



NATIONAL HEALTH
LABORATORY SERVICE



Accrediting Laboratories in the Speed of Light – The South African Experience

SLMTA/SLIPTA SYMPOSIUM

**EXPERT PANEL #2 – ACCREDITATION:
GETTING THERE AND STAYING THERE**

Presenter: Patience Dabula

Date: 08 Dec 2018

Overview

1. Background
2. Methods
3. Results
4. Challenges
5. Benefits
6. Way forward



- Established in 2001 - Act of Parliament
- Laboratories
 - Footprint in nine provinces in South Africa
 - Over 200 diagnostic laboratories + Depots country wide
 - Mandate:
 - provide cost-effective and efficient health **laboratory services** to all **public sector** healthcare providers;
 - support and conduct **health research**; and
 - provide **training** for health science education.
 - Academic Laboratories linked with all 10 Universities that have Medical Schools
- Services about 80% of the South African population
- Employs over 7000 people
- Head office in Sandringham in Johannesburg



Background

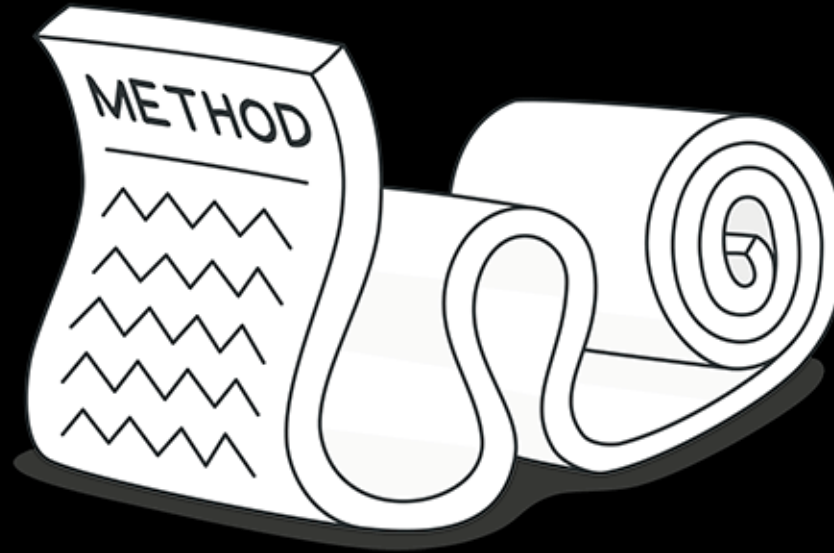
- The South African National Accreditation Systems (SANAS) is recognised by the South African Government in Act 19 of 2006 as the single National Accreditation Body
- The NHLS Strategy includes accreditation of diagnostic laboratories as one of its goals.
 - First laboratory audited in 2001
 - 20 laboratories were accredited in 2014
- NHLS facilities has achieved the following accreditation and certification:
 - ISO 15189 for Medical laboratories
 - ISO/IEC 17025 for testing and calibration laboratories
 - ISO/IEC 9001 for production and support service departments
 - ISO/IEC 17043 for PT scheme providers
 - And other authorities
- More than 80 staff full time employed in Quality Assurance



Aim

To implement the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme and the World Health Organization's Stepwise Laboratory Quality Improvement Towards Accreditation (WHO – SLIPTA) audit Checklist in order to increase the number of accredited laboratories in the NHLS





Method – 1

Focal point and Register labs

Nov 2012

Dr Yogan Pillay (Deputy Director General of Strategic Health Programmes for the South African Department of Health (DoH) Appointed **Dr Frew Benson** (Chief Director Of Communicable Diseases for DoH)

The Chief Executive Officer (CEO) of the NHLS Mr Sagie Pillay appointed **Patience Dabula** (National QA Manager) as the SLIPTA contact person

South Africa registered the first SLMTA laboratories in 2013



Method 2 - SLIPTA Auditor Training

1st - Dec 2012

Participants from 3 Countries

- 17 South Africans
- 1 Swaziland
- 1 Lesotho



2nd - Feb 2014

Participants from 2 Countries

- 16 South Africans
- 7 Swaziland



3rd - June 2014

Participants from 2 Countries

- 16 South Africans
- 2 Swaziland
- 2 Malawi



4th - Feb 2016

- 15 South Africans

5th - Feb 2018

- 26 South Africans



SLIPTA Master Trainers



**Dr Talkmore
Maruta**
Zimbabwe /
Lesotho / SA



**Nqobile
Ndlovu**
Zimbabwe /
Uganda



Janet Scholtz
NHLS
South Africa



Teferi Menekom
Ethiopia



**Preethamber
Ganputh**
NHLS
South Africa



Esther Tsheola
NHLS
South Africa



**Sikhulile
Moyo**
Zimbabwe /
Botswana

Method 3 – Training of Trainers

1st - Kenya In Country Apr 2012

- 1 Participant

2nd – In country Mar 2013

Participants from 4 Countries

- 17 South Africans
- 2 Cameroon
- 1 Zambia
- 1 South Sudan

3rd - In country Sep 2014

Participants from 3 Countries

- 18 South Africans
- 2 Nigeria
- 2 Angola

4th - ACILT ToT in South Africa 2015

- 2 South Africans

5th - ACILT ToT in South Africa 2016

- 3 Participants

6th - CDC ToT in South Africa 2018

- 3 South Africans



In Country

SLMTA ToT Master Trainers

Botswana, Cameroon, Ghana, South Africa, Zambia & Zimbabwe



Method – 4 Workshops

Preparation meeting for Trainers

Trainers met before each workshop to:

- Prepare for workshops
- Refamiliarise themselves with the material
- **Adapt some training tools** to existing NHLS methods e.g. document control, inventory management
- **Introduce new training modules** important for accreditation e.g. management review Meeting

Three Cohorts completed

	Pilot /Cohort 1	Cohort 2	Cohort 3
Workshop 1	May 2013	Oct 2014	Oct 2016
Workshop 3	Jan 2014	Jun 2015	Jun 2017



Method – 3.5 Internal Audits

3.6 External audits

Audits conducted using WHO – SLIPTA checklist

- Internal SLIPTA Audit by NHLS certified auditors
- External SLIPTA by ASLM



Stepwise Laboratory Improvement
Process Towards Accreditation
(SLIPTA)
Checklist

Audit preparation meeting

- Auditors meeting – ISO 15189 and checklist

Auditor



Auditees

- Auditee meeting - ISO 15188 and checklist

Auditee

www.emmasaying.com



Method – 3.6 Standardization of Procedures (SOP)

**IDENTIFY WHAT YOUR NEEDS ARE TO ENSURE ANY
ASSISTANCE YOU GET ADDRESSES YOUR NEEDS**

Standardisation of SOPs at national level

- **Appointed two consultants - APHL**
 - Previous NHLS staff
 - Both SANAS Assessors
 - Appointed for 5 weeks each
- **Used other consultant for lab user handbook**
 - Discipline specific experts
 - Representation from different provinces



NHLS SANAS Accreditation steps

1. Management commitment

- NHLS Strategy
- Lab identified, included in management Annual Performance Plan

2. Accreditation plan

- Prepare a plan with responsibilities and resources needed

3. QA Monthly checklist used (FMQ0029)

- Created a QA checklist from SLIPTA checklist section 2 and other questions

4. Quarterly progress report (self assessment tool FMQ0001)

- Laboratories do self assessments using a form created with all ISO clauses

5. Local QA Audits

6. Application to national office for final audit

- Local QA commits to compliance to key areas e.g. verifications, PT, MRM

7. Pre SANAS Audits

- NHLS employed SANAS Assessors and experienced Auditors
- Team use SANAS checklists

8. Application sent to SANAS for initial assessments





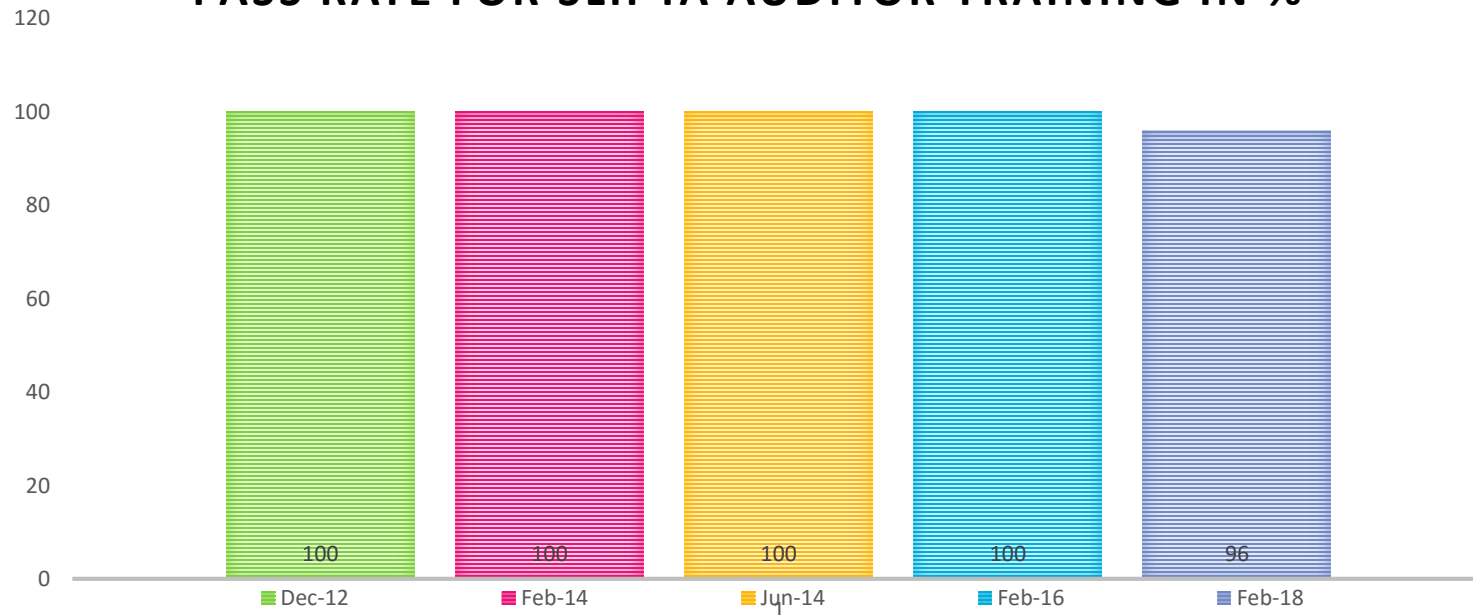
RESULTS 1 : SLIPTA Auditor Training

N = 90 - 15 = 75

15: 4 retired, 11 resigned

Dec 2012 = 17, Feb 2014 = 16, Jun 2014 = 16, Feb 2016 = 15 and FEB 2018

PASS RATE FOR SLIPTA AUDITOR TRAINING IN %



**18 NHLS ASLM
Auditors certified**

**Countries audited
by NHLS staff
on behalf of ASLM**

- 1. Lesotho**
- 2. Kenya**
- 3. Malawi**
- 4. Mozambique**
- 5. Namibia**
- 6. Tanzania**
- 7. Uganda**
- 8. Zambia**
- 9. Zimbabwe**



Results – 2 SLMTA ToT

N = 39 - 8 = 31

8: 2 retired, 6 resigned

Results: Pass Rate

ToT 1- 94% (16/17) ACILT 1 - 100% (2/2) ACILT 3 - 66%(2/3)

ToT 2 – 90% (18/20) ACILT 2 - 33% (1/3)

NHLS SLMTA Master Trainers: South African Master Trainers



Janet Scholtz

Uganda

Aug 2014



Preethamber Ganputh

SA In Country

Sep 2014



Esther Tsheola

Uganda

Aug 2014



Roy McFarlane

SA In Country

Sep 2014

Total SLIPTA Audits = 9

- 6 sets of internal audits annually from 2013 till 2018



- 3 External

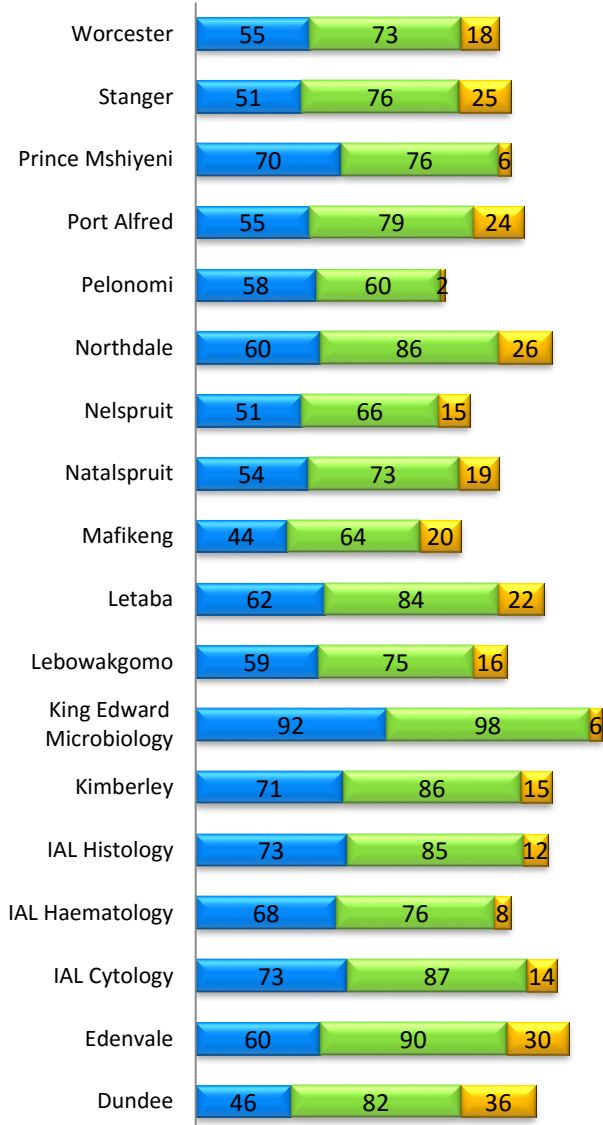


Year	Baseline	Exit	Follow Up	ASLM
2013				
2014				
2015				
2016				
2017				
2018				
Total	3	3	4	3

Results 3 Internal SLIPTA AUDITS

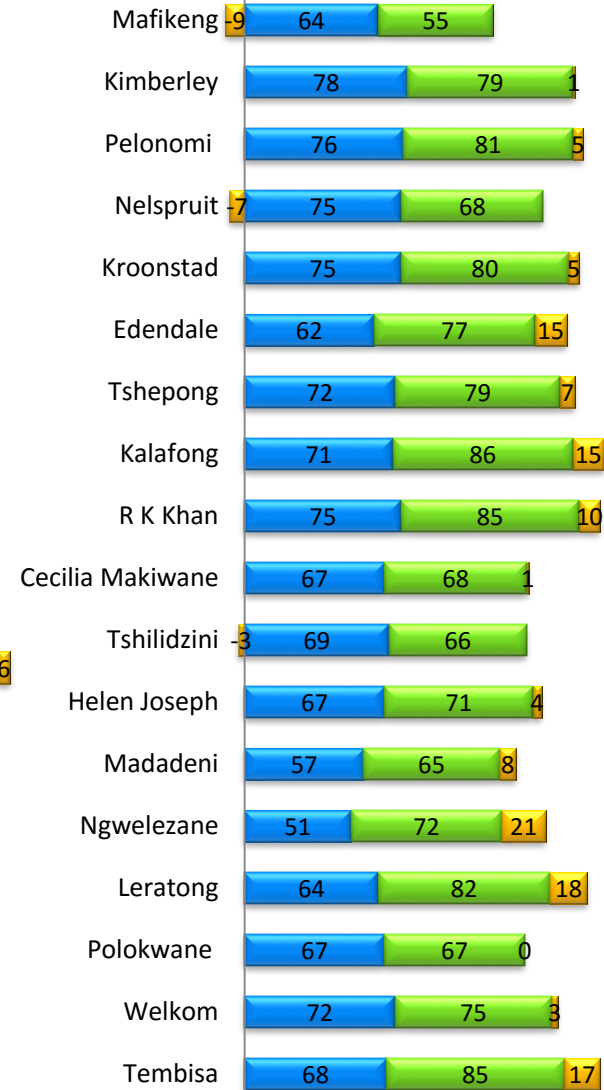
Cohort 1

■ Baseline %



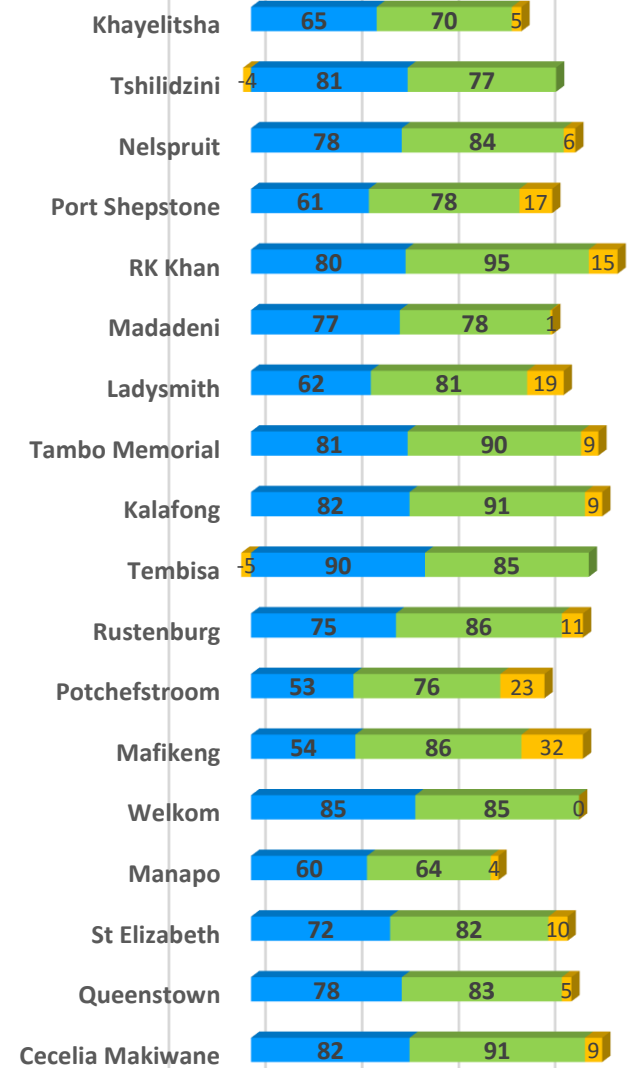
Cohort 2

■ Percentage at Exit



Cohort 3

■ Difference



Results – 4 External Audits

ASLM SLIPTA AUDITS 14 – 24 Jul 2014

Auditors from the following Countries
Botswana, Ghana, South Africa Trainees, Swaziland, Uganda, Zambia and Zimbabwe

CDC Sings the SLMTA song with NHLS
NHLS Northdale laboratory achieves 5 star after SLIPTA audit

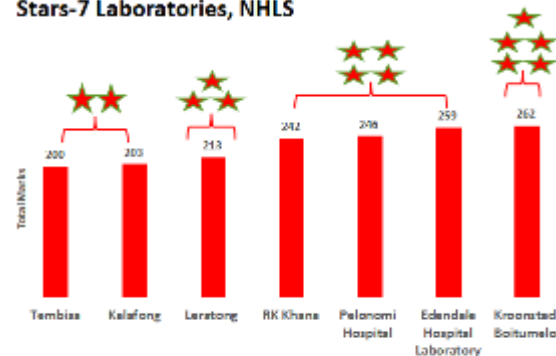


ASLM SLIPTA AUDITS

21 – 30 Jun 2016



Stars-7 Laboratories, NHLS



ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

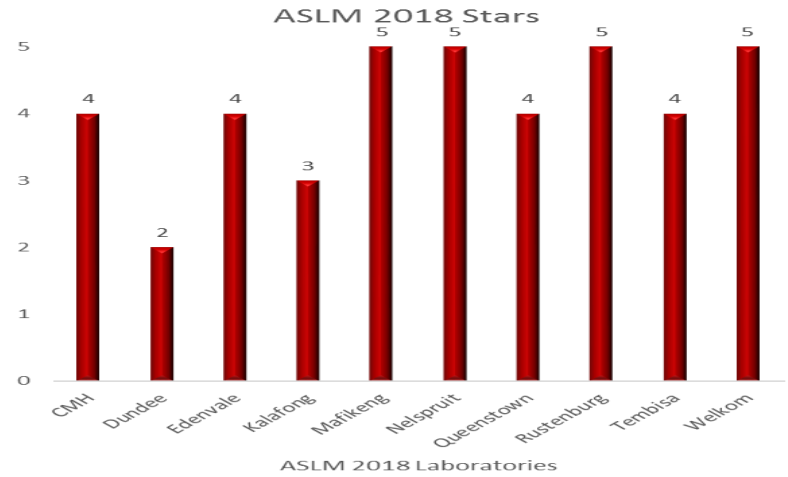
ASLM

Auditors were from the following Countries:

Nigeria, *South Africa Trainees*, Tanzania, Uganda and Zimbabwe



ASLM 2018



Results 4.5: SOP Standardization

- **One Quality manual in the NHLS**
 - Design QMS
 - Dictates standard procedures
- One Safety Manual
- Common policies – IT, HR, Finance
- 20 SOPS standardized - APHL consultants
- One laboratory user book used
- 13 procedures standardized by NHLS staff
- 7 national forms standardized



Results 4.5: SOP Standardization

ISO 15189 clauses – Examples from NHLS type

4.1 Organisation and Management responsibility **Ethics, Confidentiality, Communication, Organograms**

4.2 Quality Management System

4.3 Document Control
SOP for SOPs, Doc control, Q Pulse

4.4 Service Agreements

4.5 Examination by referral laboratories

4.6 External services and supplies

4.7 Advisory services

4.8 Resolution of complaints

4.9 Identification and control of nonconformities

4.10 Corrective action

4.11 Preventative action

4.12 Continual improvement

4.13 Control of records
QA Checklist

4.14 Evaluation and Audits
Audits, Risk management, Quality Indicators,

4.15 Management review

5.1 Personnel Orientation, Training, Competency

5.2 Accommodation and environmental conditions

5.3 Laboratory equipment, Equipment and Reagents (inventory management)

5.4 Pre-examination processes

5.5 Examination processes

5.6 Ensuring the quality of examination results
IQC and EQA review

5.7 Post-examination processes

5.8 Reporting of results

5.9 Release of results
Auto review

5.10 Laboratory Information system

Accredited SLMTA laboratories

15/35 (42.8%) SLMTA laboratories accredited in Dec 2018

No.	Laboratory	Cohort	Province (8/9)	Year of accreditation	No. of SANAS visits
1.	Northdale	1	KZN	2015	4
2.	Tshepong	2	North West	2016	3
3.	Kimberley	1 and 2	Northern cape	2017	2
4.	Kroonstad	2	Free State	2017	2
5.	Edendale	2	KZN	2017	2
6.	Helen Joseph	2	Gauteng	2017	2
7.	Pelonomi	1 Control and 2	Free State	2017	2
8.	Ngwelezane	2 and 3	KZN	2017	2
9.	RK Khan	2	KZN	2018	1
10.	Worcester	1 and 2	Western Cape	2018	1
11.	Stanger	1 and 2	Western Cape	2018	1
12.	Tambo	3	Western Cape	2018	1
13.	Letaba	1	Limpopo	2018	1
14.	Cecilia Makiwane	2 and 3	Eastern Cape	2018	1
15.	Thelle Mogoerane (Natalspruit)	1	Gauteng	2018	1

All accredited laboratories have maintained accreditation with 8 laboratories having more than one visit.

- Monthly QA checklist used to monitor maintenance
- Laboratory maintains QMS on all ISO clauses esp.
 - Document Control
 - Management review
 - Complaints monitoring
 - IQC and PT
- Internal audits
 - Local laboratory
 - QA support
- Monthly reports
- Quarterly strategic report to top management and the Board





Challenges

- Trainer and Auditor
 - Release of Trainers and Auditors due to other conflicting commitments in Area
 - Resignations from the NHLS reduces number
 - Inactive Trainers and Auditors
- Participants
 - Resignations from the NHLS reduces number
 - Workshop drop outs due to different reasons
 - Improvement projects
 - Not done during Trainer Laboratory visits
 - Not completed when coming to workshops
- Handling of appeals following audits
- Support from relevant **key** stakeholders



Benefits to the NHLS

- All QA staff in country come together - exposure
- Resources for national meetings
- Additional Trainer workshops
 - QC and Validation
 - SLMTA 2
- Additional workshops in NHLS
 - SLMTA Modules workshop
 - ISO 15189:2012 transition
 - QC workshops
- Exposure to resources outside south Africa for advise
- QI Monitoring tools
- Improved SOPs
- Improved training methods
 - IPs from training
- Creation and implementation of FMQ0029
- International recognition
 - Awards
 - Master Trainers
 - ASLM Auditors
- **Improved accreditation results**

Accreditation in the NHLS

20 – 55 laboratories accredited since 2014, Labs in bold accredited in 2018. **RED = SLMTA Labs** **Purple - Six applications with SANAS** and *Italics – ASLM SLIPTA AUDITS*, **Blue - labs passed Pre SANAS audits**

No	Province	Laboratories	No
1.	Eastern Cape	Aliwal North , Cecilia Makiwane , Dorah Nginza, Dr Malizo Mpehle memorial , East London, Livingstone, Madzikane ka Zulu , Mount Ayliff , Nelson Mandela Academic and Port Elizabeth (Willowvale + Queenstown)	10/ 38
2.	Free state	National Stat Lab, Kroonstad , Pelonomi and Universitas	4/ 9
3.	Gauteng	Braamfontein, Chris Hani Baragwanath, Charlotte Maxeke, Dr George Mukhari, Helen Joseph , Tambo , Thelle Mogoerane , and Tshwane Academic Division	8/ 24
4.	Kwazulu Natal	Addington, Catherine Booth , Edendale , Greys, King Dinuzulu , Kokstad , King Edward, Kokstad, Inkosi Albert Lithuli (+IAL Cytology IAL Histology), Mahatma Gandhi, Ngwelezane , Northdale , Prince Mshiyeni , Public Health, RK Khan and Stanger (Christ the king + Emmaus)	16/ 49
5.	Limpopo	Letaba , Matlala and Mankweng (Ellisras + Sekororo)	3/ 37
6.	Mpumalanga	Ermelo & Witbank	2/ 19
7.	Northern Cape	Kimberley and (De Aar)	1/ 5
8.	North West	Tshepong	1/ 11
9.	Western Cape	George, Greenpoint, Groote Schuur, Karl Bremmer , Paarl , Red Cross, Tygerberg and Worcester (West Coast)	8/ 17
10.	Institutes	National Institute for Communicable Diseases National Institute for Occupational Health	2/2
TOTAL			55 / 218

Summary of accreditation table

- The NHLS moved from 20 to 55 laboratories accredited since 2014
- All nine provinces have laboratories accredited
- **27/52 (52%) district municipalities** have accredited laboratories
- A total of **15/36 (42%) SLMTA laboratories** in 7 provinces are accredited since the first laboratory was registered in 2013.
- **13/31 (42%) laboratories audited by ASLM** in 7 provinces are accredited since the first ASLM in 2014
- Six applications have been sent to SANAS
- Two more laboratories have passed final audits and applications are being processed



- In House Training
 - Possible as NHLS has three Master Trainers
- Sustainability plan beyond funding
 - NHLS learning academy for workshops
 - NHLS QA budget for auditing

**Present
Situation**

Acknowledgements

- NHLS Management
- Sibongile Zimuto
- Professor Wendy Stevens
- Dr Talkmore Maruta – SLMTA and SLIPTA Master Trainer
- African Center for Integrated Laboratory Training (ACILT)
- Master Trainers outside SA – SLMTA and SLIPTA
- NHLS Staff
 - NHLS QA Managers
 - NHLS Grants office staff
 - NHLS SLMTA Trainers
 - NHLS SLIPTA Auditors
 - SLMTA and QA Staff
 - NHLS Communications and Marketing department: especially Guy Hall
- Participants - Pilot – 48, Cohort 2 – 81 and Cohort 3 - 74 = 203 + extension in laboratories



This activity is supported by NHLS and the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of [5U2GPS001328].

