‘Have your Say’
Invited short presentations from Full, Affiliate and Corporate Members

Accreditation in Sri Lanka
Hemachandra Weerawarna (LK)
President
Association for Clinical Biochemistry, Sri Lanka (ACBSL)
APFCB and IFCC contribution for Accreditation

• In April 2009 ACBSL organized a workshop on Laboratory Quality Control aiming Sri lankan laboratories to promote ISO 15189 accreditation.

• This is the first workshop of this nature, conducted by ACBSL with the help of APFCB and IFCC by the IFCC visiting lecturers.

• Only one private medical laboratory had been accredited (15\textsuperscript{th} Oct 2008), prior to this workshop.
WORKSHOP ON LABORATORY QUALITY CONTROL 4-5 April 2009

Dr Ken Sikaris (Australia)
Dr David Bullock (UK)
Dr Janet Smith (UK)
Dr Elizabeth Frank (India)
ISO 15189 Medical Laboratory Accreditation in Sri Lanka

• 13 medical laboratories, mostly private laboratories have been accredited.

• Another 5 laboratories have started the accreditation process.

• Sri Lanka Accreditation Board (SLAB) is the authoritative third party body for the accreditation.
ACBSL members involvement

ACBSL members are involved in the accreditation as

• Auditors, trained by SLAB
• providing consultancy service to prepare ISO manuals for the laboratories.
• Serving on part-time basis, after working hours.
Sri Lanka Accreditation Board (SLAB)

ASIA PACIFIC LABORATORY ACCREDITATION COORPORATION (APLAC)

SLAB is a Full Member of and is a signatory to the Mutual Recognition Arrangement (MRA) of APLAC.

Test reports issued by SLAB Accredited Laboratories (ISO 15189 & ISO 17025) in Sri Lanka will be recognized and accepted internationally.

INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC)

SLAB is a Full Member of and is a signatory to the Mutual Recognition Arrangement (MRA) of ILAC.
Sri Lanka Accreditation Board (SLAB)

• PACIFIC ACCREDITATION COUNCIL (PAC)
  SLAB has gained Full Membership status of PAC.

• INTERNATIONAL ACCREDITATION FORUM (IAF)
  SLAB is in the process of seeking membership of IAF

• SWEDISH BOARD FOR ACCREDITATION AND CONFORMITY ASSESSMENT (SWEDAC)
  SLAB has established a technical co-operation program with SWEDAC. Technical Assistance for development of SLAB accreditation activities is provided by SWEDAC funded by Swedish International Development Agency (Sida).
SLAB website, www.slab.lk
# Accredited laboratories – ISO 15189

<table>
<thead>
<tr>
<th>No.</th>
<th>Lab Name</th>
<th>Accreditation Date</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Confidence Medical Centre (Pvt) Ltd.</td>
<td>15 Oct 2008</td>
<td>GAMCA</td>
</tr>
<tr>
<td>2</td>
<td>Blue Cross Medical Centre</td>
<td>03-Jun-09</td>
<td>GAMCA</td>
</tr>
<tr>
<td>3</td>
<td>International Meditrust (Pvt) Ltd</td>
<td>26 Jan 2011</td>
<td>GAMCA</td>
</tr>
<tr>
<td>4</td>
<td>Colombo Medilab (Pvt) Ltd</td>
<td>29 Nov 2011</td>
<td>GAMCA</td>
</tr>
<tr>
<td>5</td>
<td>Medilab Lanka (Pvt) Ltd</td>
<td>23-May-12</td>
<td>GAMCA</td>
</tr>
<tr>
<td>6</td>
<td>MediSence</td>
<td>to be updated</td>
<td>GAMCA</td>
</tr>
<tr>
<td>7</td>
<td>Lanka Hospitals Corporation PLC</td>
<td>15-Dec-09</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>8</td>
<td>Asiri Hospital Laboratory</td>
<td>07 June 2011</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>9</td>
<td>Durdans Hospital Laboratory</td>
<td>23 May 2012</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>10</td>
<td>Hemas Hospitals Laboratory</td>
<td>23-May-12</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>11</td>
<td>Vindana Reproductive Health Center</td>
<td>11-Sep-09</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>12</td>
<td>Genetech Molecular Diagnostics</td>
<td>7-Jun-11</td>
<td>Genetic</td>
</tr>
<tr>
<td>13</td>
<td>National Blood Centre</td>
<td>17th Aug 2011</td>
<td>State sector</td>
</tr>
</tbody>
</table>

• GAMCA-6/13 Private-5/13 State-1/13 withdrawn 1/13

(GAMCA) - The Gulf Cooperation Council-(GCC) Accredited Medical Clinics Association

## Laboratories processing for accreditation and status

<table>
<thead>
<tr>
<th>No.</th>
<th>Lab Name</th>
<th>Status</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Health Watch</td>
<td>Applied</td>
<td>GAMCA</td>
</tr>
<tr>
<td>2</td>
<td>MediSpot Laboratory (pvt) Ltd</td>
<td>Applied</td>
<td>GAMCA</td>
</tr>
<tr>
<td>3</td>
<td>Royal Hospital</td>
<td>2nd Audit</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>4</td>
<td>Nawaloka Hospital</td>
<td>2nd Audit</td>
<td>Private Hospital</td>
</tr>
<tr>
<td>5</td>
<td>MDK Hospital</td>
<td>Applied</td>
<td>Private Hospital</td>
</tr>
</tbody>
</table>
Future plan to accredit State Sector Hospital Laboratories

- Government sector laboratories: 232
  (blood bank laboratories): 77
- Under line ministry: 53
- Under provincial ministries: 179

Staff
- Specialists: 103
- Medical laboratory technologists (MLTs): 1414
  (Sri Lanka Medical Council Registered)
- Unskilled workers: 1600
  (approximately)

Large laboratories
- 11 tertiary care hospitals
- Have 4 specialists and more than 25 MLTs
- generate an average of 2000 to 2500 test reports/day
National Program on Laboratory Quality Assurance

• Initiated by the Ministry of Health, Sri Lanka to improve quality and credibility of government laboratories inspired by a proposal given by the College of Pathologist Sri Lanka in 2011.
• Series of activities with a time frame in the proposal
• 5 major hospitals for the pilot project
• National Laboratory Quality Assurance Board (NLQAB) established under Deputy Director General (Laboratory Services), DDG(LS) with representatives from 5 professional colleges
Progress with the NLQAB

• Essential test menu decided
• Quality Targets were set
• Workshops and awareness programs were conducted with collaboration of SLAB
• Necessary Improvement of the knowledge has been initiated
• Addressed on the attitude change of workers
• Guidelines were prepared
Prepared guidelines

- Sample collection, transport and storage
- Method validation
- Equipment maintenance
- Laboratory hierarchical structure and organization
- Safety
- Waste Disposal
<table>
<thead>
<tr>
<th>Problems identified</th>
<th>Remedial measures could be initiated by ACBSL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of trained personnel as quality managers.</td>
<td>to conduct training programmes for QAM with the assistance of SLAB</td>
</tr>
<tr>
<td>Lack of knowledge to interpret IQA and EQA results.</td>
<td>To conduct training programmes on IQA and EQA interpretation.</td>
</tr>
<tr>
<td>Lack of knowledge on test interpretation and authorization.</td>
<td>To conduct workshops on test interpretation. ACBSL has already conducted workshop on test interpretation with the help of IFCC visiting lecturers in April 2009.</td>
</tr>
<tr>
<td>Problems identified</td>
<td>Remedial measures could be initiated by ACBSL</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Lack of EQC programmes especially for Haematology and Clinical Pathology tests. (For Clinical Chemistry programmes such as BioRad and Asqualab are available.)</td>
<td>To help commencing EQA programmes, specially clinical pathology and haematology.</td>
</tr>
<tr>
<td>Problem of surveillance and the cost of maintaining calibration</td>
<td>To encourage local authorities to commence calibration laboratories on ISO 17025 at a reasonable cost.</td>
</tr>
<tr>
<td>Lack of motivation to get accreditation</td>
<td>Presently, accreditation is not compulsory in Sri Lanka. Promote the government to make accreditation compulsory in future by giving a grace period.</td>
</tr>
</tbody>
</table>
The guidelines and supportive documents

- Handouts given at the workshop conducted by ACBSL with the help of APFCB and IFCC
- Laboratory Quality Management System Current Laboratory Practice Series – Training Toolkit by WHO, CLS and CDC
- Quality Standards in Health Laboratories – Implementation in Thailand, a Novel Approach, by WHO – Check list of 100 points to do the gap analysis.
- Guidelines prepared by SLAB
Thank you!
ACBSL