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CONFERENCE OVERVIEW / EXECUTIVE SUMMARY

The African Society for Laboratory Medicine (ASLM) is a pan-African organisation for laboratory professionals committed to improving diagnostic services and increasing patient access to quality laboratory testing across the continent. From 1-7 December 2012, ASLM hosted its inaugural international conference, ASLM2012, in Cape Town, South Africa, themed “Accurate Laboratory Diagnostics: A Pillar of Quality Healthcare.”

In all, ASLM2012 assembled more than 1,000 healthcare professionals and policy makers. The biennial conference of ASLM intended to create an environment in which African laboratory professionals and their international counterparts can share best laboratory practices; learn about the latest developments in laboratory medicine technologies, standards and research; and communicate their specific needs and challenges. Participants were drawn from African governments as well as non-governmental, international and multilateral organizations, academia and private entities. ASLM also sought to increase accessibility to underrepresented individuals including students and laboratory professionals from primary and secondary health facilities.

ASLM2012 welcomed Dr. Asha-Rose Migiro as the conference keynote speaker. Dr. Migiro previously served as the Deputy Secretary-General of the United Nations, and at the time of the conference served as the Special Envoy for HIV/AIDS in Africa for the United Nations Secretary-General. During her keynote address at the ASLM2012 Opening Ceremony, Dr. Migiro highlighted the challenges and successes in the fight against HIV/AIDS in Africa, as well as the critical role women play in public health and leadership positions.

A key outcome of ASLM2012 was the publication of the “ASLM2012 Ministerial Call for Action,” signed by six African Ministers of Health: Côte d’Ivoire, Kenya, Mozambique, Nigeria, South Africa and Tanzania. While pledging government support for ASLM and the ASLM2020 strategic vision, the consensus Call for Action document outlines specific commitments and tangible steps that can be taken to improve laboratory systems on every level. Both documents may be viewed at www.ASLM.org.

Four strategic goals comprise the ASLM2020 strategy:

- Strengthen the laboratory workforce by training and certifying 30,000 laboratory professionals and clinicians by 2020 through standardised frameworks.
- Transform laboratory testing quality by enrolling 2,500 laboratories in accreditation and quality improvement programmes, thereby enabling 250 laboratories to achieve accreditation by international standards before 2020.
- Work with Africa’s seven regional economic communities to ensure patient safety by developing strong, harmonised regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce in at least 25 countries by 2020.
- Strengthen national laboratory networks and promote South-South collaboration by developing laboratories that participate in an African network of national public health reference laboratories in at least 30 countries by 2020.

This report summarises the satellite sessions, presentations, plenaries and symposia that captivated more than 1,000 participants for a week in Cape Town. It also offers a window into the array and complexity of the accomplishments and challenges surrounding laboratory diagnostics and its vital role in African healthcare.
On behalf of the African Society for Laboratory Medicine (ASLM) and the organising committee of the first international conference, ASLM2012, we again extend our thanks to our countless supporters and participants. More than 1,000 laboratory professionals and policy makers attended ASLM2012 in Cape Town, South Africa, 1-7 December 2012. The conference received tremendous positive feedback from sponsors, speakers, exhibitors and attendees.

ASLM2012 provided a comprehensive programme focused on current scientific, programmatic and policy-related issues, with more than 40 satellite sessions and 700 plenary, symposia, roundtable, oral and poster presentations from 50 countries. The conference schedule covered diverse topics such as point-of-care diagnostics, antimicrobial resistance, biosafety, laboratory accreditation and policy. ASLM looks forward to building upon these conversations to offer sustainable solutions to advance laboratories across the continent.

Our inaugural conference also uniquely brought together African Ministers of Health to debate the challenges to laboratory workforce, regulation of diagnostics products and policies to govern accreditation. Together, they released an unprecedented Ministerial Call for Action which recognises the key bottlenecks to strengthening healthcare through improved laboratory services and outlines specific commitments and tangible steps that can be taken to improve laboratory systems on every level.

While ASLM2012 is a watershed moment, it is only one of ASLM’s many avenues to achieving laboratory progress in Africa. As a pan-African professional body endorsed by the African Union (AU), ASLM works in concert with governments and relevant partners to also advocate for the critical needs of laboratories via our ASLM2020 strategic vision, as outlined previously.

Achieving these goals will bring significant benefit to patients across the continent and advance laboratory medicine in Africa to international standards. Quality laboratories save lives and ensure positive health outcomes. ASLM commits its resources and the knowledge shared in this ASLM2012 Conference Report to further enhance quality laboratory systems throughout the continent.
LETTER FROM DR. TSEHAYNESH MESSELE

ASLM Chief Executive Officer

At the inaugural conference of the African Society for Laboratory Medicine (ASLM), ASLM2012, in Cape Town, South Africa, 1-7 December 2012, we proudly gathered laboratory professionals from across Africa to share their stories of improved laboratory diagnostics, accreditation successes and workforce development efforts.

This landmark conference served to continue a global conversation started during our organisation’s launch in early 2011. Laboratory services are indispensable to effective health systems, and they play a pivotal role in maintaining healthy communities. Healthy communities rely on knowledge to address disease diagnosis, outbreaks, research and development. As such, ensuring access to information remains a top priority for ASLM, and ASLM2012 provided us with a valuable tool to not only support and collaborate with our members and global partners but also to share best practices.

ASLM continuously aims to strengthen laboratory science and networks throughout Africa. The signing of the Ministerial Call for Action by ministers of health during ASLM2012 was pivotal in maintaining our momentum towards that goal. The Ministerial Call for Action consensus document pledges government support for ASLM and the ASLM2020 strategic vision, while outlining specific commitments to enhance laboratory systems throughout Africa.

The ASLM2012 conference was an important step in reaching these goals. The relationships built, the ideas generated, the connections made among organisations and colleagues across Africa will undoubtedly help build a network that will promote the improvement of laboratory services across the continent. The Ministerial Call for Action, and your support, played a prominent role in the success of our first conference, and we look forward to a continued partnership.

The highlights and summaries contained within this ASLM2012 Conference Report are yet another step towards accomplishing our vision of strengthening laboratory systems in Africa. Thank you for taking the time to read and share this document with your colleagues.
In December 2012, at the inaugural international conference of ASLM in Cape Town, an important milestone was achieved on the path to accomplishing the strategic vision of ASLM. Six African Ministers of Health (from Côte d’Ivoire, Kenya, Mozambique, Nigeria, South Africa and Tanzania) developed and signed a consensus Ministerial Call for Action, a landmark document recognising key challenges and envisioning strengthened laboratory services on the continent. The full version of the Ministerial Call for Action can be viewed at www.ASLM.org.

The Ministerial Call for Action reinforces an irrefutable existing commitment from multiple governments to enhance laboratory medicine. ASLM seeks to build upon this commitment and encourage other governments to adopt and implement its strategies and major goals, such as:

- Building a sustainable laboratory workforce.
- Accreditling laboratories to improve performance and quality.
- Improving the regulation of medical diagnostic products.
- Building laboratory networks to improve early disease detection and collaborative research.

While expressing specific programmatic commitments, the Ministerial Call for Action also further commits to supporting ASLM as the first professional society dedicated to guiding laboratory medicine on the continent. The Ministers pledged to support the implementation of the ASLM2020 Strategic Vision for improving healthcare in Africa by strengthening laboratory services.
## ASLM2012 SATELLITE SESSIONS

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<tr>
<td>8:30 am</td>
<td>ASLM Collaborating Centers (ASLC) (By Invitation Only)</td>
<td>CDC Laboratory Advisory Meeting, CDC (By Invitation Only)</td>
<td>Laboratory Procurement Optimization, The Key to Responsive and Cost-Effective Laboratory Network Services (Partnership for Supply Chain Management)</td>
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<tr>
<td>10:00 am</td>
<td>BREAK</td>
<td>Genexpert® Technology Workshop: ExpertNet/IP for the Diagnosis of Tuberculosis, HIV and New Developments (The National Health Laboratory Service, South Africa)</td>
<td>HIV Genotyping Workshop (The National Health Laboratory Service, South Africa)</td>
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<td>10:30 am</td>
<td>ASLM Ambassador’s Program (ASLM) (By Invitation Only)</td>
<td>WHO Preparatory of Diagnostics: Why It Is Important to You (WHO General)</td>
<td>HIV Testing in a National Programme: Mini-workshop and Guided Tour of Laboratories Facilities in the South African National Health Laboratory Service</td>
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<td>2:00 pm</td>
<td>The Laboratory-Clinic Interface: Where the Public Meets the Medical and Public Health Community (Columbia University)</td>
<td>Affordable and Easy-to-Implement Information System for Laboratories (African Field Epidemiology Network, ASERM)</td>
<td>African Solutions for Africa (Roche Diagnostics, South Africa)</td>
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<td>4:00 pm</td>
<td>ASLMA (By Invitation Only)</td>
<td>HIV Early Infant Diagnosis Workshops on Dried Blood Spot Collection and Rejection (The National Health Laboratory Service, South Africa)</td>
<td>Building Sustainable Partnerships to Improve the Quality of Laboratory Diagnostics (The Clinical and Laboratory Standards Institute, CLSI)</td>
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<td>5:30 pm</td>
<td>DINNER (on your own)</td>
<td>Nailing the Profile of Laboratory Professionals (The World Health Organization)</td>
<td>A Pan-African Regulatory Harmonization Working Party for In Vitro Diagnostics (Online School of Napes and Tropical Medicine)</td>
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<td>9:00 pm</td>
<td>Effective Abstracts — A Hands-On Course to Improve Your Abstract-Writing Skills (African Journal of Laboratory Medicine, ASLM)</td>
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### Quarter-Day Session Options
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### Half-Day Session Options
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### Full-Day Session Options
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# Conference Programme At-a-Glance

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**Conference Reception**

7:00 p.m.

ASLM Reception

Plenary Sessions

Break-Out Sessions

Poster Sessions

Breaks and receptions
SCIENTIFIC CONFERENCE SUMMARY

SCIENTIFIC OPENING

ASLM leaders, African Ministries of Health, dignitaries from national laboratory programmes and ASLM partners presented speeches before a delegation of nearly 1,000 conference attendees. Dr. Asha-Rose Migiro, the United Nations Secretary General’s Special Envoy to AIDS in Africa, served as the conference keynote speaker. During her address at the ASLM2012 Opening Ceremony, Dr. Migiro highlighted the challenges and successes in the fight against HIV/AIDS in Africa, as well as the critical role women play in public health and leadership positions.

Together with Dr. Trevor Peter, ASLM2012 Conference Chair, and Dr. Tsehaynesh Messele, ASLM Chief Executive Officer (CEO), the following dignitaries presented at the opening session:

- Dr. Sarah Barber, WHO Representative to South Africa
- Dr. Erica Barks-Ruggles, U.S. Consul General, Cape Town, South Africa
- Hon. Samuel Kazungu Kambi, Deputy Minister for Medical Services, Kenya
- Dr. Julia Martin, Chief Operating Officer, Office of the US Global AIDS Coordinator
- Hon. Dr. Aaron Motsoaledi, Minister of Health, South Africa
- Dr. Sagie Pillay, Chief Executive Officer, National Health Laboratory Service, South Africa
- Hon. Dr. Seif Rashid, Deputy Minister of Health, Tanzania
- Dr. Sheila Tlou, Director, UNAIDS Regional Support Team for East/Southern Africa

Overarching themes of the ASLM2012 Opening Ceremony included the continuance of collaborations between ASLM and its partners, the development and strengthening of African public health networks, the innovation of diagnostics and scale-up of medical laboratory services, and the advancement of the Millennium Development Goals and global AIDS targets. The ceremony also featured a video presentation by Dr. Robert Gallo, co-discoverer of HIV and Founder/Director of the Institute of Human Virology in Baltimore, Maryland, USA.

SCIENTIFIC TRACK SUMMARIES

1. Disease-Specific Laboratory-Based Surveillance – At the Interface of Research and Surveillance

Studies, presentations and discussions during ASLM2012 illustrated the importance of laboratory research and surveillance to strengthen public health responses to diseases. Studies provided evidence that data generated from laboratory-based investigations can serve to inform cost-effective and accurate interventions such as vaccines. The laboratory-based surveillance sessions covered disease areas ranging from HIV to hepatitis C virus (HCV) to influenza to meningitis.

Several satellite sessions set the stage for presentations and discussions surrounding the critical interface between research and laboratory-based surveillance. One specific highlight occurred during the second session of the satellite, “Addressing Ethical and Community Challenges,” when Shabir Banoo, Medicines Control Council, South Africa, made the case that capacity to facilitate ongoing regulatory review of trials and data for licensure must be strengthened. Capacity building, Banoo contended, should be focused on scientific research, regulatory challenges, and biomedical ethical issues. Banoo discussed laboratory-based surveillance initiatives necessary for the effective deployment of laboratory programmes. He cited microbicide initiatives in South Africa as an example; he explained implementation requires strict pharmacovigilance in the form of a systematic programme of surveillance to assess long-term safety with frequent use, control risk, evaluate public health impact and satisfy regulatory requirements.

Jean Marc Collard, Centre de Recherche
Médicale et Sanitaire, Niger, presented on developments in capacity building and operational research activities surrounding acute bacterial meningitis (ABM). Operational research has been deployed to help validate new diagnostic tests and to document the aetiologies, prevalence and nature of neurological sequences associated with ABM. Altogether, Collard demonstrated how recent research efforts have ultimately strengthened the epidemiological and microbiological surveillance of ABM.

Richard Njouom, Institut Pasteur, Cameroon, presented a study of HCV infection, and demonstrated the ways in which a medical laboratory can effect high-level public health decisions through the generation of research data. HCV research in Cameroon has provided decision makers with a more comprehensive set of data on sero-prevalence rates, trends and correlation factors. This, together with the data on the most dominant subtypes and genotypes in Cameroon, will help stakeholders make informed decisions and identify more accurate and cost-effective diagnostic assays.

Norosa Razanajatova, Institut Pasteur, Madagascar, discussed the importance of the laboratory in research and surveillance of acute respiratory infections in Madagascar. The National Influenza Centre, with its well-established laboratory infrastructure, has played a critical role in the surveillance of influenza viruses and other respiratory infections. Its achievements – in ensuring early detection of pandemic influenza and outbreaks due to respiratory viruses – demonstrate the need for research and surveillance programmes to be strengthened and sustained by government health ministries and other stakeholders.

Lilian Waiboci, U.S. Centers for Disease Control and Prevention (CDC), Kenya, noted that the Kenya Medical Research Institute (KEMRI)/CDC Laboratory has been collaborating with similar laboratories within Africa and globally to support outbreak investigations in many African countries including Ethiopia, Somalia, South Sudan, Tanzania, Uganda and Zimbabwe. From July to November 2012, there have been several outbreaks detected in Africa (cholera, polio, etc.). Waiboci highlighted how the Field Epidemiology and Laboratory Training Programme (FELTP) has enhanced existing laboratory capacity for disease detection in Africa, but noted that further resources, both human and reagent supplies, are required.

Emmanuel Nakouné-Yandoko, Institut Pasteur, Côte d’Ivoire, presented a lecture on the dynamics of canine rabies in Central Africa. Despite 24,000 deaths per year, rabies is still a neglected disease, causing a heavy social and economic burden in the Central African Republic. The study contended that rabies vaccination coverage has been insufficient, suggesting that surveillance needs to be further strengthened. Nakouné-Yandoko then concluded with recommendations for prevention and control strategies.

During a roundtable session, speakers described recent advances in the laboratory diagnosis and screening for cryptococcal diseases. Cryptococcal meningitis accounts for as many deaths as tuberculosis (TB) in HIV-positive patients, with prevalence ranging from 5 to 21% in patients with CD4 cell counts less than 100 cells/mm3. It was noted that crypto screening should focus on antiretroviral therapy (ART) naive patients and should be integrated into routine HIV care and treatment programmes. Special attention was given to the new lateral flow assay (LFA), which detects cryptococcal antigen (CrAg) with 99% sensitivity and 100% specificity using serum or plasma and 95% and 100% using urine.

This session provided evidence that continued laboratory research and surveillance in developing countries are an important and cost-effective means for working to prevent disease outbreaks. Although funding such studies remains a challenge, the presentations during this ASLM2012 track highlighted that the benefits of early disease detection are well worth the investment.
2. Laboratory Systems and Quality Management Systems (QMS)

Developments in quality management systems (QMS) were important focal points of the satellite sessions during the first days of ASLM2012. In the session, “Guidance on Available Tools and Approaches toward Laboratory Accreditation,” Karen McClure, Clinical and Laboratory Standards Institute (CLSI), USA, presented an overview of the World Health Organization (WHO) QMS training toolkit, which provides comprehensive materials to design and organise training workshops for various stakeholders in health laboratory processes. During another satellite session, Marion Munster, Sysmex, South Africa, discussed the development of a quality guidance tool developed for the Sysmex haematology analyser. The manual provides a step-by-step guide to the documentation and procedures required for compliance with accreditation requirements. These resources and materials are important for laboratory quality improvement; they reflect the understanding and commitment of stakeholders to improving laboratory quality, which is essential for the effective implementation of QMS.

Throughout ASLM2012, presentations and discussions on new laboratory initiatives and technologies frequently circled back to questions relating to quality and QMS. Speakers continuously supported the claim that quality clinical care is dependent on reliable and quality laboratory services. Presentations focused on challenges in implementing QMS in laboratories, especially in resource-limited settings, and also highlighted efforts to address these challenges. For example, the WHO Regional Office for Africa (WHO-AFRO) Stepwise Laboratory Quality Improvement Process Toward Accreditation (SLIPTA) model, which helps to prepare laboratories for accreditation, was discussed at a co-hosted ASLM and WHO-AFRO session.

Both the aforementioned CLSI workshop and the presentation of Emmanuel Oni Idigbe, Nigerian Institute of Medical Research, Nigeria, focused on the lack of relevant resources and human capacity in many sub-Saharan laboratories needed to implement and sustain QMS. Insufficiencies in QMS, Idigbe contended, result in inaccurate test results and significant misdiagnosis and mismanagement of clinical conditions. To address this situation, Nigeria has embraced the WHO-AFRO Strengthening Laboratory Management Toward Accreditation (SLMTA) programme, which prepares laboratories to meet medical laboratory quality requirements established by the International Organization for Standardization. The consensus was that SLMTA is an effective implementation tool and brings tangible quality improvement progress to countries enrolled in the SLIPTA process. SLMTA provides a training framework for laboratory management with the goal of preparing laboratories for accreditation based on international standards, while SLIPTA is an assessment checklist or scoring system, which can be used to measure quality improvements toward accreditation.

Improving QMS also involves strengthening the ways laboratory information is stored and maintained. Souleymane Sawadogo, CDC, Namibia, discussed Namibia’s experience in effectively implementing a basic Laboratory Information System (LIS) in tandem with QMS to overcome challenges in the provision of quality laboratory services and ensure that laboratory data from the Namibia Institute of Pathology remains accessible and of high-quality. With increased demand for prevention, treatment and surveillance, “it is paramount that laboratory systems be strengthened,” Julia Martin, Office of U.S. Global AIDS Coordinator (OGAC), USA, said. Speakers agreed that ASLM should collaborate with existing regulatory and accreditation bodies to strengthen laboratory networks and improve quality management.

Habtamu Asrat, Ethiopian Health and Nutrition Research Institute (EHNRI), Ethiopia, discussed the comprehensive quality assurance programme that Ethiopia undertook to improve laboratory diagnosis of malaria. In an assessment of current diagnos-
tic capabilities, detection performance increased significantly over three rounds and increased from 83% to 91% in the final round. Asrat’s research demonstrated that continuous trainings and targeted competency assessment programmes are needed in order to improve species identification and ensure the provision of quality healthcare.

This track showcased the breadth of quality management initiatives across different disease areas and countries in Africa. It also affirmed that stakeholders in laboratory medicine are not only concerned with access, but are also focused on quality.

3. **Point-of-Care (POC) Testing and Diagnostics**

The satellite session entitled “National Programme CD4 Testing: Insights for wide-scale service delivery” primed ASLM2012 for discussions on strategies for expanding access to point-of-care (POC) testing. Speaker Debbie Glencross, National Health Laboratory Service (NHLS), South Africa, discussed the “three-tiered” approach to deploy diagnostic technologies currently being explored by the NHLS. Although the increased access to POC CD4 testing is an important NHLS mandate, there are some sites not suitable for POC decentralised testing. The tiered approach helps to most effectively match technologies to their most appropriate laboratory facility, whether it is a rural, decentralised facility, a centralised laboratory centre or mid-volume testing facilities. Financial modelling is used to inform the placement of diagnostic technologies and to ensure cost-effective services without compromising the quality of results.

There was strong consensus at ASLM2012 that the emergence of POC technologies in recent years presents a significant opportunity to improve access to diagnostic testing in support of care and treatment programmes for HIV and other high priority diseases. For example, Belete Tegbaru, EHNRI, Ethiopia, described how POC technology would help expand access to testing and allow for immediate decisions regarding HIV care and treatment. Ilesh Jani, National Mozambican Institute of Health, Mozambique, affirmed the great promise of POC technology in Mozambique by stating that POC technology would significantly reduce loss-to-follow-up figures in facilities, especially those that are resource-constrained.

Speakers repeatedly underscored the potential of POC technology by featuring presentations on technological developments in disease areas other than HIV. Another POC rapid test recently developed at CDC for detecting active syphilis was shown by Tun Ye, CDC, USA, to reduce unnecessary treatment. With 80% sensitivity and more than 99% specificity, the majority of rapid plasma reagin (RPR) probative primary syphilis cases (97%) in remote settings will be detected same day using dual this non-treponemal/treponemal POC rapid test. Additionally, presentations were given about an oral-based diagnostic test for malaria by Nana Wilson, Morehouse School of Medicine, Ghana; the use of dried blood samples (DBS) for viral load analysis with Cobas Amplicore by Silvia Kadima, KEMRI, Kenya; and developments in an inexpensive $2/test lateral flow assay that measures Cryptococcal antigen by George Khanyinzira, Malawi.

Although POC technology presents significant opportunities in its expansion of patient access to diagnostics and improvement of patient care, its implementation presents many challenges, many of which were discussed at ASLM2012. Those challenges include building and strengthening regulatory frameworks, product evaluation systems, quality assurance systems, workforce development, data management, clinic patient workflow and connectivity of technologies, especially at decentralised facilities where it is difficult to monitor device usage. Lesley Scott, NHLS, South Africa, shared her perspective about POC in South Africa. To Scott, maintaining quality control and restructuring clinical infrastructure will be a major concern as South Africa strives to meet unmet testing needs by decentralising testing and increasing the number of facilities that need
to be monitored. Adebayo Adedeji, Nigerian Ministry of Health (MOH), Nigeria, reported on a review conducted in Nigeria to assess the level of awareness and compliance with HIV testing quality standards as well as the level of support provided to sites. Many untrained staff (>50% in private facilities, 20% in public) are performing tests and 21% of facilities do not provide pre- or post-test counselling. Overall, it was found that private facilities receive very little support and monitoring from the government and partners, and that there is little oversight of HIV testing. In a review of 20 facilities using POC technology for a simple glucometer test, Chielo Onyenekwu, Nigeria, explained that quality management processes were found to be deficient: 80% of staff using the device had not received proper training, 85% of sites had no logbook or trace of results, and 90% of sites did not perform validation.

Within this POC diagnostics track, and echoing Glencross’s satellite session, there were also presentations and discussions on the importance of integrating POC diagnostics with conventional laboratory diagnostics. Wendy Stevens, NHLS, South Africa, highlighted a holistic approach to laboratory testing that includes conventional laboratories, POC testing and sample transportation as one complementary system. Stevens articulated the urgent need for countries to develop national plans for POC technologies as well as POC policies as subsets of national strategic laboratory plans. Stevens’s NHLS colleague Jon Smith presented a geographic mapping study of laboratories in South Africa. Using vehicular transport time as a determining factor, Smith presented four potential tiers, each with a different combination of conventional and POC technology usage. He found that having facilities within three hours met clinical and coverage criteria; however, the decentralised tier was the best solution for difficult-to-reach areas.

Following the “Focus on POC Diagnostics in Africa” meeting that ASLM convened in May 2012 in Ethiopia, POC testing remained a vital topic at the ASLM2012 conference. Presentations focused on the opportunities as well as challenges for widespread POC HIV diagnostics, the development of POC algorithms, the interplay between POC and conventional diagnostic testing, and the systems needed to effectively roll out POC testing, including quality assurance, regulatory frameworks, evaluation of products and workforce development.

4. Laboratory Diagnostics

The laboratory diagnostics track covered a wide range of topics, including opportunities and advances in malaria and TB testing, HIV viral load monitoring, HIV drug resistance monitoring and the cost-effectiveness of laboratory diagnostics.

Several presentations focused on new methods and implementations involved in the diagnosis of malaria. As noted above in the POC testing and diagnostics track, Nana Wilson, Morehouse School of Medicine, Ghana presented on developments toward a saliva-based rapid diagnostic test (RDT). Additionally, Amy Bei, Harvard School of Public Health (HSPH), USA, presented a new High Resolution Melting (HRM) technology being deployed in Senegal as a faster, simpler and cheaper genotyping method for the detection of new malaria variants and monitor parasite population structures. Kutumbakana Seraphine and Daouda Ndiaye, National Institute of Biomedical Research, Democratic Republic of Congo (DRC), presented on significant improvements in the DRC’s malarial diagnostic services through ongoing efforts with The Global Fund in conjunction with the U.S. President’s Malaria Initiative (PMI). DRC has now revised its training materials in line with WHO 2010 guidelines, developed a national rapid diagnostic test scale-up plan and set up standard operating procedures for laboratory diagnosis of malaria. Furthermore, photo- and SMS-based External Quality Assessment (EQA) can be used in the DRC to assess the quality of healthcare workers performing RTDs. A look into the tuberculosis diagnostic landscape reveals new developments with the introduction of the Cepheid
GeneXpert System. The GeneXpert System reduces time to tuberculosis treatment and should be integrated into existing laboratory networks testing algorithms, Emmanuel Fajardo, Médecins Sans Frontières (MSF), South Africa, contends. Implementation challenges, however, much like in HIV and malaria testing, persist, including biosafety, quality assurance, training and infrastructure challe

There were presentations highlighting the need for introducing and strengthening HIV viral load (VL) and HIV drug resistance (HIV-DR) monitoring. In her presentation, “New Laboratory Capacity for Clinical Treatment and Vaccine Development in Africa,” Deborah Birx, CDC, USA, articulated that both VL and HIVDR to inform treatment decisions. Similarly, Don Hamel, HSPH, USA presented a study in Nigeria that showed VL testing, when incorporated into the HIV testing algorithm, produces better outcomes than CD4 alone, primarily because there is faster second-line switching and less incorrect switching. With regard to HIVDR testing, the general consensus was that it is needed especially as pre-treatment resistance is increasing, Pascal Onoala, Amsterdam Institute for Global Health and Development (AIGHD), Netherlands, stated. Even though simplified technologies for HIVDR testing exist, Nicaise Ndemb, Institute of Human Virology, Nigeria (IHVN), argued, it still has a long way to go given its limitations and infrastructure requirements.

A roundtable entitled “Approaches to Public Private Partnerships” convened executives from industry to discuss public private partnerships (PPP) in the context of strengthening laboratory medicine in Africa. Participants discussed how ASLM and private diagnostic companies can form effective partnerships to advance the implementation and use of diagnostic products together. Additionally, the group discussed the role ASLM can play in facilitating regulation of diagnostic products. The panel for this session included: Renuka Gadde, Senior Director, Global Health, BD; Kara Palomountain, President, Northwestern Global Health Foundation; Avi Pelossof, Vice President, Infectious Diseases, Alere, Inc.; Leon du Plessis, Director, Abbott Laboratories; William Rodriguez, CEO, Daktari Diagnostics, Inc.; and Knut Seifert, South African Country Manager and Senior Vice President International Public Health, Roche Diagnostics.

Patient access is not the only factor in shaping the decisions made around laboratory diagnostics; rather, cost-effectiveness of laboratory diagnostics should play a critical role in conjunction with patient access objectives. Presenters explored the cost benefits of new diagnostics. For example, Don Hamel spoke of the cost-effectiveness of scaling up viral load testing. Even though there are costs associated with that scale-up, one must also take into account the costs avoided in minimising incorrect switching and accumulated drug resistance from CD4 alone. As Aaron Motsoaledi, the South African Minister of Health, said, “It wasn’t a question of whether we could afford to implement GeneXpert, but whether we could afford not to.” Echoing the NHLS presentations made by Wendy Stevens and Jon Smith, Jason Williams, Partnership for Supply Chain Management (PFSCM), USA, made the case that there needs to be careful deliberation to achieve an optimal balance between centralised and decentralised testing. POC diagnostics should not be treated as separate from conventional diagnostics. Rather, Williams explained that there can be high costs associated with the inappropriate placement and ultimate underutilisation of conventional diagnostics, such as the FACS Calibur and FACs Count machines.

5. Laboratory Policy and Workforce Development

Satellite sessions advocated for the adoption of key laboratory guideline programmes and policies, including the WHO Prequalification (PQ) programme, WHO-AFRO SLIPTA programme, and the Global Laboratory Initiative (GLI), which is a working group of the Stop TB Partnership, formed to provide a framework for national laboratory TB programmes. During a satellite dedicated to
WHO PQ, WHO speakers Robyn Meurant and Willy Urasa presented information regarding quality assurance and the WHO PQ process. Meurant and Urasa discussed the importance of WHO oversight in assuring and improving the quality of diagnostic products, both new and old to the market. Reports from Burkina Faso and Tanzania were presented, highlighting the progress made to date in country regulation of in vitro diagnostic (IVD) tests. A satellite meeting, co-chaired by the London School of Hygiene and Tropical Medicine (LSHTM) and the New Partnership for Africa’s Development (NEPDA), explored the use of a Pan-African Regulatory Harmonization Working Party (PAHWP) to strengthen and streamline the regulation process for IVD.

In the laboratory accreditation satellite sessions and workshops, Teferi Mekonen, ASLM, Ethiopia, presented on the catalytic impact of SLIPTA, which is designed to ultimately enable countries to develop their own national laboratory strategic and operation plans and to establish a quality improvement process in a stepwise manner. This same satellite session covered GLI’s Stepwise Process towards TB Laboratory Accreditation tool, which was developed using a process of consensus among quality experts, TB laboratory managers and other stakeholders. Within the tool, ISO 15189 accreditation requirements are translated into specific activities in a TB laboratory context. These activities are grouped along the 12 quality system elements as defined by the CLSI guideline GP26 - Quality Management System: A Model for Laboratory Services, which includes elements such as personnel, equipment and process improvement. This gives laboratories insight into what has to be done, how and why.

All of the speakers in the session, “Networks, Partnerships and Policies in Laboratory Strengthening,” emphasised the significant need for partnerships and strong laboratory networks that support quality laboratory services, disease surveillance and response to epidemics across the African continent. Jean Sakandé, MOH, Burkina Faso, introduced the West Africa Laboratories Network (RESAOLAB) network in Burkina Faso, Mali and Senegal to develop continuous training plans, EQA plans and the deployment of laboratory information management systems across 45 laboratories in the network. A next step for this laboratory network is to add an additional four countries and to implement SLIPTA to improve quality of laboratory services delivered in the region. Tomori Oyewale, Redeemer’s University, Nigeria, discussed the WHO-AFRO laboratory network, which was initially established across eight laboratories in five countries in order to provide access to polio testing. The network supports linkages across the laboratories and offers equipment and staff training to meet growing demands whilst retaining quality of services. Finally, May Chu, CDC, USA, emphasised that the American Society for Microbiology (ASM) is dedicated to building sustainable science diplomacy, through introducing, correcting and building scientific networks and societies. The association has nearly 40,000 members, one third of which are international members. ASM also works on laboratory capacity building in 18 countries and is implementing mentoring programme structures in several locations. Chu ended her talk with a famous African proverb, “if you want to go fast, go alone, but if you want to go far, go together.”

Johan Van Herdeen, NHLs, South Africa, discussed quality management and Patience Dabula, NHLs, South Africa, presented the role of SLIPTA and SLMTA in accreditation in South Africa. Van Herdeen presented that proper planning and implementation of quality assurance systems are keys to the functioning of NHLS. He identified “normalisation” and “standardisation” as two key pillars to the success of an effective quality assurance system. Dabula outlined the laboratory accreditation process in South Africa and how SLIPTA and SLMTA could be integrated into the process. SLIPTA, in particular, could facilitate the accreditation process in peripheral laboratories, which the NHLS Accreditation Strategy does not target.
Lastly, presentations from CDC reviewed the key areas that need to be addressed in the realm of laboratory biosafety and biosecurity. Funding was identified as a significant obstacle to overcoming these various biosafety and biosecurity issues. Additionally, there were recommendations to form:

- Biosafety related trainings
- Chemical safety programmes
- Equipment maintenance programmes
- Occupational health initiatives such as staff vaccination programmes
- Waste management and environmental safety programmes

Implementing strong QMS is an incremental process that leads to laboratory accreditation. Of course, once laboratories are accredited, there is still much work to be done in terms of maintaining accreditation and continuing to improve and strengthen laboratories across the continent. There was strong recognition during the sessions in this track that much of that work will be driven by the partnerships and networks forged from entities in the private sector, public sector (MOHs, ASLM, CDC, Clinton Health Access Initiative [CHAI], U.S. President’s Emergency Plan for AIDS Relief [PEPFAR], WHO-AFRO). Laboratory policies in Africa are often non-existent or not implemented due to lacking prioritisation of laboratory services. In order to ensure the delivery of high-quality healthcare services, the capacity of healthcare workers must be strengthened and laboratory infrastructure and services must be improved.

SCIENTIFIC CONCLUSION

Professor Souleymane Mboup, Cheikh Anta Diop University, Dakar, Senegal, chaired the ASLM2012 Closing Ceremony and coordinated the rapporteur presentations. ASLM2012’s five conference tracks – Disease-Specific Laboratory-Based Surveillance, Laboratory Systems and QMS, POC Testing and Diagnostics, Laboratory Diagnostics, and Laboratory Policy and Workforce Development – provided a comprehensive forum for key players from government, non-governmental organisations, academic institutions and the private sector to convene and address key recent developments, challenges and strategies surrounding laboratory medicine in Africa. While each session was targeted in its area of focus and led by experts in that area, sessions from one track cannot be understood in isolation from sessions in the remaining four. Questions about quality management and accreditation were integral to the presentations on the adoption of innovative POC diagnostics. Presentations on the role of conventional laboratory diagnostics in national scale-up plans demanded careful consideration of, for example, the role of POC technologies in these same scale-up plans and workforce development. In this way, ASLM2012 elucidated for its participants the comprehensive and complex approach that is required to strengthen and build effective laboratory systems in Africa.
To celebrate and recognise the continued commitment of laboratory professionals in Africa, a new tradition of awarding honours began at ASLM2012. Nominations were received in the months leading up to the first international conference of ASLM in order to recognise the dedication, innovation and perseverance of African laboratory professionals.

Dr. Nancy Knight, Country Director of CDC-South Africa, officiated the ASLM2012 Awards Ceremony held 6 December 2012. The following categories were publicly honoured.

**Lifetime Achievement Award, presented by Professor Sinata Koualla, Permanent Secretary of the Ministry of Health for the Republic of Cameroon:**

A senior professional respected by peers globally, Professor Barry David Schoub, currently the Senior Consultant for the National Institute for Communicable Diseases and Acting Head of the Centre for Vaccines and Immunology in South Africa, was recognised with the ASLM2012 Lifetime Achievement Award for building the disciplines of virology and epidemiology in South Africa. Additionally, ASLM recognised Professor Schoub’s decades of leadership in communicable diseases, laboratory science and public health, both in South Africa and throughout the world.

**Best Laboratory Champion Clinician Award, presented by Professor Mireille Dosso, Director of Institut Pasteur in Côte d’Ivoire:**

Professor C.O. Onyebuchi Chukwu, of the Federal Ministry of Health, Abuja, Nigeria, was recognised with the ASLM2012 Best Laboratory Champion Clinician Award for playing a key role in providing laboratory services to underserved and hard to reach populations, promoting the integration of laboratory services in healthcare and serving/practicing in public and private clinics/hospitals. Professor Chukwu has championed the development of sound laboratory policies that strengthen the laboratory-clinician interface. Chukwu was first appointed the Minister of Health for Nigeria in 2010 and was reappointed in 2011.

**Best Practice in Laboratory Medicine, presented by Dr. Tsehaynesh Messele, ASLM CEO:**

Uganda National Tuberculosis Reference Laboratory (NTBRL), Department of Medical Microbiology, School of Biomedical Sciences, Makerere University, was recognised with the ASLM2012 Best Practice in Laboratory Medicine Award for enhancing quality in laboratory systems and patient care. The Uganda National TB (Tuberculosis) Reference Laboratory’s Best Practice was twofold. First, the laboratory improved its quality management systems and biosafety practices, which led to its achievement of a 5-star rating in the World Health Organization’s (WHO) stepwise accreditation scheme. The Uganda NTBRL introduced a laboratory information system (LIS) for timely reporting and developed a GeneXpert (TB rapid diagnostic tool) implementation plan. Next, Uganda strengthened its specimen referral system, by training health workers and postal staff and implementing a specimen courier system. The improved TB specimen referral system has ultimately improved service delivery and has enabled efficient utilisation of resources.

**Certificate of Recognition for Accreditation of Government Laboratories:**

The following government laboratories received accreditation from a recognised ILAC-accrediting body between October 2010 and October 2012, and received special recognition from ASLM during the ASLM2012 Awards Ceremony. ILAC is the International Laboratory Accreditation Cooperation, an international cooperation of laboratory and inspection accreditation bodies.

**Republic of Botswana:**

- Bamalete Lutheran Hospital Laboratory
- Botswana-Harvard HIV Reference Laboratory
- National TB Reference Laboratory
Nyabanga Hospital HIV Reference Laboratory

Republic of Kenya:
Kenya-AMPATH Laboratory
Nyeri Provincial General Hospital

Republic of Mali:
Mali Malaria Research and Training Centre (MRTC) Clinical Laboratory

Republic of South Africa:
NHLS: Addington Hospital Laboratory (NHLS: National Health Laboratory Services)
NHLS: Braamfontein Laboratory
NHLS: Charlotte Maxeke Johannesburg Laboratory
NHLS: Chris Hani Baragwanath Laboratory
NHLS: East London Laboratory
NHLS: Dr. George Mukhari Tertiary Laboratory
NHLS: George Provincial Hospital Laboratory
NHLS: Green Point Complex Laboratory
NHLS: Groote Schuur Hospital Laboratory
NHLS: Livingstone Laboratory
NHLS: Mankweng Laboratory
NHLS: National Institute for Communicable Disease Laboratories
NHLS: National Institute for Occupational Health Laboratory
NHLS: National Satellite Clinical Pathology Laboratory
NHLS: Nelson Mandela Academic Hospital, Mthata Laboratory
NHLS: Port Elizabeth Laboratory Complex
NHLS: Proficiency Testing Schemes
NHLS: Red Cross Children’s Hospital Laboratory

NHLS: Tshwane Academic Division Laboratory
NHLS: Tygerberg Academic Laboratory
NHLS: Universitas Academic Laboratory
NHLS: Witbank Laboratory

ASLM also recognised two additional laboratories during the ASLM2012 Awards Ceremony for their valuable work towards accreditation. Their accrediting bodies are not currently affiliated with ILAC, but their hard work is no less critical to advancing laboratory medicine and public health in Africa.

Federal Democratic Republic of Ethiopia:
Ethiopia Health and Nutrition Research Institute - HIV and Other Viral Disease Research

Federal Republic of Nigeria:
445 Nigerian Air Force Laboratory

Prior to ASLM2012, ASLM awarded the following 25 students from 12 countries an ASLM2012 Student Travel Award. Awarded students received complimentary airfare, lodging and a daily stipend to enable them to attend ASLM2012 and participate in the many educational and career-building opportunities. More than 250 students applied for the award, and selection was based on quality of their submitted abstract.

Samuel Abdi, Ethiopia
Oladimeji Abisola, Nigeria
Anthony Ahumibe, Nigeria
Grace Bartonjo, Kenya
Cyrille Dedhiou, Senegal
Nkongho Franklyn Egbe, Cameroon
Jennifer Giandhari, South Africa
Tao Issoufou, Burkina Faso
Silvia Kadima, Kenya
Pierre Patrick Mukadi Kaningu, Democratic Republic of the Congo
ASLM2012 CONFERENCE AWARDS

Ernest Lango-Yaya, République Central Africaine
Mura Ngoi, Tanzania
Chioma Nwuba, Nigeria
Babatunde Odetoyn, Nigeria
Jeremiah Ogoro, Kenya
Lilian Okeke, Nigeria
Chinelo Onyenekwu, Nigeria
Ifeyinwa Osegbe, Nigeria
Diagne Rokhaya, Senegal
Aicha Sarr, Senegal
Lee Schroeder, United States of America
Moussa Thiam, Senegal
Nasir Umar-Tsafe, Nigeria
Loveness John Uria, Tanzania
Innocent Uwimana, Rwanda
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SUPPORTERS:

Bill & Melinda Gates Foundation (BMGF)

Guided by the belief that every life has equal value, BMGF works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people’s health and giving them the chance to lift themselves out of hunger and extreme poverty.

U.S. Centers for Disease Control and Prevention (CDC)

The U.S. CDC aspires to create a world where people live healthier, safer, and longer lives. The U.S. CDC’s global health mission is to protect and improve health globally through science, policy, partnership, and evidence-based public health action.

U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)

PEPFAR is a U.S. government initiative to help save the lives of those suffering from HIV/AIDS around the world. This historic commitment is the largest by any nation to combat a single disease internationally, and PEPFAR investments also help alleviate suffering from other diseases across the global health spectrum. PEPFAR reflects the U.S. commitment to the shared responsibility among donor and partner nations and others to make smart investments to save lives. This global epidemic requires a comprehensive, multisectoral approach that expands access to prevention, care and treatment. As PEPFAR works to build upon its successes, it is focusing on transitioning from an emergency response to promoting sustainable country programs.

PARTNERS:

Abbott Molecular

Abbott’s rapidly growing molecular diagnostics business provides physicians with critical information based on the early detection of pathogens and subtle changes in patients’ genes and chromosomes, allowing for earlier diagnosis, selection of appropriate therapies and monitoring of disease progression. The business includes instruments and reagents used to conduct sophisticated analysis of patient DNA and RNA.

Daktari Diagnostics

Daktari Diagnostics develops point-of-care diagnostics that address the needs of patients, healthcare providers, and institutions in resource limited settings. We strive to provide the highest quality diagnostics, at an affordable price, that can be used by anyone, anywhere in the world.
Roche

Roche focuses on developing medicines and diagnostics that will help patients live longer, better lives. We strive to address unmet medical needs through excellence in science – from early detection and prevention of diseases to diagnosis, treatment and treatment monitoring.

PLATINUM LEVEL SPONSORS:

BD Biosciences

BD is a leading global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents. The Company is dedicated to improving people’s health throughout the world. BD is focused on improving drug delivery, enhancing the quality and speed of diagnosing infectious diseases and cancers, and advancing research, discovery and production of new drugs and vaccines.

Cepheid

Cepheid is a leading molecular diagnostics company dedicated to improving healthcare by developing, manufacturing, and marketing accurate yet easy to-use molecular systems and tests. Cepheid focuses on applications where accurate, rapid, and actionable test results are needed most, in critical and healthcare associated infections, women’s health, genetic diseases and cancer.

GOLD LEVEL SPONSORS:

Clinical and Laboratory Standards Institute (CLSI)

CLSI’s mission is to develop best practices in clinical and laboratory testing and promote their use throughout the world, using a consensus driven process that balances the viewpoints of industry, government, and the health care professions.

SILVER LEVEL SPONSORS:

Association of Public Health Laboratories (APHL)

APHL is the U.S. non-profit representing governmental laboratories. As the primary advocate for public health laboratories, APHL works internationally to aid development of national public health laboratories, laboratory policy, strategic planning, information systems and laboratory networks through partnerships, mentoring and twinning.
**American Society for Clinical Pathology (ASCP)**

With more than 100,000 members, ASCP is the world’s largest professional membership organisation for pathologists and laboratory professionals. Our mission is to provide excellence in education, certification and advocacy on behalf of patients, pathologists and laboratory professionals across the globe.

**Children’s Investment Fund Foundation**

The Children’s Investment Fund Foundation aims to demonstrably improve the lives of children living in poverty in developing countries by achieving large-scale, sustainable impact. We believe that every child deserves to survive, thrive and mature into adulthood in a supportive and safe environment.

**SPONSORS:**

**Beckman Coulter**

Beckman Coulter develops, manufactures and markets products that simplify, automate and innovate complex biomedical testing. Our diagnostic systems are found in hospitals and other critical care settings around the world and produce information used by physicians to diagnose disease, make treatment decisions and monitor patients.

**Cen-Med Enterprises**

Cen-Med Enterprises has been in the laboratory services and distribution business since 1992. With a commitment to provide reliable supply chain solutions and services to sites throughout the globe, Cen-Med has been named one of the fastest-growing privately held companies in the healthcare industry by Inc. Magazine.

**Global Scientific Solutions for Health**

Global Scientific Solutions for Health (GSSHealth) is a scientific consulting firm providing laboratory quality assurance solutions to multi-centre, international research and public health programs. We provide guidance on project design and implementation, establish communication networks, and mentor laboratory scientists and managers to ensure accountability and sustainability.

**Hostalite**

Hostalite is an established information technology solution provider for website design, hosting, domain name registration, networking, I.C.T. solutions, data recovery, software development, search engine optimisation and email marketing. Our time tested quality-centric implementation methodology ensures that we deliver solutions that address specific business challenges. Our clients are diverse and include web services for ASLM.org and the ASLM2012 Conference.
Lasec

Lasec is an African supplier of many internationally recognised brands of scientific and laboratory equipment with offices in five main centres in South Africa and representation in forty-two African countries and expanding operations to cover areas outside of Africa. We take pride in positioning ourselves as a partner to our clients, assisting them in achieving optimal precision, performance and results.

Zyomyx, Inc.

Zyomyx, Inc., a diagnostics company in California, is an innovator in the development and commercialisation of proprietary diagnostic platforms. Zyomyx will launch a low-cost, disposable and quantitative point-of-care CD4 test, specifically designed to meet requirements of low-resource settings and increase global access to HIV testing and treatment.

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