MASTER PLAN FOR THE PUBLIC HEALTH LABORATORY SYSTEM IN ETHIOPIA


Ethiopian Health and Nutrition Research Institute (EHNRI)
Federal Ministry of Health, Ethiopia
MASTER PLAN FOR THE PUBLIC HEALTH LABORATORY SYSTEM IN ETHIOPIA

Second Edition
(2009 – 2013)

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Foreword

Laboratory services are essential components of the health care system. In Ethiopia, the public health laboratory system is currently in development and has yet to mature to its full capacity. Therefore, the implementation of laboratory-dependent disease prevention and control programs has been faced with many challenges.

The Ethiopian Health and Nutrition Research Institute (EHNRI) was mandated by the Federal Ministry of Health to strengthen the national laboratory system in October 2005. As the technical arm of the Ministry of Health and the responsible body for building the capacity of the national laboratory system, EHNRI prepared the first Laboratory Master Plan in 2005 with the focus on building the HIV laboratory system. Significant achievements have been made in HIV laboratory services. However, HIV/AIDS services have advanced separately from other laboratory services that are equally important for the efficient and effective delivery of health services.

The second edition of the Master Plan is hence produced to address this gap to provide national guidance for the integrated development of clinical and public health laboratory services. The Master Plan envisions that the gains made in the field of HIV/AIDS care are leveraged to elevate the quality of services provided by the entire laboratory, and not only that of a specific division or program. It emphasizes the integrated approach to comprehensively improve patient care services and to avoid duplication of programs and efforts so that resources may be utilized effectively.

This Master Plan describes seventeen strategic objectives. Plans are laid out with specific goals under each strategic objective. EHNRI will be working with regional laboratories, partner organizations, professional associations, and experts from different fields for the realization of theses objectives so that efficient and reliable public health laboratory services are rendered to the people of Ethiopia.

On behalf of EHNRI, I would like to take this opportunity to thank all those who contributed to the development of this document. In particular, I would like to thank the Clinton Foundation HIV/AIDS Initiative for all of its support in the development of both the first and second editions of the Laboratory Master Plan.

Thank you,
Tsehaynesh Messele
Director General, EHNRI
Abbreviations

AIDS  Acquired Immunodeficiency Syndrome
ART  Antiretroviral Treatment
DACA  Drug Administration and Control Authority
DNA PCR  Deoxyribonucleic Acid Polymerase Chain Reaction
EHNRI  Ethiopian Health and Nutrition Research Institute
EQA  External Quality Assessment
FBO  Faith-Based Organization
FMoH  Federal Ministry of Health
HAPCO  HIV/AIDS Prevention and Control Office
HIMS  Health Information Management System
HIV  Human Immunodeficiency Virus
HSDP  Health Sector Development Program
IQC  Internal Quality Control
IT  Information Technology
JCI  Joint Commission International
LIMS  Laboratory Information Management System
M&E  Monitoring and Evaluation
NEQAS  National External Quality Assessment Scheme
NGO  Non-Governmental Organization
NLQSG  National Laboratory Quality Steering Group
NLTWG  National Laboratory Technical Working Group
OI  Opportunistic Infection
PFSA  Pharmaceutical Fund and Supply Agency
PID  Patient Identification
PPT  Proficiency Panel Testing
QA  Quality Assurance
QC  Quality Control
REQAS  Regional External Quality Assessment Scheme
SCMS  Supply Chain Management System
SNNPR  Southern Nations Nationalities and Peoples Region
SOPs  Standard Operating Procedures
STI  Sexually Transmitted Infection
TB  Tuberculosis
TOT  Training of Trainers
TWG  Technical Working Group
WHO  World Health Organization
Executive Summary

The Master Plan for the Public Health Laboratory System in Ethiopia (hereinafter “Master Plan”) serves as the blueprint for the development of Ethiopia’s public health laboratory system. The Master Plan also provides national operational guidelines for public health laboratories, laboratory-dependent health programs, and donor organizations looking to fill resource gaps. This document describes specific strategies and plans for the development and implementation of laboratory services nationwide for the years 2009 through 2013.

This Master Plan is divided into seventeen strategic objectives. Each section of the strategic objectives contains a description of the situational analysis, specific strategic approaches, planned activities, and goals to achieve by the year 2013. The following are the strategic objectives described in this second edition of the Master Plan:

Strategic Objective 1:
To identify, plan, and build capacity for diagnostic services of integrated diseases
This objective describes strategies, plans, and goals to standardize laboratory services and equipment for the national laboratory system in Ethiopia.

Strategic Objective 2:
To develop integrated laboratories
This objective addresses merging of the general laboratory components to that of the ART laboratory program to facilitate integrated laboratory systems for maximum resource utilization and service coverage.

Strategic Objective 3:
To build the capacity of the Regional Laboratories
This objective seeks to support the decentralization of health services by developing the capacity of the Regional Laboratories to enable their effective coordination, leadership, and management of their respective regional laboratory programs.

Strategic Objective 4:
To improve procurement, supply, and distribution of laboratory reagents and supplies
This objective ensures timely distribution and appropriate supply of laboratory instruments, reagents, and other materials.

Strategic Objective 5:
To expand and strengthen the National Laboratory Quality System
This objective pursues the expansion of the National Laboratory Quality System for integrated diseases through accreditation, external quality assessment program scale-ups, and capacity building.
Strategic Objective 6:
To conduct post-market surveillance to ensure that diagnostic instruments and products available throughout the country perform reliably and meet national quality standards
This objective describes methods and activities to continually monitor laboratory instruments and products to ensure their sound performance for high quality testing services.

Strategic Objective 7:
To expand and strengthen standardized training programs for laboratory personnel and other health care workers
This objective aims at ensuring the standardization of laboratory trainings across the country and the appropriate training of all relevant laboratory and health care personnel.

Strategic Objective 8:
To improve human resource recruitment, selection, motivation, and retention
This objective seeks to ensure an ample supply of a skilled and productive workforce in the national laboratory system through effective recruitment, selection, motivation, and retention mechanisms.

Strategic Objective 9:
To improve the management of equipment service and maintenance
This objective pursues the effective management of equipment service and maintenance so that all laboratory instruments are functional to enable uninterrupted testing services.

Strategic Objective 10:
To establish and strengthen laboratory networking nationally and internationally
This objective addresses the national laboratory system’s networking needs to facilitate logistics, specimen movement, instrumentation usage, and information technology linkages within and between laboratories.

Strategic Objective 11:
To develop a data management system
This section describes strategic plans to improve data management of the national laboratory network to facilitate effective data capture, storage, and analysis as well as effectual monitoring and evaluation systems.

Strategic Objective 12:
To develop an effective national monitoring and evaluation system
This objective seeks to develop a strong monitoring and evaluation system for sound program assessments through the standardization of tools and indicators, cooperation with partner organizations, and linkage with existing systems.
Strategic Objective 13:
**To evaluate new technologies for public health laboratory services throughout the country**
This objective deals with the evaluation of new technologies and their subsequent introduction into the national laboratory system to address the health priorities of the country.

Strategic Objective 14:
**To strengthen operational research to prevent and control diseases in the country**
This section describes how operational research activities will be prioritized and subsequently pursued through strengthened research capacity and strategic partnerships with other major research institutions.

Strategic Objective 15:
**To elevate EHNRI’s status as a center of excellence by fostering closer ties with other major public health institutions and national reference laboratories**
This objective seeks to raise the profile of EHNRI such that it gains the recognition of being one of the premier public health institutions and reference laboratories in Africa.

Strategic Objective 16:
**To improve communication with relevant stakeholders**
This section addresses issues related to advocacy on the role of the laboratory in the health care delivery system as well as transparency among stakeholders for efficient program management.

Strategic Objective 17:
**To develop a plan for sustainability of the national laboratory system**
This objective aims at ensuring the development of sustainability plans for the activities of the national public health laboratory system.
Preface to the Second Edition

This Master Plan is designed to serve as a blue print for the development of Ethiopia’s clinical and public health laboratory services. The first edition of the Master Plan was created in 2005, with a focus on the antiretroviral treatment (ART) laboratory system. It was crafted through a participatory, inclusive, and consultative process involving all key stakeholders. A core team drawn from EHNRI was mandated to develop the initial draft of the plan. The draft formed the working document for the broader workshop to develop and finalize the plan. This consensus workshop involved a wider spectrum of participants, including representation from regions. Following the consensus meeting, the EHNRI team, in conjunction with representatives from regions, finalized the document by incorporating recommendations from the meeting. The Master Plan’s subsequent implementation was primarily overseen by EHNRI with support from Regional Health Bureaus.

Following the first edition of this plan, significant progress has been made in developing EHNRI’s capacity to support the national laboratory system and to bring ART laboratory services to health facilities throughout the country. Automated analyzers have been installed in 93 laboratories; a national training program for CD4, clinical chemistry, and hematology has been rolled out from a training of trainers (TOT) workshop at EHNRI to Regional Laboratories; the new national rapid test algorithm has been implemented; and external quality assessment (EQA) programs have been scaling up for rapid tests, CD4, clinical chemistry and hematology. In addition, EHNRI has undergone a reform in order to better execute its responsibilities. These changes have included the creation of a National Laboratory System Division to oversee EHNRI’s support in developing the country’s laboratory network. Furthermore, since the original plan was published in 2005, the laboratory program’s focus has shifted from an emphasis on HIV to an integrated approach for all laboratory services. This second edition of the Master Plan updates the original strategy to account for new developments and to address the evolving priorities of the country.

Similar to the first edition, the initial draft of the second edition of the Master Plan was created by an EHNRI task force. This draft was then presented to various stakeholders during a consensus meeting held in Adama in June 2008, which included representation from the Regional Health Bureaus, Regional Laboratories, academic institutions, professional associations, the private sector, as well as donor and implementing partner organizations. This document was finalized with the recommendations made at the Adama review meeting.
Introduction

In its work for the Ethiopian public, EHNRI is guided by a vision to exemplify a center of excellence in public health, nutrition, research, and quality laboratory systems in Africa. To the aim of realizing this vision and in accordance with the mission of the Institute, EHNRI strives to promote the health of the Ethiopian people by addressing priority public health problems through research, development of sustainable quality laboratory systems, and advocacy.

This Master Plan for the Public Health Laboratory System in Ethiopia defines the strategy by which EHNRI will fulfil this mission and elevate the standard of Ethiopia’s public health and clinical laboratories over the next 5 years. The Master Plan pertains to the public health laboratory system, which includes all laboratories whose work promotes the health and well-being of the public (e.g. facilities involved in water and air quality, food and beverage safety, environmental health, and clinical diagnostics). These strategies have been defined by assessing the gap between current services and the country’s goals for the future. Through these strategies, EHNRI aims to develop an affordable and sustainable system, whereby quality laboratory services are accessible to all Ethiopians, while reliable and high-quality results provide valuable guidance to clinical decision making throughout the country. Additionally, EHNRI’s long-standing commitment to scientific research will be focused on improving the country’s response to critical health issues.
Background: Laboratory Services in Ethiopia

The health care system of Ethiopia includes community health services, health posts, health centers and hospitals at district, regional and central referral levels. According to the recent report on Health Indicators from the Federal Ministry of Health (FMoH) for 2006/2007, there are 143 hospitals, 690 health centres, 1,376 health stations and 9,914 health posts with potential health service coverage of 86.7% [FMoH Health Indicators, 1999 EC].

The current laboratory system in Ethiopia is organized in a structure that follows the general health care delivery system of the country. This system incorporates hospitals at the federal, regional, zonal and district levels in addition to health centers and health posts. Diagnostic laboratories are the main components of these facilities from the health center level upwards, although the size and complexity of the laboratory differ at each type of facility. The FMoH is dedicated to ensuring that medical laboratory services are accessible to all Ethiopians. Where laboratories do not exist, there should be a referral system in place for sending specimens to the nearest reference laboratory.

At the apex of this system, there are several Regional Laboratories and a National Reference Laboratory at EHNRI. There are currently eight Regional Laboratories located in Addis Ababa, Amhara (Bahir-Dar and Dessie), Oromia (Adama and Nekemt), SNNPR (Awassa), Tigray (Mekelle) and Harrari Regions (Harrar). In regions without a Regional Laboratory (Dire Dawa, Gambella, Afar, Benishangul-Gumuz, Somali), the regional referral hospital laboratories serve this function. The Regional Laboratories fall under the Regional Health Bureaus and are designed to serve as reference laboratories, conduct trainings, ensure quality assurance (QA)/ quality control (QC) of the existing laboratories in their jurisdictions, and support the peripheral laboratories with supplies or capacity building. In addition, there are several laboratories under the Armed Forces Health Department, Police Forces Health Department, university laboratories, or those linked to blood bank centers, private hospitals, and non-governmental organizations (NGO), as well as stand-alone private laboratories.

EHNRI

EHNRI was established by an Act of Parliament (Proclamation No. 26/1996) of the Federal Democratic Republic of Ethiopia. EHNRI was established with the mandate to serve as Ethiopia’s National Center of Excellence to perform referral medical laboratory services relating to the occurrence, causes, prevention, and diagnosis of major diseases of public health importance; to establish and support national laboratory quality assurance programs and systems; and to train personnel on existing and new diagnostic and programmatic tools. In 2005, the FMoH gave EHNRI the additional responsibility of leading and strengthening the national laboratory system. EHNRI is further mandated to conduct operational research related to infectious and non-infectious diseases, nutrition, and traditional medicine. EHNRI serves as a National Reference Center for the entire country, rendering highly specialized diagnostic services that cannot be conducted elsewhere within...
the country. Additionally, EHNRI implements national external quality assessment schemes. EHNRI, in collaboration with key stakeholders, is currently working on the development of a National Policy on Public Health Laboratory Services and National Policy Guidelines with the objective of establishing a standard public health laboratory system in the country.

Several other key government agencies support the laboratory system. The Drug Administration and Control Authority (DACA) oversees regulatory activities and is thus responsible for permitting the entry of diagnostic laboratory reagents and supplies to the country. Certification for laboratory personnel as well as laboratory services is undertaken by the Department of Health Services and Training at the FMoH. The Pharmaceutical Fund and Supply Agency (PFSA) of the FMoH is responsible for the purchase and distribution of laboratory equipment, reagents and consumables.
Strategic Objective 1

To identify, plan, and build capacity for diagnostic services of integrated diseases

Situational Analysis

Laboratory standards for the integrated diagnosis of diseases will be necessary for all levels of the laboratory system to define the services required at each facility. The standards will be set such that all critical health issues can be addressed by Ethiopia’s laboratory system. These standards will guide the priorities of EHNRI and the national program in developing the capacity of laboratories, based on the gap between the standards and the current state of the system.

A preliminary draft of laboratory standards is currently being developed by the National Laboratory Technical Working Group (TWG). Once submitted, EHNRI will review, revise, and approve a final draft to serve as the country’s National Laboratory Standards.

To ensure that laboratory needs are identified, activities are well planned, and laboratories are developed for the diagnosis and treatment of integrated diseases, the following strategies will be employed:

Strategies

• Determine necessary laboratory services to be rendered at each tier of the laboratory system.
• Develop the laboratory system at each level as per the testing requirements and corresponding instrumentation defined by the National Laboratory Standards
• Focus development and capacity building efforts on attaining the national standards.
• Ensure that laboratory testing services are accessible to all Ethiopians by distributing testing capacity in a rationalized and tiered laboratory network
• Develop referral linkage system between the tiers of the laboratory network

Planned Activities

Systemize laboratory standards and tiers of testing services
Currently, public health laboratory services are provided at five levels (Figures 1 and 2):
1. National Laboratory (EHNRI)
2. Regional Laboratories and Federal Hospitals
3. Specialized General Referral Hospital Laboratories
4. Zonal / District Hospital Laboratories
5. Health Center Laboratories
Figure 1. Current public health laboratory system- Administrative structure

Dotted arrows indicate interactions between independent entities

DACA: Drug Administration and Control Agency
FBO: Faith Based Organization
HAPCO: HIV/AIDS Prevention and Control Office
NGO: Non-Governmental Organization
PFSA: Pharmaceutical Fund and Supply Agency
However, a new laboratory system structure has been proposed, which categorizes laboratories in four levels (Figure 3):

- **Level IV**: National Reference Laboratory (EHNRI)
- **Level IIIa**: Regional Laboratories
- **Level IIIb**: Laboratories of the Federal Health Institutions, including Uniformed Forces
- **Level IIIc**: Central Blood Bank Laboratory
- **Level IIa**: Regional Specialized Hospital Laboratories
- **Level IIb**: Zonal Hospital Laboratories
- **Level IIc**: District Hospital Laboratories
- **Level Ia**: Health Center laboratories
- **Level Ib**: Health Posts

Private laboratories are also subject to this categorization of laboratory services, spanning Levels I through IV.
Minimum laboratory standards are being defined for laboratories at each tier of the system in consideration of the availability of resources and disease burden in Ethiopia. These minimum standards will be created in reference to the “Maputo Consensus Report” formally known as *Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization* (Maputo, Mozambique, January 2008). The relevant sections of the Maputo Consensus Report may be referenced in Appendix 1 and 2. In accordance with these standards, laboratory services and corresponding instrumentation will be prescribed for each level by the National Laboratory TWG.
Develop laboratories to meet National Laboratory Standards

EHNRI will work with regions, partners, and stakeholders to coordinate efforts and focus resources on bringing each tier of the network up to the standards. In order to do so, an annual assessment of laboratories, conducted in coordination with the quality program, will be utilized to identify gaps between the current state of laboratories and the national standards. Infrastructure improvements, procurement of equipment and supplies, training of laboratory workers, and maintenance are among the interventions that may be utilized to improve the laboratories.

In order to fill the gaps, interventions will first target priority diseases. Fundamental and cross-cutting laboratory techniques at the peripheral laboratory level (e.g. microscopy) will also be prioritized. Other gaps such as the decentralization of quality assurance programs will be addressed subsequently in a phased approach.

Standardize instrumentation and other testing platforms

In order to provide laboratory services and manage testing volumes in accordance with the National Laboratory Standards, a minimum configuration of equipment and testing supplies will be required. The necessary medical devices designated for the different laboratories will be outlined in the National Laboratory Standards, which will be created in reference to the “Maputo Consensus Report” (Appendix 2).

The network of common laboratory instruments and other testing devices will be designed to promote harmonization in selecting equipment and to provide the appropriate testing capacity at each level of the laboratory.

Further details about instrumentation procurement are described in Strategic Objective 4. Design of the instrument network is discussed further in Strategic Objective 10 on laboratory networking.

2013 Goals

- Essential laboratory services have been introduced at each level of the system, as defined by the National Laboratory Standards
Strategic Objective 2

To develop integrated laboratories

Situational Analysis

With the advent of the national ART program, laboratory services were required to scale-up rapidly in order to meet the increased testing demand. Resources were focused on building the capacity of ART laboratories, often housed separately within the general laboratory of a hospital. In particular, significant attention has been given to HIV diagnosis, staging, and monitoring (HIV rapid testing, hematology, clinical chemistry, and CD4 counting). While HIV/AIDS patients have benefited from these advances, the improvements have often been limited to the aforementioned tests and not always shared with the other patients of the health care system. As such, HIV patients requiring general microbiology, parasitology, or opportunistic infection (OI) testing have received only limited benefits in those areas even though these tests are also crucial to HIV care. Similarly, non-HIV patients presenting for hematology or clinical chemistry testing may not benefit from the same quality of services that are provided through the ART program. It is understood that HIV/AIDS patients rely upon a variety of laboratory services and many of those services rendered to HIV/AIDS patients are also essential for the diagnosis and treatment of other diseases. In order to harmonize the successful advances in ART laboratory services with the work of the general laboratory and move toward the development of integrated laboratories, the following strategies will be employed:

Strategies

- Integrate the physical space dedicated to ART services with the rest of the clinical laboratory to remove perceptions among laboratory workers that ART services are handled separately from the routine operations of the laboratory
- Integrate testing of general laboratory patients into the testing of ART patients. The same medical devices will be used for all patients
- Harmonize and standardize procurement of laboratory reagents and supplies to ensure that the supplies available to ART patients are available for all patients of the laboratory. This will also ensure that the maximum buying power of the Ministry of Health is harnessed to achieve optimal cost savings
- Extend quality assurance programs developed for the ART laboratory to all laboratory disciplines and ensure that the same quality of laboratory services are available to diagnose all diseases for all patients
- Extend data management systems to encompass all tests
• Extend training programs to comprehensively address all laboratory disciplines and practices
• Extend safety programs to comprehensively address the entire laboratory
• Where appropriate, integrate sample referral of HIV samples with the referral network for other diseases and utilize or build upon the same sample transportation systems for all specimens

Planned Activities

Assess ART laboratories to identify duplication and opportunities for integration
EHNRI will work with Regional Laboratories, facilities, and partner organizations to assess ART laboratories and create recommended guidelines for integrating ART activities into the general laboratory. Stakeholders will work together to develop integrated laboratories and remove unnecessary vertical silos from all laboratories in the country. Those facilities performing chemistry and hematology tests separately for non-ART patients will be supported to integrate their testing.

Assess current procurement practices and supply requirements to identify opportunities for standardization and integration
Sample collection supplies, open-system reagents, and safety supplies are among the examples of products for which fragmented supply chains currently exist in Ethiopia. Products for the HIV program are procured centrally, while products for general patients are procured separately. Consequently, the general laboratory often receives products of a lesser quality and the full buying power of the Ministry of Health is not harnessed for pooled procurement of common products. This practice also complicates the standardization of products and quality standards. EHNRI will evaluate opportunities for pooling general laboratory needs for procurement through PFSA, from which hospitals can in turn procure the same quality of supplies for all of its facilities and laboratory programs. Until PFSA’s capacity is fully developed, EHNRI will work with partners to identify temporary or short-term solutions for these services.

Extend quality assurance programs to all testing services
Significant developments in quality assurance programs for HIV testing, clinical chemistry, hematology, and CD4 testing have produced quality improvements in the ART laboratory. These programs will be extended to address all laboratory testing areas. The national and regional EQA programs will be expanded to encompass other diseases, while quality control measures, logs, and documentation implemented for the ART laboratory will be extended throughout the general laboratory. More information on Quality Assurance plans is provided in Strategic Objective 5.
Extend data management systems to encompass all tests
Emphasis will be placed on data management for all laboratory tests. In addition to the reporting formats that EHNRI has distributed in the Communications Handbook for ART laboratory services, EHNRI will work with Regional Laboratories to support improved data collection for all laboratory services. For more on data management systems, refer to Strategic Objective 11.

Extend training programs to comprehensively address all laboratory disciplines and needs
The majority of laboratory training programs currently address HIV. These programs will be extended to other priority diseases. The National Training Office at EHNRI will map out training priorities for the country and will work with stakeholders and partners to develop plans for addressing training gaps. See Strategic Objective 7 for further detail on training plans.

Extend safety programs to comprehensively address the entire laboratory
The National Health and Safety Guidelines document is being finalized in order to promote safe laboratory practices. The National Health and Safety Officer will oversee the implementation of the manual in all laboratories of the country.

Integrate sample referral networks for all diseases
Vertical systems have resulted in separate sample referral networks for CD4, chemistry, hematology, DNA PCR, tuberculosis (TB), surveillance samples, supply logistics, and other specialized services. These systems will be reviewed to identify opportunities for integration. A robust sample referral network will allow the country to achieve the vision of a tiered laboratory network with strong linkages between each level, regardless of the sample type. Further information on this activity is discussed in Strategic Objective 10.

2013 Goals

• Establish integrated laboratories without distinctions between the general laboratory and the ART laboratory
• All patients receive the same quality of services and supplies, regardless of disease
• All laboratory workers have access to training and conduct safe laboratory practices, regardless of the disease or program with which they work
• A harmonized, quality sample transportation network allows access to all referral testing services, regardless of disease
Strategic Objective 3

To build the capacity of the Regional Laboratories

Situational Analysis

As the national reference laboratory of the country, EHNRI has the mandate to build the capacity of Regional Laboratories. EHNRI has employed infrastructure upgrades, training programs, quality assurance programs, supply chain initiatives, and other strategies to assist the Regional Laboratories and upgrade their ability to provide laboratory services for integrated diseases. However, as there remains a significant gap between their current state and National Laboratory Standards, EHNRI will strive to improve its efforts to support capacity building at the Regional Laboratories. In March 2008, the National Laboratory System Division was created at EHNRI to enhance the Institute’s support to the country’s laboratory network. This division will play a central role in fulfilling EHNRI’s responsibilities for strengthening regional laboratory systems. To this end, the following strategies will be employed:

Strategies

• Strengthen the National Laboratory System Division at EHNRI to enable dedicated human resources for supporting the Regional Laboratories
• Coordinate and harmonize partner activities to achieve the most efficient use of available resources
• Support decentralization of laboratory services by strengthening physical and technical capacity of Regional Laboratories. Over time, further capacity building and operational support of peripheral laboratories and regional quality assurance programs will be conducted by the Regional Laboratories themselves
• Identify major infrastructure deficiencies at regional laboratories, advocate for funds and coordinate the activities of supporting partners to foster support for reaching the National Laboratory Standards
• Transfer best practices for supporting national laboratory programs from EHNRI to the regional levels (e.g. quality assurance, procurement and supply planning, training coordination, and maintenance program management)
• Coordinate, standardize and strengthen training workshops and mentorship programs to improve the technical and management skills of laboratory workers at all Regional Laboratories
• Ensure that referral and communication networks between all laboratories are functional and efficient to permit the communication of information and referral from peripheral
laboratories to Regional Laboratories and from Regional Laboratories to the national reference laboratory

Planned Activities

**Strengthen the National Laboratory System Division of EHNRI**

The National Laboratory System Division is one of three new divisions at EHNRI. The National Laboratory System Division will coordinate national programs for quality assurance, training, maintenance, and logistics. Also, the Division will respond to requests received from regional and peripheral laboratories. The mandate of the National Laboratory System Division is to:

- Establish and update national guidelines and manuals for laboratory safety, training, maintenance, and quality assurance
- Ensure that all laboratories in the national public health laboratory network are appropriately supplied at all times through proper quantification, procurement, and distribution
- Ensure that all laboratories in the national public health laboratory network are equipped with functioning machines and operating at acceptable quality standards so as to produce accurate laboratory results
- Direct national training programs so that laboratories are staffed with qualified people in a standardized manner
- Manage communications between EHNRI and Regional Laboratories/federal hospital laboratories such that requests and information are handled appropriately and expeditiously
- Establish a national laboratory quality system with proper laboratory management, training documentation, monitoring, and implementation
- Coordinate an efficient sample referral network
- Solicit and mobilize resources for the Division’s activities

It is essential for EHNRI to provide excellent support to regional and peripheral laboratories as listed above in order to enable those laboratories to carry out their responsibilities. Therefore, EHNRI will seek to ensure that positions in the Division are staffed with highly skilled human resources at all times to ensure uninterrupted programs in these critical areas.

**Maintain the National Laboratory Technical Working Group as a forum for coordinating partner activities at all levels**

The National Laboratory TWG, chaired by the Director General of EHNRI, provides a venue for sharing information between partners and harmonizing efforts. Such opportunities will facilitate transparency between stakeholders, implementing partners and technical experts, which will be essential for identifying areas of synergy and overlap. This will avoid
duplication of efforts and promote cooperative partnerships, thereby maximizing the use of available resources.

Implementation plans from partnering organizations will be shared with the TWG. The chair of the TWG will assume ultimate responsibility for directing the harmonization of activities between partners.

Support further decentralization of laboratory services by actively building the capacity of Regional Laboratories through mentorship, training, and central support services

In order to extend access to essential laboratory services to all Ethiopians, EHNRI will continue to support decentralization by strengthening Regional Laboratories. Over time, further capacity building and operational support of peripheral laboratories and regional quality assurance programs will be conducted by the Regional Laboratories. Through the National Laboratory System Division, EHNRI will utilize a variety of methods to build the capacity of Regional Laboratories to support the operations of peripheral laboratories below them. This approach will include:

- Annual planning/review meetings
- Training programs and workshops
- Mentorship
- Site assessments
- Provision of guidelines and recommendations
- Centralized support services (e.g. maintenance, procurement)
- Infrastructure development
- When appropriate and available, allocation of financial resources

Training programs for Regional Laboratories will also address the management of a laboratory network in order to improve their capacity for supporting their peripheral laboratories.

Mentorship will be provided to Regional Laboratories to improve laboratory operations and to assist with the development of regional programs in quality assurance, training, maintenance, supply chain logistics, and sample transportation. As described further in Strategic Objective 7, the National Training Office within EHNRI’s Quality Department will work with key stakeholders to standardize these training and mentorship programs.

Develop regional programs in quality assurance, training, maintenance, supply chain logistics, monitoring and evaluation, and sample transportation

Detailed strategies for each of these activities are described in greater detail in the subsequent strategic objectives. Examples of key activities will include the development of regional quality assurance programs, a “pull-system” for procurement of laboratory supplies from regions to PFSA, regional training teams, and regional maintenance workshops.
**Develop Regional Liaison Officers to assist the peripheral laboratories to communicate with Regional Laboratories and to assist the Regional Laboratories to communicate with EHNRI**

EHNRI’s Communication Handbook outlines the role of Regional Liaison Officers to support the Regional Laboratories fulfil some of their major objectives and responsibilities. Stationed at the Regional Laboratories, Regional Liaison Officers facilitate communication, data gathering, and channelling of requests for assistance between peripheral laboratories, Regional Laboratories, and EHNRI. Currently, the Regional Liaison Officer positions are seconded by partner organizations. However, in the interest of sustainability, they are to be absorbed into the government system. Through the directorship of the Regional Laboratories, the responsibilities of the Regional Liaison Officer will be redefined as priorities of laboratory programs evolve. These officers will be identified, trained, and supported to ensure that all sites have access to the communication, data, and referral networks of the system.

**Conduct comprehensive annual assessments to evaluate the infrastructural, logistical, and technical capacities of the country’s laboratories**

To evaluate the capacity of the national laboratory system, annual assessments of all laboratories will be conducted.

At each laboratory, information pertaining to the following will be collected:

- Physical set-up
- Human resources
- Laboratory equipment
- Available tests
- Supplies
- Quality assurance
- Specimen referral
- Communication
- Training
- Safety
- Clinician observations and feedback (if applicable)

The assessments will provide rational bases for determining the needs of each laboratory and the overall network to support the continued operations of national laboratory services. Recommendations resulting from these assessments will include specific actions for EHNRI and the regions to undertake in order to strengthen laboratory services in the country.
2013 Goals

- All Regional Laboratories will meet the infrastructure and technical requirements defined by the National Laboratory Standards
- All Regional Laboratories will mirror the services of EHNRI on a regional level to support the peripheral laboratory networks of their respective regions
- Regional Liaison Officer positions will be absorbed into the government system and their responsibilities will be mandated by EHNRI and the Regional Laboratories
- Communication and referral networks between all laboratories will be effective and efficient
Strategic Objective 4

To improve procurement, supply, and distribution of laboratory reagents and supplies

Situational Analysis

In order for laboratories to provide quality laboratory services in a timely manner, proper laboratory supplies in sufficient quantities must be available. The laboratory system suffers from frequent stock-outs of laboratory reagents and supplies at both the national and facility-level. These stock-outs are attributed to several factors, including:

- Insufficient capacity of distribution systems resulting in untimely delivery of supplies
- Poor inventory management resulting in emergency orders placed with insufficient lead-time
- Lack of transparency in distribution plans and lack of follow-up with sites after deliveries
- Lack of consumption data leading to inaccurate forecasts of supplies
- Poor adherence to standard operating procedures (SOP) and protocols at some facilities resulting in under/over-consumption of certain supplies
- Lack of harmonization between the procurement practices of the facilities and the central procurement for national programs

In light of the current challenges facing the national laboratory system, the strategies listed below describe methods for pursuing improved procurement and distribution of laboratory supplies in a sustainable manner:

Strategies

- Strengthen capacity for forecasting and supply chain management at EHNRI
- Collaborate with PFSA to harmonize procurement and distribution systems to supply the needs of the integrated laboratory
- Collaborate with PFSA to improve laboratory supply management at the facility level
- Implement criteria for rationalized selection and procurement of equipment and supplies
Planned Activities

**Rationalize equipment procurement**

Selection and procurement of medical devices will be guided by the following criteria:

1. International track-record of the manufacturer
2. Local track-record of the manufacturer or designated distributor
3. Previous and current experience with the instrument in the country
4. Robust, reliable, and high-quality performance of selected instruments (ease of use, frequency of breakdowns)
5. Instrument throughput and efficiency
6. Reasonable cost of instrument, consumables and reagents (long-term cost will be assessed)
7. Service and maintenance requirements
8. Availability and reliability of local service and maintenance providers or ability of manufacturer to support after-sales services
9. Reliability and flexibility of reagent supply
10. Network design which facilitates the implementation of quality assurance programs

An evaluation of products prior to procurement will be conducted by EHNRI in collaboration with DACA.

Procurement practices will aim to bring standardization to the laboratory network, improve quality management, and allow for cost savings in the procurement of supplies. A number of equipment and reagent procurement principles will be implemented. For example:

- Lease agreements will be considered in addition to the standard practice of purchasing equipment. For those situations where leasing options are cost-effective, such arrangements will provide the flexibility to upgrade equipment when volumes increase and to replace non-performing instruments.
- The number of manufacturers per type of analyzer will be limited to 2 to 4 in order to maintain standardization of the laboratory network and avoid fragmented reagent purchasing
- Considerations will be given to equipment and reagent manufacturers with local representation
- A monopoly of only one brand or one supplier will be avoided in order to prevent national-level reagent shortages due to supplier limitations
- When possible, consolidated purchasing will be used in order to access bulk purchase discounts. This will apply to combining orders between laboratories and public health programs such as HIV/AIDS, malaria, TB, and OIs.
- Reduced pricing structures will be accessed wherever feasible, e.g. under the Clinton Foundation reagent agreements and World Health Organization (WHO) bulk purchasing mechanisms
• Purchasing will be done only through vendors who have received prequalification approval

Ensure proper and timely laboratory reagent and supplies procurement and distribution

Regular and reliable supply of reagents on a timely basis is critical to the delivery of quality laboratory services. To achieve this, strategies to build capacity in procurement planning, warehousing, and distribution systems for necessary supplies will be employed.

PFSA has the responsibility of managing national procurement of medical supplies, which includes ordering, shipment clearance, storage, distribution, and inventory control. While PFSA builds its capacity to fully assume its duties, PFSA will work closely with EHNRI, Regional Health Bureaus, FMoH, and relevant partner organizations to ensure regular procurement and distribution of supplies.

EHNRI will oversee and coordinate partners in the technical aspects of procurement, which include writing specifications, forecasting test volumes, quantifying supplies, and defining distribution requirements. PFSA will then procure, store and distribute supplies according to EHNRI’s recommendations. EHNRI will continue to monitor national stock levels to avoid emergency orders and to prompt “push” deliveries when necessary. Also, EHNRI will oversee the laboratory procurement budget and price negotiations in addition to reviewing inventory reports in order to avoid stock-outs. Furthermore, EHNRI will support efforts to improve regional capacity for effective supply chain management by:

• Considering regional supply needs and logistic capacity when procuring nationally;
• Leading technological evaluations and creating standards for supplies to provide sound guidance for the regions’ own procurement decisions;
• Coordinating training programs for the regions to advance technical knowledge in laboratory logistics; and
• Advocating for the needs of the regional and peripheral laboratories to relevant stakeholders.

Presently, quantifications for laboratory supplies primarily rely upon morbidity and program data due to the absence of reliable consumption data. To complement forward-looking forecasting, historic data of past consumption will be collected and analyzed to generate more robust forecasts. A laboratory data reporting system, which includes consumption data collection is being developed and will be implemented at sites with the support of partner organizations. EHNRI’s Communications Handbook provides direction on the reporting of consumption data through Regional Laboratories for EHNRI, where data can be aggregated and analyzed for future forecasts. These programs will also be implemented in collaboration with the Regional Health Bureaus, which are often responsible for overseeing the supply chain for the peripheral laboratories in their jurisdiction.
The strengthening of the laboratory logistics system will be in coordination with the FMoH’s *Health Commodities Supply System Master Plan* (informally known as the “Logistics Master Plan”). Until implementation of the Logistics Master Plan is fully achieved, the Logistics Unit will devise detailed plans for the procurement and distribution of laboratory reagents and supplies.

Efficient supply and distribution management will include:

- Coordination of supply chain movements at the central level by the Logistics Unit at EHNRI. EHNRI will invest in further strengthening the Logistics Unit in order to foster sustainability of laboratory supply chain management.
- Assignment of Regional Logistics Officers for each Regional Laboratory/Health Bureau
- Efficient transport support for distribution of supplies, clear communication with sites, and early planning for distribution
- Development of a procurement plan that is harmonized with the Logistics Master Plan and with Supply Chain Management System (SCMS). This plan will address regional storage and distribution as well as protocols for emergency orders that are needed to fill shortages
- Inventory management training and support for facilities

**Harmonize procurement and distribution for integrated laboratories**

In order to optimize and efficiently use available resources, procurement plans and distribution networks for all laboratory supplies will be integrated whenever possible.

The Logistics Unit at EHNRI will liaise closely with stakeholders and partners to harmonize plans for procurement and distribution of laboratory supplies. As new procurement and logistics needs arise, they will be incorporated into exiting systems whenever possible so as to avoid the development of fragmented or parallel systems. Emphasis will be placed upon improved communications between stakeholders, better documentation of logistics data, and careful planning. This will ensure that integration of operations does not weaken the ability to deliver efficient and effective quality services.
2013 Goals

- Procurement and distribution of laboratory supplies occur in a regular manner that is predictable and reliable, regardless of the disease or program for which they are used
- Forecasts are updated on a quarterly basis
- National stock-outs of vital supplies are eliminated
- Consumption data is collected from all laboratories throughout the country
- Supply chain management systems for integrated diseases are established
Strategic Objective 5

To expand and strengthen the National Laboratory Quality System

Situational Analysis

The National Laboratory Quality System (NLQS) Operational Plan was developed in December 2006 to establish a system for ensuring high quality laboratory services for integrated diseases such as HIV, TB, and malaria. Currently, EHNRI is participating in international EQA schemes in HIV (HIV rapid testing, CD4, clinical chemistry, hematology, DNA PCR), TB, bacteriology, and malaria. The HIV External Quality Assessment (EQA) Scheme was developed in 2007 to be used as a model for other infectious diseases that can follow a similar phased and decentralized approach.

In May 2007, the National External Quality Assessment Scheme (NEQAS) Program was launched in a pilot phase with the administration of proficiency panel testing (PPT) to 20 ART monitoring laboratories (federal and regional hospital laboratories, Regional Laboratories) for HIV rapid test, CD4 count, clinical chemistry and hematology analyses. In June 2008, the NEQAS program expanded from 20 to 52 sites. By the end of 2009, the NEQAS program will grow to include all ART hospital laboratories and Regional Laboratories nationwide.

Led by the success of the NEQAS program, the EQA program rolled out to the regional level; the pilot Regional External Quality Assessment Scheme (REQAS) Program was inaugurated in September 2007. Modelled after the NEQAS Program, each Regional Laboratory was responsible for implementing EQA programs for HIV rapid testing at 5 to 20 peripheral laboratories in their respective regions. By 2010, the REQAS Program is expected to include all health centers and testing points for HIV rapid testing.

Each round of NEQAS and REQAS is concluded by a stakeholders’ meeting. Test results are reviewed and corrective measures are planned to improve the testing quality as well as the EQA program implementation itself.

The only EQA schemes that are currently active throughout the country are specific to HIV/AIDS. Most recently, EHNRI initiated the development of a national EQA program for TB. National quality programs for other diseases like malaria, OIs, and sexually transmitted infections (STIs) will be developed and incorporated into existing EQA systems.
Strategies

• Achieve international accreditation of the National HIV Reference Laboratory at EHNRI and support the accreditation of laboratories at tiers throughout the system as a means of improving and ensuring adherence to high quality standards
• Activate the accreditation process for all other laboratories at EHNRI
• Activate the accreditation process for Regional Laboratories to guide the development of the laboratory system toward comprehensive and integrated quality programs at all levels
• Ensure the establishment and continued development of the National Laboratory Quality System Program
• Conduct annual assessments to evaluate the country’s laboratory infrastructure, logistics, and technical capabilities
• Develop and implement laboratory QA/QC logs for all laboratory disciplines of all laboratories
• Establish a national SOP database at EHNRI and ensure the standardization and availability of SOPs and test flow charts for laboratory tests
• Develop a supervisory and assessment system as a routine part of the QA program
• Ensure systems for routine calibration and maintenance of instruments
• Ensure safety standards at all laboratories and testing facilities
• Improve procurement practices to ensure the provision of standardized, quality laboratory reagents and supplies to all sites. Controls and calibrators are distributed regularly and reliably

Planned Activities

Achieve laboratory accreditation
The polio laboratory at EHNRI is the first laboratory in Ethiopia to receive international accreditation. EHNRI is currently preparing for Joint Commission International (JCI) laboratory accreditation of the National HIV Laboratory. Preparations are also under way for the accreditation of the National Food Safety Laboratory. With the aim of becoming a center of excellence in public health laboratory services and research, obtaining accreditation will be a significant milestone for EHNRI. It is anticipated that EHNRI’s HIV laboratory will be ready for accreditation early 2009.

In the future, to promote quality improvements throughout Ethiopia’s laboratory system, an accreditation committee will define accreditation standards for each level and an independent public entity will give accreditation to those laboratories that qualify. EHNRI will provide technical assistance and support to those public laboratories seeking accreditation in pursuit of having all public laboratories accredited in time to come. Although the accreditation process for regional laboratories is expected to extend beyond
2013, the preparation process will be activated at those laboratories in order to ensure that their development is guided toward comprehensive and integrated quality programs.

Continue the expansion of the National Laboratory Quality System Program

A comprehensive and integrated quality management system will be implemented throughout all levels of the laboratory system. Testing processes within all laboratories will be governed by national quality guidelines and policies. The NLQS Operational Plan, developed by EHNRI, describes a comprehensive plan to construct a system that will promote quality laboratory practices that yield reliable and accurate testing. The program supports integrated laboratory services and addresses the 12 essential elements of a total quality system, which include:

1. Organization
2. Personnel
3. Assessment
4. Process Control
5. Documents and Records
6. Equipment
7. Information Management
8. Occurrence Management
9. Process Improvement
10. Customer Services
11. Facilities & Safety
12. Purchasing and Inventory

EHNRI is overseeing the rollout of the NLQS Operational Plan in conjunction with the Regional Laboratories and referral hospital laboratories at the federal and regional levels. Private sector laboratories will be included in the rollout of the REQAS program.

Roles and Responsibilities

The National Laboratory Quality Steering Group (NLQSG) serves as an advisory body for all laboratory quality programs and approves quality policies. The NLQSG includes national level representation from the national level laboratories at EHNRI, Regional Laboratory Heads, stakeholders and partners.

Management of the NLQS is performed by the Head of the Quality Department in the National Laboratory System Division of EHNRI. The Quality Department assumes the duties of developing national guidelines, plans, manuals and SOPs. The Quality Department houses staff committed to supporting the NLQS, which include the Head of the Quality Department and the National QA Manager who have the core responsibilities of coordinating and running the national activities of the NLQS programs. The Quality Department is also supported by the National Training Manager, Safety Officer, and the Maintenance Team.
Regional Quality Officers coordinate and provide oversight of quality schemes at their respective regions. At the site level, Quality Officers implement and monitor quality activities. Important responsibilities include laboratory practice auditing and verification, EQA program coordination and performance assessment, document management, assay validation, and technical assistance. The NLQS networking will follow the technical support structure of the national laboratory system (Figure 3).

Elements of the EQA Schemes
A combination of methods will be utilized to assess the quality of laboratory services, which primarily include proficiency testing and onsite evaluation and review. Other methods like rechecking and specimen splitting will be employed as necessary. Notably, the rechecking method for quality improvement is utilized in a limited manner as it is very laborious for the reference laboratories and it is not conducive to speedy investigations.

In addition to the onsite supervision provided by Laboratory Mentors, EHNRI and/or Regional Laboratories will conduct onsite evaluations to help determine the basis and solution for unacceptable quality of tests through training, equipment maintenance or another approach. These visits will be part of the biannual mobile QA team visits, with assessment team members drawn from EHNRI and the regions.

Furthermore, EQA program expansions will be accompanied by efforts to build sustainability for QA systems at large. For example, to move away from dependence on international institutions for proficiency panels and partner organizations for logistic support (e.g. distributing panels, conducting site evaluations, etc.), plans will be created to build national capacity for in-country QA panel preparation and logistics for sustainable EQA programs.

Along with the EQA programs for HIV, EHNRI is currently developing an integrated EQA program for TB and malaria. Additional EQA programs for other priority diseases including OIs and STIs will be developed in accordance with international guidelines and integrated into the national EQA program.

Data gathered from all EQA results and subsequent site assessments will be compiled and maintained in a Quality Assurance Database at EHNRI. The database will be updated and managed by the National Quality Assurance Office of EHNRI’s Quality Department.

Qualified Personnel
Personnel should have the education, experience and motivation necessary to adhere to the requirements of a QA program. To this end, in-service quality training will be ongoing.
National and regional training workshops will be conducted periodically to introduce participants to the principles and procedures of quality management and to strengthen the practice and review of quality procedures. Implementation plans for training programs are described in further detail in Strategic Objective 7.

**Standard Operating Procedures and test flow charts**
See “Document structure and control “below.

**Equipment Maintenance**
See Strategic Objective 9 for information on equipment maintenance.

**Internal quality control**
Testing performance within each laboratory will be assessed by internal quality control (IQC) checks established for each test. An acceptable range of results will be established for each assay. In the case where results are outside this range, laboratories must adhere to their written procedures for corrective action. Quality control checks should be documented in logbooks and periodically reviewed by the Quality Manager for HIV, TB, malaria, STIs, OIs, and other priority diseases.

**Results verification and documentation, staff competency records, temperature logs, and stock control**
Procedures for results verification, lot verification, storage temperature tracking, and stock control requirements will be strengthened at all laboratories. EHNRI will provide template forms and draft SOPs for these procedures. Also, EHNRI will help institute a system for monitoring the uptake and performance of quality measures through routine audit systems and training.

Regional Laboratories will also institute a system for monitoring staff testing competency at each laboratory. This will involve documentation and review of (i) staff qualifications at the time of hiring, (ii) in-service training and (iii) semi-annual or annual assessments of competency. Staff responsible for quality at each laboratory will maintain competency records. Regional and central quality managers will assess staff competency records during periodic audits.

**Document structure and control**
A system will be established at each laboratory to list and maintain all quality documentation including SOPs. Procedures will be put in place to control, maintain, distribute, and update these documents. ENHRI will provide guidelines on document management and will develop standardized SOPs and forms.
QA/QC logs will be developed and implemented for all laboratory disciplines for all laboratories. Logs will be standardized and EHNRI will provide support to Regional Laboratories as they implement QA/QC logs at the peripheral laboratories below them.

Audits/monitoring of the quality system
Regular quality audits of individual laboratories will be conducted as part of QA team visits. These audits should be instructional for laboratories and serve to ensure compliance to quality policies and procedures. Furthermore, these visits are opportunities to further access technical expertise. EHNRI will produce an annual quality management report for the FMoH. This report will be shared with all Regional Health Bureaus.

The primary focus of the quality management program will be to strengthen EHNRI’s capacity to support the regions and to strengthen the Regional Laboratories to undertake these activities for their peripheral laboratories. As Regional Laboratories take on additional responsibilities in laboratory management, each region will establish quality plans based on the policies, guidelines, and templates supported by EHNRI. Regional Laboratories will share reports with EHNRI.

2013 Goals

- The National HIV Laboratory and Food and Safety Laboratory have achieved accreditation
- All other laboratories at EHNRI have begun the process of preparing for accreditation
- Regional Laboratories have begun the preparation process for accreditation
- In addition to HIV rapid testing, QA panels for CD4, clinical chemistry, hematology, TB, and malaria are made at EHNRI.
- All Regional Laboratories and hospital laboratories are participating in national EQA programs for all priority diseases
- All Regional Laboratories independently conduct their own REQAS programs for HIV, TB and malaria, including in-house preparation of controls
- Logistics for panel distributions and site assessments are handled by the Regional Laboratories with limited support from EHNRI and partner organizations
- Site assessments regularly follow each round of the EQA program in a regular and systematic fashion
- QA logs, forms and SOPs are standardized across all laboratories and are utilized as part of routine laboratory activities
Strategic Objective 6

To conduct post-market surveillance to ensure that diagnostic instruments and products available throughout the country perform reliably and meet national quality standards

Situational Analysis

As laboratory services have been expanding in Ethiopia, a number of new medical devices, including rapid tests, analyzers, laboratory and clinical consumables, and other instruments have been used by laboratories throughout the country. Although EHNRI has conducted extensive evaluations of new technologies, the use and performance of such devices in the field may differ from the conditions of the initial study. EHNRI will employ the following strategies to monitor the post-market performance of new technologies and ensure that patients receive reliable and high quality testing services:

Strategies

• Respond to reports from laboratories and facilities when adverse events are observed
• Actively collect data on performance of medical devices from all available sources
• Carry out re-evaluations of products as deemed necessary

Planned Activities

Conduct post-market surveillance of medical laboratory devices used in the country

In collaboration with DACA, EHNRI will conduct post-market surveillance of medical laboratory devices that are utilized in laboratories throughout the country. Sites are to notify EHNRI should they observe adverse performance of medical devices in the laboratory or testing site. Guidelines for notification will be developed and distributed by the Quality Department. Following such notifications, if deemed significant, EHNRI will investigate the event and will conduct further investigations in collaboration with DACA should the emergence of similar adverse events be detected as a trend across the system.

In collaboration with DACA, data regarding the performance of medical laboratory devices will be actively collected to determine that the devices perform reliably and according to the quality and safety standards accepted at the time of the original product evaluation. The performance of devices in the laboratory will also be evaluated against pre-determined monitoring and evaluation (M&E) indicators.
Data from external quality assurance programs will be analyzed to detect unacceptable performance of medical devices. Additional surveillance efforts will draw upon maintenance and service reports; data collected by the EHNRI Maintenance Team; literature reviews; local, regional and international published data; and user surveys and feedback.

All data on post-market surveillance will be maintained by the Quality Department at EHNRI. EHNRI will actively share data with other international institutions conducting post-market surveillance of similar devices as well as with other major reference laboratories in order to benefit from experiences elsewhere and to share learnings with partner institutions.

Should the Quality Department determine that a device does not perform according to standards, it will recommend that the device be recalled and, if necessary, may facilitate the replacement with a more appropriate product. Grounds for recall are not limited to quality and safety; they may also include instrument reliability and breakdown frequency, which can interrupt essential testing services and jeopardize the quality of care afforded to patients at sites relying upon such devices.

Medical devices which impact the greatest number of patients will be given priority when planning post-market surveillance activities. Examples of high-priority devices include automated analyzers, rapid tests, and test strips. Re-evaluations of products will be conducted periodically as per national guidelines.

2013 Goals

• An active surveillance system is in place for ongoing monitoring of the performance of all major medical laboratory devices employed in the country’s laboratories
• Corrective action or recall has been performed on devices which did not perform to acceptable standards, as defined by EHNRI
Strategic Objective 7

To expand and strengthen standardized training programs for laboratory personnel and other health care workers

Situational Analysis

EHNRI is the home of the first school for medical laboratory technology in Ethiopia. As such, training is a core competency of the Institute and will be leveraged in strengthening the laboratory training programs of the country. EHNRI, Regional Laboratories, and partner organizations have all played a critical role in supporting various training programs. In the past, many in-service trainings have been provided in isolation as needs arise or without a long-term focus on integrating, standardizing, and regularizing training activities. Such discordance hampers the sustainability of training programs and leads to ineffective use of resources. In addition, weak systems for data collection and trainee selection have resulted in sub-optimal attendance at workshops. The following strategies will be employed to address these challenges and create a harmonized plan for laboratory trainings; these strategies will be pursued with the aim of moving in a phased and methodical approach towards filling training gaps across all laboratory disciplines:

Strategies

- Establish a National Training Office at EHNRI to coordinate and plan laboratory trainings in the country
- Ensure identification and prioritization of laboratory training needs for integrated diseases
- Standardize the quality of training curricula and training program implementation across all disciplines and geographies working in collaboration with responsible institutions
- Ensure in-service, specialized, and long-term training for laboratory professionals
- Strengthen collaborations with the Ministry of Education to improve pre-service training
- Leverage collaborations with professional associations to improve in-service training
- Disseminate new information and developments in laboratory technology and operational research for integrated diseases
- Harmonize the training program with the NQLS program
- Support the development of regional training teams to conduct in-service trainings for laboratory personnel and other health care professionals at facilities throughout the country
- Strengthen M&E of in-service training activities in the country in order to track progress against training goals and identify areas where corrective actions are necessary
- Fully transition technical and logistic capacity for laboratory trainings from partner agencies to the national system for sustainability
Reduce reliance on special workshops and move toward greater institutionalization of in-service training, whereby ad-hoc in-service interventions transition to improved pre-service training, routine refresher workshops, and mentoring.

**Planned Activities**

*Strengthen central training planning and coordination*

The National Training Office at EHNRI will:

- Coordinate efforts to identify and prioritize laboratory training needs
- Oversee the coordination and planning of trainings as well as mentorship to address those gaps
- Support the development and standardization of training curricula and mentorship programs
- Reduce duplicative efforts between various stakeholders through effective coordination
- Ensure that appropriate human resources are available for EHNRI-supported trainings
- Support the development of regional training teams for capacity building in the regions.

*Conduct training needs assessments*

A comprehensive training needs assessment will lead to a long-term plan to develop laboratory personnel, in conjunction with schools of medical laboratory technology, to meet the country’s needs. Moreover, as new technologies and laboratory practices become available, EHNRI will advocate for their inclusion in the pre-service curricula at schools of medical laboratory technology. Training needs will be measured against National Laboratory Standards to identify gaps between current skill levels and those required to meet the standards.

*Standardize trainings*

EHNRI will develop simple, but appropriate in-service training workshops for integrated diseases that can be easily adapted by regional training providers.

Training materials will be developed in close collaboration between EHNRI, Regional Laboratories, and partners. The training materials will be standardized to internationally accepted norms. At the same time, they will be flexible and adaptable to a range of different training contexts and modalities, such as residential short courses and in-service and pre-service trainings. These materials will be easily customized by the regions and may alternatively serve as a set of standards to which they may develop other training courses. Additionally, in order to continue building regional capacity, opportunities for participation in external training courses will be provided.
Though adaptation may occur across regions and over time, all curricula should conform to the general standards approved by EHNRI. Training for all laboratory techniques should be conducted in accordance with the SOPs provided in a national SOP database developed by the Quality Department of EHNRI.

**Ensure the delivery of effective, quality in-service trainings**

**Facility-based training and the development of regional training teams**

A national training program in ART laboratory monitoring (CD4 count, clinical chemistry, and hematology) was formally established in 2007 with the introduction of a TOT course. Teams were established in each region in order to cascade the training down to each facility with a focus on ART laboratory services. The rollout of this training will be continuous in order to compensate for high turnover of laboratory staff and to provide refresher trainings. Furthermore, the regional training teams will receive ongoing support and mentorship from EHNRI in order to build the teaching capacity in regions.

Efforts will also focus on improving the selection of trainers and trainees, as well as identifying additional trainers with the requisite talent and motivation for transferring knowledge and skills to laboratory personnel. It may be necessary to invest in improving the TOTs to create a cadre of trainers with sufficient depth of technical knowledge and experience to teach effectively. Opportunities to improve the training curricula will also be pursued to make it more interactive, practical, and linked to real-life testing situations.

Though this initial program focused on HIV/AIDS, the training capacity brought to the regions will be utilized to address all laboratory training priorities for integrated diseases. Further planning will identify additional training gaps in technical areas beyond HIV; EHNRI will orchestrate a coordinated plan to identify synergies with existing training programs, identify resource requirements, and call upon partner organizations for technical assistance when necessary. Laboratory techniques for TB, OIs, microbiology, malaria, other parasitology, and hepatitis represent a few examples of other training areas that will be explored, prioritized, and planned further by the National Training Office (see below for strategy on future identification of training priorities).

**Laboratory-specific training on instrument operation, maintenance, and the role of vendors**

With the scale-up of laboratory services for integrated diseases, new medical laboratory devices will be placed at sites around the country. Instrument vendors will provide training at the time of installation, support national training programs for follow-up and refresher trainings, and conduct on-site training at the time of service visits.

**Laboratory management training**

Management skills are critical at both the supervisory level and the routine operational level to ensure good laboratory practices (i.e. test results are processed and returned on-time with
consistent high quality). All laboratory staff should receive laboratory management training, especially those working in hospital laboratories where a limited number of technicians carry out all laboratory work.

In 2007, laboratory management trainings were introduced with the support of partners. Evaluation of the program, refinements, and further rollout will proceed in subsequent years. These measures will also aim to fortify the initial training in inventory management, preventive maintenance, and quality assurance, which were delivered in 2007.

Strong management is also necessary for the development of the laboratory network at the national level. General management skills such as human resources management, forecasting, budgeting, strategic planning, and negotiation are all required to effectively manage the laboratory system in Ethiopia. Through collaborations with local training institutions, partner organizations, and international training institutions, EHNRI will continue to strengthen the skill sets of national-level managers.

Build laboratory capacity through mentorship
Mentorship programs will be used to improve technical skills and management skills at various levels throughout the laboratory network. In order to maximize the impact of national training programs, mentorship will be closely linked with workshop trainings, as mentors will follow-up with trainees in person and reinforce new concepts at the site level. Mentorship will be essential to consolidating skills taught in the workshops and converting these to everyday practice in the laboratories.

Qualified mentors must possess an exemplary level of expertise in order for such programs to be effective. Mentors will demonstrate resourcefulness and creativity to overcome local challenges, coupled with a highly refined technical understanding to ensure laboratories’ adherence to quality standards.

Standards for laboratory mentorship programs will be determined by EHNRI. Partners supporting the mentorship program will work closely with the National Training Office to ensure that mentorship is standardized at a high level of quality across the country. To support a standardized approach, EHNRI will also provide training to mentors.

Maintain the national training database
A national training database will be maintained by the National Training Office. The database will allow for organized data on training requirements and training delivery, in order to:

- Serve as a mechanism for improved selection of trainees
- Serve as a mechanism for documenting training attendance
- Document follow-up and mentorship
• Monitor and evaluate progress of training plans

In order to track laboratory personnel and the training they have received, the database may be populated from the following sources of data:

• Invitations and attendance registers for organized trainings
• Laboratory Information Management Systems
• Regional Laboratories and Regional Health Bureaus
• Partner agencies

A resource will be identified to support the National Training Office in maintaining and updating the database.

**Identify training needs on an ongoing basis**

The National Training Office will coordinate closely with the NQLS Program. The Quality Assurance Office will regularly update and advise the National Training Office, as laboratories’ performance in quality assurance programs will guide the identification of future training needs.

Training needs will also be identified through laboratories’ own assessments of their requirements and future needs that will emerge with the introduction of new technologies. Furthermore, the mentorship program will ascertain competency gaps through the direct observation of laboratory staff as they address the testing demands. Partner agencies and vendors that have direct contact with laboratory staff will provide additional insight to the National Training Office as future training needs are considered.

**Conduct monitoring and evaluation of in-service trainings**

In order to ensure standardized quality of training across all integrated diseases, a system of monitoring and evaluation will assess the quality and impact of trainings conducted. This will allow for modifications as appropriate and ensure that trainings are having the necessary impact to make progress toward the goals of the Master Plan.

An immediate assessment of trainees’ understanding of content will be conducted by delivering a pre-test and post-test at the time of training.

Trainees’ retention of material and the impact of trainings in the laboratory will be assessed by monitoring the status of quality and the level of productivity in the laboratory before and after the training. Mentorship following workshop trainings will also be used as a mechanism to assess the impact.

The M&E program will be organized by the National Training Office. M&E tools for trainings will be developed in collaboration with training partners. M&E results will be aggregated, analyzed, and presented by the National Training Office to the Head of the
Quality Department and appropriate stakeholders. A training committee, organized by the National Training Office, may periodically review feedback in order to advise necessary action in the event that a training program is not adequately filling the targeted gap.

**Develop and ensure long-term training programs**

The on-going expansion of laboratory services for integrated diseases will require a steady supply of laboratory personnel. Over time, the Master Plan envisions reduced reliance on special workshops and greater institutionalization of in-service training, whereby ad-hoc in-service interventions will transition to improved pre-service training, routine refresher workshops, and mentorship programs.

Trained staff will be needed to cater to the increased human resource requirements and as replacements for staff lost to attrition. EHNRI will collaborate with the schools of medical laboratory technology to periodically review the volume and nature of trainings, as well as to monitor and assess the production of suitably qualified technical graduates over the long term. Additional long-term training initiatives may be undertaken by the Ministry of Health and/or Education for the training of technicians and scientists at international institutions or in collaboration with other international partners or professional associations.

An adequate supply of laboratory managers is also crucial for the development of the country’s laboratory system. The feasibility of introducing a management certificate program to the schools of medical laboratory technology will be examined. A curriculum would then be developed in collaboration with the FMoH, Ministry of Education, and partners with management expertise.

**2013 Goals**

- Ad-hoc in-service interventions have transitioned to improved pre-service training, routine refresher workshops, and mentoring
- All laboratories have at least the minimum number of technicians trained in all of the technical disciplines required of that laboratory, as defined by the National Laboratory Standards
- 50% of all laboratory staff in the country have been trained in all areas identified as high priority
- 75 % of technicians in all laboratories have received training in one or more levels of laboratory management
- A standardized, systematic approach to trainee selection ensures that trainings have their maximum impact on the correct target population
- M&E of all training programs is standard and methodical
Strategic Objective 8

To improve human resource recruitment, selection, motivation, and retention

Situational Analysis

Few assessments have been conducted to investigate the rate of human resources attrition in the national laboratory system. Insufficient supply of qualified human resources, particularly those with specialized technical skills, presents a formidable challenge to the ability of the laboratory system to satisfy the needs of the national laboratory network. In addition to the insufficient pool of qualified candidates, recruitment of staff is challenged by the lack of clear standards that determine the appropriate level of qualifications for a given position. Furthermore, low morale and job dissatisfaction reduce staff productivity.

Strategies

- Develop selection and recruitment criteria
- Develop and implement staff retention plans at different levels of service
- Develop mechanisms for job satisfaction and motivation
- Identify and implement avenues for increasing staff productivity
- Outsource services to the private sector when necessary and appropriate

Planned Activities

Develop recruitment and selection criteria

To safeguard the staffing of well-qualified professionals at all laboratories in Ethiopia, selection and recruitment criteria will be developed in consideration of the National Laboratory Standards. Depending on the tier level of the laboratory and its volume of services, criteria of qualifications (e.g. education level and years of professional experience) for each position type will be set to guide the selection and recruitment efforts of the laboratory.

Increase job satisfaction and human resource retention

The availability of trained personnel depends on the output of the various training programs and staff retention efforts at different levels of service. Without ongoing effective training programs, the pool of knowledgeable staff will reduce to inadequate levels for supporting a functional laboratory. At the same time, without effective strategies to retain staff, valuable, experienced staff will be lost.
The following methods will be employed to boost staff morale and motivation:

- Routine guidance and management
- A good work environment supplied with the necessary materials and functional equipment, and a clean, well-organized laboratory
- Safe working conditions with dedicated space for breaks and desk work
- Diversity of tasks
- Opportunities for formal trainings and peer-to-peer knowledge transfer
- Standardized wages and per diems
- A fair and reliable system for recognition and reward
- Transparent and well-defined communication channels, opportunities to address grievances, and responsive management
- Career paths that allow for progression and access to trainings that support career advancement

Laboratory managers will be expected to support the staff through the efficient direction of laboratory activities to create a productive work environment.

Laboratory staff members work regularly with various biological and chemical substances that may affect their health and safety. Feeling safe about occupational hazards is an important component of a laboratory professional’s job satisfaction and emotional well-being. Accordingly, the National Health and Safety Guidelines will be implemented in every laboratory. Such measures include the provision of proper personal protective wear and post-exposure prophylaxis whenever applicable.

Attention will also be given to keeping personnel interested in their work. This is of particular importance for laboratory technicians who perform very simple and repetitive procedures and have minimal need for mental focus (e.g. automated analyzers requiring repetitive tasks, long hours at a microscope, etc.). Rotation schedules will be encouraged to introduce variety to the work. This approach is also beneficial in that personnel are cross-trained to perform multiple laboratory techniques, which is helpful in ensuring that a particular laboratory service is not entirely dependant on one person.

Standard procedures for assigning per diems and other allowances should be followed to prevent remuneration inequity and resentment among co-workers of similar roles and qualifications. EHNRI and the National Laboratory TWG will formulate recommendations for streamlining per diems, reimbursements and compensation associated with trainings, secondments, and other programs that supplement the public system.

Staff motivation will be fostered through appropriate recognition. This includes financial and non-financial incentives. Notably, promotions should always be awarded to individuals
on a merit basis. Creating career paths and opportunities for growth motivates employees to demonstrate high-quality efforts.

**Maximize the potential of current human resources**

As described in Strategic Objective 7, laboratory management will be addressed through targeted trainings and mentorship in order to improve the management of human resources and to maximize staff productivity.

**Partner with the private sector**

Contracting work to the private sector as an extension of services offers an opportunity to ameliorate the scarcity of human resources in the public sector. The delegation of services to the private sector will be carefully designed in order to not compromise the quality standards of the national laboratory system. Also, careful efforts should be made to not underscore already existing inequities, particularly with respect to salaries.

**2013 Goals**

- Clear and transparent laboratory staff recruitment and selection criteria are in place
- Staff retention have improved as compared to 2009 turnover rates
- Per diems and supplementary compensations are standardized across all laboratory programs
- Rotation schedules and safe working conditions as per the National Health and Safety Guidelines for Public Laboratories have been implemented in all laboratories
- Venues for responding to staff grievances are established for employees of the national laboratory system at all levels
Strategic Objective 9

To improve the management of equipment service and maintenance

Situational Analysis

Patients can only receive quality medical care if laboratory equipment is maintained in a functioning state at all times. As the laboratory capacity to support the diagnosis of integrated diseases scales up throughout the country, an expanding instrument network will place a greater burden on the national laboratory equipment maintenance program. A rationalized strategy, including a phased approach to capacity building, will be required to address the country’s maintenance needs. This will include provisional solutions for the interim phase. To date, the system has been challenged by prolonged instrument downtime; lack of advance planning for post-warranty service; inadequate capacity at the central, regional, and facility levels to address instrument breakdowns in a timely manner; and poor adherence to preventive maintenance protocols. However, several corrective measures have been taken in 2007, including the placement of a Maintenance Team Leader and Expert in the Quality Department, improved systems for capturing maintenance data and requests received by EHNRI, the procurement of additional spare parts, and initial negotiations with instrument vendors for service and maintenance agreements. The following strategies will be implemented to address remaining challenges and ensure that all patients in the country have access to uninterrupted testing services:

Strategies

• Ensure a regular and uninterrupted maintenance and service system for all laboratory instruments and infrastructure
• Streamline communication between facilities, regions, EHNRI, and service providers at the time of instrument breakdowns and rapidly mobilize maintenance technicians to ensure the maximum expediency in repairing instruments and resuming testing services
• Move toward a tiered, national equipment maintenance program which is coordinated by EHNRI and supported by each Regional Health Bureau, with clear responsibilities delineated at each level
• Strengthen EHNRI’s ability to coordinate response to service and maintenance requirements by establishing a robust portfolio of maintenance options (both in-house and contracted)
• Monitor the performance of instruments and service providers to ensure adherence to performance and service standards
• Whenever possible, bundle the procurement of service and maintenance into the purchase of reagents
Planned Activities

**Strengthen central maintenance coordination and planning**

A highly organized system of communication and data-documentation, coordinated between EHNRI’s Lab Response Unit and the Maintenance Team, will allow for the urgent dispatch of technicians to address instrument breakdowns. Communication and feedback to facilities will be executed immediately upon completion of a service visit to ensure that testing services are resumed.

Careful cost-benefit analyses will guide decision-making when selecting appropriate service options for each instrument: EHNRI engineers will address needs when appropriate while other needs may be addressed by leasing instruments, purchasing service contracts, or bundling service and maintenance into the cost of purchased reagents. Additionally, the Quality Department will advise on matters of instrument selection and procurement to ensure that the long-term costs of instrument maintenance are considered prior to instrument purchase.

When purchased, specialized instruments will be procured with a service contract. Warranties will be closely monitored to ensure a smooth transition and uninterrupted service into the post-warranty phase.

Service contracts for specialized instruments will be managed by EHNRI. The Maintenance Team will be responsible for contacting service providers and evaluating their performance.

A maintenance database at EHNRI will track open requests, monitor the performance of instruments throughout the country, identify facilities in need of additional training, ensure timely preventive maintenance, monitor performance of service providers, and capture operations data on instrument down-time to inform strategies for further improvement in the program. The information captured by the maintenance database will facilitate EHNRI’s post-market surveillance activities, as described in Strategic Objective 6.

The EHNRI Maintenance Team will set minimum standards for instrument performance. A periodic review of data on maintenance activities and instrument performance will determine if instruments are performing to standard or if there is a need to withdraw a platform from the national system.

Provisions will be put into place to allow for the removal of laboratory equipment that has been rendered non-functional or obsolete.

**Establish tiered service and maintenance network**

A clear plan will be developed to delineate between service requirements which are addressed by the facilities, regions, EHNRI and contracted service providers.
EHNRI
The Maintenance Team within the Quality Department at EHNRI will develop its capacity by upgrading human resources, knowledge, and skills for the provision and management of equipment service and maintenance. The team will liaise closely with the Lab Response Unit to receive incoming requests and coordinate feedback to sites.

The core team of maintenance technicians at EHNRI will receive specialized training and the requisite certification from manufacturers prior to servicing specialized instruments. Specialized instruments will only receive service from certified service providers or by certified technicians from EHNRI. EHNRI will monitor the performance of outside service providers.

EHNRI will ensure that adequate stocks of spare parts are available in the country to minimize instrument downtime when parts must be replaced.

An instrument maintenance training workshop will be established at EHNRI. The Maintenance Team will provide training on preventive maintenance and repair of basic instruments. The team will also provide support and capacity building to the Regional Laboratory Maintenance Workshops in the country.

Regions
Regional maintenance technicians will support the service and maintenance of basic laboratory equipment. They will also maintain a Regional Laboratory Maintenance Workshop, where spare instruments and adequate stocks of essential spare parts will be stored.

A designated telephone number will be established at each region to receive and respond to maintenance requests from facilities and to receive and respond to maintenance communications from EHNRI.

EHNRI will build the capacity of the regional laboratory maintenance workshops by providing them with training, mentorship, and guidelines. EHNRI will provide guidance on the quantity and specifications for spare part requirements.

Regional maintenance technicians will provide training to laboratory technicians throughout the region on proper preventive maintenance and basic troubleshooting.

Facilities
Laboratory managers at each facility will be responsible for ensuring that instruments in the laboratory are maintained properly, daily controls and calibrators are run, and maintenance logs are kept up to date (and will analyze this documentation prior to releasing patient data).
Maintenance technicians at the health facility will be responsible for ensuring that basic infrastructure is properly maintained and functioning in accordance with the country’s minimum laboratory standards. Maintenance technicians at the facility may also perform simple preventive and curative maintenance on basic laboratory equipment.

2013 Goals

- Overall instrument downtime in the country is reduced to 5%
- Regular preventive maintenance reduces the number of instrument breakdowns to less than one per machine per year
- Regional Laboratory Maintenance Workshops have been established, staffed, trained, and certified in each region of the country
- Data is captured and regularly analyzed to improve maintenance activities on all instruments in the country
- Service agreements are in place for all automated analyzers either through separate contracts, lease agreements, or bundling with reagent purchases
Strategic Objective 10

To establish and strengthen laboratory networking nationally and internationally

Situational Analysis

The health care system in Ethiopia relies upon a tiered network of laboratories and reference laboratories, with an increasing degree of specialization at each tier. As part of this design, specialized instruments have been placed at various laboratories throughout the country, including automated analyzers for hematology, chemistry, and CD4; molecular diagnostics like DNA-PCR; and culture systems. TB liquid culture facilities and additional molecular diagnostic laboratories are planned for the near term. In order to utilize this network effectively, it is essential that communications and data systems are established between laboratories. Also, logistics systems must be in place to ensure that samples requiring specialized testing can be referred from one tier to the next. In the event of an instruments breakdown or sample backlogs, nearby laboratories must be able to refer samples to others where back-up services are provided. Sample transportation services have been implemented at some levels of the system, but they have not been uniformly effective throughout. They have also been implemented with varying degrees of effectiveness. In order to upgrade laboratory networking and strengthen the sample referral network, the following strategies will be employed:

Strategies

• Ensure functional laboratory networking among EHNRI, Regional Laboratories, and peripheral laboratories
• Ensure that instrument networks are rational and provide sufficient capacity
• The network design should accommodate as many patients requiring testing services; the testing capacity at a single point in the network should not limit the number of patients that can access the service
• Strengthen the Logistics Unit of the National Laboratory System Division at EHNRI, which will be responsible for supporting the logistic systems required to refer samples and distribute supplies
• Ensure the establishment of national information technology (IT) laboratory networking systems
• For highly specialized testing needs, ensure that effective linkages exist with other international reference laboratories in the African region
Planned Activities

Ensure a rational instrumentation network
Automated analyzers and instruments for specialized testing will be placed to ensure a rational total instrument network, based on the following principles:

1. As per the National Laboratory Standards, required test services must be accessible to all sites
2. Testing demand at each site must be quantified and mapped
3. Machine utilization should be maximized, taking into consideration constraints such as low utilization at rural laboratories and day-to-day fluctuation in testing demand
4. Instrument placement is based on tests offered at each level of laboratory, with more complex tests higher in the hierarchy
5. Sites most likely to receive instruments are potential ‘hubs’, which are sites with higher testing demand and/or many potential transportation routes to and from sample collection sites
6. Sites most likely to receive instruments have appropriate resources, such as infrastructure, human resources, and expertise
7. The degree to which an instrument network is centralized will be limited by sample stability times during transportation from sample collection site to testing site
8. Specimen collection sites should be assigned to both a primary and backup testing site. EHNRI will work with regions to enforce this relationship.
9. Placement will enhance accessibility to testing services in locations where sample transportation may not be able to accommodate the needs at a particular site

Appendix 2 lists the major instruments that should be available at each tier of the laboratory.

Implement the Communications Handbook
EHNRI has issued a Communications Handbook to define protocols for communicating requests between laboratories. This handbook will be updated and implemented to ensure that all laboratories understand how to elevate requests for referral testing, supplies, service and maintenance, or any other support service.

Upgrade communications infrastructure
EHNRI, regions, and partners will review the communications infrastructure and ensure that resources are coordinated for the provision of necessary telephone, fax, and internet connections to those laboratories which lack the necessary means to communicate with other laboratories in the network.

Establish effective and efficient specimen/sample transport
An efficient laboratory network requires that samples be transported from small laboratories (e.g. district, health center) to larger laboratories (Regional or National) for specific tests. A system for reliable and safe sample collection, transport, and delivery will be established for
all sites that require tests to be conducted at other laboratories. Sample stability has a
significant influence on the design of a transportation system. Thus, standard procedures for
sample transport will be developed for all assays to ensure quality of results. Similarly,
procedures will be developed to ensure that results are provided in a timely manner so that
maximum care is achieved. New processes or technologies which improve turnaround time
will be investigated and implemented whenever possible.

**Review current laboratory systems and identify opportunities for improvement**

Though it may not be possible to conduct all laboratory tests at every laboratory in the
system, all facilities must have **access** to the necessary laboratory services for their level, as
defined by the National Laboratory Standards. When services are not available on site, sample transport networks can bring access to sites by ensuring samples are tested at facilities where the capacity exists.

EHNRI, regions, and partner organizations have implemented an initial system of sample transportation. Discussions will be held with Regional Laboratories overseeing sample transportation to review the current system in each region and identify opportunities for improvement. This review will assess opportunities to integrate sample transportation for all assays and sample types (e.g. CD4 count, TB, dried blood spot, QA samples, surveillance, and others). EHNRI will also lead an effort to define and standardize which health care staff will be responsible for transporting samples, so as to reduce the impact on laboratories when a technician departs for a prolonged period of time to transport samples. It is recommended that non-technical staff perform this activity. All workers involved in sample transportation will receive training on pertinent sections of the Quality Manual and the National Health and Safety Guidelines. Per diem rates for those transporting samples will also be standardized across the program to reduce the risk of alienating certain workers.

**Improve the quality and safety of sample transportation systems**

Not all facilities have received the requisite supplies for packaging and transporting samples appropriately. Facilities’ practices will be compared against the standards described in the sample transportation SOPs (provided by the Quality Department at EHNRI) and the National Health and Safety Guidelines, which follow international regulations. Essential supplies for quality and safety of sample transportation will be procured and distributed as a matter of urgency, and ongoing review will ensure that quality sample transportation and safety supplies are replenished as necessary. These supplies include cool boxes, packing supplies, and spill kits. All handlers who have not been trained will receive instruction in the safe handling of blood samples, biosafety, and spill containment and clean-up.
Collaborate with other international reference laboratories for highly specialized testing services

For highly specialized testing services, EHNRI will facilitate the referral of samples to other international reference laboratories.

Establish IT networking of laboratories

See Objective 11 on Data Management Systems. In particular, the establishment of IT networking of laboratories will be harmonized with the greater telemedicine capacity building efforts of the national health care delivery system.

2013 Goals

- All laboratories are equipped with proper instrumentation of their tier level as per National Laboratory Standards
- All laboratories in the country have reliable means by which to communicate information to other laboratories in the network
- All hospitals and health centers in the country have effective sample transportation systems which transport samples safely and in quality conditions to the next laboratory tier
- Turnaround time of results for referred tests have been reduced from 2009 turnaround times
- Automated instruments at reference laboratories are utilized at greater than 50% of their capacity, indicating efficiency in the instrument network
Strategic Objective 11

To develop a data management system

Situational Analysis

Laboratory systems rely upon and generate large amounts of data. Capturing, transferring, analyzing, and storing data effectively are essential components of a laboratory program and is necessary for M&E and targeted improvements. Presently, these systems are informal and reliant largely on paper-based systems. There are a number of advantages to this approach, but also a number of inherent weaknesses, which will have increasing impact as paper-based systems will start to fail or become time-demanding under high volumes. The paper-based system is time-consuming, deducts from the time that laboratory workers spend performing analyses, and does not guard against errors in the transcription of data. Such systems are also not conducive to rapid analysis of data. In addition, data systems are required for the requisition of laboratory services and recording results, which are critical for the effective delivery of laboratory services. However, current systems lack standardization across laboratories. Additionally, program management and projections are challenged by the lack of aggregate data on testing volumes; such data must be centralized at EHNRI. In order to improve data systems throughout the country, the following strategies will be employed:

Strategies

- Define data management systems and processes and implement standardized data management principles, procedures and forms
- Ensure infrastructure and technical capacity for laboratory data management
- Upgrade most laboratories to electronic data management systems in staged implementation, starting with the high volume sites
- Ensure support for program management and projections
- Ensure that data systems are sustainable and allow for future expansion
- Synchronize patient identification between the Laboratory Information Management System (LIMS) and Health Information Management System (HIMS)

Planned Activities

Define data requirements

Laboratory data management principles will be developed for test requisition, data capture, and results forwarding to clinical facilities. This covers establishment of a comprehensive and robust laboratory data management system that integrates with patient data management systems. Strict procedures for data management during the pre-analytical, analytical and
post-analytical phases of testing are required to ensure the reliable production and delivery of accurate test results. A number of issues that will need to be addressed include patient identification, test requisition requirements, analytical data management, and post-test data management. Standardized formats for data forms and transactions will be implemented at all sites. The standardized data management procedures will be applicable to both paper-based and electronic systems and will be implemented through guidelines, trainings, and other initiatives at the laboratories.

**Implement data management systems and processes**

Common standards of data management will be implemented at all levels of the laboratory system. A summary of the flow of patient and testing data from the clinic to the lab and back to the clinic is outlined in Figure 4 below.

Figure 4: Overview of testing data flow
Pre-analytical data management

(i) Patient Identification

In order to prevent specimen and result mix-ups as mobile patients access testing through different clinics and laboratories and to assist in the longitudinal monitoring of all patients, it is advisable that a national, universal unique patient identification system be employed. The patient identification (PID) number system should be universally accepted and assignment should be centrally monitored.

EHNRI and Regional Laboratories will assist laboratories to institute a unique identifier system to ensure safe tracking of patient samples. PID numbers at the hospitals will be synchronized between the LIMS and HIMS for smooth information management and records retrieval within the facility.

All laboratories under the NEQAS will have a laboratory identification number known only by the QA programs at EHNRI and Regional Laboratories. Results will then be provided according to specific codes in order to maintain confidentiality.

(ii) Test Requisition Requirements

Test requisition forms will be standardized across the country. Certain data on test requisitions are required to ensure a high degree of quality assurance during testing and accurate transmission of results back to the correct site and patient file. Laboratories will be instructed to reject samples that are not received with the appropriate test requisition information.

Analytical Data Management

Key intra-laboratory procedures are needed to ensure high integrity capture; storage and transmission of test requisition; data analysis and final interpretation. Logbooks will be used to record receipt of samples and the results. Copies of test requisitions and results will be archived for periods of time to be defined by EHNRI and Regional Laboratories. Systems for validating test results will be in place (e.g. lab head signature, or electronic monitor); in cases where test validation fails, follow-up procedures will be followed. This will be a key source of data for monitoring laboratory performance and for resolving lost or questioned results.

Post-test data management

Testing will not be complete until the result has been transmitted to the clinic and is placed in the patient file. The laboratory must ensure the results are transferred from the laboratory back to the clinic. A number of mechanisms will be evaluated, including:

- Manual collection of results from the laboratory by site representative or patient
- Delivery of results via courier system
- Faxing results or other electronic and telecommunications transfer, if confidentiality is respected
In addition, a logbook or copies of the test results will be archived within the laboratory to provide back-up data in case of queries or lost results. Each facility will adhere to systematic archiving.

**Electronic laboratory information management system**

An electronic data management system will be implemented at all regional and hospital laboratories. These laboratories will be networked electronically to facilitate exchange of information easily. Also, aggregate data on testing volumes will be centralized at EHNRI to assist in program management and projections. Reference laboratories will be networked first. Interfaces with manual systems will be used at hospitals prior to integration into the electronic network.

A pilot program is now in place at several sites in Addis Ababa to assess an electronic LIMS.

A nationwide LIMS will exhibit the following characteristics:

- For commercial systems, annual maintenance fees must be affordable and sustainable for the government system
- Data must be owned by the government and not by a private enterprise. Accordingly, the data must reside on a government server and not on the server of an outside company
- There must be capacity within the government system to manage and access the data directly and without fees
- Data retrieval must be flexible and simple. No fees should be in place for accessing the data
- Back-up systems must be in place to ensure that patients can still be registered and testing procedures can still run even when there is a system outage
- Back-up reservoirs should exist in the system to allow for safe storage and retrieval of data in the event of a system collapse
- The system must be designed to accommodate scale-up. In other countries, systems with cumbersome processes for communicating data across the network have proven to slow down as the system grows. A system installed in Ethiopia will eventually network all regional and hospital laboratories, all of which process a considerable daily workload. The system must be robust enough to network data across this large scope without slowing down laboratory activities.
- The system will capture and provide data in a way which can be used to improve forecasting for reagents and supplies
- Adequate training will be provided to all users and also to EHNRI to allow EHNRI to administer the database independently without the need for routine support from the vendor
- The system should be fully customized to the Ethiopian situation based on user requirements
• Commercial systems should have an international track record with large laboratory networks and vendor support should be readily available in the country

**Ensure support for program management**

EHNRI will develop key data points to be tracked for the purposes of M&E and to establish accurate forecasts for reagents.

To ensure that program managers have sufficient support in data management, data clerks or analysts will be assigned and trained.

**2013 Goals**

• A full-fledged data management team has been established at EHNRI and it is involved in systems design, training, M&E, and technical support
• All Regional Laboratories are electronically networked to a national LIMS
• All hospital laboratories in Addis Ababa are incorporated into the electronic network
• All major hospital laboratories in the regions are incorporated into the electronic network
• All laboratories which are not incorporated into the electronic network have implemented manual systems which are integrated into the national LIMS
• All hospitals and laboratories utilize a unique patient identification system to significantly reduce errors in matching test results to patients
• All hospitals and laboratories utilize standardized test requisition forms
Strategic Objective 12

To develop an effective national monitoring and evaluation system

Situational Analysis

Currently, there is no monitoring and evaluation system in the national laboratory program. The few M&E activities that are conducted are typically focused on vertical programs, rather than a systemic M&E of the laboratory program as a whole. As the scope of responsibilities and the number of competing priorities continue to increase, it has become necessary to appraise the progress and effectiveness of all laboratory programs. The following strategies will be followed to develop an effective and functional national M&E system:

Strategies

• Work with partners to develop appropriate monitoring indicators and tools
• Standardize indicators across all organizations working in similar programs
• Ensure the setting of national and regional targets for laboratory diagnosis and monitoring of integrated diseases. Develop corresponding work plans and budgets.
• Ensure on-going M&E of laboratory programs

Planned Activities

Develop a monitoring and evaluation system

The plan for M&E of integrated laboratory services includes monitoring strategies to evaluate the rollout of various laboratory programs at all levels.

EHNRI will play a central role as the coordinating body of the M&E for the national public health laboratory system. Through the data-reporting framework established in the Communications Handbook, a laboratory M&E system will be developed and implemented in a phased approach. The National Laboratory System Division of EHNRI will oversee implementation and management of national M&E activities, which will include:

• Identification of data required from all key stakeholders
• Development of indicators for data collection
• Development of data collection systems
• Development of operational plans
• Budgeting
• Planning and coordination of operations
• Performance of periodic assessments of regional and national laboratory systems
The movement of data will follow the reporting scheme illustrated in Figure 5 below.

Figure 5. Data reporting scheme for M&E activities

Coordinate and develop monitoring indicators and tools
To fulfil the objectives of the current plan, EHNRI will coordinate the development of indicators and tools to monitor national and regional targets. These indicators will be used to conduct mid-term and end-term evaluation of programs. Input, process, output, outcomes and impact indicators will be included.

The establishment of key performance metrics for M&E will be directed by the National Laboratory TWG. To minimize the burden of establishing and maintaining M&E systems, whenever possible, indicators will be standardized through cooperative efforts with stakeholders like other government agencies, international/national partners, and donors. This process will limit the number of indicators to be collected and ensure that the most useful indicators are prioritized. This will also minimize efforts entailed in collecting multiple but similar sets of indicators for each stakeholder. Indicators will be selected carefully to measure quality, not just quantity, of service or programs. In addition, the cooperative establishment of M&E indicators will systematize data collection efforts and ensure timely provision of data for evaluations. For the sake of sustainability and ease of implementation, M&E systems will integrate existing data collection systems whenever possible. Examples of M&E tools that may span multiple applications include the HIMS and LIMS, which are anticipated to be in full operation by the end of 2009. For the ease of data record retrieval, analysis, and security, data will be electronically compiled into databases.

EHNRI’s National Laboratory System Division will lead the implementation of the M&E system, alongside the LIMS, and in collaboration with the EHNRI IT Department and partner organizations.
M&E tools will be utilized at the national level for:

- Evaluating program impact and providing appropriate feedback
- Monitoring and improving productivity of the country’s laboratories
- Conducting cost-benefit and cost-effectiveness analyses
- Program Planning
- Forecasting supplies
- Ensuring adequate stock-levels of supplies
- Infrastructure strengthening

**Ensure on-going monitoring and evaluation of laboratory programs**

EHNRI will review operational progress of the laboratory program. Specific activities will include:

- Review of M&E indicators for laboratory services, assessing the levels of national and regional targets achieved
- Periodic site visits for on-going assessments of service delivery, capacity, and limitations.
- Development and ongoing review of operational plans for increased testing volume and the extension of services
- Development of plans for on-going laboratory upgrades
- Review of plans for long and short-term technical and managerial training
- Review of ongoing NLQS
- Review of ongoing supplies procurement, storage and distribution
- Review of all training programs
- Review of the provision of instrument service and maintenance
- Review of laboratory safety
- Review of specimen transport and other sample logistics
- Review of laboratory data management system
- Provisions of periodic reports from EHNRI to the FMoH on key M&E indicators of laboratory program effectiveness and feedback to implementers, as appropriate

**2013 Goals**

- M&E indicators are routinely and systematically collected, analyzed, and reported across all major laboratory programs
- Operational plans are updated regularly in response to M&E indicators
- Notable improvement in M&E indicators has been achieved relative to those at the start of the M&E program
Strategic Objective 13

To evaluate new technologies for public health laboratory services throughout the country

Situational Analysis

New technologies have allowed for significant improvements in the quality of care, volume of testing, and decentralized access to laboratory services throughout the country. The continued scale-up of health care services across diseases, especially HIV, TB, and malaria, will drive the development of new technologies. As part of this commitment to focus applied research on solving critical public health issues, EHNRI will prioritize the evaluation of new technological solutions. As an international center of excellence, EHNRI strives to work at the forefront of new technological developments and to conduct evaluations that will benefit decision-makers throughout Africa.

Strategies

- Consider technological evaluations as a high priority for those products which can offer significant improvements in the delivery of laboratory services. Evaluations will be led by the Public Health Research and Reference Service Division at EHNRI.
- Leverage the insights afforded by The National Laboratory System Division, which interacts as a first line of support to regional laboratories and facilities, to identify technologies that show the potential to significantly improve the delivery of laboratory services.
- Collaborate with international research institutions in the identification and evaluation of new technologies.

Planned Activities

As new technologies become available, EHNRI is committed to ensuring that Ethiopia benefits quickly from cutting-edge solutions to improve the delivery of laboratory services at all levels of the system, in both specialized testing and routine site-level testing. In particular, priority will be given to evaluating those technologies which:

- Enhance the overall disease control programs of the country through improvements in specialized testing services offered at reference laboratories
- Enhance the performance of existing platforms and techniques already placed at facilities throughout the country
- Improve testing throughput
- Allow point-of-care testing to support the decentralization of laboratory services
• Improve sample collection and prolong sample stability for improving the country’s sample referral network
• Offer substantial cost savings over other products which are of comparable quality and already in use

To carry out these activities, it will be particularly important that ENHRI is well-resourced to carry out evaluations and is able to perform evaluations in the shortest time possible. Also, whenever applicable and possible, collaboration will be sought with international research institutions for the identification and evaluation of new technologies. This will maximize available resources and heighten the influence of the findings.

Following successful evaluations, the National Laboratory System Division will work with laboratories around the country to support the coordinated implementation of new technologies. This will include procurement, installation, training, and vendor support.

2013 Goals

• In-house technical capacity (instruments and human resources) to carry out independent evaluations has been instituted
• Evaluation time for new technology is reduced to under three months
• EHNRI is recognized as a leader among African laboratories in identifying and implementing technological improvements in the delivery of laboratory services
• Collaborations have been conducted with other African centers of excellence for the evaluation of new technologies
Strategic Objective 14

To strengthen operational research to prevent and control diseases in the country

Situational Analysis

Due to the scarcity of resources in Ethiopia, operational public health research has been limited. However, such research is essential for understanding the host-pathogen relationship and the risk of emerging diseases within the context of a developing country. Ethiopia will continue to focus operational research efforts on major public health concerns and will provide timely data for evidence-based decision-making at the FMoH level. Although basic research – investigations centered towards the fundamental and the theoretical to advance scientific knowledge without the objective of immediate practical application – is also important for understanding health concerns, prioritization will be given to operational research in the interest of maximizing available resources to service the immediate and most critical needs of the country.

Strategies

- Prioritize operational research such that it reflects the public health needs of the country
- Strengthen national and regional capacity to conduct operational research.
- Ensure the development of strategic partnerships with organizations in Ethiopia as well as international institutions and partners.

Planned Activities

Prioritize operational research

Operational research will consist of those investigations that lead to improved laboratory processes and systems to diagnose and monitor patients for care. Operational research undertaken by the national laboratory system will reflect the public health needs of the country. HIV/AIDS, TB, and malaria have been identified by the Health Sector Development Program (HSDP) as three key diseases that account for a significant proportion of the disease burden in Ethiopia; improving control of these diseases is critical.

Operational research of other diseases and conditions not specifically prioritized by HSDP will also be conducted. However, such research endeavors must be supported by evidence that warrant their pursuit. Examples of appropriate substantiation include indications of increased morbidity and/or mortality linked to the particular disease/condition, epidemics that call for immediate research efforts, and special cases like provision of funds for the
research of specific diseases or conditions. All considerations for conducting operational research will be made by weighing the urgency and necessity of the project against the availability of testing methodologies, infrastructure, and resources to properly and successfully conduct research.

As the National Laboratory System Division at EHNRI directly supports the operational systems of the laboratory network, regular exchange of information between that Division and the Public Health Research and Reference Service Division will be essential for improving research activities. Such collaborations will help ensure that the research aims of the Public Health Research and Reference Service Division are aligned with the needs of the country and that they maintain their relevance to public health.

**Strengthen national capacity for operational research**

Through centralized and coordinated efforts at EHNRI, operational research activities will inform decision makers on how to improve the overall delivery of laboratory services. To meet this objective, EHNRI will:

- Recruit and support scientists to build local capacity in operational research
- Strengthen research capability at the regional level

**Forge strategic partnerships**

Collaborations will also aim to strengthen relationships with other premier research institutions and establish long-lasting skill sets and physical capacity for future research. Furthermore, partnership agreements will be established with research institutions and partners. These agreements will facilitate common understanding of the roles and responsibilities of each participating party and establish standard procedures.

**2013 Goals**

- Review of Ethiopia’s laboratory system operations has become routine
- Several improvements in laboratory system operations have been introduced as a result of the operational research conducted by EHNRI, regions, and all concerned bodies
Strategic Objective 15

To elevate EHNRI’s status as a center of excellence by fostering closer ties with other major public health institutions and national reference laboratories

Situational Analysis

EHNRI has a long history as a premier center of research and public health laboratory services in Ethiopia. The Institute has also fostered close relationships with other major public health institutions and national reference laboratories through its participation in international conferences, training programs, quality assurance schemes, and research projects. As EHNRI moves toward international accreditation, re-affirms its dedication to applied research, and further enhances its service to the public health priorities of the country, it strives to do so at a level of excellence which is exemplary to other countries facing similar challenges. EHNRI also plans to capitalize upon opportunities for more frequent collaboration in research studies and technological evaluations with other major international institutions in order to elevate its profile as an international center of excellence. To this end, the following strategies will be employed:

Strategies

• Actively seek opportunities for collaboration in applied research and technological evaluations with other major public health and national reference laboratories, especially those in the African region
• Prioritize activities which are at the forefront of innovation and discovery, with a practical and immediate application to ameliorating the country’s critical public health problems
• Share data and best practices from the country’s experience in developing clinical and public health laboratories, particularly the quality and logistics systems which are designed to support them

2013 Goals

• Active collaboration has been achieved with at least two centers of excellence in Africa
• Joint peer-reviewed operational research articles have been published and presentations have been given at local, African regional, and international conferences on topics of mutual interest
• There are regular exchanges of scientific visits between EHNRI and partner institutions
Strategic Objective 16

To improve communication with relevant stakeholders

Situational Analysis

There are numerous stakeholders of the Ethiopian national laboratory system and effective communication is essential for harmonizing efforts. Currently, communication with the public is limited and communications between the laboratories within the national network are sporadic as are communications between partner organizations. Consequently, efforts are duplicated, resulting in inefficient use of resources.

In order to effectively coordinate national laboratory programs, EHNRI has the duty to effectively publicize the goals of the national laboratory system. Implementing partners, in turn, bear the responsibility of opening up channels of communication for efficient collaborations. Moreover, better communication is vital for creating transparency so that stakeholders receive clear directions with respect to how the government of Ethiopia seeks to run current and future programs. To achieve improved internal and external communications, the strategies listed below will be followed:

Strategies

• Ensure advocacy on the role of the laboratory in the management of integrated diseases at all levels of the health care system
• Establish and maintain frameworks for regular communication
• Establish collaborations with national and international laboratories
• Expand the activities of the National Laboratory Technical Working Group

Planned Activities

Advocate for the role of laboratory

There is increasing recognition for the importance of the laboratory’s role in the public health system. Also, there is greater participation of the laboratory in policy formulation for disease prevention and control programs. EHNRI will therefore continue to engage in activities to advocate for the role of the laboratory in the development of the country’s health care system.
As such, EHNRI will continue to:

- Have consistent presence at FMoH executive meetings to bring important laboratory issues to attention and to promote the laboratory agenda
- Advocate for policies and resources to improve the country’s laboratory programs
- Establish and maintain regular dialogue with development partners and institutions to ensure professional linkages and focus resources on laboratory priorities

Improved advocacy of the laboratory at the FMoH will carry the benefit of having the FMoH promulgate the agenda of the national laboratory system to the public as part of the government’s broader health campaigns. This channelling of the laboratory’s agenda will help to bring to public light laboratory services and the crucial role that they play in the health system.

A national laboratory policy is planned to highlight the roles of the laboratory. Such a document will foster greater understanding of the laboratory system as a whole and clarify its operational elements, thereby facilitating communications with stakeholders.

As laboratory advocacy within the Regional Health Bureaus are currently lacking in many regions in Ethiopia, the interface between the Regional Health Bureau and the Regional Laboratory needs to be strengthened, particularly in light of the growing complexities of health programs with laboratory components.

**Establish and maintain frameworks for regular communication**

A well-functioning communication framework is required at all levels of the system. At the site level, regular internal meetings are vital to the coordinated functioning of the laboratory within the context of the larger medical facility. At the national and regional levels, the Laboratory Response Unit at EHNRI will be developed to effectively manage communications between the regions and EHNRI in a timely manner and in accordance with the Communications Handbook.

To foster clear understanding of the activities undertaken by the regions and partner organizations, the National Laboratory TWG will convene regularly to provide a forum for the discussion of these various efforts. In addition, regular large-scale meetings will be called by EHNRI with relevant stakeholders to share the progress of their respective activities, exchange ideas, and harmonize plans.

**Establish collaborations with national and international laboratories**

As described in Strategic Objective 15, through collaborations in applied research, technological evaluations, and sharing of best practices, stronger ties with national and international laboratories will be forged. These cooperative efforts will create opportunities for publicizing the endeavors of the national laboratory system.
**Expand the activities of the National Laboratory Technical Working Group**

The National Laboratory TWG, which reports to EHNRI, assists with planning and harmonization of national laboratory programs. The TWG will be responsible for reviewing the implementation of the Master Plan. The TWG will also advise stakeholders on laboratory aspects of the national program.

The Director General of EHNRI serves as the chairperson of the TWG. Membership of the TWG consists of leading laboratory experts from institutions around the country, including regional representation, laboratory experts from local partners, and international advisors. Expertise in key testing areas is required, as well as leadership in quality control, instrumentation, logistics, and human resources.

The TWG will meet once per month and smaller sub-groups will be broken out to focus on special projects at the request of the TWG Chairperson.

**2013 Goals**

- The role and goals of the national laboratory system are well-understood by all stakeholders
- At all laboratories, internal meetings are conducted regularly
- Communication within the laboratory network is effective
- Collaboration has been conducted with national and international laboratories
- TWG meetings are held routinely and subgroups produce deliverable work on a regular basis
Strategic Objective 17

To develop a plan for sustainability of the national laboratory system

Situational Analysis

Donor assistance has accelerated the expansion of laboratory services nationwide. However, in the long term, Ethiopia must be able to sustain the current laboratory services in the absence of partner organizations. Specific areas of laboratory services have benefited disproportionately as compared to the laboratory system as a whole. In addition, the growth of laboratory services has not always been accompanied by the concomitant development of government capacity. In order maintain the progress that has been gained and to ensure that laboratory services are pursued in a sustainable manner, the following strategies will be employed:

Strategies

- Transfer knowledge and skills to government personnel
- Remove parallel or fragmented systems and develop integrated laboratories in order to create efficient programs which can be transitioned more easily in the future
- Evaluate long-term and total costs of programs prior to implementation in order to ensure that they can be supported by the government budget in the future, if necessary
- Programs will be integrated into existing systems when feasible; this will promote efficient provision of services by minimizing the need for duplication in human resource and infrastructure requirements
- Ultimately, in order to integrate laboratory services throughout the national laboratory system, ownership of laboratory programs must be fostered and supported at the regional levels.

2013 Goals

- Sustainability analysis is conducted on all laboratory programs prior to commencement
- Government capacity exists to transition programs and systems over to the FMoH budget and personnel, should donors and implementing partners depart
## Appendix 1: Minimum Laboratory Testing Services at Each Tier of the Laboratory

**Excerpts from Maputo Consensus Report**

### ANNEX E

**CHART OF LAB TESTS BY LEVEL WITH EXAMPLES OF EQUIPMENT AND VENDORS FOR EACH TEST**

**LEVEL I**

<table>
<thead>
<tr>
<th>Test</th>
<th>Examples of Kit/Equipment</th>
<th>Vendor/Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Serology Rapid Test</td>
<td>HIV Rapid Test Kits</td>
<td>Country-specific; various vendors</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Hemoglobinometer</td>
<td>Hemocue AB, Sweden</td>
</tr>
<tr>
<td>Urine Pregnancy Rapid Test</td>
<td>Beta HCG urine kits</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Urine Dipstick</td>
<td>Multi-parameter reagent strips</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Whole Blood Glucose</td>
<td>ACCU-CHEK Glucometer</td>
<td>Roche Diagnostics, Switzerland</td>
</tr>
<tr>
<td></td>
<td>Bayer Elite</td>
<td>Siemens USA</td>
</tr>
<tr>
<td>AFB Smear</td>
<td>Light microscope</td>
<td>Various vendors</td>
</tr>
<tr>
<td></td>
<td>Ziehl-Neelsen stain, Fluorescent Stain (high vol)</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td>Malaria Smear</td>
<td>Wright-Giemsa Stain Pack</td>
<td>Various vendors</td>
</tr>
<tr>
<td></td>
<td>Field Stain A and B</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Malaria Rapid Test</td>
<td>Malaria Rapid Test Kits</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Wet Mounts - Direct Microscopy</td>
<td>Light microscope</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Rapid Syphilis Test (RST)</td>
<td>RST Kits</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Chemistry: ALT and Creatinine</td>
<td>Roche Hemofoton Plus</td>
<td>Roche Diagnostics, Switzerland</td>
</tr>
<tr>
<td></td>
<td>VITROS DT60 II</td>
<td>Ortho-Clinical Diagnostics</td>
</tr>
<tr>
<td></td>
<td>Humalyzer 2000</td>
<td>Human GmbH, Germany Chem-Labs Limited, Nairobi</td>
</tr>
<tr>
<td></td>
<td>BA-88</td>
<td>Mindray Medical International Ltd., China</td>
</tr>
<tr>
<td>Spectrophotometer</td>
<td></td>
<td>Various vendors</td>
</tr>
</tbody>
</table>

*Mention of any products, equipment, or vendors in this document does not indicate endorsement by the World Health Organization, the U.S. Government, the American Society for Clinical Pathology, the Clinton Foundation, the Bill & Melinda Gates Foundation, or the Global Fund. The above list includes examples of products, equipment, and vendors and should not be considered all-inclusive.*
## ANNEX E

### CHART OF LAB TESTS BY LEVEL WITH EXAMPLES OF EQUIPMENT AND VENDORS FOR EACH TEST*

#### LEVEL II

<table>
<thead>
<tr>
<th>Test</th>
<th>Examples of Kit/Equipment</th>
<th>Vendor/Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Serology Rapid Test</td>
<td>Refer to Level I</td>
<td></td>
</tr>
<tr>
<td>HIV Serology by EIA</td>
<td>Refer to Level III</td>
<td></td>
</tr>
<tr>
<td>CBC with Automated Differential</td>
<td>CELL-DYN Series (1600cs, 1700, 1800)</td>
<td>Abbott Laboratories, USA</td>
</tr>
<tr>
<td>AcT Diff II</td>
<td></td>
<td>Beckman Coulter, USA</td>
</tr>
<tr>
<td>XX-21N</td>
<td>Sysmex, Japan</td>
<td></td>
</tr>
<tr>
<td>CBC - Manual</td>
<td>Light Microscope</td>
<td>Orion, Japan or Nikon, Japan; various vendors</td>
</tr>
<tr>
<td>Wright-Giemsa Stain Pack</td>
<td></td>
<td>Various vendors</td>
</tr>
<tr>
<td>CSF (Body Fluid Cell Counts)</td>
<td>Light Microscope</td>
<td>Orion, Japan or Nikon, Japan; various vendors</td>
</tr>
<tr>
<td>CD4 (absolute)</td>
<td>FACSCaliber</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td>EasyCD4</td>
<td>PointCare NOW</td>
<td>PointCare Technologies</td>
</tr>
<tr>
<td>Chemistry Panel</td>
<td>Fully Automatic</td>
<td>Biomedical Systems International, Italy</td>
</tr>
<tr>
<td>IL 300+</td>
<td></td>
<td>Instrumentation Laboratory, Distributed in conjunction w/ Coulter</td>
</tr>
<tr>
<td>HumasTAR 400</td>
<td></td>
<td>Human GmbH, Germany</td>
</tr>
<tr>
<td>BS-120, BS-200</td>
<td></td>
<td>Mintray Medical International Ltd., China</td>
</tr>
<tr>
<td>Whole Blood Lactate</td>
<td>Accutrend Lactate</td>
<td>Roche Diagnostics, Switzerland</td>
</tr>
<tr>
<td>AFB Smear</td>
<td>Light microscopy or fluorescent (high vol)</td>
<td>Olympus, Japan or Nikon, Japan; various vendors</td>
</tr>
<tr>
<td>Cryptococcal Antigen Test</td>
<td>Crypto-LA test (latex agglutination test)</td>
<td>Wampole Laboratories, USA</td>
</tr>
<tr>
<td>India Ink Stain</td>
<td>India Ink Stain</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Refer to Level I</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Refer to Level III</td>
<td></td>
</tr>
<tr>
<td>Gram Stain</td>
<td>Gram's stain pack</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td>Malaria Rapid Test</td>
<td>Refer to Level I</td>
<td></td>
</tr>
<tr>
<td>TPPA/TPHA/RPR</td>
<td>Syphilis serology tests</td>
<td>Various vendors</td>
</tr>
<tr>
<td>RST kits</td>
<td></td>
<td>Various vendors</td>
</tr>
<tr>
<td>MacroVue RPR Card Test Kit No. 104</td>
<td></td>
<td>Becton, Dickinson and Company, USA</td>
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<tr>
<td>Type and Crossmatch</td>
<td>Blood bank typing reagents</td>
<td>SANYO, Japan</td>
</tr>
<tr>
<td>Urine Dipstick with Microscopy</td>
<td>Multi-parameter reagent strips</td>
<td>Medion Diagnostics GmbH, Germany</td>
</tr>
<tr>
<td>Urine Pregnancy Rapid Test</td>
<td>Light microscope</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Wet Mounts - Direct Microscopy</td>
<td>Refer to Level I</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Test</th>
<th>Examples of Kit/Equipment</th>
<th>Vendor/Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Serology Rapid Test</td>
<td>Refer to Level I</td>
<td></td>
</tr>
<tr>
<td>HIV Serology by EIA (Automated)</td>
<td>ADVIA Centaur XP</td>
<td>Siemens USA</td>
</tr>
<tr>
<td></td>
<td>VITROS ECI</td>
<td>Ortho Clinical Diagnostics</td>
</tr>
<tr>
<td></td>
<td>AxSYM, Architect, Pham</td>
<td>Abbott Laboratories, USA</td>
</tr>
<tr>
<td>HIV Serology by EIA</td>
<td>HIV EIA kits</td>
<td>Various vendors</td>
</tr>
<tr>
<td>Viral Load</td>
<td>Ektachip Load Assay</td>
<td>Cavid, Sweden</td>
</tr>
<tr>
<td></td>
<td>NucliSens EASYQ with MiniMAG NA Purification</td>
<td>bioMerieux</td>
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<tr>
<td></td>
<td>VERSANT HIV RNA 2.0 Assay (IDNA)</td>
<td>Siemens USA</td>
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<td></td>
<td>AMPLICOR HIV-1 MONITOR Test with manual extraction</td>
<td>Roche Diagnostics, Switzerland</td>
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<tr>
<td></td>
<td>COBAS AmpliPrep with COBAS AMPLICOR Analyzer</td>
<td>Roche Diagnostics, Switzerland</td>
</tr>
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<td></td>
<td>CBC with Automated Differential</td>
<td>HORIZA France</td>
</tr>
<tr>
<td></td>
<td>CBC - Manual</td>
<td>Various vendors</td>
</tr>
<tr>
<td></td>
<td>CSF (Body Fluid Cell Counts)</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>CD4 (% and absolute)</td>
<td>Refer to Levels I &amp; II</td>
</tr>
<tr>
<td></td>
<td>Urine Dipstick with Microscopy</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>Whole Blood Lactate</td>
<td>Refer to Levels I &amp; II</td>
</tr>
<tr>
<td></td>
<td>AFB Culture and Susceptibility</td>
<td>Refer to Levels I &amp; II</td>
</tr>
<tr>
<td></td>
<td>Biochemical test reagents or systems</td>
<td>Various vendors</td>
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<tr>
<td></td>
<td>MycoPrep™ Specimen Digestion/Decontamination Kit</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td></td>
<td>SensiDisc™ Anti-mycobacterial Discs for use in</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td></td>
<td>culture media</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BACTEC MGIT 960 / Liquid based Culture System</td>
<td>Becton, Dickinson and Company, USA</td>
</tr>
<tr>
<td></td>
<td>Microbiology Smear / Culture / Suscept</td>
<td>Gram’s stain pack</td>
</tr>
<tr>
<td></td>
<td>AFB Smear</td>
<td>Various vendors</td>
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<td>Biochemical test reagents or systems</td>
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<td></td>
<td>Prepared packaged media</td>
<td>Various vendors</td>
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<tr>
<td></td>
<td>Kirby Bauer or other susceptibility disc methods</td>
<td>Various vendors</td>
</tr>
<tr>
<td></td>
<td>Malaria Smear</td>
<td>Refer to Level I</td>
</tr>
<tr>
<td></td>
<td>Malaria Rapid Test</td>
<td>Refer to Level I</td>
</tr>
<tr>
<td></td>
<td>Rapid Syphilis Test (RST)</td>
<td>Refer to Level I</td>
</tr>
<tr>
<td></td>
<td>TPPA/TPIRA/RPR</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B</td>
<td>Variety of kits</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C</td>
<td>Variety of kits</td>
</tr>
<tr>
<td></td>
<td>Automated Hepatitis B/C Serology (high volume)</td>
<td>Roche Diagnostics, Switzerland</td>
</tr>
<tr>
<td></td>
<td>Type and Crossmatch</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>Urine Pregnancy Rapid Test</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>Wet Mounts – Direct Microscopy</td>
<td>Refer to Level I</td>
</tr>
<tr>
<td></td>
<td>Cryptococcus Antigen Test</td>
<td>Refer to Level II</td>
</tr>
<tr>
<td></td>
<td>India Ink Stain</td>
<td>Refer to Level II</td>
</tr>
</tbody>
</table>

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Appendix 2: Minimum Requirements for Laboratory Equipment at Each Tier of the Laboratory

Excerpts from Maputo Consensus Report

**Annex G: General Equipment Requirements for Each Level of a Laboratory Network**

<table>
<thead>
<tr>
<th>LEVEL I</th>
<th>TEST/OTHER</th>
<th>EQUIPMENT</th>
<th>MODEL #1</th>
<th>MODEL #2</th>
<th>MODEL #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated ALT and Creatinine</td>
<td>Centrifuge, bench, non-refrigerated, with standard motor</td>
<td>Fisher 13-100-582</td>
<td>Beckman Coulter USA</td>
<td>Heraeus</td>
<td></td>
</tr>
<tr>
<td>Automated ALT and Creatinine</td>
<td>Centrifuge, bench, non-refrigerated, with standard motor; Accepts 13 x 100mm blood tubes, 240V, 50/60Hz</td>
<td>Beckman Coulter USA</td>
<td>Heraeus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated ALT and Creatinine</td>
<td>4ºC lab refrigerator, 240V (to hold supplies)</td>
<td>Isotemp/Fisher</td>
<td>Domestic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFB Smear</td>
<td>Biological Safety Cabinet Type I (Level I-II)</td>
<td>Baker (Level I-II)</td>
<td>Labconco Class I Series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbiological Transport</td>
<td>4ºC lab refrigerator, 240V (to store specimens until pick-up)</td>
<td>Isotemp/Fisher</td>
<td>Domestic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th><strong>LEVEL II</strong></th>
<th><strong>TEST/OTHER</strong></th>
<th><strong>EQUIPMENT</strong></th>
<th><strong>MODEL #1</strong></th>
<th><strong>MODEL #2</strong></th>
<th><strong>MODEL #3</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>General Laboratory Equipment- Centrifuge Maintenance</td>
<td>Tachometer (to verify speed)</td>
<td>Beckman Coulter</td>
<td>Heraeus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Serology</td>
<td>Centrifuge, bench, non refrigerated, with standard motor-Accepts 13x100mm blood tubes, 240V, 50/60Hz</td>
<td>VWR International Tube Rotator</td>
<td>Drummond Omega Diagnostics IMMUTREP ROTATOR OD171 (battery / electric)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Serology</td>
<td>3D bi-directional rotator 240V, 50/60Hz</td>
<td>BioTek EL800</td>
<td>Dynex MRX Molecular Devices EMax</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Serology</td>
<td>4°C lab refrigerator</td>
<td>Domestic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Serology</td>
<td>Incubator</td>
<td>NuAire, Inc. Autoflow Napco Boekel Scientific</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV Serology</td>
<td>Automated ELISA plate reader (wavelength range 405 - 630)</td>
<td>BioTek EL800</td>
<td>Dynex MRX Molecular Devices EMax</td>
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<tr>
<td>HIV Serology</td>
<td>Automated ELISA plate washer (8 or 12 strip) with waste container</td>
<td>Thermo Scientific Wellwash Finstrip Bio-Tek ELX 50</td>
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<tr>
<td>HIV Serology</td>
<td>EIA incubator</td>
<td>Fisher</td>
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<tr>
<td>Automated CBC with Automated Differential</td>
<td>Blood tube rocker/rotator</td>
<td>VWR-12620-960 Orbitek-Rocker Mini Rotator-Vortex</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Automated CBC with Automated Differential</td>
<td>4°C lab refrigerator, 240V</td>
<td>Domestic Isotemp/Fisher</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4</td>
<td>Blood tube rocker/rotator</td>
<td>VWR-12620-960 Orbitek-Rocker Mini Rotator-Vortex</td>
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<td></td>
</tr>
<tr>
<td>CD4</td>
<td>4°C lab refrigerator, 240V (to store controls and calibrators)</td>
<td>Isotemp/Fisher Domestic</td>
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<td></td>
</tr>
<tr>
<td>Automated Chemistry Panel</td>
<td>Centrifuge, bench, non-refrigerated, with standard motor</td>
<td>Fisher 13-100-582 Beckman Coulter Heraeus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated Chemistry Panel</td>
<td>4°C lab refrigerator, 240V (to hold supplies)</td>
<td>Domestic Isotemp/Fisher</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Automated Chemistry Panel</td>
<td>(-20°C) lab freezer (not self-defrosting) (to store reagents or aliquots of reagents/calibrators)</td>
<td>Domestic</td>
<td></td>
<td></td>
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<tr>
<td>Automated Chemistry Panel</td>
<td>Water distiller, complete with wall bracket and tubing</td>
<td>Barnstead International Thermo Scientific</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>LEVEL II</td>
<td>TEST/OTHER</td>
<td>EQUIPMENT</td>
<td>MODEL #1</td>
<td>MODEL #2</td>
<td>MODEL #3</td>
</tr>
<tr>
<td>----------</td>
<td>------------</td>
<td>-----------</td>
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<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>AFB Smear</td>
<td>Biosafety Cabinet Class II (if this level will perform any TB activity other than direct specimen smearing, BSC Class II is required)</td>
<td>Baker SterilGUARD</td>
<td>NuAire Labguard</td>
<td>Labconco Purifier Logic Class II</td>
<td></td>
</tr>
<tr>
<td>Cryptococcal Antigen Test</td>
<td>Centrifuge (1000 x g)</td>
<td>VWR-14231-854</td>
<td>Napco (Levels I-III)</td>
<td>Precision Scientific</td>
<td></td>
</tr>
<tr>
<td>Cryptococcal Antigen Test</td>
<td>56°C Water bath, 15L, 240V, 50/60Hz</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
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</tr>
<tr>
<td>Cryptococcal Antigen Test</td>
<td>4°C lab refrigerator, 240V (to store specimens until testing and for kit reagents)</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
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<tr>
<td>Gram Stain</td>
<td>Incubators (CO2 and nonCO2)</td>
<td>Fisher</td>
<td></td>
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<tr>
<td>Gram Stain</td>
<td>4°C lab refrigerator, 240V (to store media)</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TPPA/TPHA</td>
<td>Centrifuge, bench, non-refrigerated, with standard motor</td>
<td>Fisher 13-100-582</td>
<td>Beckman Coulter</td>
<td>Heraeus</td>
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</tr>
<tr>
<td>TPPA/TPHA</td>
<td>4°C lab refrigerator, 240V (to hold supplies)</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
<td></td>
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<tr>
<td>TPPA/TPHA</td>
<td>Blood tube rocker/rotator (optional)</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>Centrifuge, bench, non-refrigerated, with standard motor</td>
<td>Fisher 13-100-582</td>
<td>Beckman Coulter</td>
<td>Heraeus</td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>Blood tube rocker/rotator</td>
<td>VWR-12620-960</td>
<td>Orbitek-Rocker</td>
<td>Mini Rotator-Vortex</td>
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</tr>
<tr>
<td>Type and Crossmatch</td>
<td>4°C lab refrigerator with continuous temperature monitoring capability</td>
<td>Domestic</td>
<td>Thermo Scientific</td>
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<tr>
<td>Type and Crossmatch</td>
<td>(-40°C) laboratory freezer refrigerator with continuous temperature monitoring capability</td>
<td>Domestic</td>
<td>Thermo Scientific</td>
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</tr>
<tr>
<td>Type and Crossmatch</td>
<td>56°C Water bath, 15L, 240V, 50/60Hz</td>
<td>VWR-14231-854</td>
<td>Napco (Levels I-III)</td>
<td>Precision Scientific</td>
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</tr>
<tr>
<td>Type and Crossmatch</td>
<td>Platelet rotator</td>
<td>Thermo Scientific</td>
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<tr>
<td>Type and Crossmatch</td>
<td>Platelet incubator</td>
<td>Thermo Scientific</td>
<td>Fisher</td>
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<tr>
<td>Type and Crossmatch</td>
<td>Test tube agglutination viewer</td>
<td>BD Diagnostics</td>
<td>Fisher</td>
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<tr>
<td>Urine Dipstick - Microscopy</td>
<td>Centrifuge</td>
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<tr>
<td>Microbiological Transport</td>
<td>4°C lab refrigerator, 240V</td>
<td>Domestic</td>
<td>Isotemp/Fisher</td>
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</tbody>
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### LEVEL III (Additional)

<table>
<thead>
<tr>
<th>TEST/OTHER</th>
<th>EQUIPMENT</th>
<th>MODEL #1</th>
<th>MODEL #2</th>
<th>MODEL #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Laboratory Equipment – pH Meter Maintenance</td>
<td>Autoclave (verification indicator)</td>
<td>Daigger</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Laboratory Equipment – Centrifuge Maintenance</td>
<td>Tachometer (to verify speed)</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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