NATIONAL TB REFERENCE LABORATORY (NTRL)

ANNUAL PROGRESS REPORT October 1, 2018 - September 30, 2019

Reference Laboratory

Timely Accurate Diagnostics for a TB-Free Africa



MINISTRY OF HEALTH

Who We Are

Mission

Provide quality laboratory services and strengthen SRL diagnostic network through leadership and expert guidance; and reduce the burden of TB in supported countries.



Every person in Sub-Saharan Africa has access to quality TB diagnostic services.

Our Values

Innovative: Freedom, Decisiveness, Creativity, Independent

Integrity: Honest, Standard Adherence, Ethical

Professional: Quality, competent, knowledgeable, responsive, accountable.

Community: Respect, Trust, Cooperation, Loyalty, Security, Relationship, Friendship

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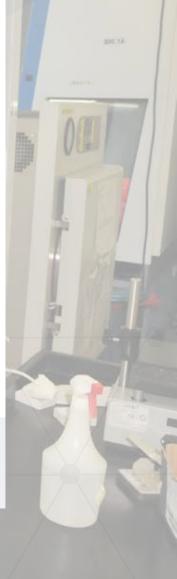
Editorial & Design

Niche Kreative Limited









LIST OF ACRONYMS

AFB	Acid Fast Bacilli
BSC	Biological Safety Cabinets
BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention
NTRL	National Tuberculosis Reference Laboratory
NTLP	National Tuberculosis and Leprosy Program
DST	Drug Susceptibility Testing
EQA	External Quality Assessment
FM	Fluorescence Microscopy
IQC	Internal Quality Control
ISO	International Organization for Standardization
IJ	Lowenstein Jensen
LPA	Line Probe Assay
LIMS	Laboratory Information Management System
LQMS	Laboratory Quality Management System
MDR-TB	Multi Drug Resistant Tuberculosis

MGIT	Mycobacteria Growth Indicator Tube
МоН	Ministry of Health
МТВ	Mycobacterium tuberculosis
NALC	N-Acetyl L Cysteine
NGO	Non-Governmental Organization
NTLP	National Tuberculosis and Leprosy Programme
NTM	Nontuberculous mycobacteria
QA	Quality Assurance
SOP	Standard Operating Procedures
SRL	TB Supranational Reference Laboratory
SANAS	South African National Accreditation System
тв	Tuberculosis
KOFIH	Korea Foundation for International Health Care
wно	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis
Xpert	Xpert MTB/RIF assay (Cepheid, Sunnyvale Ca, USA)
ZN	Ziehl Neelsen Stain

GLOBAL FUND EXTENTS FUNDING FOR REGIONAL TB LAB STRENGTHENING PROJECT

The grant making team in a group photo at the NTRL/SRL complex in Butabika, Kampala



ECSA-HC, led by the Director General, Prof Yoswa Dambisya and SRL Uganda led by the Director, Prof Moses Joloba, convened at the National TB Reference Laboratory in Butabika, Uganda between 26th and 29th March 2019, for a grant making meeting with officials from Global Fund led by the Senior Fund Portfolio Manager, Paul McCarrick. The three-day meeting was aimed at discussing the strategies of consolidating and scaling up the gains made during the first phase of project implementation, whilst mitigating the challenges faced using proven solutions. It was also intended to harmonize grant documents, proposed workplan, budget and performance framework with the available funding for the second phase of the regional TB lab strengthening project.

The meeting was preceded by a visit to the Permanent Secretary Ministry of Health (MOH) Uganda, who applauded the role of the regional grant in improving TB diagnostics and creating a stronger regional TB lab network in Uganda and the region. The Permanent secretary, on behalf of MOH, committed to supporting Uganda SRL, as best, to ensure sustainability of positive project results.

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SRL Uganda staff in a group photo after a training session. Continous training and mentorship is key to maintaining high quality standards

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FOREWORD BY THE DIRECTOR

Thank you for taking time to read about us. Your interest in learning more about us and what we do in the world of TB in Africa is yet another opportunity for us to share our story, and inspire one more person to join the fight against TB.

As the National TB Reference Laboratory (NTRL) of Uganda, our story is one of an arduous journey of resilient commitment to eliminate TB in Uganda.We started out as the Uganda Bacteriological Investigation Unit in the 1950s, evolved and grew over the years to become known as NTRL in the 1990s.We are statutorily established under the National Tuberculosis and Leprosy Program (NTLP) of the Ministry of Health.

> I am also pleased to inform you that owing to the Uganda government's support and commitment to fight TB that culminated into our overall good performance in TB diagnostics, NTRL Uganda received accreditation from the World Health

Organisation (WHO) in April 2013, making us the first Supranational TB Reference Laboratory (SRL) in Sub-Saharan Africa and the second after Algeria in Africa.

Consequently, we now serve a dual purpose as NTRL Uganda; and on the other hand, as SRL Uganda. While we continue to diligently execute our mandate as NTRL Uganda, we now have the added responsibility of supporting other NTRLs in East, Central and Southern Africa (ECSA) region to improve their TB diagnostics. The extra responsibility has served to help us forge new friendships and partnerships and this has seen a sharp rise in our overall capacity across board in terms of human resource and training, up-to-date world class technology and overall improvement in testing for TB in Uganda.

Beyond achieving the supranational lab status, we have continued to strive to improve our services to serve our clients better. To that effect, NTRL has since received accreditation from the reputable South African National Accreditation System (sanas) for 'Medical Testing Laboratory Tuberculosis and Molecular Tuberculosis' – ISO 15189:2012 in May 2018; as well as further accreditation from sanas for 'Proficiency Testing by Interlaboratory Comparisons' – ISO/IEC 17043:2010 in October 2018 further attesting to our world-class technical competency in TB diagnostics.

None of the achievements would have been possible without the tremendously committed team at NTRL; the confidence, support and guidance from government, our founders and all partners. We immensely appreciate your support. I do sincerely hope that you enjoy reading this report and get to know more about our work at NTRL.

On the SRL front, under the Global Fund supported 'Regional TB Lab Strengthening Project' in partnership with the East, Central and Southern Africa Health Community (ECSA-HC), we currently support and mentor national TB Labs of 21 countries in the region to build resilient and sustainable TB diagnosis systems.

Prof Moses Joloba - Director NTRL Uganda / SRL Uganda

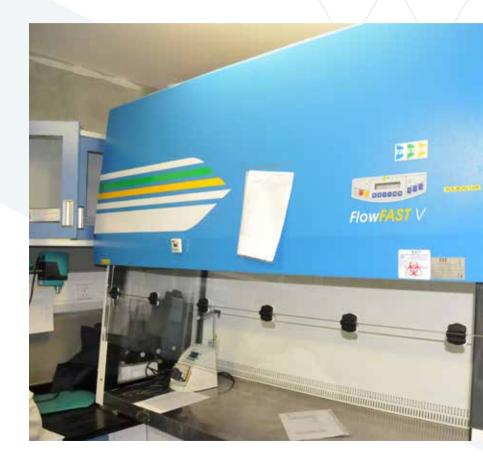


Session in progress: A section of members discussing the performance framework during the grant making meeting, in Kampala Uganda

ECSA-HC and NTRL/SRL Uganda teams worked closely, in groups each with a Global Fund representative to address comments and incorporate recommendations by the donors, into the extended funding portfolio.

INTRODUCTION

The national TB services delivery platform in Uganda is composed of the National TB and leprosy programme (NTLP) which is mandated to oversee the overall TB service delivery in the Country. The national TB Reference laboratory (NTRL) is mandated to oversee the TB laboratory service delivery in the country. The laboratory is a main pillar in the End-TB strategy and a strong TB laboratory network is key towards TB control. The Uganda NTRL has a well-organized functional network of laboratories made of [52] intermediate and peripheral laboratories. Laboratory services are arranged with support supervision from the NTRL and intermediate labs to the peripheral labs. NTRL provides leadership and technical guidance to all laboratories in the national TB laboratory diagnostic network so they can provide quality laboratory services that contribute to the reduction of the TB and leprosy burden in the country. Additionally, NTRL provides laboratory services for TB diagnosis, surveillance and monitoring. The NTRL is a WHO designated supranational TB laboratory (SRL), one of only three SRL in the WHO-AFRO region to receive that status. The intermediate and peripheral labs offer GeneXpert testing smear microscopy services. The NTRL Uganda is one of the few countries globally that managed to implement a functional External quality assessment (EQA) for smear microscopy since 2005 through blinded rechecking. With the introduction of GeneXpert, the country established a hub system where by sites without Xpert machines refer samples to sites with Xpert machines for testing.



EXECUTIVE SUMMARY

During 2018/2019 NTRL Uganda has shown remarkable improvement in TB service delivery system through quality smear microscopy and Xpert testing systems, the country laboratory network, Laboratory Quality Management systems (LQMS) owing to attainment of ISO 17043 accreditation, maintenance of ISO 15189 accreditation. Improved TB data Recording and information Reporting, sample referral system and EQA for smear and Xpert.

Uganda started implementing Xpert testing strategy in 3 sites with 3 machines (i.e. NTRL, Murchison Bay and Lira) and currently has 237 Xpert testing sites (with 259 machines) among the 1,521 TB diagnostic centers. This difference in number of sites indicates that these two testing methods are still complementary for some time before full implementation of Xpert for all strategy.

NTRL Uganda conducted training and capacity building national refresher trainings in ZN microscopy for 205 peripheral lab staff in Masaka and Bukomansimibi.

In May 2019, AHD Data call was made to 706 Health facilities (HFs) across all health regions, covering the period of Jan-June 2019. Data was received from approximately 85% (604/706) of the HFs. Of these, 62% (373/604) reported that they had completed a training of health workers in Advanced HIV Disease management, 55% (206/373) health facilities reported data on Urine TB LAM.

Through its role as a regional SRL, the lab conducted various activities towards achieving its mandate including: Trainings of Quality Management systems, Bio safety and Bio security, TB data management, developing of TB lab National Strategic plans, providing External Quality Assurance panels for all 18 project countries, support and mentorship for Drug Resistant and TB prevalence surveys and in 4 countries, Benchmarking visits at SRL for 63 staff across ECSA subregion, supported the adoption and integration of TB Laboratory Information Management Systems in 4 countries, training of NTRLs in WHO recommended TB diagnostics, supporting the TB lab capacity assessments across 6 African countries.



A lab scientist at work. Using a range of technologies, we ensure reliability of TB laboratory results through proficiency testing

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1.0 MICROSCOPY NETWORK

Smear microscopy using Ziehl Nielsen (ZN) microscopy remains the first diagnostic test for most presumptive TB patients. District laboratories performing ZN increased from 1,521 in Implementation year 2017/18 to 1667, during the Implementation year 2018/2019, with over 1,000 of the facilities with ZN smear microscopy services owned by the government and 230 by private not-for-profit organizations. An estimated 15% (of diagnostic facilities have microscopes that are semi/none functional or monocular. The national TB microscopy network remains the more accessible diagnostic means to the TB Patients to as low as Sub county levels. The Microscopy network has more than doubled in the last 10 years from 839 Diagnostic units in 2009 to 1667 by the end of 2018. The Uganda TB Microscopy network is currently 90% light microscopy and about 10% Fluorescent Microscopy.

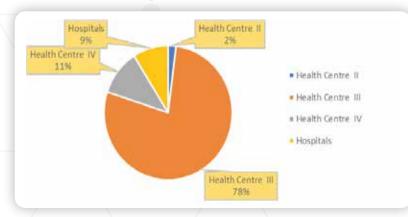


Table 1: Summary of Microscopy TB diagnosticHealth Facilities by Level

Level of Health Facility	Number of Microscopies
Health Centre II	33
Health Centre III	1301
Health Centre IV	184
Hospitals	49
Total	1667

More than 80% of the smear microscopy for diagnostics is currently done at the Health center II(s) and III(s). Majority Health Center IV and Hospitals are focused Genexpert sites and mostly do microscopy for treatment follow-up.

Graph I: Summary of Microscopy TB diagnostic Health Facilities by Level



Smear Microscopy for diagnostics is currently mostly done at the Health center II(s) and III(s) and those sites above Health centre III without GeneXpert part machines. All the other sites currently mostly do microscopy for treatment follow-up

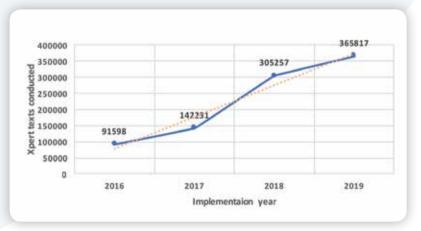
Key Achievements in the Microcopy network

- I0 Microscopy sites upgraded from Light Microscopy to Fluorescent Microscopy, for example Arua region which received 4 Fluorescent machines from one of the implementing partners (GLRA). The sites that were identified for this upgrade included Lodonga HCIII in Yumbe district, Moyo mission HC III, Adumi HC IV in Arua district, and Nyapea Hospital in Zombo district.
- The Regional Equipment maintenance teams have had their capacity enhanced and have been able to do repairs in 98 Microscopy sites that had faulty and nonfunctional Microcopies.

2.0 **GENEXPERT NETWORK**

The GeneXpert network has developed between 2018 and 2019, there are currently 253 GeneXpert machines installed in 237 health facilities to improve access to early and rapid diagnosis of TB and DR-TB, this however accounts for only 16% coverage, 83 HCIVs are still operating without GX machines. 97% of the machines, and 93% of the modules within the GeneXpert Network are functional.

Graph showing a growing trend of GeneXpert tests conducted between 2016 and 2019





During the implementation period, there was a growing trend of RR/ MDR cases detected, the graph below shows an increasing trend between 2016 and 2019, which can be attributed to the increasing utilization of GeneXpert technology from 52% in 2016 to 77% in 2019.

Graph showing RR/MDR case Detected between 2016 and 2019



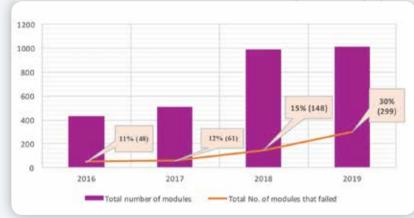
GeneXpert Module functionality and Replacement

During this reporting period, a total of 344 modules were replaced. 31% of modules were replaced within 5 working days and 49% within 10 working days. There is sharp reduction in GeneXpert equipment repair turnaround time, and evidently shows very limited equipment down time due to non-functional modules, largely attributed to signing the comprehensive service agreement between MOU and Cepheid Inc.

However, this being the first MoU signed by the company globally, there was a learning process which continued to improve over the

year, for instance 92% of faulty modules in August 2019 and 100% of faulty modules in September 2019, were replaced within 5 working days, thereby reducing down time.

Graph showing GeneXpert functional modules and module failure rate



GeneXpert Turn Around Time for machine repairs and servicing

In 2018/19 all GeneXpert machines with the network were serviced during a comprehensive equipment service campaign that was conducted, the campaign will be moved into a 2^{nd} phase of servicing for the machines which will be done along with on-going site interventions.

All machines were calibrated, except those at 3 sites, including Kangurumira HCIV, Kalagala HCIV and Kanoni HCII whose computers were reported lost or stollen. It should however

be noted that the local vendor initially faced delays in receiving XpertCheck kits from Cepheid to start the calibration process, however by end of April 2019, 95% of GeneXpert machines had been calibrated.

Software updates and upgrade carried out in all sites. This supported to ensure that all facilities transitioned to Xpert MTB/ RIF Ultra.

Graph showing the average turn around time for repair of GeneXpert Machines

(considering no. of days between when the break down is reported to when the machine is repaired)



NTRL provided timely remote technical support to GeneXpert users, which involved trouble shooting, resolving potential functional jams, and data reporting concerns through phone calls, e-mails and social media plat forms. Onsite training of users in GeneXpert



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sample processing and maintenance was conducted during site supervision visits. Overall the error rate reduced from 6% in 2018 to 3% in 2019, whilst increase in test workload, reduced equipment breakdown time.

Data Connectivity

All facilities have GxAlert software. However, due to challenges in implementation, only 9 Xpert sites are currently using the system. The NTRL is currently piloting a new software called LabXpert, this software is currently installed in 12 health facilities and 9 are very active. There is need to support the development and pilot of LabXpert software.

Challenges faced and Gaps identified in the GeneXpert Network:

- Lack of computer anti-virus installed in all sites, thus the need for routinely scanning and cleaning the operation system.
- 2 The need to conduct further capacity improvement for regional Biomedical engineers to carry out GeneXpert servicing.
- 3 Lack of an online software or connectivity solution to monitor GeneXpert repairs. Therefore, NTRL is only able to manually track the cases that have been reported by users either through watsup, email or phone call.

2.1 **TB DIAGNOSIS USING URINE TB LAM**

Uganda received a donation of 5000 Urine TB LAM test kits from ALERE in May 2016 and a pilot study was done in 2 NRHs and 14 RRHs in 2016. Following the pilot, Uganda adopted the use of LF- LAM in June 2017 and recommended its use among adult HIV positive presumptive TB patients with CD4 cell counts \leq 100 or very ill HIV positive presumptive TB patients regardless of CD4 cell counts. Since then the TBLAM test has been distributed to all RRH and District Hospitals and a limited number of HCIVs.

In October 2018, the MoH NTLP conducted an evaluation of the first year (June 2017 – June 2018) of Urine LAM implementation in order to guide countrywide scale up. Following this evaluation, Uganda incorporated Urine TB LAM testing into Uganda National guidelines for Advanced HIV Disease (AHD) Management in May 2019 and recommended its use among; (1) Adults and adolescent People Living with HIV (PLHIV) with CD4 \leq 200 cells/µL regardless of TB signs and symptoms (2) TB symptomatic PLHIV children with CD4 \leq 200 cells/µL (3) Seriously ill PLHIVs (including adults, adolescents and children) regardless of TB signs and symptoms and CD4 count or if CD4 count is unknown. The use of Urine TB LAM does not eliminate the need for other diagnostic tests such as GeneXpert MTB/RIF Ultra, culture or sputum-smear microscopy.



Performance progress on Implementation of Urine TB LAM in Uganda-(Data call Results)

In Uganda, 917 health facilities have been mapped and prioritized to offer a comprehensive package of care to all PLHIVs presenting with Advanced HIV Disease (AHD). These were selected based on the patient workload and accessibility of CD4 equipment.

In May 2019, AHD Data call was made to 706 Health facilities (HFs) across all health regions, covering the period of Jan-June 2019. Data was received from approximately 85% (604/706) of the HFs. Of these, 62% (373/604) reported that they had completed a training of health workers in Advanced HIV Disease management, 55% (206/373) health facilities reported data on Urine TB LAM. The overall training coverage on Advanced HIV Disease Management among priority HFs is 41% (373/917), as of July 15, 2019. Regional Implementing partners should prioritize AHD trainings across all health regions so as to bridge this huge gap.

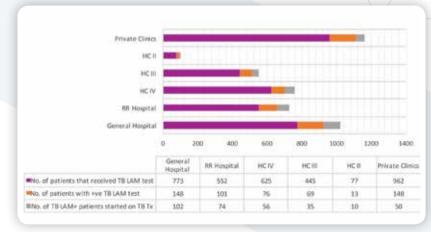
Utilization of Urine TB LAM

The utilization of Urine TB LAM in Uganda is still suboptimal. Results from the Jan-June 2019 data call indicated that 40% (3,453/8,597) of the PLHIV clients with CD4 \leq 200 cells/µL receive Urine TB LAM. Of the 40% AHD patients that received a urine TB LAM test, 16% (556/3,453) tested positive, and 59% (327/556) of these received TB treatment.

The low utilization of Urine TB LAM could be due to limited stocks of Urine TB LAM commodities nationally, knowledge deficiencies

among clinicians regarding the eligibility criteria for Urine TB LAM and limited coverage of Urine TB LAM across all DTUs among others. The reasons for low treatment coverage among TB LAM positive patients need to be investigated and mitigation measures implemented. In addition, there is an urgent need to scale up Urine TB LAM training to cover all the 917 AHD priority sites Furthermore, the quality of AHD trainings that were conducted across all health regions need to be assessed by NTRL/NTLP, and conduct targeted mentorships to all DTUs implementing Urine TB LAM

Graph showing Urine TB LAM tests conducted, rate of positivity and patients that receive treatment thereafter by level of care.



Out of 8597 HIV patients with a CD4 count of less than 200, 40% (3453) were subjected to a Urine TB LAM test, of whom 16% (556) patients were found to be positive for TB and 59% (327) were started on TB treatment.

3.0 **EXTERNAL QUALITY ASSURANCE**

There are 3 methods of External Quality assessment; Blinded Rechecking, Proficiency testing and Onsight supervision. Uganda as a country implements 3 methods concurrently; Blinded Rechecking for the Microscopy diagnostic network on a quarterly basis, Proficiency panel testing for the GeneXpert sites biannually and onsite evaluation (supervision) for both networks either as targeted for sites identified or the scheduled annual supervisions at whenever resource allow.



INCEPTION MEETING FOR PHASE II OF THE REGIONAL LABORATORY STRENGTHENING PROJECT



Delegates from 21 countries in East Central and Southern Africa Health Community - ECSA HC meeting at Radisson Blu, Nairobi to introduce Global Fund Regional TB Laboratory Strengthening Project to new countries.

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A Global Fund grant of USD 4,500,000 was been awarded to East Central and Southern Africa Health Community - ECSA HC in collaboration with the Ministry of Health of Uganda through National TB Reference Laboratory to support the Uganda SRL and other countries to improve TB Diagnosis in the ECSA region.

3. Blinded Rechecking EQA Scheme

Blinded Rechecking EQA, a WHO recommended system for External Quality assessment for Laboratories with functional microscopy networks was first introduced in the country in 2006 as a pilot in selected regions. The Microscopy network gradually increased and by the end of 2009, at least 810 of the 839 diagnostic facilities nationwide were participating in the scheme at the end of 2018 a total of 1255 facilities out of 1667 were enrolled on the scheme.

The average Regional Blinded Rechecking Participation during this period Oct 2018- Sept 2019 was 61% (National Target 80% per quarter). Regions like Fort Portal, Arua and Hoima and Kampala Central were able to achieve the 80% participation for one than one quarter in 2018. Regions Jinja, Gulu and Mbale registered the least participation rates.

An analysis of the National annual EQA data for the year 2018 shows that at 83% percent of all sites TB Microscopy participated in blinded rechecking for at least once as shown in Table 2



Table: Summary of Blinded Rechecking EQAPerformance Uganda 2018

	Number	Percentage
Number of operational laboratories	1,666	83%
Number of those rechecked (%)	1,389	
Number of positive slides rechecked	3,529	
Number of negative slides rechecked	27,957	
Overall percentage positives in laboratories'	7%	
routine		
Number (%) of laboratories with more than I	37	3%
HFP	140	74%
Number (%) of laboratories with 100% true positives		
Number (%) of laboratories with more than I	22	1%
FN		.,
	755	89%
Number (%) of laboratories as good as controllers at detecting positives (>=95%)		

Feedback Reports were sent to all Participatory Laboratories through with the CPHL Hub System or through the respective Regional Implementing Partners.

Achievements

- The Microscopy network has continued to grow from 1587 to 1667 Health facilities in 2018.
- More sites have continued to enroll and participate.

Challenges in Implementation of Blinded Rechecking EQA

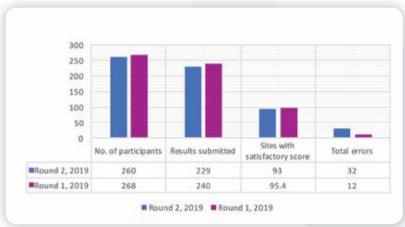
- Non timely sampling of Slides by the District TB Leprosy Supervisors
- Non timely rechecking of slides by the DLFPS
- Non timely return of feedback especially those sent through the CPHL Hub system
- Intermittent facilitation of district personnel to do targeted supervisions for Labs identified with errors at rechecking.

3.2 GENEXPERT EXTERNAL QUALITY ASSURANCE

The Uganda National Tuberculosis Reference Laboratory-NTRL/ Supra-national Reference laboratory (SRL-Uganda) has strongly instituted an ISO 17043:2010 accredited GeneXpert External Quality Assurance (EQA) scheme as a mechanism of ensuring quality, reliable and accurate testing from GeneXpert diagnostic centers across Uganda. The proficiency testing (PT) is a snapshot in time and a brief view of how patient samples are tested. The main objective of this scheme is to develop an Xpert® MTB/RIF and Xpert® MTB/ RIF Ultra PT program utilizing equipment and supplies available in most National TB Reference Laboratories to produce PT items that are; safe, stable up to 36°C, feasible for use in resource limited settings and precise in efforts to aid Xpert® MTB/RIF Xpert® MTB/RIF Ultra quality assurance programs. These programs include two separate challenges during the calendar year i.e. (February and August). Each round is composed of a panel including five (5) dried tube specimens (DTS). Prior to analysis, each specimen requires rehydration with Xpert® Sample Reagent (SR). Subsequent steps are conducted as per participants' internal standard operating procedures. Each panel is accompanied by complete instructions and participants are expected to return test results within 44 days from the shipment date.



Summary of GeneXpert PT scheme round one and two:



Round | 2019 performance

A total of 268 panel sets were dispatched to all functional GeneXpert testing laboratories. At time of analysis a total of the two hundred twenty (220) sites were able to submit results, three (3) participants could not provide results due to non-functional machines and twenty-five sites never submitted any response. Ten sites scored below 80%. These included; Anyeke HC IV Mengo Hospital, Bugono HCIV, Bwindi Community Hospital, Bwizibwera HC IV, Masaka R.R. Hospital, Serere HC IV, Entebbe General Hospital Laboratory Kasambya HC IV.

Round 2 2019 Performance

Two hundred forty (240) sites participated in this round. At the time of analysis (closing date for receipt of feedback from participants),

a total of two hundred twenty-nine (209) sites were able to submit test results putting the result return rate at 88.1%. Six (6) participants (2.3%) could not provide results due to non-functional machines (computer missing) and twenty-five (25) sites (9.6%) never submitted any response. Sites missing computers included; Kangulumira HC IV, Kalagala HC IV, Kanoni HC IV, Lwengo HC IV, Kisenyi HC IV (was down by the time of the shipment) and Buvuma HC IV (machine was not yet installed).

There was slight decline of (1.8%) results return rate. This was attributed to a back-to-back shipment of the panels and a reduction in number of respondents. Sites with unacceptable scores are not routinely followed up for support

Challenges

- Some testing personnel have not yet appreciated the significance of PT panels. This is noticeable on their attitude towards the scheme.
- There were technical challenges with some personnel at sites to generate required data from the GeneXpert machines to submit to the PT provider.
- There was noticeable delay in result submission from a number of sites with some not even responding.
- Results returned through the hub system were received late and others were completely misplaced.
- Data analysis still remain a challenge since there is no electronic system.

4.0 TARGETED SUPPORT SUPERVISIONS FOR THE NATIONAL NETWORK

As a requirement NTRL does targeted support supervisions to all the 12 regions with sites identified with challenges in both Microscopy and GeneXpert testing in the different regions.

The supervisions usually done at least once a year are meant to help in trouble shooting of reasons and finding solutions to challenges like errors in both blinded rechecking and GeneXpert PT panels tested at those sites, additionally those that may not be participating in the schemes to find out what the reasons for their no participation may be. These visits are done together with the Lab focal persons and District TB Leprosy supervisor in the respective districts and in each district the activity commence with a visit and discussion with the District Health department leadership, the DHOs

During this reporting period, targeted support Supervisions were only done in 5 (Gulu, Fort Portal) Mbarara, of the planned 12 Regions during the period. 25 Health facilities in seven Districts were targeted in Fort Portal Region, 18 Sites in 8 districts were targeted in Mbarara Region, and 5 Sites in Gulu Region





A patient visiting a health worker in Kayunga hospital. NTRL supports such facilities in a bid to continously improve in-country TB diagnostics

5.0 CENTRAL TB REFERENCE LABORATORY-CTRL

During this Period the former NTRL in Wandegeya was designated as the Central TB Reference Laboratory (CTRL) as the only public TB culture and drug susceptibility testing other than the National Tuberculosis Reference Laboratory-NTRL in Butabika. This facility is currently housed at the former NTRL site located at the National Tuberculosis and Leprosy Control Programe premises in Wandegeya. All the staff and support for supplies and consumable are currently coordinated from the NTRL.

The intention or scope of work for this facility is to act as TB culture lab for Kampala and the central TB regions as well as act as a backup laboratory for the NTRL. This facility is also expected to coordinate External Quality Assurance activities as well as support supervision for Kampala and the central TB region.

Currently the following tests are performed at this lab:

Xpert MTB/Rif-Ultra

20

2 Both LED and bright field microscopy

3	Both Solid/LJ and Liquid/MGIT culture
4	MGIT Drug susceptibility Testing
5	Both 1 st and 2 nd Line Probe Assay

Test Workload from October 2018 to September 2019

CATEGORY	TEST OUTCOMES
MTB NOT DETECTED	6274
MTB DETECTED	939
RR DETECTED	23
ERRORS	29

The table above indicates a low positivity rate of 12.9% due to the fact that the catchment area for the laboratory is inclusive of multiple private clinics in Kampala as well as a lot of outreaches that are conducted that have a low positivity rate.

All the 23 Rifampicin resistant cases could be verified as having been referred to the Mulago National Referral Hospital for MDR TB management.

The error rate of 0.4% is a good sign that the samples processing technique or instrument maintenance is good that facilitates such good outcomes.

Microscopy and culture

The laboratory only re-initiated LJ and MGIT culture in August and September 2019 respectively mainly serving Mulago MDR TB treatment site. On average 30 sputum samples are received every week to the laboratory for routine culture follow up. A total of 231 samples have were received during these 2 months-better analyses of this indicator will be done during the subsequent reporting periods.

Other tests-LPA and DST

These were initiated in November 2019 and reporting on these will happen in the subsequent reporting period.



6.0 SUPRA REFERENCE LABORATORY (SRL UGANDA) ACTIVITIES

COUNTRY TECHNICAL SUPPORT

During the implementation period January to March 2019, SRL Uganda with support from ECSA-HC conducted three trainings including: development of a lab specific National Strategic Plan, administering of Lab Network assessment tool, and data management for TB labs. One short term Technical Assistance visit was conducted to Malawi to support implementation of QMS and provide support to the ongoing Drug Resistance Survey (DRS). Zimbabwe attended a bench marking visit on preparation of GeneXpert PT panels.

Country	Date of Activity	Details of TA Support Provided	Comments/Recommendations
Malawi	28 th Jan —9 th Feb 2019	 Follow up of previous DRS recommendations Strengthen the quality of sample collection Strengthen sample transport TAT Strengthen sample processing TAT 	The lab management to develop a TBLIS job aid and have all technical staff oriented on its use The NTP management is strongly recommended to procure router for wireless internet to enable TBLIS accessed in the BSLIII lab and microscopy lab by respective technical personnel.
Mozambique	29th ApriL-10 th , May 2019	Follow up on the previous recommendations for the visit made in December 2017 Technical assistance in the interpretation of 2nd line LPA results as well as review place of LPA in the labTB diagnostic algorithm.	Always follow the SOP for the follow up of positive cultures since a procedure for the preparation of blood agar is available as well as the materials required can easily be accessed at the laboratory.
Mauritius	18 th June to 21 st June 2019	 Review progress in implementing 2nd line LJ DST To follow-up actions from previous technical assistance 	Equipment service, calibration and maintenance needs to be explored for all critical equipment
Kenya	3rd – 14th June 2019	 Provide technical support 1st and 2nd line liquid medium DST (MGIT) Provide mentorship in species identification (microscopically through cell morphology) 	To validate the use of 2nd line drug powders at NTRL and resume the provision of 2nd line phenotypic DST services to its clients

TRAINING ON LAB SPECIFIC NATIONAL STRATEGIC PLANNING

SRL Uganda with support from external strategy consultants conducted a one-week training for the managers of NTRL ad key SRL staff on strategic planning for laboratory services from January 21-25, 2019 in Entebbe, Uganda.

During the project MTR in 2017, a recommendation towards attaining project sustainability was made, as a way of bridging the critical gap of lack of proper and implementable laboratory focused strategic plans for all the NRLs in the target countries.

The training aimed at equipping participants with knowledge on principles, concepts and approaches to development of effective laboratory strategic plans, supporting the country participants to develop their country-specific roadmaps to develop new or update existing national laboratory strategic plans, developing draft/review country strategic framework for their laboratory strategic plans with an aim of strengthening in-country system, and developing long-term technical assistance needs in areas of laboratory strategic planning for the countries for governments and partners to take up beyond the ECSA-HC support. The training was attended by 24 participants (14 male and 10 female), 17 were country representatives and 7 were from SRL Uganda. A preliminary assessment of the exposure to strategic planning processes and related training indicated that 4.5% (only one participant) had ever received any training in similar area but a high 59.1% had participated in any strategic planning process. More training details can be found in the training report attached.



TRAINING ON TB LAB NETWORK ASSESTMENT TOOL

The network Assessment training was conducted between 11th and 15 February 2019 in Kampala, Uganda, and involved participants from all the 17 countries including Uganda under the Global fund ECSA-HC project. During the steering committee meeting held in Mozambique between 28th to 31st November 2018, there was a concern of having country's TB lab networks functional and monitored for proper diagnosis and management of MTB respectively.

SRL Uganda with support from ECSA-HC and USAID developed a concept for the development of capacity of personnel to assess National TB diagnostic networks and systems by training specific personnel on using the TB Diagnostic Network Assessment Tool (TB-Net Tool) for strengthening TB lab networks within the countries. A total of 24 lab personnel (17 from other countries and 7 from SRL Uganda) were oriented on the tool and participated in a hands-on field assessment of the TB lab network in Uganda that included National, intermediate, peripheral and private not for profit labs. The information captured was aggregated and used to provide recommendations and key actions for MOH and relevant stakeholders on how to improve the network functions or reallocation of resources respectively.

TRAINING ON DATA MANAGEMENT FOR TB LABS

As a recommendation of Midterm Review (MTR) conducted in 2017, towards strengthening the data management and reporting function within participant country NTRLs. SRL Uganda with support from ECSA -HC conducted a three-day training in data management for lab data managers, between March $12^{th} - 14^{th}$, 2019 in Kampala, Uganda. The training aimed at imparting knowledge skills and competency in data collection, handling, analysis, presentation and dissemination, familiarizing trainees in the use of the basics tools and frameworks used in developing and monitoring data management systems and Introducing trainees to the fundamentals of Data Demand and Use within the Laboratory.

A total of 19 participants attended the training (4 females and 15 males) among whom were three representatives from SRL Uganda, a post training evaluation indicated that 56% participants of the participants in attendance rated the training very good in attaining and accomplishing the objectives of the training, while 31% score the training at good, it is therefore evident that majority of participants felt that the objectives of the training were met and minority felt otherwise.

Participants were tasked with conducting a data quality assessment for the systems and processes used in TB lab data management and there after developing a action measures to bridge gaps identified.



Training in session: A trainer from SANAS takes NTRL staff through a procedure

PROFICIENCY TESTING MICROSCOPY

A total of 26 laboratories were sent panels in this round of Microscopy PT. This round also covered the 19 National TB Reference Laboratories supported by the regional Global Fund, The East Central and Southern Africa Health Community (ECSA HC) and Uganda Supranational Reference Laboratory (SRL) grant. The 26 labs in 20 countries Swaziland, Somalia, Somaliland, Botswana, South Sudan, Seychelles, Burundi, Rwanda, Eritrea, Mauritius, Malawi, Uganda (2 labs), Zimbabwe (2 labs), Namibia, Tanzania (2 labs), Kenya, Mozambique (2 labs), Zambia (3 labs), Lesotho and Liberia.

Only 25 laboratories participated in this round and 25 submitted results within the stipulated deadline. Therefore, only results for the 25 labs were analyzed. Three participants (12%) performed both ZN and FM, eight participants (32%) performed ZN and fourteen participants (56%) performed FM. The number of participants performing ZN & FM has increased from one in Aug-2018 to three in Feb-2019.

 Table 1. Showing comparison of staining techniques

Technique	Aug-2018	%	Feb-2019	%
ZN	9	36	8	32
FM	15	60	14	56
ZN&FM	1	4	3	12
TOTAL	25	100	25	100

PROFICIENCY TESTING GENEXPERT

A total of 268 panel sets were dispatched targeting 268 functional GeneXpert testing laboratories. 247 of the sites were within Uganda and 21 were NRL laboratories and research institutions under the Uganda-SRL network. At time of analysis (closing date for receipt of feedback from participants), a total of the two hundred forty sites were able to submit results putting the result return rate at 89.6%, three participants (1.2%) could not provide results due to non-functional machines and twenty-five sites (9.3%) never submitted any response as shown below in the table;

Summary of feedback from participants

Response rate	Non- functional at time of analysis	No response
89.6% (240/268)	1.2%(3/268)	9.3% (25/268)

BENCHMARKING ACTIVITIES

Country	ZIMBABWE	Date of Activity	28 th January – 8 th February, 2019			
Details of TA p	Details of TA provided:					
A benchmarking visit was organized for the laboratory manager of NTRL Zimbabwe, to visit Uganda SRL as an avenue for knowledge exchange between the two laboratories particularly with regards to						
, ,		ube Specimen (DTS) method.Tl	he participant did not have any prior knowledge on preparation of DTS panels.			
Comments/ Recomm	nendations from the bench	nmarking visit:				
It is however recommended that a follow-up visit to Zimbabwe National TB reference laboratory should be carried out by the Uganda SRL in order to help set up the DTS preparation scheme and ascertain whether the lessons learned during the training are being practiced by the staff.						
Communication with participants should be more often for continuous discussion on the Assay trained on.						
Participant needs to give feedback to SRL on the progress of implementation of the DTS technique that was trained on.						
Participants to develop SOPs and any form related to DTS GeneXpert PT preparation.						
SRL to provide on-site mentorship DTS GeneXpert PT preparation for to Zimbabwe NTRL						
Country	NAMBIA	Date of Activity	28 th January – 8 th February, 2019			
Details of TA provided:						
A honorbmarking visit was organized for the laboratory manager of Namihia NITPL to visit Liganda SPL as an avenue for knowledge exchange between the two laboratories						

A benchmarking visit was organized for the laboratory manager of Namibia NTRL, to visit Uganda SRL as an avenue for knowledge exchange between the two laboratories particularly with regards to

on GeneXpert PT preparation using the Dry Tube Specimen (DTS) method. The participant did not have any prior knowledge on preparation of DTS panels.

Comments/ Recommendations from the benchmarking visit:

It is however recommended that a follow-up visit to Namibia National TB reference laboratory should be carried out by the Uganda SRL in order to help set up the DTS preparation scheme and ascertain whether the lessons learned during the training are being practiced by the staff.

Communication with participants should be more often for continuous discussion on the Assay trained on.

participant needs to give feedback to SRL on the progress of implementation of the DTS technique that was trained on.

Participants to develop SOPs and any form related to DTS GeneXpert PT preparation.

SRL to provide on-site mentorship DTS GeneXpert PT preparation for to Namibia NTRL

7.0 LEARNING AND SHARING

Through workshops, trainings, meetings, and visits, we learn and share together. Our target is to mentor other countries in our network to build their own resilient and sustainable TB Lab systems. We serve as a demonstration site, offering training and peer to peer



mentorship for both local and regional lab personnel in various essential skill sets. Our teams also make several visits to various in country and regional sites to train, mentor, encourage and challenge the personnel to do better.



NATIONAL TB REFERENCE LABORATORY ANNUAL PROGRESS REPORT



7. COMMUNICATION AND ADVOCACY



NATIONAL TB REFERENCE LABORATORY ANNUAL PROGRESS REPORT



NATIONAL TB REFERENCE LABORATORY ANNUAL PROGRESS REPORT

7.2 NTRL UGANDA HOSTS THE NATIONAL TUBERCULOSIS LABORATORY NETWORK ASSESSMENT CONFERENCE

The National Tuberculosis Laboratory Network assessment and disseminating report two weeks conference ended recently at Hotel Africana. The NTL disseminating and assessment report research was conducted by the consultants from USAID- Washington, CDC, World Health Organization (WHO), and United States (US) government partners. The National Tuberculosis's Reference Laboratory centre-Butabika where the hosts.

Assistant commissioner, ministry of health, in charge of national laboratory services, Dr. Suzan Nabadda said during the closing of the conference meeting that the National Health Policy (NHP II) advocates of "attainment of a good standard of health by all people in the country.

"To achieve this, all levels within the tailored laboratory network need to function effectively in order to provide quality laboratory services. This includes point of care services that provide increased access to essential diagnostic services,"

Health laboratory services are essential for the delivery of quality health care and should be accessible to all people in the country. The government, together with development partners, have made commendable efforts towards improvement of health for the people of Uganda through the development of policies and establishment of appropriate programs to ensure implementation. Nabadda said that apart from the routine diagnosis and management of disease conditions, information derived from health laboratories contributes towards health research, surveillance for priority diseases, identification of infections and anti-microbial resistance (AMR), management of disease outbreaks and forensic investigations.

She said that Health laboratories enhance adequate and timely health interventions, contribute towards early disease detection, response and prevention of infections of global importance. Prof. Moses Joloba, Director, Supranational Reference Laboratory-Centre said the disseminating report conference brought together specialists/consultants who plays big role in improve the quality of laboratory services and will consequently improve on TB diagnosis and strengthen sample harvesting, transportation and processing. Uganda's Supranational Reference Laboratory plays a pivotal role in bringing both tech and training to many countries. It is a "supranational" lab because it supports 21 countries across Africa to conduct complicated TB tests.

The Supranational National Reference Laboratory is a regional centre of excellence in the provision of tuberculosis diagnostic services and training. It is the only one of its kind in Sub-Saharan Africa, outside South Africa.

NATIONAL TB REFERENCE LABORATORY ANNUAL PROGRESS REPORT

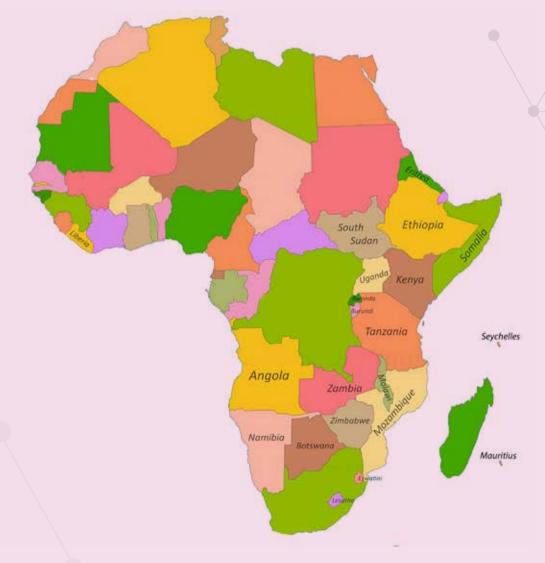


Participants pose for a group photo during the national TB laboratory network assessment conference

8.0 **PROJECT IMPLEMENTATION TEAM**

21 BENEFICIARY COUNTRIES OF THE GLOBAL FUND REGIONAL TB LAB STRENGTHENING PROJECT

Angola Botswana Burundi Eritrea Eswatini Ethiopia Kenya Lesotho Liberia Malawi Mauritius Mozambique Namibia Rwanda Seychelles Somalia South Sudan Tanzania Uganda Zambia Zimbabwe





Timely Accurate Diagnostics for a TB-Free Africa

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MINISTRY OF HEALTH