

Building Laboratory Capacity to Improve Access to Effective Diagnostic Tests

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Cape Town, South Africa



- The African Society for Laboratory Medicine (ASLM) is a pan-African professional body launched in 2011 and endorsed by the African Union
- ASLM partners include:
 - African Ministries of Health and institutions
 - African Union
 - World Health Organization
 - UNAIDS
 - Society for AIDS in Africa
 - United States Centers for Disease Control and Prevention
 - CHAI
 - Other major international partners

2008 Maputo Declaration

- Highlighted need for integrated laboratory support for major diseases
- Called on governments to develop and implement national laboratory strategic plans



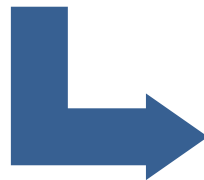
2008 WHO Yaoundé Resolution

- Declared need to strengthen public health laboratories in Africa
- Emphasized need to establish laboratory centers of excellence



2009 Kigali Meeting

- Launched WHO-AFRO Stepwise Laboratory Accreditation program



2010 Kampala Statement

- Called for creation of ASLM

ASLM's vision for 2020 has four primary goals:

Laboratory workforce development – *30,000 healthcare workers trained*

Laboratory accreditation – *2,500 labs certified, 250 labs accredited*

National and regional regulatory strengthening – *regulatory harmonization for IVDs in 8 regional economic communities*

Network of African National Public Health Reference Laboratories (NPHRLs) – *30 NPHRLs networked*

ASLM Ministerial Call for Action for Laboratory Strengthening in Africa

- Adopted in Cape Town, Republic of South Africa, on December 5, 2012
- Signed by 14 Ministers of Health



MINISTERIAL CALL FOR ACTION

- STRENGTHENING LABORATORY SERVICES IN AFRICA -

We, the undersigned Ministers of Health from African countries, attending and meeting at the 1st International Conference of the African Society for Laboratory Medicine (ASLM), Cape Town, South Africa, December 1st-7th, 2012 under the theme "Accurate Laboratory Diagnostics – A Pillar of Quality Health Care"

ARE DEEPLY CONCERNED by the huge burden of infectious diseases of public health significance, and rising levels of communicable and non-communicable challenges faced by our continent owing to, among others: weak health systems including poor laboratory systems, inadequate quality of laboratory services, inadequate resources and critical shortages of laboratory workforce;

RECALLING the Abuja Declarations on HIV/AIDS, Malaria, TB, and Other Related Infectious Diseases;

ACKNOWLEDGING the 2008 WHO issued Resolution AFR/RC58/R2 for strengthening public health laboratories in the African region;

COGNIZANT of the Maputo Declaration in 2008 that called for integrated laboratory support for major diseases and calling on governments to develop and implement national laboratory

WE HEREBY:

1. **COMMIT** ourselves, in collaboration with our partners, to endorse and strengthen the Laboratory Education Partnership Initiative (LEPI) and professionalize laboratory practice in the continent, aimed at strengthening our health systems; and to providing periodic reports on the status of implementation;
2. **COMMIT** to develop and promote harmonized regulations and policies that govern the quality of diagnostic products and medical devices through the establishment of an African Harmonization Work Group on Diagnostic Products and Medical Device Regulations in collaboration with Regional Economic Communities;
3. **COMMIT** to develop departments, units or entities of medical laboratory services within the Ministries of

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Challenges

- Lack of awareness around crypto testing
- Inadequate laboratory capacity to perform testing
- Test access



ASLM's Role

- Raise awareness through promulgating best practices and guidelines on crypto testing
- Strengthen laboratory capacity by facilitating training opportunities, the adoption of Quality Assurance programs and the improvement of Lab-Clinical Interface
- Promote test access through collating and sharing product validation data

1. Raising awareness

- POC Meeting, Addis Ababa, Ethiopia, May 2012
- Looking forward to convening policy makers, MOH leaders and partners, donors



Observational study (Ongoing)

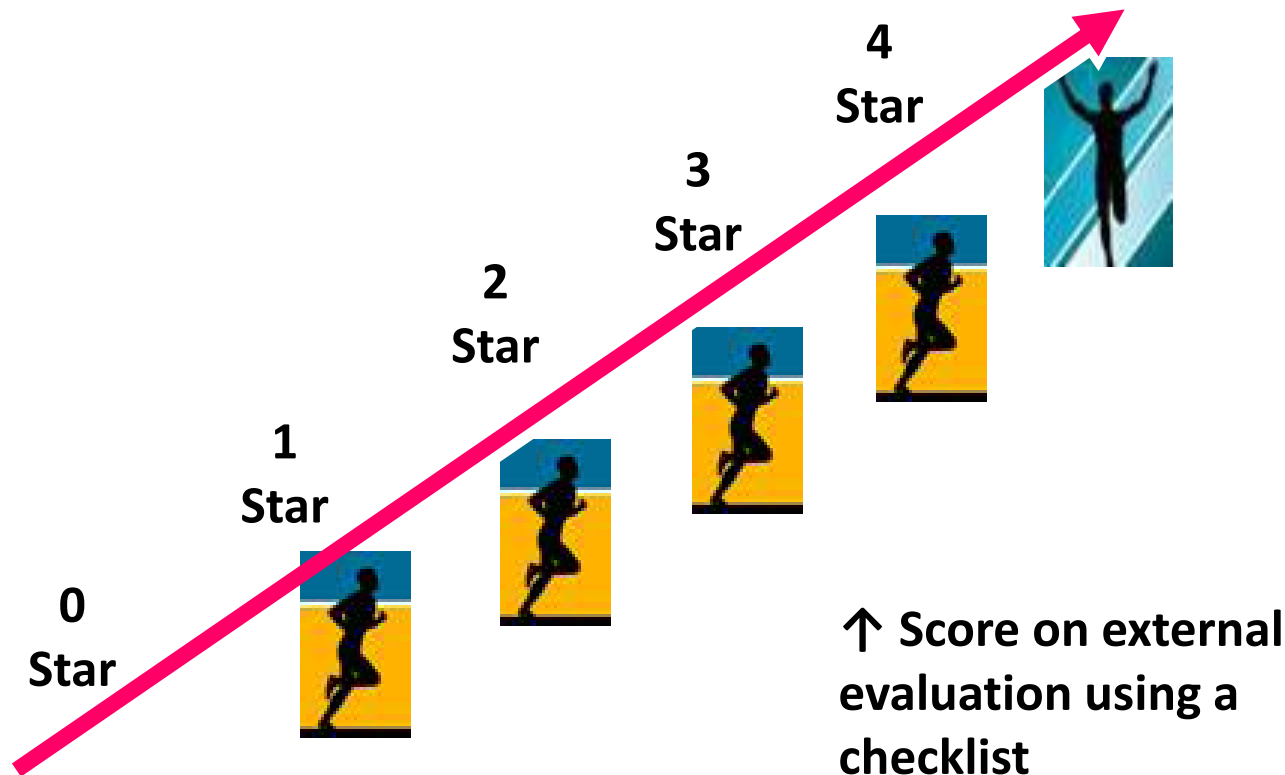
Aims

1. To determine the prevalence of CrAg in plasma among PLHIV with CD4 count ≤ 200 cells/ μ l attending Mbabane Government Hospital.
2. To understand the factors associated with positive plasma CrAg and CSF CrAg among PLHIV (CD4 count ≤ 200 cells/ μ l) attending Mbabane Government Hospital.
3. To evaluate the feasibility and barriers to routine CrAg screening and preemptive treatment among PLHIV (CD4 count ≤ 200 cells/ μ l).
4. To share lessons learned and the implications for a national roll out of a CrAg screen and treat program.
5. To determine the sensitivity of urine for CrAg LFA compared with CrAg plasma in the study population*

- Nearly 100 participants have been recruited since (August – November 2014)
- Response rate however has been low
- Study originally for 4 months
 - May be extended to 6 months to reach the required sample size

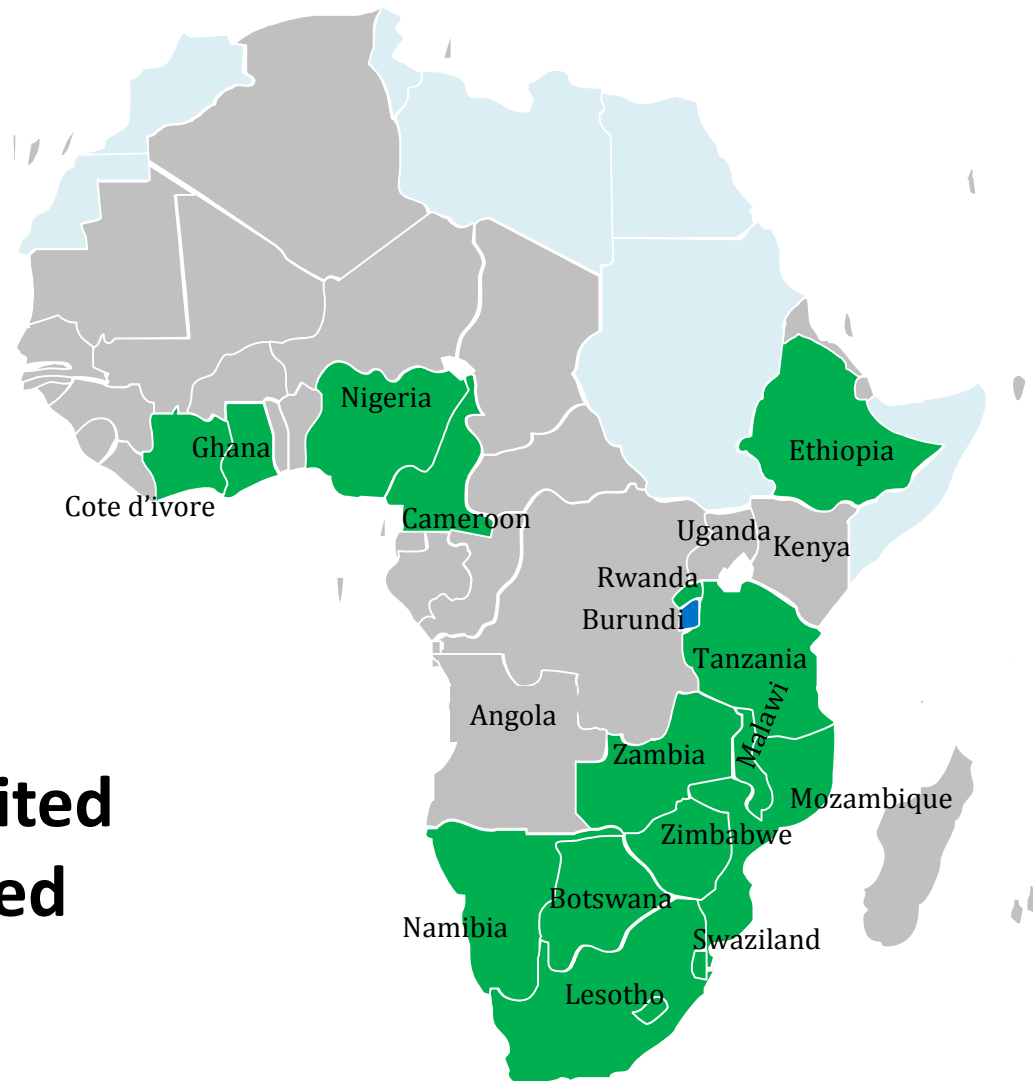
2. Strengthening Laboratory capacity

SLIPTA: A framework to encourage, support and recognize the implementation of QMS in medical laboratories in a stepwise manner

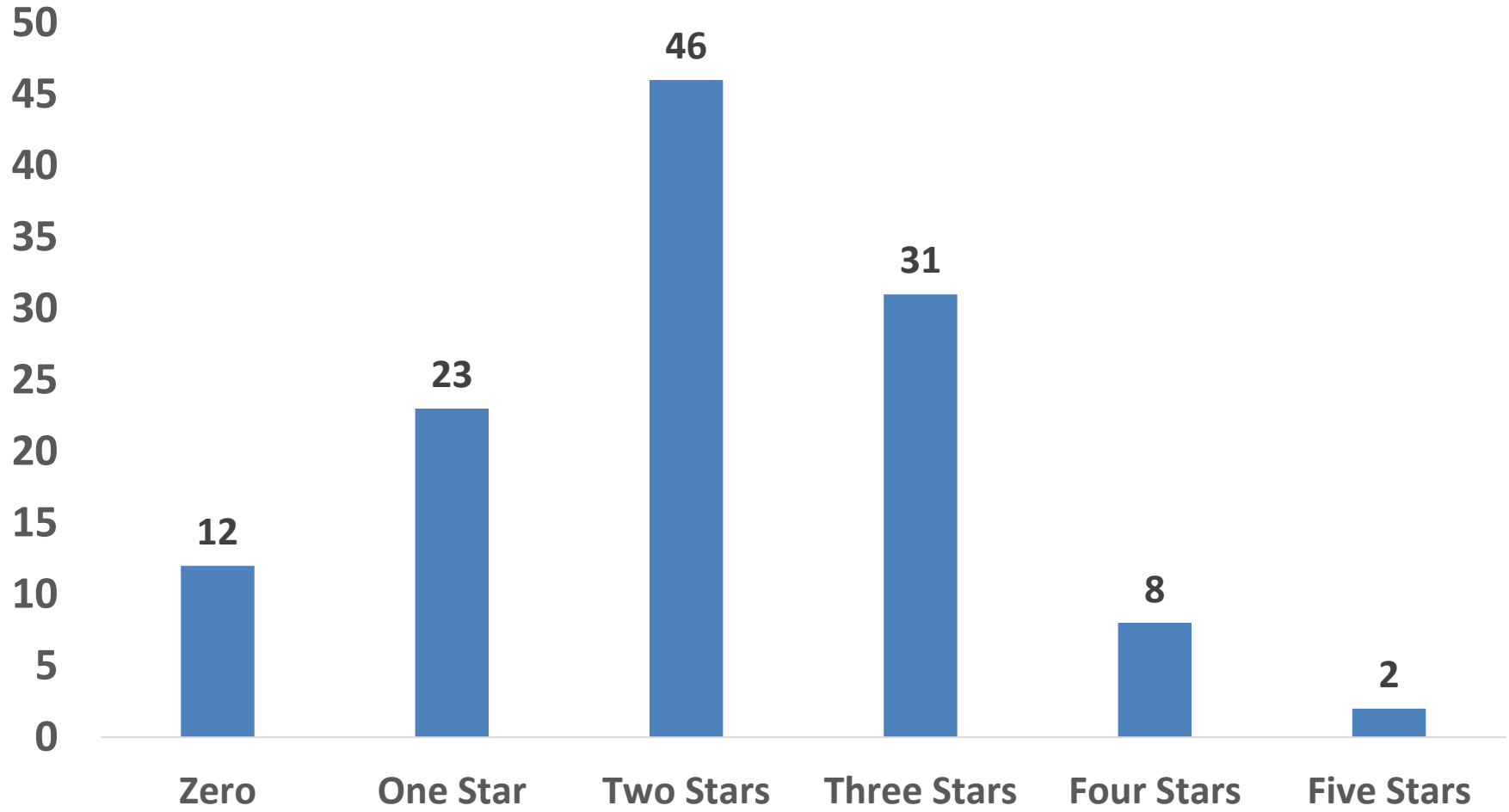




16 Countries visited
132 labs Audited



Audited Laboratories: Star Distribution (n=122)



- Curriculum development
 - Sudan
 - Cameroon
- Conducted in service trainings including mentorship and ISO standard trainings
 - Namibia
 - Tanzania (planned)



Regional meetings to develop regulatory mechanisms

- ASLM plays an advocacy role
 - ✓ Promote timely new technology introduction
 - ✓ Quality products
- Support regional organisations in moving this agenda



Report of

The 2nd African Regulatory Forum on Medical Diagnostics

Cape Town, South Africa

21-24th January 2014



EAST AFRICAN COMMUNITY REGIONAL PROJECT ON HARMONIZATION AND STRENGTHENING OF THE REGULATION OF MEDICAL DEVICES AND DIAGNOSTICS

**A REGIONAL PROJECT OF THE EAST AFRICAN COMMUNITY (EAC) IN
COLLABORATION WITH THE WORLD HEALTH ORGANIZATION
(WHO), THE AFRICAN UNION (NEPAD AGENCY), THE LONDON
SCHOOL OF HYGIENE AND TROPICAL MEDICINE (LSHTM) AND THE
AFRICAN SOCIETY OF LABORATORY MEDICINE (ASLM), THE ASIA
HARMONIZATION WORKING PARTY (AHWP) AND OTHER PARTNERS**

THANK YOU

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE