

2014 National Tuberculosis Reference Laboratory Annual Report

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ACRONYMS

AFRIMS	Armed Forces Research Institute of Medical Services
AFB	Acid-Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ARG	AIDS Research Group
ARMM	Autonomous Region of Muslim Mindanao
CAR	Cordillera Administrative Region
CHO	City Health Office
CTRL	Cebu Tuberculosis Reference Laboratory
DOH	Department of Health
DOTS	Directly Observed Treatment, Short Course
DRS	Drug Resistance Survey
DSSM	Direct Sputum Smear Microscopy
DST	Drug Susceptibility Testing
DSTB	Drug Susceptible Tuberculosis
DTRL	Davao Tuberculosis Regional Laboratory
EQA	External Quality Assurance
FLD	First-Line Drug
GAA	General Appropriations Act
Global Fund	The Global Fund to Fight AIDS, Tuberculosis, and Malaria
ICRC	International Committee of the Red Cross
IMPACT	Innovation and Multi-Sectoral Partnership to Achieve Control of Tuberculosis
IMS	Information Management System
ITRMC	Ilocos Training and Regional Medical Center
KMITS	Knowledge Management Information Technology Service (DOH)
KOFIH	Korea Foundation for International Healthcare
KOICA	Korea International Cooperation Agency
LCP	Lung Center of the Philippines
LED-FM	Light-Emitting Diode Fluorescence Microscopy
LIS	Laboratory Information System
LJ	Löwenstein-Jensen
LNSP	Laboratory Network Strategic Plan
LPA	Line Probe Assay
LRD	Laboratory Research Division (RITM)
LSU	Laboratory Services Unit
MDR-TB	Multidrug-Resistant Tuberculosis
M&E	Monitoring and Evaluation
MEU	Monitoring and Evaluation Unit
MGIT	Mycobacteria Growth Indicator Tube
MSH	Management Sciences for Health
MTB	<i>Mycobacterium tuberculosis</i>
NCR	National Capital Region
NEQAS	National External Quality Assessment Scheme
NMTRL	Northern Mindanao Tuberculosis Reference Laboratory
NTP	National Tuberculosis Control Program
NTRL	National Tuberculosis Reference Laboratory
PBSP	Philippine Business for Social Progress
PHP	Philippine Peso

PMDT	Programmatic Management of Drug-Resistant Tuberculosis
PRU	Policy and Research Unit
PSQM	Program Support and Quality Management
PTSI	Philippine Tuberculosis Society, Inc.
QA	Quality Assurance
RHU	Rural Health Unit
RIF	Rifampin
RITM	Research Institute for Tropical Medicine
SIAPS	Systems for Improved Access to Pharmaceuticals and Services Project
SLD	Second-Line Drug
SLH	San Lazaro Hospital
SOP	Standard Operating Procedure
SUN	Support Unit of NTRL
TAT	Turnaround Time
TDU	Training and Development Unit
TML	Tuberculosis Microscopy Laboratory
TOT	Training of Trainers
TU	Technical Unit
UP-PGH	University of the Philippines–Philippine General Hospital
USAID	United States Agency for International Development
WHO	World Health Organization

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FOREWORD

The year 2014 marked the 12th anniversary of the National Tuberculosis Reference Laboratory (NTRL). This year saw bigger changes and greater challenges within NTRL as an institution that leads and manages the National Tuberculosis Control Program (NTP) laboratory network, which addresses organizational strengthening, intensive capacity building in leadership and management of laboratories, monitoring and evaluation (M&E), institutionalization of new standard operating procedures (SOPs), adoption of new technologies, establishment or expansion of laboratories, continuation of our mandate to provide technical assistance to the laboratory network, and significant engagement in training and research.

This report describes the procedures and processes adopted by NTRL to strengthen its capacity as an institution, and its efforts to strengthen the NTP laboratory network and the services it provides. The report serves as a good reference for NTP laboratory network managers, program coordinators, partners, and other stakeholders to inform them of NTRL's accomplishments. This report is the first of its kind and is being shared with the NTP laboratory network and other stakeholders.

On behalf of Dr. Noel G. Macalalad, who headed NTRL in the year of this report, it is with great pleasure that I present to you the Annual Report for the National Tuberculosis Reference Laboratory for January to December 2014. I hope you will find this report both informative and helpful, and that it will give you a greater understanding of the work undertaken by our department.

I thank all of our staff—from the laboratory and administrative aides to the unit staff and unit heads—for their strong commitment, hard work, and willingness to learn and grow in the process.

I wish to thank our mother institution, the Research Institute for Tropical Medicine (RITM), led by Director Socorro P. Lupisan; Dr. Ana Marie Celine G. Garfin, NTP Manager; DOH regional offices, regional, provincial and city NTP medical, nurse and medical technologist coordinators and all of our partners, including the United States Agency for International Development (USAID); Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund), through principal recipient Philippine Business for Social Progress (PBSP); World Health Organization (WHO); International Committee of the Red Cross (ICRC); International Organization for Migration; and Systems for Improved Access to Pharmaceuticals and Services Project (SIAPS) (implemented by Management Sciences for Health) for their continuous support of and assistance to NTRL. I especially thank Dr. Arthur B. Lagos and Dr. Lynette P. Adorio-Arce for their valuable assistance in the development of this report.

Ma. Cecilia G. Ama, MD
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PREFACE

The 2014 NTRL Annual Report is the result of the discussions between NTRL management and technical staff, and SIAPS technical advisors. This report came about for the purpose of documenting NTRL's annual performance as it provides technical leadership in the NTP laboratory network.

This is the first time that NTRL has produced an annual report of this kind since its inception in 2002. The report will serve as a reference point for improving NTRL's performance in the coming years.

The contents of the report are the result of NTRL's critical review of their activities in 2014, together with the relevant data that were generated as a result of their activities; and were painstakingly collected by the NTRL Technical Units. The data in this report should not be taken as a reflection of the NTP laboratory network's overall performance but only as the result of NTRL's efforts. We hope that the report will inspire our fellow NTP laboratory network managers in their efforts to improve the laboratory services in their respective areas.

Arthur B. Lagos MD; Lynette P. Adorio-Arce MD; Ma. Cecilia G. Ama, MD,
Manila, 2015

INTRODUCTION

NTRL is the central reference laboratory of the NTP laboratory network; it is one of the reference laboratories within Research Institute for Tropical Medicine (RITM) of the Department of Health (DOH). Basic and specialized TB laboratory services are provided at NTRL in support of NTP case finding, research, and surveillance. As a reference laboratory of RITM, NTRL conducts research; performs a limited number of TB diagnostic tests; conducts laboratory trainings; and provides the external quality assurance (EQA) panel tests for TB microscopy and culture for the National External Quality Assurance Scheme (NEQAS), implemented in over 300 hospital-based laboratories.

More than a service provider, NTRL has been mandated to provide technical leadership in the NTP laboratory network. It is responsible for leading the development and implementation of laboratory national strategic plans, policies, guidelines, standards, and programs for training and quality assurance. NTRL also plays a major role in the management of laboratory services, together with the regional, provincial, and city medical technologist coordinators. NTRL informs NTP across a broad range of matters, including the overall performance of the NTP laboratory network, the adoption and use of new diagnostic technologies, and the status of the laboratory management systems.

This annual report is the first of its kind for NTRL. The following provides a general picture of NTRL's activities and accomplishments related to service and development in 2014. It documents the expansion of laboratory services and adoption of new technologies in the context of new developments in TB diagnosis and treatment.

SECTION 1: ORGANIZATIONAL STRENGTHENING

Institutional Capacity Building

With ongoing technical assistance from USAID, through the SIAPS Project, NTRL has been implementing organizational development activities since 2011. The goal was to increase NTRL's capacity to lead and manage the NTP laboratory network. The activities and achievements were the following:

1. NTRL revised its organizational structure (figure 1) based on the findings and recommendations of the NTRL Human Resource System Assessment Report, completed by SIAPS in 2012. The streamlined structure aimed to improve NTRL's effectiveness and efficiency, and enabled NTRL to better adapt to a rapidly changing environment. The new structure was approved and implemented by RITM. In addition, the SIAPS NTRL Human Resource System Assessment Report became part of the ISO 9001:2008 documentation, and became the basis for identifying and requesting new permanent positions from DOH/Department of Budget and Management. Figure 1 shows the revised organizational structure of NTRL.

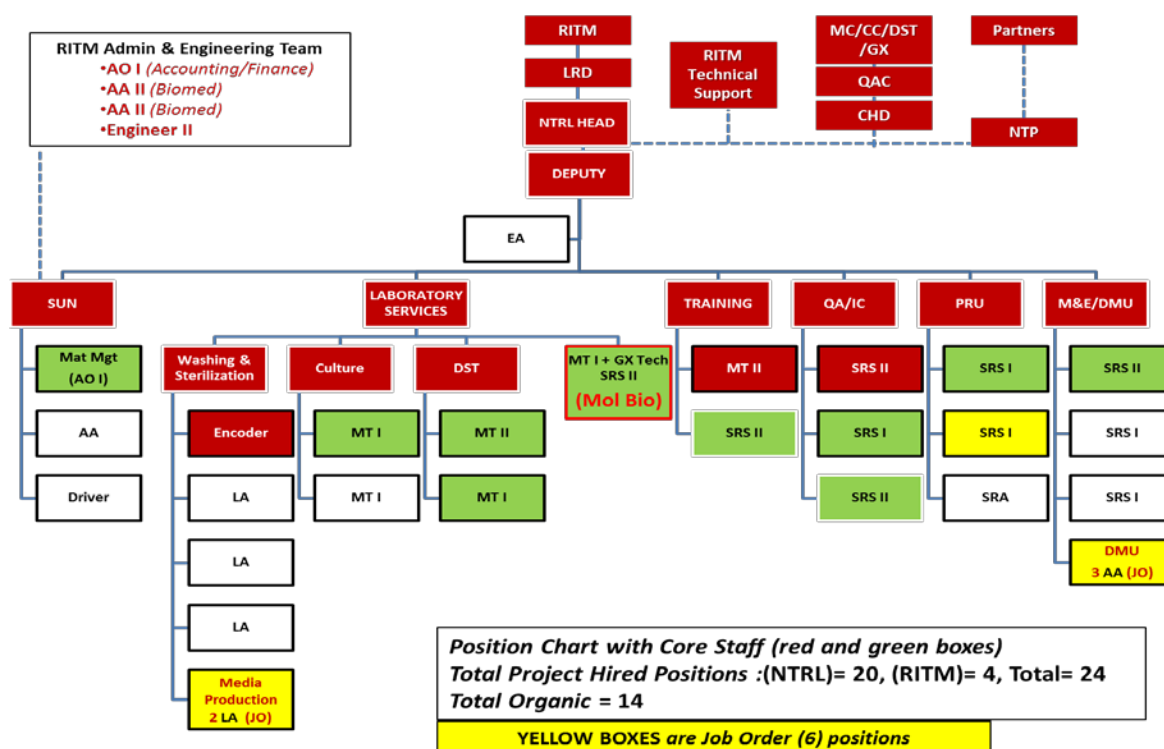


Figure 1. Revised NTRL organizational structure, 2014. Source: NTRL

2. The restructuring process included the reorganization of NTRL's five key technical units (TUs), which include: 1) Program Support and Quality Management (PSQM), 2) Policy and Research Unit (PRU), 3) Laboratory Services Unit (LSU), 4) Training and Development Unit (TDU), and 5) Monitoring and Evaluation Unit (MEU), as well as the administrative or Support Unit of NTRL (SUN) which is critical in providing support to the TUs. The functions of each TU were also redefined to avoid overlap and provide further clarity of roles (annex A). This process included the description of the functions of the TU Heads to highlight their roles as leaders and managers (annex B).
3. The NTRL M&E Working Group was created to improve internal coordination and collaboration of M&E activities among the different TUs. The aim was to strengthen the information utilization capability of the NTRL TUs and management to support decision making, planning, and reporting.
4. To improve organizational capacity for information management, the NTRL Information System—which covers the flow, management, and use of data—was enhanced with the development of the NTRL Information System SOPs for Laboratory Information Management, with technical assistance from SIAPS. The document describes the management procedures for data received from the regions and the monitoring activities of the TUs. It includes procedures for data aggregation, validation and analysis, provision of feedback to reporting sites/units, and archiving. The SOPs were adopted by NTRL in their entirety, and approved by RITM for implementation. The Information System SOP became part of RITM's documentation requirements for ISO 9001:2008 certification.
5. To improve individual capacity for information management, SIAPS trained NTRL staff from MEU, PSQM, and TDU on laboratory information utilization. This training aimed to improve individual skills on laboratory data and information management from data collection, collation, and summarization of data, to analysis and information use for reporting and decision making.
6. The NTRL planning process was enhanced, which led to the development of “more focused” work plans. The enhanced process emphasized basic steps in planning, including a comprehensive situational analysis, problem identification and root cause analysis, prioritization of problems and challenges, development of objectives and activities, and the creation of an M&E plan to measure institutional performance and results.

The entire process was supported by the rational use of available data, which generated the evidence that guided the development of the strategies, activities, and indicators for M&E. The overarching priority gaps/challenges were summarized into themes to be addressed in 2015 as follows: organizational capacity development and strengthening, laboratory systems development and strengthening, and individual capacity improvement.

The 2010–2016 NTRL strategic plan was revisited in December 2014 in preparation for the development of the 2015 NTRL work and financial plan.

7. Skill-building activities for NTRL TUs were implemented through workshops and mentoring sessions conducted by SIAPS on the following management functions: (1) planning, (2) laboratory network monitoring, and (3) laboratory information utilization. Other trainings implemented by NTRL management were the following:
 - a) ISO 15189 and Good Clinical Laboratory Practice Training
 - b) Short Course on Health Care Monitoring and Evaluation
 - c) Short Course on Strategic Planning
 - d) Short Course on Policy Implementation
 - e) Basic Course on Research Methods
 - f) Short Course on Epi Info, Version 7
8. Through the DOH reorganization program, four new permanent items with salary grade 15 and above were allocated by RITM. The orientation for new employees was conducted by RITM Personnel Officer in partnership with NTRL HR personnel. The NTRL staffing pattern for 2012 and 2014 is shown in Table 1 below.

Table 1. Staffing Pattern of NTRL, 2012 and 2014

Type of Staff	2012	2014
	No. (%)	No. (%)
Organic/Permanent	15 (26%)	12 (29%)
Contractual/Global Fund Hired	42 (74%)	30 (71%)
Total	57 (100%)	42 (100%)

SECTION 2: POLICY ENVIRONMENT

One of NTRL's priorities in 2014 was the creation of an enabling environment that supports improvements in the laboratory network and the delivery of diagnostic services for NTP. Several policies and reports, as well as 16 internal SOPs, were created and approved. These included:

1. **Second National Drug Resistance Survey on Tuberculosis in the Philippines:** This is the second survey undertaken by NTP, through the leadership of NTRL. The survey showed the prevalence rates of multidrug-resistant TB (MDR-TB) and other drug resistance patterns in the country. The results were used to inform NTP decision makers, policy makers, strategists, planners, health workers, and other stakeholders involved in TB control.
2. **NTP Laboratory Network Strategic Plan (LNSP):** The document describes the strategic direction, goals, and objectives for the NTP laboratory network in the short to medium term. The plan was approved and dissemination started in 2014.
3. **DOH-AO No. 2014 – 0032 Guidelines for the Scale-Up and Use of Xpert MTB/RIF Assay:** The issuance describes the country's policies and guidelines that support the adoption, scale-up, and use of Xpert MTB/RIF Assay in the NTP diagnostic framework. It also defines the roles and responsibilities of relevant stakeholders in the Xpert MTB/RIF Assay implementation process.
4. **National TB Laboratory Biosafety Guidelines:** The National Tuberculosis Biosafety Guidelines is a manual developed in 2012 by a core team from RITM and NTRL with partners from the University of the Philippines–Philippine General Hospital (UP-PGH); Center for Health Development, National Capital Region (NCR); Quezon City, City Health Office (CHO); Lung Center of the Philippines (LCP); Philippine Tuberculosis Society, Inc. (PTSI); and NTP. The manual provides a guide to laboratory personnel for the safe handling of specimens to protect not only the laboratory personnel but also the community.
5. **Trainer's Guide and Reference Manual on Solid Culture and Drug Susceptibility Testing for *Mycobacterium tuberculosis*:** This guide was developed to provide standardized instructional resource material adapted to the Philippine setting for the training of laboratory technicians assigned to perform culture and drug susceptibility testing (DST) of *Mycobacterium tuberculosis* (MTB). This serves as a resource for facilitators and trainees in organizing, managing, and conducting a standardized training course and workshop for culture and DST.
6. **Standard Operating Procedures:** In collaboration with technical partners, internal SOPs were developed or updated, such as (1) the Biosafety Level 3 Laboratory SOP, (2) NTRL Laboratory Information Management, and (3) Materials Management.

SECTION 3: LABORATORY NETWORK MANAGEMENT

TB Microscopy Laboratories (TMLs)

Sputum microscopy is still the most commonly used test to detect cases and monitor patients' treatment response bacteriologically. The network of TMLs is necessary to provide quality-assured TB diagnosis using sputum microscopy—still the most accessible diagnostic test in NTP at this time. The TML mapping done by NTRL in 2012 showed that the NTP laboratory network is composed of 2,561 laboratories, most of which are lodged within the primary-level rural health units (RHUs) and health centers. The majority of the laboratories (2,174 [85%]) belong to the public sector, while 387 (15%) are private laboratories.

In 2004, a quality assurance program for TB microscopy was jointly developed by NTRL, WHO, and the Japan International Cooperation Agency. The program was fully implemented by the local government units under the supervision of the regional TB teams and NTRL starting in 2004. An analysis of EQA implementation from 2011 to 2014 showed that the participation of TMLs is less than optimal, with a four-year average of only 81%. The proportion of TMLs with acceptable performance (i.e., less than 5% major errors) out of those that participated in EQA had a four-year average of 92%. However, the average proportion of TMLs with acceptable performance, when computed against the total number of TMLs, was lower, at 74%. Moreover, only 63% (387/615) of TMLs with major errors were given feedback by the NTP EQA team for quality improvement.

Caution is advised when interpreting these figures as the total number of TMLs has not been updated since 2012. Information regarding TMLs with regular EQA participation is not available at this time. Table 2 shows the results of EQA implemented from 2011 to 2014.

Table 2. Results of EQA implementation in the Philippines from 2011–2014

	2011		2012		2013		2014	
	No.	%	No.	%	No.	%	No.	%
a. Total TMLs*	2,561		2,561		2,561		2,561	
b. TMLs with EQA	2,047	80	2,016	79	2,041	80	2,129	83
c. TMLs with acceptable performance (less than 5% major errors):	1,947		1,932		1,945		1,775	
1. % TMLs with acceptable performance over labs in EQA (c/b)		95		96		95		83
2. % TMLs with acceptable performance over total TMLs (c/a)		76		75		76		69

*Based on 2012 mapping by NTRL

Adoption of LED-FM for TB Microscopy

The NTP started using light-emitting diode fluorescence microscopy (LED-FM) in 2013. There were 72 LED-FM microscopes available for the laboratory network in 2014, coming from

various donors such as the Global Fund, Korea Foundation for International Healthcare (KOFIH), and Korea International Cooperation Agency (KOICA). The plan for 2014 was to install LED-FM microscopes in 57 TMLs located in three high-burden regions: NCR (25), Central Luzon (13), and CALABARZON (19). However, LED-FM microscopes were installed in only seven TMLs (one in NCR, and six in CALABARZON), or 16% of the target by the end of 2014 (table 3).

Table 3. Number of TMLs using LED-FM established under the scale-up plan, 2014

	Target	Achieved
NCR	25	1 (4%)
Central Luzon	13	0
CALABARZON	19	6 (32%)
Total	57	7 (12%)

Xpert MTB/RIF Assay

The country started the use of Xpert MTB/RIF Assay (GeneXpert) in late 2011. A total of 119 machines were available for NTP use by the end of 2014 (table 4). The Global Fund provided 100 machines that were placed in labs across the country. Machines from KOFIH were used in Palawan for the DetecTB Project, while the ICRC machine was installed in Quezon City Jail. Ten machines from UNITAID were installed in select Metro Manila hospitals and Marikina CHO, while the Armed Forces Research Institute of Medical Services (AFRIMS) machine was installed in the Armed Forces of the Philippines Medical Center.

Table 4. Number of GeneXpert units in the Philippines by source, 2011–2014

Source	No.
The Global Fund	100
UNITAID	10
KOICA	1
KOFIH	6
ICRC	1
AFRIMS	1
Total	119

The target for 2014 was to establish 85 GeneXpert laboratories in the following priority areas: (1) select areas in the country's high-TB burden regions, including NCR, Central Luzon (Region 3), and Southern Tagalog (CALABARZON, or Region 4A); (2) the disaster-hit areas, particularly in the Eastern Visayas region (Region 8); and (3) the selected Programmatic Management of Drug-Resistant TB (PMDT) expansion areas. The GeneXpert scale-up achievements, based on the target areas for 2014, were: 58% for the three high-burden regions, 100% for the disaster-hit areas, and 72% for the selected PMDT expansion sites (table 5).

Table 5. Number of GeneXpert laboratories by priority area and target, Philippines 2014

Type of area	Target (No. and %)		Established (No. and %)	
High TB burden areas (NCR, 3, 4A)	36	42%	21	58%
Disaster Areas	13	16%	13	100%
PMDT sites	36	42%	26	72%
Total	85		60	71%

A total of 60 new GeneXpert laboratories were established by the end of 2014 for a total of 84 GeneXpert laboratories (cumulative from 2011) providing services throughout the country. The highest proportion of the laboratories was in NCR with 23%, followed by CALABARZON with 10% and the regions of Central Luzon, Eastern Visayas, and Western Visayas with 8% each (table 6).

Table 6. Cumulative number and distribution of GeneXpert laboratories by year and region, Philippines 2011–2014

Region	2011	2012	2013	2014	2014 (%)
NCR	5	5	11	19	23%
CAR	1	1	1	1	1%
1	1	1	1	2	2%
2	0	0	0	2	2%
3	0	0	0	7	8%
4-A	1	1	2	8	10%
4-B	0	1	1	5	6%
5	1	1	1	3	4%
Subtotal Luzon	9	10	17	47	56%
6	1	1	1	7	8%
7	1	1	1	5	6%
8	0	0	0	7	8%
Subtotal Visayas	2	2	2	19	23%
9	1	1	1	3	4%
10	1	1	1	4	5%
11	1	1	1	4	5%
12	1	1	1	3	4%
CARAGA	1	1	1	3	4%
ARMM	0	0	0	1	1%
Subtotal Mindanao	5	5	5	18	21%
TOTAL	16	17	24	84	100%

Note: CAR=Cordillera Administrative Region; ARMM=Autonomous Region of Muslim Mindanao

However, of the 84 laboratories established, only 55 were submitting reports by the end of 2014 (tables 7, 8, and 9). Only 30 of 47 (64%) laboratories were reporting in Luzon, 11 out of 19 (58%) in Visayas, and 14 out of 18 (78%) laboratories in Mindanao.

Table 7. List of reporting GeneXpert laboratories, Luzon, 2014 (n=30)

Region	Facility
NCR (n=14)	San Lazaro Hospital
	Lung Center of the Philippines
	PTSI-Quezon Institute
	Dr. Jose Rodriguez Memorial Hospital
	East Avenue Medical Center
	Quezon City Jail
	Marikina City Health Office
	Moonwalk Health Center
	Lacson Health Center
	Dra. Elvira M. Lagrosa Health Center
	Philippine Orthopedic Center
	Pasig General Hospital
	Mandaluyong Main Laboratory
	National TB Reference Laboratory
CAR (n=1)	Baguio General Hospital and Medical Center
R-1 (n=1)	Ilocos Training and Regional Medical Center
R-2 (n=1)	Regional Office II Cagayan Valley
R-3 (n=4)	DOH Regional TB Laboratory 3
	San Jose City General Hospital
	RHU 1 Malolos
	Bulacan Medical Center
R-4A (n=4)	De La Salle Health Sciences Institute
	Batangas Medical Center
	General Emilio Aguinaldo Memorial Hospital
	Antipolo CHO
R-4B (n=3)	Oriental Mindoro Provincial Hospital
	Osipal Ng Palawan
	DetecTB
R-5 (n=2)	Sorsogon Medical Mission Group Hospital
	Bicol Medical Center

Table 8. List of reporting GeneXpert laboratories, Visayas 2014 (n=11)

Region	Facility
R-6 (n=4)	Dr. Rafael S. Tumbokon Memorial Hospital
	Western Visayas Medical Center
	SARA RHU
	Teresita Ledesma Jalandoni Provincial Hospital
R-7 (n=1)	Cebu TB Reference Laboratory
R-8 (n=6)	Salvacion Oppus Yniguez Memorial Provincial Hospital
	Ormoc City Health Office
	Eastern Samar Provincial Hospital
	Northern Samar Provincial Hospital
	Eastern Visayas Regional Medical Center
	Calbayog City Health Office

Table 9. List of reporting GeneXpert laboratories, Mindanao, 2014 (n=14)

Region	Facility
R-9 (n=3)	Zamboanga City Medical Center
	Dr. Jose Rizal Memorial Hospital
	Margosatubig Regional Hospital
R-10 (n=6)	German Doctors
	Northern Mindanao TB Reference Laboratory
	Mayor H.A. Ramiro Sr. Regional Training Hospital
	Xavier University-CHCC
	Iligan Society of Internist
R-11 (n=2)	Bukidnon Provincial Medical Center
	Davao TB Regional Laboratory
	Davao Regional Hospital
R-12 (n=1)	Koronadal City Health Office
CARAGA (n=2)	Adella Serra Ty Memorial Medical Center
	CARAGA Regional Hospital

TB Culture Laboratories

NTP planned to have 28 functional TB culture laboratories for the TB laboratory network by 2016. By the end of 2014, 22 (79%) laboratories were already functional, in both public and private sectors. All of the high-burden regions (i.e., NCR, 3, and 4A) already had culture laboratories (table 10).

Table 10. List of TB culture laboratories by region, Philippines 2014

Luzon: 12	
Public (n=9)	Private (n = 3)
Dagupan Doctors Villaflor Memorial Hospital (R-1)	De La Salle Health Sciences Institute (R-4A)
DOH-Region II TB Laboratory (R-2)	Sorsogon Medical Mission Group Hospital and Health
DOH-Region III TB Laboratory (R-3)	Services Cooperative (R-5)
Batangas Medical Center (R-4A)	PTSI-Quezon Institute (NCR)
Bicol TB Regional Laboratory (R-5)	
Baguio General Hospital and Medical Center (CAR)	
Lung Center of the Philippines (NCR)	
UP-PGH Medical Research Laboratory (NCR)	
National TB Reference Laboratory (NCR)	
Visayas: 3	
Public (n=2)	Private (n = 1)
Western Visayas Medical Center (R-6)	Dr. Pablo O. Torre Memorial Hospital (R-6)
Cebu TB Reference Laboratory (R-7)	
Mindanao: 7	
Public (n=5)	Private (n = 2)
Zamboanga City Medical Center (R-9)	CDO Polymedic Medical Plaza (R-10)
Northern Mindanao TB Reference Laboratory (R-10)	The Doctors Clinic Hospital, Inc. (R-12)
Davao TB Reference Laboratory (R-11)	
Davao Regional Hospital (R-11)	
CARAGA TB Culture Laboratory	

Liquid Culture Using Mycobacteria Growth Indicator Tube

NTP started the use of liquid culture for the diagnosis of TB using Mycobacteria Growth Indicator Tube (MGIT). Liquid culture using MGIT has the advantages of higher yield and shorter turnaround time, although at a higher cost when compared to using Ogawa media. In 2014, four culture laboratories were already utilizing or about to utilize MGIT (table 11), with a view of using MGIT in two more laboratories by 2016.

Table 11. TB culture laboratories performing liquid culture with MGIT, Philippines 2014

1. National TB Reference Laboratory (Muntinlupa City, NCR)
2. Philippine TB Society, Inc. (Quezon City, NCR)
3. Cebu TB Reference Laboratory (Cebu City, Central Visayas)
4. Lung Center of the Philippines (Quezon City, NCR)

DST Laboratories

Seven of the existing culture laboratories were envisioned to perform DST for first-line drugs (FLDs), or both FLDs and second-line drugs (SLDs). At the end of 2014, there were three functional DST laboratories including the Cebu Tuberculosis Reference Laboratory (CTRL), NTRL, and LCP; four other planned DST laboratories were not yet functional, namely PTSI, Davao TB Regional Laboratory (DTRL), Northern Mindanao Tuberculosis Reference Laboratory (NMTRL), and Ilocos Training and Regional Medical Center (ITRMC) (table 12). Five DST laboratories participated in the DST proficiency testing process administered by NTRL in 2014. Of these, three passed: NTRL, LCP, and CTRL.

Table 12. Status of DST laboratories scale-up, Philippines 2014

Facility	Region	Status
1. NTRL	NCR	Functional; performing FLD & SLD DST
2. LCP	NCR	Functional; performing FLD DST
3. PTSI-QI	NCR	Not functional; ongoing DST Proficiency
4. ITRMC	Ilocos	Not functional; awaiting completion of construction work; and installation of ventilation and AC system.
5. CTRL	Central Visayas	Functional; performing FLD & SLD DST
6. NMTRL	Northern Mindanao	Not functional; staff for DST Training
7. DTRL	Davao	Not functional; ongoing DST Proficiency

Line Probe Assay

NTP planned to establish three line probe assay (LPA) laboratories for the TB laboratory network. These were NTRL, CTRL, and NMTRL. However, only NTRL was functional by the end of 2014.

NTRL Participation in Disaster Response: Support for the Restoration of Laboratory Services in Typhoon Yolanda (Haiyan) Affected Areas

NTRL provided two GeneXpert machines, laboratory supplies and conducted onsite training of the staff for Xpert MTB/RIF Assay in the Eastern Visayas Regional Medical Center. Smearers' kits for TB microscopy were distributed to the region to allow for the establishment of remote smearing stations. NTRL closely coordinated with NTP for the rehabilitation of selected microscopy laboratories.

Challenges in the Expansion of the Laboratory Network

- Delays in LPA operationalization were due to issues in the procurement of laboratory supplies and delay in the replacement of a faulty machine in CTRL.
- Delays in the expansion and operationalization of the culture laboratories were due to:
 - Delays in infrastructure improvements
 - Delayed delivery of supplies
 - Staff turnover
- Challenges for TB culture laboratory upgrades to MGIT included delays in the completion of facility renovations and delays in the delivery of laboratory supplies.
- Challenges in the selection of laboratories for LED-FM expansion by DOH Regional Offices
- Unavailability of medical technologists and management on the training date
- No central planning on Logistics and Supply Management
- Difficulty in setting schedules for training
- Issues that delayed DST expansion and operations were non-functional status of culture laboratory and staff still undergoing proficiency testing.

SECTION 4: TRAINING AND DEVELOPMENT

Trainings Conducted by NTRL for NTP Laboratory Workers

In 2014, a total of 18 training courses were conducted by NTRL with 189 lab workers trained. The training courses were for LED-FM, Xpert MTB/RIF Assay, quality assurance (QA) direct sputum smear microscopy (DSSM), Training of Trainers (TOT) DSSM, and culture (table 13). The majority of the trainings were for GeneXpert operators due to the high training demand related to the NTP's scale-up plan.

Table 13. Number of trainings conducted and total lab workers trained by NTRL, 2014

Training Course	No. trainings	No. staff trained
Xpert MTB/RIF Assay	11	117
QA-DSSM	4	46
TOT-DSSM	1	7
TB culture	1	6
LED-FM	1	13
Total	18	189

Table 14 shows the distribution of GeneXpert trainees by areas of operation.

Table 14. Distribution of GeneXpert trainees by areas of operation, 2014

Area	Number	%
Disaster areas	20	17%
PMDT labs	61	53%
DOH Regional Offices	12	10%
KOFIH DetectTB Project	11	10%
AFRIMS	3	3%
NTRL	8	7%
TOTAL	115	100%

Most of the trainees passed the various courses that they attended, with the exception of QA-DSSM training, where only 80% passed the course (table 15). Of the 15 trainees from Region 1 (Ilocos Region), 8 (53%) did not pass the course; these are QA controllers. The controllers performed poorly on slide reading (with false readings and quantification errors).

Table 15. Number and percentage of trainees that passed training requirements by category of training, 2014

Training Course	No. of trainees	No. (%) passed
TB culture	6	6 (100%)
LED-FM	13	13 (100%)
TOT-DSSM	7	7 (100%)
QA-DSSM	40	32 (80%)
Xpert MTB/RIF Assay	115	115 (100%)
Total	171	163 (95%)

RITM Laboratory Research Division Training Program Accomplishments

As one of the reference laboratories under the RITM Laboratory Research Division (LRD), NTRL TDU performance was evaluated based on RITM indicators. Table 16 shows the performance of TDU for LRD (RITM) and NTRL-TDU indicators.

Table 16. TDU annual performance based on LRD indicator

Performance Indicator (LRD)	Output
a. 80% of request for training support are acted upon/answered within one week of request (LRD)	96% (22/23)
b. Conducted 71 training days (LRD)	132% (94 days)
c. 80% of participants rated training as good and better (LRD)	98% (185/189)
Performance Indicator (NTRL-TDU)	Output
d. 80% of the targeted/expected participants attended and trained	91% (189/207)
e. 80% of the participants passed the standard set in specific training	90% (170/189)
f. At least 50% or 8 facilities conducting DSSM trainings assessed	62.5% (5/8)

Training Financing

In 2014, the laboratory-related trainings were financed through DOH and partners. These included:

- DOH through sub-allotted funds to the regional office
- The Global Fund for trainings in Xpert MTB/RIF Assay and culture
- Technical assistance partners:
 - USAID's Innovations and Multi-Sectoral Partnerships to Achieve Control of Tuberculosis (IMPACT) Project for trainings on DSSM, QA-DSSM, and TOTs
 - USAID's SIAPS Project for training on Laboratory Information Management and Utilization
- KOFIH DetecTB in Palawan
- WHO for two batches of Xpert MTB/RIF Assay training for Typhoon Yolanda-affected areas

SECTION 5: QUALITY MANAGEMENT

Ensuring Quality Products and Services (ISO Certification)

As part of the RITM certification, NTRL was certified for ISO 9001:2008 under TUV Rhineland and started the process for ISO 15189 accreditation with technical assistance from IMPACT through FHI-360. An approved action plan to achieve accreditation in two years was implemented. Good Clinical Laboratory Practice training was also conducted through this technical assistance.

TB Microscopy Quality Assurance

TML mapping conducted by NTRL in 2012 showed a total of 2,561 TMLs in the NTP laboratory network; however, there is no updated information regarding the number. The annual proportion of TMLs that participated in EQA from 2011 to 2013 is 80%. Overall, only 76% (1,946/2,561) of the TMLs had acceptable performance (i.e., those with less than 5% major errors).

NEQAS

A total of 365 laboratories for acid-fast smear proficiency and 8 TB culture laboratories for TB culture proficiency were enrolled in the NEQAS program in 2014. NTRL prepared 1,460 slides (730 pairs of negative and positive slides) for the acid-fast bacilli (AFB) proficiency test, while 8 culture isolates were prepared for TB culture proficiency. The challenge for NEQAS implementation was the insufficient manpower to prepare the assessment materials.

SECTION 6: FIELD MONITORING ACTIVITIES

Joint Monitoring Activity with NTP

The purpose of the joint monitoring visits was to: 1) gather and validate NTP quarterly reports, 2) assess the drug and laboratory supply status in the Regional Warehouse, and 3) conduct rapid assessment of directly observed treatment, short course (DOTS) implementation at the different types of health facilities (TMLs located in RHUs and hospitals, PMDT facilities, GeneXpert laboratories, and culture centers). These visits were conducted in the Schistosomiasis Control and Research Hospital, Eastern Visayas Regional Medical Center GeneXpert laboratory, Basey RHU, regional medical centers in Bacolod City and Iloilo City, and DOH Regional Office 6 in Iloilo City.

The monitoring team used the standard monitoring checklist based on the NTP Manual of Procedures. Field observations and interviews were conducted. Feedback was given to the health team after every visit.

SECTION 7: LABORATORY INFORMATION MANAGEMENT

The MEU, LSU, and PSQM collaborated with the Knowledge Management Information Technology Service (KMITS) in the development of the Laboratory Module for Integrated Tuberculosis Information System.

Development and Standardization of Laboratory Forms

MEU, in collaboration with NTP and NTRL TUs, revised and developed standardized recording and reporting forms to allow the assessment of indicator-based performance of the laboratory network.

Development of Guidelines on Recording and Reporting

Guidelines were developed for Xpert MTB/RIF Assay, culture, and DST to standardize recording and reporting procedures. Two batches of orientations were conducted to introduce the changes in recording and reporting. The orientations were done in coordination with NTP, DOH-KMITS, the Global Fund, and USAID-Innovations and Multisectoral Partnerships to Achieve Control of Tuberculosis Project (IMPACT).

SECTION 8: SUPPLY MANAGEMENT

In an effort to address gaps, laboratory supply management was strengthened by NTRL with technical assistance from USAID's SIAPS Project.

- NTRL did the forecast and coordinated the distribution of laboratory supplies.
- New supply management flow for GeneXpert cartridge was started in 2014. NTRL did the quarterly forecasts and PBSP distributed the cartridges.
- A total of 8 AFB Ziehl-Neelsen kits were evaluated by NTRL for 2014. Results were forwarded to the DOH Materials Management Division and NTP for appropriate actions in relation to procurement for the TB laboratory network.

SECTION 9: RESEARCH

NTRL participated in the following research:

1. **“Feasibility, effectiveness, and safety of 9-month treatment regimen for multidrug-resistant TB in the Philippines.”** The NTRL serves as the laboratory for this research. This research is ongoing.
2. **“Evaluation of the use of Xpert MTB/RIF Assay in the Philippines.”** This study aimed to evaluate the performance and impact of the Xpert MTB/RIF Assay in the detection of MTB and rifampicin resistance among drug-resistant TB suspects seen in PMDT.
3. **“Second National Drug Resistance Survey on Tuberculosis in the Philippines.”** The second survey aimed to determine the prevalence of MDR-TB and other resistance patterns among new and previously treated patients.
4. **“Surveillance of Pyrazinamide and Moxifloxacin Resistance Among TB Patients in the Philippines.”** This was part of WHO’s multi-country study, which will also be conducted in Azerbaijan, Bangladesh, Belarus, and South Africa. It aimed to assess the proportion of resistance to moxifloxacin and pyrazinamide among TB cases in the Philippines.

SECTION 10: FINANCING

NTRL developed its 2014 Work and Financial Plan in consonance with the 2014 Annual Project Procurement Plan and the Project Procurement and Management Plan. Both plans were reported as part of the Department of Performance Commitment and Review accomplishment for ISO 9001:2008 certification.

NTRL was sub-allotted 12 million Philippine pesos (PHP) from NTP under the General Appropriations Act (GAA) to be used for maintenance and other operating expenses (table 17).

Under the Global Fund's New Funding Model, RITM was a service provider. The amount of almost PHP 15 million was allotted for human resources, equipment, GeneXpert cartridges, calibration, and maintenance; M&E, and overhead costs. The purchase of laboratory supplies was financed largely through NTP sub-allotment and partly through Global Fund.

Table 17. Operating budget of NTRL, 2014

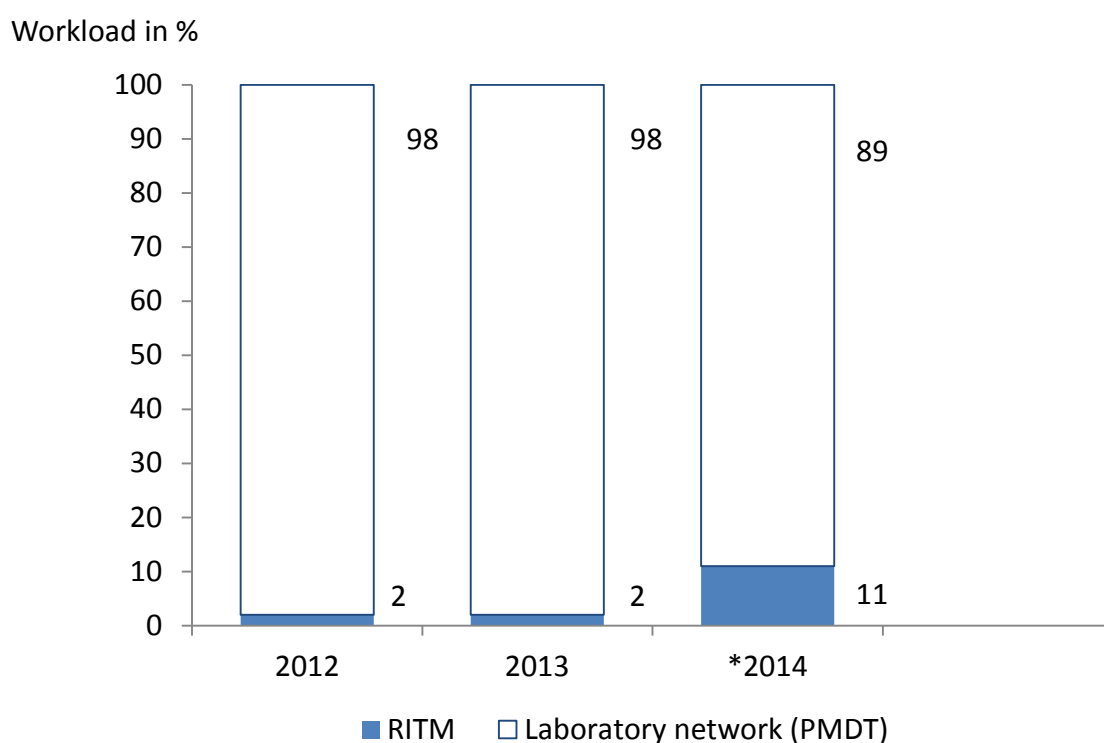
Year	GAA Budget	The Global Fund
2012	PHP 10 M	GF Phase I: P 40 M
2013	PHP 14 M	GF Phase II: P 42 M (Total for lab PHP 113,842,104.89)
2014	PHP 12 M	New Funding Model + incentive: PHP 15M

SECTION 11: LABORATORY SERVICES

NTRL provided laboratory services to referring units such as PMDT treatment facilities, non-functional culture laboratories, and research projects. The procedures performed at the NTRL laboratories were smear microscopy, Xpert MTB/RIF Assay, culture, DST (FLDs, SLDs), and LPA.

Test Procedures

DST



* Partial data for 2014

Figure 2. DST workload by source of specimens, 2012–2014

Figure 2 shows that the proportion of NTRL DST workload coming from referrals from PMDT diagnostic services is higher than that coming from RITM. In 2012 and 2013, NTRL's workload from RITM was only 2% compared to the remaining 98% examined from the laboratory network.

Data for 2014, although still incomplete, showed an increase in the number of specimens coming from RITM. The data from RITM was from January to September 2014 only, while that of the PMDT network was from January to June only.

Xpert MTB/RIF Assay**Table 18. Summary of Xpert MTB/RIF Assay results in 2014**

Xpert MTB/RIF Assay	2014*	
Number tested	1,358	
Number MTB detected	538	40%
Number rifampicin-resistant	264	49.6%
Rifampicin resistance not found	272	50%
Rifampicin resistance indeterminate	2	0.4%
Number MTB negative	820	60%

Media Preparation**Table 19. Media preparation by type, 2013 and 2014**

	No. of tubes		% Change
	2013	2014	
Ogawa media	22,000	52,690	140%
LJ media	11,000	26,089	137%

Workload**Table 20. Laboratory services workload by type of test, 2013 and 2014**

	2013	2014	% Change in workload
DSSM	6,794	9,244	36%
Xpert MTB/RIF Assay	1,298	1,358	4.6%
TB culture	2,176	4,171	92%
DST	2,249	2,193	-2.5%

TB Culture

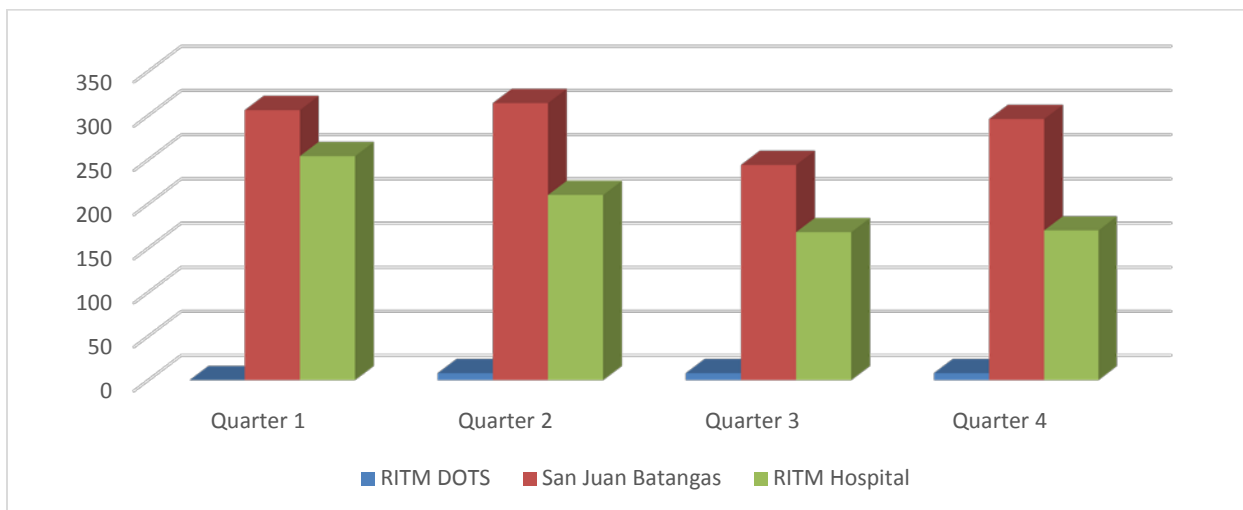


Figure 3. Quarterly TB culture workload in NTRL, 2014

Figure 3 shows that the highest number of specimens processed for culture in NTRL for 2014 came from research conducted in San Juan Batangas, followed by specimens coming from RITM (hospital, inpatient) and, lastly, the RITM-DOTS clinic.

PMDT DSSM Workload

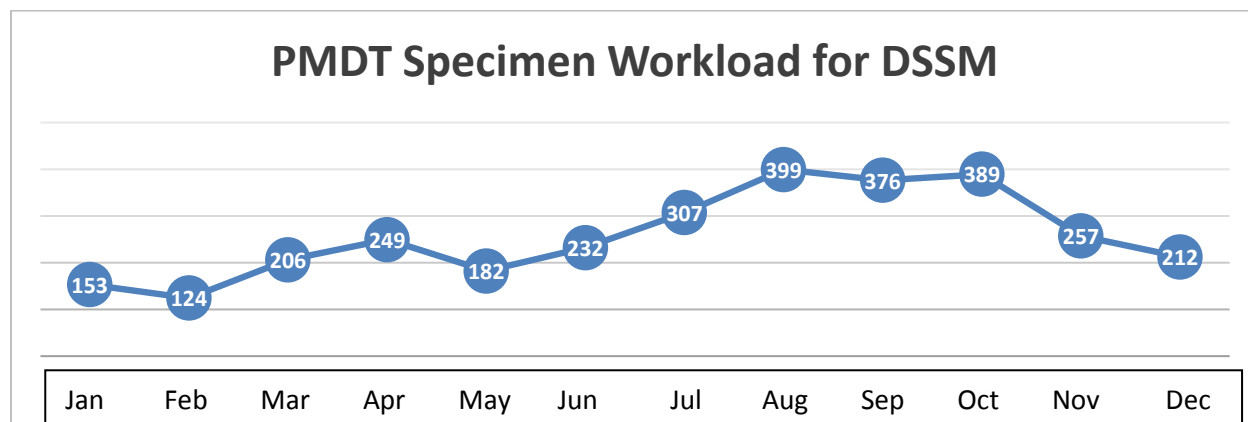


Figure 4. Monthly DSSM workload referred from the laboratory network, 2014

Figure 4 shows the monthly trend of specimen referrals for DSSM from the PMDT network. A total of 3,086 specimens were tested in 2014.

AIDS Research Group (ARG) DSSM Workload

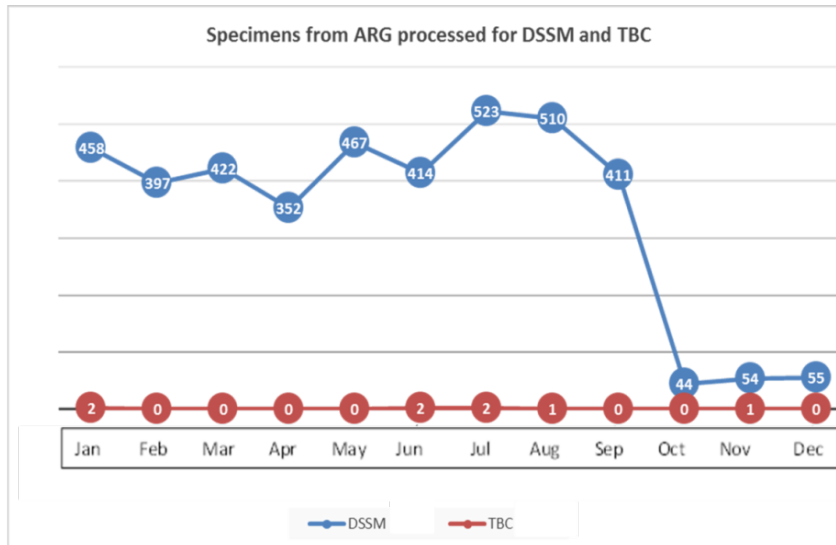


Figure 5. DSSM and TB culture workload from ARG by month, 2014

Figure 5 shows the monthly trend for specimens referred from the RITM ARG for DSSM and TB culture. In 2014, a total of 4,107 specimens were tested with DSSM and 8 (0.19%) were processed for TB culture.

Turnaround Time (TAT)

Xpert MTB/RIF Assay TAT

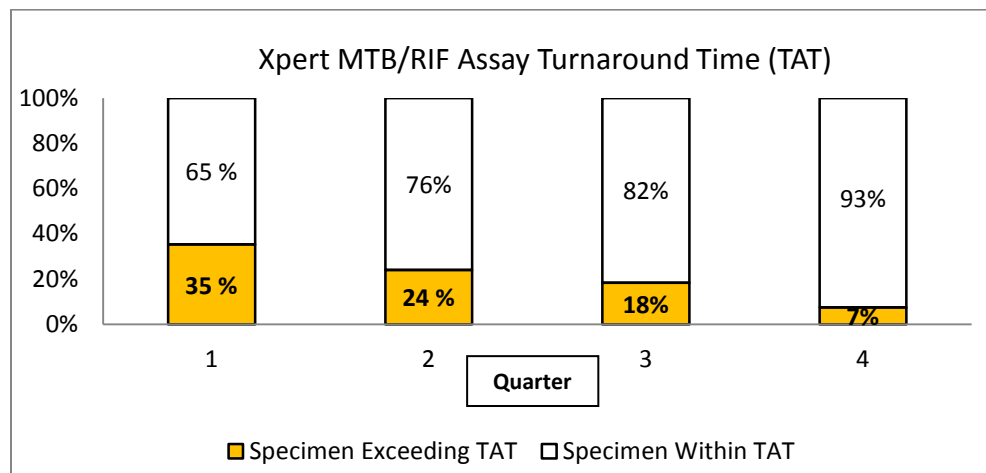


Figure 6. Proportion of GeneXpert tests within standard TAT in NTRL, 2014

Figure 6 shows that in all quarters, the majority (65–93%) of tests were within the TAT. The decrease in the number of tests exceeding TAT throughout the four quarters illustrates an improvement in laboratory performance in terms of promptness of processing of specimens and releasing of results.

DSSM TAT

Table 21. Quarterly DSSM performance by TAT, 2014

Quarter	Total Specimens	Specimens within TAT	%	Specimens Exceeding TAT	%
1	982	958	98	24	2
2	971	960	99	11	1
3	1,099	768	70	331	30
4	574 (partial)	432	75	142	25
Total	3,626	3,118	86	508	14

Table 21 shows that the majority of DSSM tests fall within the TAT of five days. However, in Quarters 3 and 4, there was an increase in the number of tests that exceeded the TAT.

ANNEX A. FUNCTIONS OF NTRL MANAGEMENT AND TECHNICAL UNITS

Management

1. Provide leadership and strategic direction to NTRL units and laboratory network
2. Oversee development and implementation of human resource development plan for NTRL staff
3. Supervise all NTRL staff to ensure that each are performing tasks based on their job description and in accordance with the unit's mandates and plan
4. Make and implement decisions based on available data, information, and knowledge
5. Review and approve NTRL and unit annual work and financial plan
6. Monitor the activities of NTRL to ensure they are in keeping with its goals and objectives
7. Mobilize internal and external resources to support the conduct of activities of NTRL and laboratory network and ensure their efficient utilization
8. Provide technical assistance to NTP on matters related to TB laboratory
9. Work closely with RITM management and its other units to ensure prompt and adequate support to NTRL plans and programs
10. Collaborate with stakeholders and partners to ensure coherence and complementation of goals, targets, and strategies
11. Develop and implement unit procedural manual and guidelines

Administration Unit

1. Provide administrative support to NTRL management related to personnel matters including, but not limited to, hiring, orientation, capability building, monitoring of attendance, and evaluation of performance in coordination with the RITM personnel unit
2. Manage budgetary and financial matters in coordination with the RITM finance and budget office including, but not limited to, preparation of financial requirements, request for financial support, facilitating release of funds, tracking expenditures, and liquidation/reimbursement
3. Coordinate with concerned offices to facilitate procurement, distribution, monitoring, and maintenance of supplies and equipment
4. Consolidate and monitor NTRL annual work and financial plan
5. Implement measures to ensure safe, clean, and environmentally-friendly office and well-maintained building (facility management)
6. Develop and implement systems to facilitate internal and external communication processes
7. Provide administrative support to other NTRL units
8. Facilitate day-to-day coordination and administration of NTRL activities and services
9. Prepare and submit periodic reports
10. Prepare work plan and budget for the unit
11. Monitor and evaluate outputs and outcomes related to their functions
12. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions

Laboratory Services Unit

1. Perform TB laboratory tests for NTP, RITM, and other clients and ensure prompt release of results to requesting offices/agencies
2. File and maintain printed and electronic copies of all laboratory forms and records
3. Perform TB laboratory tests for research, surveillance, and special surveys
4. Assist in the development of technical specifications and standards for laboratory facilities, equipment, supplies, and consumables for NTP laboratory services
5. Develop and implement ISO procedural manual and work instructions
6. Prepare and assist in the distribution of quality assured-culture media for the laboratory network
7. Manage the internal quality system on laboratory procedures of the unit
8. Assist other units by acting as trainer, mentor, resource person, and monitor
9. Prepare and submit periodic reports
10. Prepare work and financial plan for the unit
11. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions

Training and Development Unit

1. Provide technical inputs in the development of NTP laboratory training policies and guidelines
2. Develop, update, and conduct the NTP laboratory training program for staff at NTRL and the rest of the NTP laboratory network based on the analysis of training needs
3. Develop effective TB laboratory training courses including tools, modules, etc.
4. Develop and conduct TOT program for NTP laboratory training
5. Provide technical support in the roll-out of training for TB laboratory tests
6. Monitor and evaluate the implementation of the NTP laboratory training program
7. Serve as trainer, facilitator, and resource person for selected training courses
8. Coordinate with and engage other institutions and agencies involved in capability building activities related to TB laboratory
9. Prepare and submit periodic reports
10. Prepare work plan and budget for the unit and network
11. Certify laboratory training facilities based on set standards
12. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions

Program Support and Quality Management Unit

1. Develop the quality assurance program and standards for all TB laboratory tests implemented in the NTP including, but not limited to, culture and DST, rapid diagnostic technologies, and TB sputum microscopy
2. Provide technical leadership and assistance for the implementation of the QA program for NTP laboratory services
3. Monitor and evaluate the implementation and results of the TB laboratory QA program

4. Lead in the development of technical specifications and standards for laboratory facilities, equipment, supplies, and consumables for NTP laboratory services
5. Evaluate TB test kits, laboratory equipment, and other supplies to determine if products tested meet NTRL standards, and provide product test results to NTP, RITM, and other relevant offices to guide product selection, procurement, and use
6. Conduct laboratory tests for QA program for NEQAS, culture, DST, and rapid diagnostic tools such as GeneXpert
7. Provide technical support in the expansion and maintenance of the NTP laboratory network based on LNSP
8. Assist in monitoring and evaluation of the status and performance of the NTP laboratory network in collaboration with other TUs
9. Assist other units by acting as trainer, mentor, resource person, and monitor
10. Prepare and submit periodic reports
11. Prepare work plan and budget for the unit
12. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions

Policy and Research Unit

1. Coordinate the process of developing, updating, and disseminating policies, guidelines, and standards for the TB laboratory
2. Monitor and evaluate the implementation of NTP laboratory policies, guidelines, and standards
3. Manage the development and implementation of the TB laboratory policy and research agenda
4. Coordinate capacity building of laboratory network staff to design and implement TB laboratory policies and research
5. Provide technical support in the conduct of research and other special studies
6. Promote the use of study results for policy development, planning, decision making, and improvement of NTP laboratory performance
7. Assist in generating technical and funding resources for research
8. Prepare and submit periodic unit reports
9. Prepare work plan and budget for the unit
10. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions

Monitoring and Evaluation Unit

1. Organize M&E activities for NTRL and the NTP laboratory network
2. Develop M&E framework, systems, processes, and tools for NTRL and the NTP laboratory network in coordination with NTP
3. Develop and implement the NTP laboratory network M&E plan according to LNSP indicators
4. Provide technical support in TB laboratory data management and information utilization
 - a. Collect, encode, consolidate, and analyze data, information, and knowledge

- b. Manage, store, and safekeep all data, information, and knowledge (Knowledge Management)
 - c. Promote the use of data, information, and knowledge for planning
 - d. Participate in the development and implementation of NTP M&E
5. Monitor and evaluate the overall performance of the TB laboratory network and NTRL in collaboration with key NTRL TUs
- a. Collaborate with other TUs, technical partners, and stakeholders in matters related to their functions
6. Prepare and submit periodic reports, including the NTRL quarterly and annual performance report
7. Prepare work and financial plan for the unit

ANNEX B. FUNCTIONS OF NTRL TECHNICAL UNIT HEADS

Leadership Functions

1. Establish a clear direction for the unit in accordance with NTP, RITM, and NTRL's vision and goals
2. Define the unit's goals and communicate these clearly to unit members and stakeholders
3. Promote unity, transparency, and accountability within the unit
4. Build the unit's capacity to enable unit staff to achieve the goals and objectives; this includes training, coaching, and provision of appropriate tools to increase staffs' knowledge and skills
5. Lead the unit in developing sound strategies and plans to achieve its goals and objectives
6. Align internal and external stakeholders to the unit's goals and objectives
7. Mobilize people and resources to support implementation of the strategic plan
8. Coordinate with other TUs and management to ensure harmonious cooperation and collaboration
9. Motivate and inspire the unit to overcome obstacles

Management Functions

1. Organize the unit, including staffing and the development of unit policies and procedures to ensure order and discipline
2. Lead the development of unit work plans and budget guided by priorities, timelines, and resource limitations
3. Allocate resources to implement the work plan
4. Monitor the implementation of the work plan; use monitoring information to make adjustments and achieve good quality outputs
5. Evaluate unit performance and outputs; manage and use evaluation results to inform strategies and plans
6. Ensure the development and submission of comprehensive unit reports in a timely manner
7. Work with management and, if needed, other stakeholders to address unit problems, grievances, and conflict