ASEAN ASSOCIATION OF CLINICAL LABORATORY SCIENCES (AACLS)

MIMLS (Malaysia), PATELKI (Indonesia), AAMT (Thailand), SAMLS (Singapore), PAMET (Philippines) and BAMLS (Brunei) are the member associations of ASEAN Association for Clinical Laboratory Sciences (AACLS). PAMET hosted the 14th ASEAN Conference of Clinical Laboratory Sciences at the Manila Hotel on November 27 - 30, 2012 in conjunction with the 48th PAMET Annual Convention. PAMET President Dr. Leila Florento has been elected as the AACLS President for 2013-2014.



The AACLS and PAMET officers and board of directors during the Opening Ceremony of the 14th ASEAN Conference in Clinical Laboratory Sciences in conjunction with the 48th PAMET Annual Convention held at The ManilaHotel last November 27-30, 2012.

# ASIA ASSOCIATION OF MEDICAL LABORATORY SCIENTISTS (AAMLS)

The founding members of AAMLS are MIMLS (Malaysia), BAMLS (Brunei), SAMLS (Singapore), AMTT (Thailand), PATELKI (Indonesia), PAMET (Philippines), JAMT (Japan), HKMTA (Hong Kong), KAMT (Korea) and AIMLTA (India). TAMT (Taiwan)is the newest member of the Association. The current President of AAMLS is Dr. Rachana Santiyanont of AMTT. PAMET Pres. L. Florento sits as one of the directors of the association.



# INTERNATIONAL FEDERATION OF BIOMEDICAL LABORATORY SCIENCES (IFBLS)

The 30th World Congress of Biomedical Laboratory Sciences which was held in Berlin, Germany on August 18-22, 2012 was officially represented by PAMET Pres. Leila Florento and auditor Ms. Luella Vertucio.

#### INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE (IFCC) & ASIA AND PACIFIC FEDERATION OF CLINICAL BIOCHEMISTRY (APFCB)

**IFCC General Conference Meeting:** The IFCC General Conference meeting was held at Crown Plaza, Kuala Lumpur, Malaysia last November 18-20, 2012. PAMET was represented in the meeting by Pres. L. Florento and the Sec. Gina Noble.

#### Joint IFCC Activities in the APFCB Region

Dr. Gary Myers was the IFCC-Abbott visiting lecturer for 2011-2012. He was one of the plenary speakers during the AACLS conference in Manila. His topic was "Current Markers for Cardiovascular Diseases". Dr. Tony Badrick, who is the chair of the APFCB Laboratory Management Committee, was one of the speakers during AACLS Conference in Manila last November, 2012. Mr. Joseph Lopez, the immediate past president of APFCB and the chairman of APFCB Congress and Conferences was also one of the plenary speakers during the AACLS conference in Manila.

#### Reference Intervals Project (involving Japan, APFCB and IFCC)

PAMET-Iloilo Chapter members led by Mr. Reynan Rolle will conduct a study on **"Establishment of Reference Intervals for Common Blood Chemistry and Hematology Analytes Among Reference Individuals in Iloilo City"**. This study will be conducted in collaboration with IFCC – Committee on Reference Intervals and Decision Limits (IFCC-CIRDL) through its chairman, Dr. Kiyoshi Ichihara of Yamaguchi University in Japan. The said organization is currently conducting a worldwide multicenter study on reference intervals, and Iloilo City, through this study, has been chosen to represent the Philippines. Dr. Kiyoshi Ichihara visited the PAMET- Iloilo Chapter during the launching of the project last October 21, 2012.





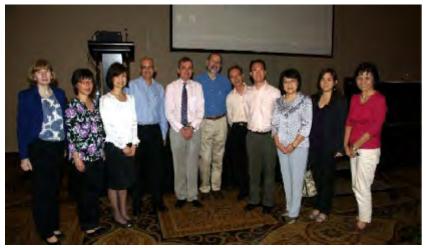
PAMET was well-represented in different societies and government agencies. Our role in health care services is highly significant and we would like PAMET to be visible and well represented.

Report Prepared by: Leila Monserrat-Florento, RMT, PhD, PAMET President.



## Singapore Association of Clinical Biochemists SACB 2012 Activities Report

Singapore Association of Clinical Biochemists (SACB) started their year's activities with the Annual Scientific Meeting held in Orchard Hotel on 24th March 2012. The sessions were a combination of Diagnostic company sponsored speakers as well as prominent overseas and local speakers. Our company sessions included "Novel markers in lung cancer" by Dr Sandy Yeo from Abbott Diagnostics (Singapore) Pte Ltd; "A new era in liver disease diagnostics: Non-invasive markers of liver fibrosis" by Dr Katherine Soreng of Siemens Healthcare Diagnostics and "Lipoprint System – an advanced test for LDL subfractions" by Ms Cherynn Lai of All Eight (Malaysia) Sdn Bhd. Our invited overseas speakers were Dr Ken Sikaris (Australia) presenting on the "Reference Intervals – Getting it right for the first time" and A/Prof Tony Badrick (Australia) presenting on "Taking control of your quality control". Our local speakers were A/Prof Tay Sun Kuie sharing on "HPV genotypes 16 & 18 in cervical cancer screening"; and Dr Lincoln Tan on "Prostrate screening – PSA and beyond".



Members of SACB Council with some of our speakers from our Annual Scientific Meeting

In March we jointly organized a workshop with Bio-Rad on Uncertainty of measurement by A/Prof Tony Badrick.

In August 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 14th module of our SACB Education Programme was held between August and October 2012 for ten weeks duration. The lectures comprised: Diabetes in laboratory medicine and HbAIc testing; Delta checks in action – an essential quality improvement tool; Body fluid testing in the clinical laboratory; Patient safety and laboratory errors; Method evaluation; Creatinine and eGFR; Automation in the clinical microbiology lab – it's about time The role of the molecular lab in a pandemic outbreak; Evaluation of biochemical markers of bone metabolic disorders' Analysis and interpretation of biomarkers of cardiovascular disease. This programme is well received by our members and the Association will continue to support the education of our members.

Reported by: Dr Sharon Saw, Secretary, SACB



## Aneuploidy and its consequences in male infertility

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#### Introduction

Chromosome abnormalities are an important factor in the etiology of male infertility and about 5% of recurrent abortion cases are resulted from genetic origin (Schlegel 2012). The sperm cells carry a demonstrable background level of aneuploidy and chromosome breakage (Kim et al 2009), however, a number of risk factors might lead to increase this baseline. Aneuploidy is one of the most common and serious chromosomal abnormalities recognized in man, and it is responsible for a large portion of human morbidity and mortality, including infertility, pregnancy loss, infant death, congenital malformations, mental retardation, and behavioral abnormalities (Hecht and Hecht 1987). The ability to categorize and screen human sperm for aneuploidy would lead to understanding the factors causing this chromosomal abnormality as well as possible preventive strategies.

Currently there are two possible explanations or hypothesis for this increased aneuploidy rate have been suggested. According to the first hypothesis, 47,XXY spermatocytes can achieve meiosis and produce a high frequency of 24,XY spermatozoa (Homer et al 2012). On the other hand second hypothesis stated that, only diploid 46, XY germ cells are able to achieve meiosis (Berner et al 2012) and meiotic abnormalities are induced by a deleterious testicular environment. The latter hypothesis is supported by the fact that in XXY mice, XXY germ cells are absent and only XY germ cellsare able to achieve meiosis (Brahem et al 2011).

Furthermore, reproductive difficulties have been associated not only with somatic chromosomal abnormalities but also with cytogenetic abnormalities in the germ cells of infertile individuals with a normal constitutional karyotype due to difference of sperm pH in in-vitro fertilization. Many authors have reported a higher frequency of sperm chromosome aneuploidy rate in patients with abnormal sperm parameters compared to controls (Pang et al., 1999; Honda et al 2000). However, increases in sperm aneuploidy have been reported for all infertility phenotypes including oligozoospermia (low concentration), asthenozoospermia (poor motility) and teratozoospermia (poor morphology). It is clear that increased aneuploidy frequencies of spermatozoa are positively correlated with increasing severity of infertility with the highest levels reported in men with severe oligoasthenoteratozoospermia and sperms retrieved from testicular sperm extraction in cases of non-obstructive azoospermia (Pang et al., 1999).

#### **Cytogenetic rearrangements**

The conventional cytogenetic methods, 'chromosome banding' and 'karyotyping' are very informative and still commonly used. However, these techniques are limited to the detection of numerical chromosomal aberrations aneuploidy and polyploidy. Molecular cytogenetic approaches facilitate the detection of submicroscopic structural variants(SVs) and have been crucial for studying complex rearrangements generated by more than two chromosomal breakage events, refining breakpoints and performing cross-species comparisons (Kim et al 2012). These newer approaches have mostly relied on the use of 'fluorescence in situ hybridisation' (FISH; Emery 2013) where fluorescence microscopy reveals the presence and localisation of defined labeled DNA probes binding to complementary sequences on targets, traditionally metaphase chromosome spreads. To assist detection of events such as translocations, whole chromosome-specific DNA probes or 'paints' have been used (Cremer et al., 1988; Motoyama et al 2011).



To increase resolution, shorter probes have been introduced (for example, fosmids and very recently oligonucleotide libraries; Yamada et al., 2011) and/or the target has been refined by replacing condensed chromosomes with extended chromatin fibres ('Fibre-FISH'; Emery BR 2013). Furthermore, Fibre-FISH is now facilitated by an automated procedure called 'molecular combing' (Emery 2013).

Alternative targeted approaches have simplified copy-number variants (CNV) detection (Filges et al 2012) for example, 'real-time qPCR' (Stamouliset al 2011) and 'MLPA' (multiplex ligation-dependent probe amplification) are broadly used to detect recurrent events in clinical genetics (Stamoulis et al 2011). While these different approaches are restricted to specific regions, some FISH-based techniques have been developed to detect genomic aberrations at the whole-genome level without prior knowledge. For example, copy number differences between two genomes can be detected using 'comparative genomic hybridisation' (CGH; Stamouliset al 2011); and subtle translocations and complex rearrangements can be characterised using techniques derived from chromosome painting such as 'M-FISH' (multiplex-FISH; Emery 2013) where all chromosomes are differentially coloured in a single experiment. These methods are experimentally demanding, labour-intensive and the resolution arestill limited.

To date, the development of fluorescence in-situ hybridization (FISH) and its application to the study of the sperm aneuploidy rate enabled us to look into a comparatively large number of spermatozoa, using a chromosome-specific DNA probe that can be detected by fluorescence microscopy.

#### Structural chromosome abnormalities

FISH assessment of structural chromosome segregation patterns in sperm is made possible through the use of locus specific subtelomeric and centromeric specific probes. It is clear that structural rearrangements can give rise to unbalanced gametes. The extent of unbalanced sperm is clearly associated with the chromosomes involved, size of the involved segment, presence of heterochromatin, tendency for recombination events, and break points at G-positive or G-negative bands (Emery 2013). The presence of unbalanced gametes has relevant clinical ramifications as this can lead to pregnancy loss.Offspring affected with chromosomal abnormalities are dependent on the chromosomes and segments involved.The percentage of unbalanced sperm identified in these studies ranges from 1–54%.

To date, over 30 reciprocal translocations have been studied; in these cases the percentage of unbalanced spermatozoa is much higher than that found for inversions and Robertson translocations, with a range of 29–81%. In addition, there is some evidence suggesting the presence of an inter-chromosomal effect (ICE) for certain chromosomes (Martin et al., 2008); that is abnormal behavior of one or more chromosomes not involved in the structural rearrangement. Thus, these individuals may be at an increased risk of chromosome non-disjunction for additional chromosomes not involved in the structural rearrangement.

#### **Carriers of sex chromosome Aneuploidies**

The incidence of Klinefelter syndrome and 47,XYY syndrome is relatively common, each occurring in approximately 1:1,000 live births. Several studies have been published reporting the frequency of sperm aneuploidy in non-mosaic/mosaic Klinefelter syndrome individuals, (47, XXY and 46, XY/47,XXY, respectively.A significant increase in sex chromosome disomy has been reported for almost all patients studied (Poplinski et al 2010). In non-mosaic 47, XXY individuals an average of 6% (range 1–25%) disomic sperm has been reported, with mosaic 46,XY/47,XXY individuals having a lower frequency of 3% (range 0–7%). Additionally, evidence has been provided of an increase in autosome disomy levels compared to fertile controls (Rives et al 2010). Approximately ten studies have also reported a significant increase in sex chromosome disomy levels in 47,XYY individuals with an average of around 4% (range 0.1-14%).



However, it should also be noted that number of patients enrolled for investigating sperm aneuploidy frequencies in individuals with sex chromosome aneuploidies in these studies was small. However results suggest that the additional sex chromosome is not always eliminated during spermatogenesis and that some aneuploid cells are capable of initiating and completing meiosis, resulting in aneuploid gametes (Motoyama et al 2011). It is reassuring that the vast majority of studies have reported healthy karyotypically normal offspring as an outcomes of pregnancies following ICSI. Two 47 XXY conceptuses accounting for around 10% of published cases have been reported (Poplinski et al 2010). The increase in sperm aneuploidy has been mirrored by an equivalent increase in aneuploidies in embryos observed after preimplantation genetic diagnosis (PGD) (Kim et al 2012).

Until recently, most meiotic investigations of sex chromosome aneuploidy addressed the question as to how the extra or missing chromosome get there in the first place? However, with the emergence of assisted reproductive technologies (ART) to treat human infertility, the flip side to this question is becoming increasingly important.

Thus it is concluded that the aneuploidy sperm has a comparable lifespan compared with euploid sperm. The increased aneuploidy rates were negatively correlated with sperm concentration, motility and percentage of normal forms thus it may be responsible for increased risk for transmitting genetic abnormalities to their offspring and further contribute to 'early' spontaneous abortions due to aneuploid cells of paternal origin.

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## Prevalence of Inborn errors of Metabolism in India

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Inborn errors of metabolism are a heterogeneous group of disorders resulting from abnormalities of synthesis, transport and turnover of dietary and cellular components. They are individually rare but collectively form a group of >500 disorders presenting with a spectrumof clinical features ranging from mild to lethal forms which are usually overlapping with non-metabolic conditions like infection and intoxication. The disorders usually follow an autosomal recessive inheritance. The expression of these disorders is a combined effect of genes and the environment.Early diagnosis and intervention helps in reducing the morbidity and mortality rates amongst the affected individuals. Diagnosis also helps to initiate prenatal diagnosis in the subsequent pregnancies and hence reduce the burden and also dilute the disease causing gene pool.

The diagnostic approaches are targeted to metabolite profiles detected on analytical platforms such as amino acid analyzer (Ion exchange Chromatography), Gas Chromatography Mass Spectrometry (GCMS), Reverse phase High Performance Liquid Chromatography (HPLC), Tandem Mass Spectrometry (TMS) and others. The enzyme assays are performed by fluorometric, spectrophotometric, immunometric, radio isotope assays, HPLC etc while molecular methods include targeted mutation analysis by RFLP, ARMS, PCR, restriction enzyme digestion, whole gene sequencing, multiple ligation, probe amplification assays (MLPA), gene sequencing, comparative genomic hybridization (1) gene expression (2) and whole genome exome sequencing(3).

#### Incidence of Inborn Errors of Metabolism (IEM)

The incidence of IEMs is highly variable for different disorders and it also varies widely between different populations depending on its structure, reproductive practices and other factors. The US African Americans show an incidence of I in 400 for hemoglobinopathies, I in 4500 for congenital hypothyroidism, I in 15,000 for PKU, I in 100,000 for most of the fatty acid disorders (except MCAD) and organic acidemias (4). A birth prevalence of I in 784 live births has been reported in United Kingdom by Sanderson et al (5) where in the frequency of mitochondrial disorders was I in 4929, lysosomal storage disorders was I in 5175, amino acid disorders excluding PKU was I in 5354, organic acid disorders I in 7962, and fatty acid oxidation disorders as I in 12,938.

#### Incidence of IEMs in India

India has a large population with a high birth rate and consanguineous practice in several communities suggesting possibility of high occurrence of these disorders. In 2006 March of Dimes have reported a birth defect prevalence of 64.4/1000 live births in India(6). There are several case reports, independent small scale studies and a few multicentric efforts reporting occurrence of several IEMs across thecountry.

A multicentric study published in 1991 by ICMR collaborating centers have reported metabolic defects as basis of mental retardation in 65 out of the total 1314 patients studied (i.e. 5%). A subsequent study from North India by Kaur et al (7) showed that around 2.5% of the total 2560 patients evaluated for a suspected metabolic disease were diagnosed to have an amino acid disorder. A tertiary care public hospital from Mumbai had seen 1016 cases of inherited disorders over a period of 25 years of which 20% had amino acid defects with albinism being most common followed by alkaptonuria, urea cycle defects and others, 5.7% had organic acidemia wherein glutaricaciduria type I was the most common defect followed by methyl malonicacidemia, propionic acidemia, fatty acid oxidation defects and so forth; 4,3% had either mitochondrial or respiratory chain defects, 18.6% had mucopolysaccharidosis, 0.7% mucolipidosis and 24.5% had other lysosomal storage disorders. A genetic disorder in I out of 20 hospitalized children further accounting to I out of 10 childhood deaths has been reported by Rao and Ghosh in 2005(8).



A study conducted by Nagaraja et al(9) in Bangalore on 3550 high risk individuals showed an abnormal acylcarnitine profile in 113 patients which equates to 3.2 % of the study population. Newborn screening for aminoacidopathies in 98,256 babies conducted in Karnataka, a state in south of India overeight year period from 1980 – 1988 using thin layer chromatography showed single aminoacidopathy in 46 and general aminoacidemiain 70 babies. A recent new born screening of 4946 babies by Tandem Mass Spectrometry carried out in Andhra Pradesh- a neighboring state in south India, showed out of range values for 47 babies suggesting a 1% screen positivity(10).Newborn screening for G6PD in 109 live births in West Bengal has reported deficiency in 14.68% newborns (11).

As a government initiative, Indian Council of Medical Research (ICMR) has funded a multicentric new born screening project for Congenital Hypothyroidism (CH) and Congenital Adrenal Hyperplasia (CAH) and high risk screening for aminoacidopathies, organic acidemias and fatty acid oxidation defects in 2007.

In addition there are several case reports and small scale studies on individual disorders or a particular group of disorders. The studies are conducted at metabolite, enzyme and molecular level. All these studies together suggest significant evidence of IEMs in India.

Though there are several studies reported in India over last 30 years suggesting significant occurrence of IEMs in India there is a void of diagnostic and screening centers. The studies are conducted in both public and private set ups, however there are very few centers offering a comprehensive diagnostic facility. The centers are in the government institutes, private hospitals, stand-alone referral laboratories etc. The diagnostic facilities offer baseline tests for like amino acid estimations using HPLC, urinary organic acid analysis by GCMS, acyl carnitine estimation by TMS and florimetric enzyme assays for lysosomal storage disorders. There are several laboratories which carry out mutation analysis on research basis however commercially available testing facilities are very few. Centers offering diagnostic facilities for neurotransmitters, sterol synthesis defects, purine pyrimidine defects etc. are lacking.

Newborn screening is voluntary paid for service facility provided by private service providers. These service providers have a national network and receive sample from all over the country. States like Goa and Kerala and public centers in other cities have also initiated newborn screening projects. All these suggest that NBS has started taking its baby steps in India.

#### Treatment of IEMs:

The therapy for IEM is instituted at different levels in different disorders. The therapeutic options includesubstrate deprivation(phenylalanine restriction in Phenyl Ketonuria, Branch chain amino acid restriction in Maple syrup urine disease etc), supplementation of deficient products (thyroid hormone in congenital hypothyroidism, Arginine in Urea cycle disorders stimulation of alternate pathways (carnitine supplementation in organic acidemias, penicillamine in Wilson disease), supplement vitamin cofactors (biotin in multiple carboxylase deficiency, pyridoxine in homocystinuria), enzyme replacement (Pompe, Gaucher, Hurler etc), organ transplant (liver in tyrosinemia, glycogen storage disease etc), gene therapy etc (12). The above therapeutic modalities are being offered in India however they are expensive and out of reach of an average Indian. Prenatal testing in subsequent pregnancies offers an opportunity to avoid birth of an affected child thus reducing the burden.



#### Parents support group for IEMs

Apart from the economic burden, the families with an affected child also face social and emotional trauma while managing the patient. Since the disorders are rare it is important that parents and caregivers of affected children interact and exchange the problems encountered while managing the affected child. There are a few societies in India like lysosomal storage support society – LSDSS (<u>http://www.lsdss.org/</u>) and Metabolic Errors and Rare Diseases - MERD India (<u>http://merdindia.com/</u>) whichfunctions to promote awareness and assistance to these families. The societies also approach government agencies for implementing reforms which could reduce the cost of supplements, formula foods, replacement enzymes etc.

#### Database of genetic diseases in India.

The Indian genome is significantly diverse due to genetic heterogeneity that has occurred due to migration from Africa, Middle East and west Asia, southern China and South-east Asia (13). There is also significant inbreeding amongst the religion, geographic area and within family members (consanguineous marriage practice). Thus, it is obvious that the mutation/variations amongst Indians would be significantly different than those reported in Western population. It is essential to have a database repository of gene variants found in several genetic disorders. One such effort has been made by Sanchari et al (14), the group has released the Indian genetic disease database (<u>http://www.igdd.iicb.res.in</u>) which includes an integrated repository of growing number of mutation data on common genetic diseases affecting the Indian population. Database giving information on prevalence of IEMs in the state of Andhra Pradesh is also available (<u>http://biochem.uohyd.ernet.in</u>).

Thus, it is evident that though a comprehensive report on incidence of IEMs is lacking their existence in India cannot be overlooked. It is time for the individual centers to collaborate and offer reliable diagnostic services at affordable prices. The database on Indian variants should be updated regularly for concise information. The clinicians and support service groups should beactive for better disease and patient management.

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### Tietz Textbook of Clinical Chemistry and Molecular Diagnosis

# Authors: Carl A Burtis, Edward R Ashwood and David E Bruns (eds). 5th edition 2012. Published by Elsevier, USA. ISBN: 978-1-4160-6164-9. 2238 pages, 909 illustrations.

Reviewer: Joseph Lopez

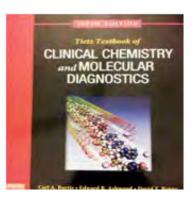
Books by the distinguished editorial team of Ashwood, Bruns and Burtis (in alphabetical order) (e.g. 1) have become established as the texts of choice among practitioners of clinical chemistry. An early book of theirs on molecular diagnostics was separately published some years ago (2). Since this field is now integralpart of the diagnosticslaboratory, any new text of clinical chemistry will need to incorporate it.

The compilation of a comprehensive, authoritative text in a field that grows by leaps and bounds is aHerculean task. The editorshave recruited 6 associate editors, 5 reviewers and 99 contributorsfor this purpose. The book is divided intosix sections which contain a total of 60 chapters, all of which are written by experts in their respective fields.

Some chapters are entirely new. In response to popular demand, the editors have commissioned a chapter on haemostasis and coagulation, for the first time. As the previously well defined boundaries within the laboratory medicine become blurred, the inclusion of this topic should come as no surprise. Sections from chapters in previous editions have been prised out into new chapters and others have been extensively revised from previous editions to bring them up to date.

The book is a remarkable achievement by the editors who,to their immense credit, have successfully distilled the vast corpus of current knowledge into a single text. The previous separate volumes on clinical chemistry and molecular diagnostics (1,2) had a total of 1219 pages between them. At about a thousand more pages, this books contains far more information. It is about as big as a book can get in size. As such, it would seem almost ungracious to point out any omissions but I would have wished to see, inter alia, something on laboratory information systems and a wider discussion on ethics in clinical chemistry, a topic that has sensibly been placed in the opening chapter. The challenge of producing a single volume may have made it necessary exclude some other topics as well. Perhaps future books on clinical chemistry will include our part in regenerative medicine, personalised medicine and patient safety, and, the impact of clinical laboratories on the environment (here, I must acknowledge an interest).

Be that as it may, this book is an imperative, encyclopaedic reference that should adornany library or laboratory. The editorial teamhasmaintained and expanded on the fine tradition started by Norbert Tietz. Long may they continue with their noble endeavour.





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## How phi makes PSA a better cancer detection marker

#### BY BERNARD C. COOK, PHD, DABCC, FACB

Prostate cancer (PCa) is the second most common cancer found in American men and the second leading cause of cancer death after lung cancer, with approximately 241,000 new cases reported in 2011. Annually, about one in six men will be diagnosed with PCa sometime in their lifetime, but only 1 in 36, or approximately 34,000 men, is expected to die of the disease. PCa is typically not a lethal disease, and more men die with their disease than from it. This makes PCa a potentially costly disease to manage. Today, tests for prostate-specific antigen (PSA) are widely used to screen for PCa, and to manage established PCa.

#### The PCa Screening Dilemma

Early detection of PCa with PSA testing benefits many men, but the PSA test is far from perfect. PSA is not a classic tumor marker, in that its expression is highest in benign cells –some prostate tumors produce little PSA. Since its clinical acceptance as a detection tool, patients are increasingly evaluated and diagnosed at lower PSA concentrations, where PSA is less specific for PCa. At lower levels, PSA primarily reflects the presence of benign prostatic hyperplasia (BPH) and not cancer. This lack of specificity for cancer can lead to unnecessary prostate biopsies and the risk of post-procedure infection and bleeding. Depending on the clinical setting, the cancer positivity rate for typical prostate biopsies from men with elevated PSA levels is only 20–40%. In other words, as many as four out of five prostate biopsies result in negative findings for PCa. In fact, every year in the U.S. as many as 750,000 prostate biopsies are negative. These negative biopsies come with significant cost to the healthcare system, as well as considerable medical risks to the patient. For example, rectal bleeding following biopsy is fairly common, and the procedure poses a significant risk for infection. Furthermore, patients increasingly are infected with fluoroquinolone-resistant E. coli (4).

Radical prostatectomy has always been known to have the risks of incontinence and impotence. So there has always been a controversy whether PSA screening has more benefit than risk. In May 2012, the U.S. Preventive Services Task Force heightened this controversy when it issued an updated statement on PSA testing for men. The Task Force gave PSA screening a "D" rating, recommending that most men avoid getting regular PSA tests (1). The chair of the Task Force did not consider studies that demonstrated survival benefit for men who were screened with PSA (2,3).

The limited specificity of PSA for detecting PCa – especially clinically significant PCa – has been the focus of much of the attention regarding the screening controversy. A significant cancer is a cancer that will shorten a man's life and typically has a Gleason Score (GS) of 7 or greater

When a prostate biopsy is positive for cancer, the dilemma becomes how to appropriately manage the man's treatment. Certainly, a high-grade cancer (GS  $\geq$  7) should prompt consideration of aggressive treatment options. But the decision whether to treat a low-grade cancer, such as a GS 6, is less clear. Even some GS 7 cancers can be appropriately managed with conservative treatment. Many of these cancers do not kill men over a 10–20 year time period, and physicians have many treatment options available. Therefore, the challenge is how to use PSA to help identify significant PCa.



#### PSA: The Standard Screening Biomarker for PCa

In 1986, the Food and Drug Administration (FDA) first approved PSA as a biomarker for monitoring men with PCa. Shortly thereafter, PSA gained popularity a screening tool for PCa and was approved in 1994 as an aid in PCa detection in conjunction with digital rectal examination (DRE). As the limitations of PSA as a PCa detection tool became increasingly apparent, however, researchers and clinicians explored derivatives of PSA in an attempt to increase the marker's specificity.

Further research showed that the rate of PSA increase—the velocity or doubling time—appeared to be an important indicator of significant disease. Researchers also looked at the percentage of free PSA as a function of total PSA (%free PSA) as a means to improve cancer specificity of PSA. Even after considerable research into various derivatives, the diagnostic performance of PSA today does not match, for example, that of cardiac troponin in diagnosing acute myocardial infarctions.

#### Searching for a Better Screening Biomarker

Despite decades of clinical research, no clear consensus has emerged on the benefits of PSA screening. Further prospective studies are needed to settle the important issues outlined here. In light of the limitations of PSA as a PCa detection tool, much effort has been focused over the years on alternate biomarkers to supplement, or even replace the PSA test, as a tumor detection tool.

Even with the enormous research efforts focused on this disease, investigators have not uncovered an abundance of viable biomarkers for early detection of PCa. Recently, however, an isoform of free pSA has gained attention for increased specificity of PCa, supplementing information from initial PSA test results. While not yet able to completely replace PSA as a screening tool, this marker appears to provide significant additional information for clinicians making patient management decisions for men with a modestly elevated PSA of 4–10 ng/mL.

#### Free PSA is Complex

PSA exists in two different forms in serum: a complex of PSA and alpha-I-antichymotrypsin (complexed PSA), and a free form, not bound to an inhibitor (free PSA) (5). Researchers demonstrated that %free PSA was higher in benign tumors and lower in cancerous tumors, thereby improving the biomarker's specificity for PCa.

Researchers discovered that free PSA is not one, but at least three different molecules, all enzymatically inactive (Figure 1). One form, BPSA, is degraded at two specific sites on the protein (amino acids 145 and 182) and elevations in blood are associated with benign prostatic hyperplasia ( $\underline{6}$ ). A second, poorly characterized form is an intact form of PSA, but it is denatured and therefore enzymatically inactive. This form is known as intact PSA (non-native, non-nicked) ( $\underline{7}$ ). A third form is the pro-enzyme form of PSA, termed proPSA. Native proPSA contains a seven amino acid leader sequence that HK-2 and other activating enzymes cleave off to produce active PSA. Degraded forms of proPSA also exist with pro-sequences of five-, four-, and two-amino acids (Figure 2) ( $\underline{6}$ ). While its biology is not fully understood, [-2]proPSA is more highly associated with the peripheral zone of the prostate gland in cancer tissue. Researchers also have demonstrated that the protein can be accurately and reliably measured.

The first assay for [-2]proPSA was a micro titer plate format developed for research by Hybritech. Beckman Coulter acquired Hybritech in 1995 from Eli Lily. Beckman Coulter has developed an automated immunoassay for [-2]proPSA that is performed using the family of Access immunoassay systems. Analytical performance is very robust, with an assay limit of blank (LOB) (0.50 pg/mL). The limit of detection LOD) was determined as a value that is 1.645 standard deviations higher than LOB at 0.69 pg/mL. The limit of quantitation (LOQ) was determined to be 3.23 pg/mL(upper 95% CI concentration). The Access Hybritech p2PSA assay does not demonstrate any "hook" effect up to 15,000 pg/mL [-2]proPSA. Access Hybritech p2PSA exhibits total imprecision of < 20% at [-2]proPSA concentrations between the LOQ of 3.23 pg/mL and 10 pg/mL, and  $\leq 10\%$  at[-2]proPSA concentrations > 10 pg/mL. This analytical performance has been published (8).



#### The Prostate Health Index

Similar to free PSA, which has no discriminating value by itself, [-2]proPSA demonstrates better performance when combined with total PSA and free PSA in a multi-marker index. The Prostate Health Index (phi) is calculated using the following formula: p2PSA/free PSA\*sqrtPSA. Hybritech free PSA and total PSA assays must be used in the phi calculation, which is programmed into the analyzer. The system automatically performs the calculation and reports the phi score. The phi index can be computed with either the Hybritech or WHO calibration. In June 2012, the FDA approved Hybritech pPSA to be used in the Beckman Coulter Prostate Health Index, or phi, for use as an aid in distinguishing prostate cancer from benign prostatic conditions, for prostate cancer detection in men aged 50 years and older with total PSA in the 4.0 to 10.0 ng/mL range, and with digital rectal examination findings that are not suspicious for cancer. Prostatic biopsy is required for diagnosis of cancer.

In the pivotal multi-center study to demonstrate the clinical efficacy of phi, a total of 658 men were studied (324 with prostate cancer and 334 without prostatecancer). Briefly, the men were recruited from seven medical centers andwere 50 years and older, with a negative DRE and a histological confirmed diagnosis by prostate biopsy examination. Mostof the men (79.3%) were undergoing their initial prostate biopsy. Median age was 63 years for both cancer and benign disease subjects. Total PSA did not differ between the groups. The study analysis compared the ability of the phi index to discriminate PCa from benign disease in comparison to total PSA (9). The researchers evaluated prostate biopsy results and compared them to results of PSA, free PSA, [-2]proPSA, and their derivatives, including phi. ReceiUsing receiver operating characteristic (ROC) curve analysis, the area-under-the-curve (AUC) was 0.708 for phi index and 0.516 for total PSA, proving the enhanced power of phi. Fixing the sensitivity at 90%, the specificity of phi was 31.1% compared to 10.8% for PSA (p < 0.001). This translates to 2.9-foldgreater specificity for phi versus total PSA.

#### What's next for phi?

Future research using phi will likely uncover new clinical utilities. For example, phi has demonstrated an association with the GS on prostate biopsy, with the probability of  $GS \ge 7$  increasing as phi increased. A better indicator of aggressive prostate cancer is desperately needed, and phi might fill that void. Given evidence of a more dangerous cancer, a physician may recommend more aggressive treatment strategy for an individual. Active surveillance is a prostate cancer management program where a known but low grade cancer is followed with regular PSA testing and prostate biopsies, e.g., once per year. There have been reports that phi may predict those patients that will fail active surveillance, and should be more closely monitored or never entered into a surveillance program. Finally, because PSA is sometimes poorly sensitive to post-radical prostatectomy recurrence of prostate cancer, phi may be a more sensitive and specific test with which to monitor for cancer recurrence. Of course, these and other applications of phi must be thoroughly studied by researchers before physicians will consider using phi for these novel utilities.

#### The Search Goes On

PCa remains a challenging disease to detect and manage, even after many years of experience and extensive research. We have long recognized that PSA as a screening biomarker has limitations, and that over-diagnosis and overtreatment of PCa are common. But for now, PSA is the most effective biomarker available for helping to detect PCa. The availability of phi makes PSA a more effective marker for PCa in the challenging PSA range of 4-10 ng/mL. Future research will undoubtedly focus on combinations of protein and nucleic acids markers to add to the initial information provided by total PSA. The combined role of imaging studies is another emerging strategy. It will take time for physicians to gain comfort in making decisions with these new tools, and in the meantime, PSA will remain as the primary tool for helping detect PCa.



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Figure 1. Typical proportions of PSA and free PSA isoforms in prostate cancer serum (redrawn from Kiyo J. Med 2003; 52:86–91.)

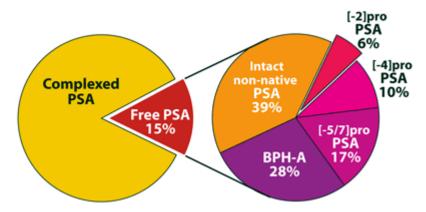




Figure 2. Molecular schematic of [-2] proPSA structure, depicting truncated leader sequence.

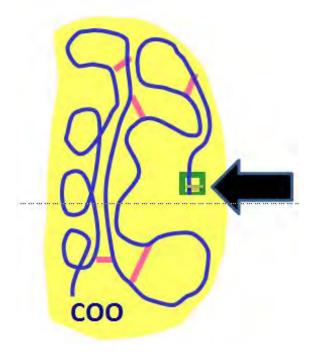


Figure 3. Receiver Operating Characteristic curve analysis comparing PSA and phi. Sanda (manuscript in preparation) REDRAW TO SHOW PSA AND phi ONLY + REMOVE % FREE PSA IN LEGEND

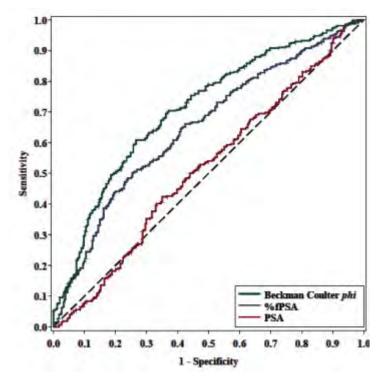




Figure 4. Probability of prostate cancer on biopsy for Beckman Coulter phi in patients with PSA between 4 and 10 ng/mL (Hybritech Calibration of PSA and free PSA)

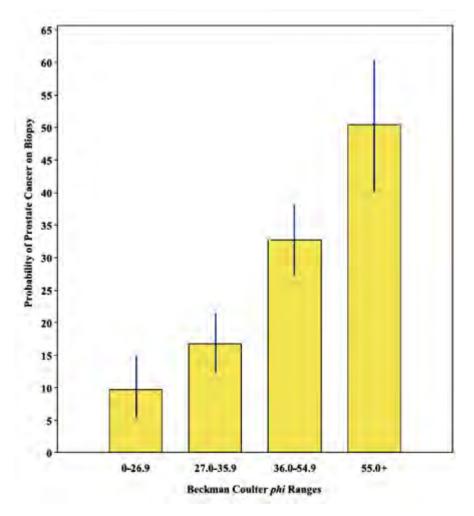
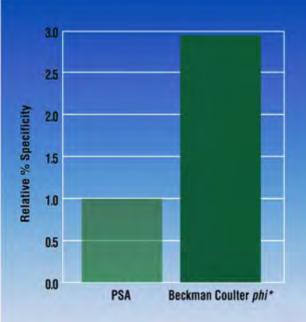


Figure 5. Relative specificity of phi compared to total PSA at fixed sensitivity of 90% in the 4-10 ng/mL range (Hybritech calibration)





# Questions can be answered with a simple blood test

Beckman Coulter Prostate Health Index (phi) significantly improves prostate cancer detection compared to PSA and %fPSA and provides personalized results for individual risk assessment1-3

# [-2]proPSA \* √tPSA = **phi**

...indicated for use as an aid in distinguishing prostate cancer from benign prostatic conditions, for prostate cancer detection in men aged ≥50 with total PSA ≥4.0 to ≤10.0ng/mL and DRE not suspicious for cancer...



**fPSA** 

Stay Connected With your web-enabled camera phone scan the QR Code with a QR Code reader application. Get the latest information at w.ProstateHealthIndex.org

#### Reference

HIGH RISK

LOW RISK

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Contact us to learn more about how phi impacts you as a physician, patient or laboratorian



## Clinical Validation of a Multiplex Diagnostic Assay for Ten Sexually Transmitted Infections

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#### Abstract

To facilitate the identification of co-infections and the reduction in antibiotic misuse, a multiplex approach for the detection of sexually transmitted infections is proposed. This study reports the clinical validation of a multiplex diagnostic assay for rapid, simultaneous screening of ten sexually transmitted infections from a single sample. The STI Multiplex Array involves DNA amplification using highly sensitive primers and spatial separation and detection using Evidence biochip array technology. The multiplex assay detects viral, bacterial and protozoan pathogens with high sensitivity and specificity and enables detection of co-infections.

Keywords: Multiplex, Biochip Array technology, STIs, Co-infection

#### Introduction:

Sexually transmitted infections (STIs) present a major public health concern worldwide (1) Most STIs are easily treated, however these are often asymptomatic (2) and can therefore lead to further transmission of infection. Untreated STIs can have serious implications for reproductive, maternal and newborn health (3) increase the risk of transmission of other pathogens such as HIV (4,5) and can result in long term disability.

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.

This study reports the clinical validation of a novel multiplex diagnostic assay to rapidly screen for the presence of ten STIs simultaneously, from a single urine or swab sample. The assay detects viruses (Herpes simplex I and II), bacteria (Chlamydia trachomatis, Neisseria gonorrhoea, Treponema pallidum, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Haemophilus ducreyi) and protozoa (Trichomonas vaginalis).

#### **Materials and Methods:**

The STI Multiplex Array (Randox Laboratories Limited, Crumlin, UK) was validated using bacterial cultures and residual clinical DNA samples to determine sensitivity and specificity. DNA extractions were performed using both the Qiagen Symphony (Qiagen, Crawley, UK) and the Abbott m2000sp systems (Abbott, Maidenhead, UK), following the manufacturers' instructions.

Multiplex PCR was performed, incorporating all target-specific, highly sensitive primers in a single reaction. The amplified specific pathogen sequences were spatially separated and detected using biochip array technology, which involves hybridisation, conjugation and chemiluminescent detection. The biochips were then analysed using the Evidence Investigator analyser and dedicated software (Randox Laboratories Limited, Crumlin, UK)(Fig I).



Quality Control Material for Molecular Diagnostics (QCMD, Qnostics, Glasgow UK) was tested for Chlamydia detection in several panels. The panels (CTA05, CTB05, CTB10, CTA11, CTB11) included the Swedish variant and negative samples.

Results are reported as positive or negative for each of the pathogens. The assay includes controls for the extraction, amplification and biochip steps of the assay to ensure confidence in the results.





#### **Results:**

Assay clinical sensitivity and specificity was determined for all commonly tested STIs by comparison to routinely performed uniplex qPCR assays from an NHS hospital (Table 1). Of the samples which tested positive for an infection, 20% harboured at least one additional infection.

#### Table I: Sensitivity and specificity

	True	False	True	False	Sensitivity	Specificity
STI	Positive	Positive	negative	negative	(%)	(%)
Chlamydia trachomatis	105	1	192	1	99	99
Neisseria gonorrhoea	17	3	279	1	94	99
Herpes simplex virus 1	44	0	252	3	94	100
Herpes simplex virus 2	24	2	274	0	100	99
Treponema pallidum	5	0	295	0	100	100
Trichonomas vaginalis	3	1	296	0	100	100
Mycoplasma hominis	28	7	196	6	82	97
Mycoplasma genitalium	3	2	232	0	100	99
Ureaplasma urealyticum	25	2	203	7	78	99
Haemophilus ducreyi	1* culture	0	236*	0*	100*	100*

\* Haemophilus ducreyi was confirmed using culture strains due to rare occurrence.



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\* Haemophilus ducreyi was confirmed using culture strains due to rare occurrence.

Assessment of the Quality Control Material for Chlamydia detection showed that the multiplex assay consistently identified all positive and negative samples correctly in both swab and urine over a broad range of copies/ml (23 to 5700 for CTB10, 23 to 57000 for CTA05 and CTB05 and 25 to 500000 for CTA11 and CTB11).

The analytical specificity of the STI Multiplex Array was tested against 62 non-target pathogens, including those that can be found in the urogenital tract. No cross-reactions were detected with the exception of Neisseria lactamica which cross-reacted with Neisseria gonorrhoea. However this bacterium is infrequently isolated from adults and would not be commonly found in the target regions where sexually transmitted infections colonise.

The STI Multiplex Array was tested for potentially interfering endogenous and exogenous substances, which may be encountered in swabs and urine specimens. These were tested in both urine and swab samples positive and negative for Chlamydia. None of these substances caused any interference with the assay at the concentrations tested (Table 2).



Sample Matrix	Substance Tested	Concentration
Urine	Blood	1%
	Blood	2%
	Albumin	3 mg/ml
	Glucose	5 mg/ml
	Antibiotics (Amakacin/gentamicin)	60 µg/ml
	Acidity	pH 4
	Alkalinity	pH 9
Swab	Galpharm cold sore cream (5% acyclovir)	2%
	Clotrimazole fungal cream (1%)	2%
	Vagisil Anti-Itch Cream (2% Lidocaine)	2%
	Vagisil Deodorant Powder	2%
	Femfresh Daily Intimate Wash	2%
	Femfresh feminine freshness deodorant	2%

#### Table 2: Test for potentially interfering substances.

#### **Conclusions:**

The Randox STI Multiplex Array, allows simultaneous detection of bacterial, viral and protozoan pathogens from a single urine or swab sample, permitting the identification of co-infections that would be missed by current routine medical practice and otherwise remain undiagnosed. This allows more effective, tailored treatment, which may reduce broad spectrum antibiotic use and, in turn, reduce build-up of antibiotic resistance.

Clinical validation of the Randox STI Multiplex Array produced consistently high sensitivity and specificity for all ten STIs confirming that the assay is robust, sensitive and specific. Because of its straightforward protocol, the assay can easily be performed in a standard pathology or hospital laboratory using routine sampling and PCR equipment in conjunction with the Evidence Investigator.

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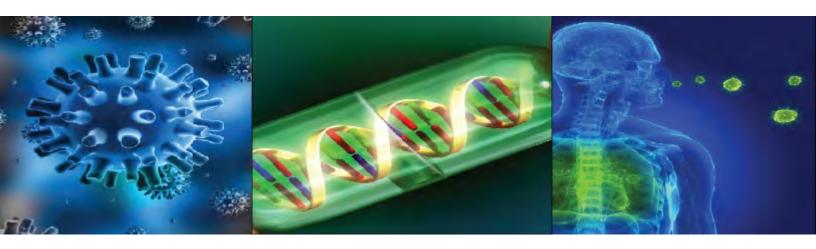


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