



MINISTRY OF HEALTH

MALAWI: LABORATORY STANDARDIZATION WORKSHOP

STANDARDIZATION OF LABORATORY TESTS,
TECHNIQUES AND EQUIPMENT



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Abstract

In April and May 2009, the Ministry of Health, with technical assistance from the USAID | DELIVER PROJECT, Task Order 1, conducted a laboratory standardization workshop to develop a standard list of tests, techniques, and equipment for the national laboratory system.

The workshop involved all stakeholders of the laboratory system and resulted in a comprehensive list of standardized tests, techniques, equipment, and products that are required to provide laboratory testing services to meet the needs of clinicians and patients in Malawi.

Cover photo: Ministry of Health Laboratory Standardization Workshop; Sunbird Hotel; Lilongwe, Malawi, May 2009



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ACRONYMS

ABO	antibodies blood group
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
APTT	activated partial thromboplastin time
ART	antiretroviral therapy
ARV	antiretroviral (drug)
ASOT	antistreptolysin O titer
AST	aspartate aminotransferase
ATLAS	Assessment Tool for Laboratory Services
CD4	T4 or helper lymphocytes, the quantitative count of these cells
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
CHAI	Clinton HIV/AIDS Initiative
CHSU	Community Health Sciences Unit
CMS	Central Medical Stores
DBS	dry blood spot
DHO	district health officer
DMO	district medical officer
EID	early infant diagnosis
ELISA	enzyme-linked immunosorbent assay
EMLS	Essential Medical Laboratory Services
ESR	erythrocyte sedimentation rate
FBC	full blood count
FSH	follicle-stimulating hormone
GF	Global Fund
GGT	gamma-glutamyl transpeptidase
Hb	hemoglobin
HIV	human immunodeficiency virus

HTSS	Health Technical Support Services
HUTAP	Howard University Technical Assistance Program
JSI	John Snow, Inc.
LDH	lactate dehydrogenase
LFT	liver function tests
MOH	Ministry of Health
MOF	Ministry of Finance
PAM	Physical Assets Management Unit
PCR	polymerase chain reaction
PT	prothrombin time
QA	quality assurance
QC	quality control
QECH	Queen Elizabeth Community Hospital
Rh	Rhesus factor
RMS	Regional Medical Stores
SDP	service delivery point
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic pyruvic transaminase
SOP	standard operating procedure
STI	sexually transmitted infection
SWAp	sector wide approach
TB	tuberculosis
TPHA	treponema pallidum haemagglutination test
TSH	thyroid-stimulating hormone
TWG	technical working group
USAID	U.S. Agency for International Development
WBC	white blood cell
WHO	World Health Organization
ZN	Ziehl-Neelsen

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EXECUTIVE SUMMARY

The mandate for the USAID | DELIVER PROJECT in Malawi has expanded to include laboratory supplies, which is a relatively new area of focus for the Malawi Ministry of Health (MOH). An assessment of Malawi's laboratory system found that to successfully manage the logistics system for laboratory supplies, the laboratory testing services needed to be standardized for each level of the system.

Standardization is the setting of test menus, techniques, equipment, and operating procedures for each type of test, at each level of the system. The project's interest in standardizing laboratory testing services is directly related to its focus on improving the availability of laboratory reagents and consumables.

Standardization has many programmatic, clinical, and supply chain benefits, including easier management of the supply chain because of a reduced number of products; an increased accuracy in forecasting as standard practices are put in place; and the ability to compare results between facilities, both for quality assurance and clinical management of patients.

To standardize the laboratory testing services, the Ministry of Health Diagnostics Unit held a standardization workshop, which the USAID | DELIVER PROJECT facilitated. The workshop included participants who were either customers of or service providers within the laboratory system. During the workshop the advisors used a variety of references and tools to guide participants in making decisions that will be the most appropriate for the Malawi situation.

During the first day of the workshop, a plenary session, participants from different cadres and levels of the system were asked to share their vision for laboratory testing services in Malawi. This provided a basis for selecting the test menus for each level of the system. The last four days of the workshop involved a key number of laboratory staff tasked with selecting techniques, equipment, and products to fulfill the testing menus. The techniques and equipment were chosen after considering the infrastructure and capacity at each level of the system.

The participants then identified the required steps to ensure that standardization is a reality in the everyday practice of laboratory testing. The participants acknowledged that the standards must be approved by the MOH and the procurement unit. After the standards are approved, they must be disseminated and communicated to all stakeholders. Refresher trainings for laboratory staff will be conducted to ensure the standards can be met. Also, an ongoing process for annual reviews of the standardized list by a standardization committee will be established to accommodate new technologies and changes in testing practices.

Standardization offers benefits and opportunities for Malawi that outweigh the challenges associated with the process of achieving that standardization. Dedication from the MOH and support from all the development partners in Malawi will be necessary for standardization to become a reality.

BACKGROUND

The USAID | DELIVER PROJECT's mandate in Malawi has expanded to include laboratory supplies, which is a relatively new area of focus for the Malawi Ministry of Health (MOH). During an assessment of Malawi's laboratory system, it was determined that to successfully manage the logistics system for laboratory supplies, an overarching policy for the standardization of supplies needed to be implemented.

Standardization is the setting of test menus, techniques, equipment, and operating procedures for each level of the system. The management of laboratory supply chains is a challenging, complex undertaking because of the wide range of commodities required to conduct a single laboratory test. It is even more challenging when multiple platforms and techniques are used for the same tests in the country. As each platform requires its own unique products, when a wide range of equipment is used throughout the system, the quantification, procurement planning, and inventory management is difficult and costly because of the large number of different products that must be managed.

BENEFITS OF STANDARDIZATION

The USAID | DELIVER PROJECT's interest in standardizing laboratory testing services is directly related to the project's focus on improving the availability of laboratory reagents and consumables. However, standardization not only benefits the supply chain but also benefits the program and the clinical performance of laboratory services.

Standardization benefits the overall management of the program by enhancing the ability to predict need, allowing for the rational allocation of resources and systematic planning for scaling up of services. In terms of managing human resources, standardization achieves greater efficiency in training and management of staff because the same testing techniques are used at each level of the system, training programs are simplified, and staff can more easily transfer between facilities. Standardization also supports the development of a robust quality assurance program because it allows for results to be compared across facilities, increasing the reliability and consistency of test results.

For clinical services, standardization facilitates uniform and consistent case definition and case management, and thus improves service provision to the clients. Comparison and interpretation of results from different laboratories throughout the system is possible; therefore, clients can easily transfer between facilities. Clinical audits can be conducted with meaningful results and the quality of testing between sites can be compared.

The supply chain benefits, mentioned previously, are directly related to fewer types of products that must be managed. As a result, rational decision making in product selection, forecasting, quantification, and procurement can occur. Due to the fact that a larger volume of fewer products will be procured, rather than a small volume of a wide variety of products, the program can more effectively negotiate prices and service contracts. When all facilities are using the same products, stock can be redistributed between facilities to correct stock imbalances, thereby reducing the risk of stockouts and wastage.

MALAWI SITUATION

The Essential Medical Laboratory Services (EMLS) for the districts and health centers was developed in 2002 (see table 1). A recent assessment by the USAID | DELIVER PROJECT indicated that while most health centers and districts are able to provide all the tests on the EMLS, there are a number of reasons why the tests are not always being performed. A lack of functioning equipment and reagents is one reason but, also, a lack of communication between laboratories and clinicians as the clinicians are not always aware the tests are available and, therefore, do not request them.

If the laboratory system in Malawi is to be strengthened, the physicians need to be assured that the necessary tests can be provided when needed; the laboratory staff also need to be confident that they will have all the necessary tools to perform the testing when it is requested. Standardization is the first step in building a reliable laboratory system, but the process of standardization must consider the needs of both the medical and laboratory staff.

A key recommendation from the recent assessment was that the Ministry of Health Diagnostics Unit develop standard test and testing technique menus, by level, that are agreed-upon, disseminated, implemented, and advocated for with all clinical and laboratory staff. By including both clinicians and laboratory staff in the process of standardization, physicians would be encouraged to use the laboratory services to enhance their clinical practice and the laboratory staff would have an opportunity to ensure that all the necessary equipment and products are included on the standardized list.

The assessment also pointed to the variety of the equipment available in Malawi. Table 2 shows the different equipment observed in the sample of laboratories visited during the assessment. If procurement of equipment continues, Malawi will have an unmanageable variety of equipment that requires different reagents and different service engineers to maintain the equipment. It was obvious from the assessment that there is a need to standardize and develop a transparent process for selecting equipment.

The process of standardizing laboratory testing services offers Malawi a number of opportunities. It has given them an opportunity to update the EMLS and expand the testing services available at each level of the system to ensure that current needs are met. It also offered an opportunity to evaluate the equipment currently in use in the country and to decide what features and criteria are most critical when selecting laboratory equipment to be used. In addition, it has led to the development of a comprehensive list of laboratory products required to support these testing services.

Table 1: Essential Medical Laboratory Services

Health Center - Rural	Health Center - Urban	District Hospital
Collection of sputum samples for TB	Hemoglobin	Hemoglobin
	TB microscopy	Total WBC and differential
	HIV screening	Blood transfusion screening
	Urine microscopy	TB Microscopy
	Stool microscopy	HIV screening
	Antenatal syphilis screening	Urine microscopy
	Malaria microscopy	Stool microscopy
	Urine chemistry	Antenatal syphilis screening
		Malaria microscopy
		Urine chemistry
		Blood glucose
		CSF analysis—microscopy, India Ink, gram, and ZN stains, protein and glucose

Table 2: Brands of Automated Equipment Observed

Hematology Machines	CD4 Machines	Chemistry Machines
ABX Pentra 60	EPIC	Humalyser 2000
Coulter ACT Diff 5	BD FACS count	Humalyser 3000
Coulter ACT Diff 8	Partec Cyflow SL3	Vitros DT 60
Sysmex KX21	Point of care	Humastar 180
Micros 60		
Humacount		

METHODOLOGY

This technical assistance facilitated the process of standardizing laboratory test menus, techniques, equipment, and products used in Malawi. The USAID | DELIVER PROJECT facilitated a standardization workshop for the Ministry of Health Diagnostics Unit that included customers and service providers within the laboratory system. As previously mentioned, the importance of all clinical and laboratory staff being involved in the process of standardization cannot be overemphasized. The laboratory system must provide the testing services that are needed by the clinicians to manage their patients if the system is to be effectively utilized.

The standardization activity focused on the central, district, and health center laboratories. The reference laboratories were not included as these facilities need to have more flexibility in the products that they procure because of the nature of their work, including research, surveillance, and quality assurance. However, for products included on the standard list, the reference laboratory will source these from the Central Medical Stores (CMS), but specialized products will be procured separately.

Throughout the workshop, the advisors used a variety of references and tools to guide participants to make decisions that will be most appropriate for the Malawi situation. The project would like to recognize the assistance of the staff from Howard University Technical Assistance Program (HUTAP) who were present at the workshop and who were able to give the participants information about the equipment that they had gathered during previous research.

PLENARY SESSION (DAY ONE)

Day 1 of the standardization workshop was designed as a plenary workshop the participants could share ideas and visions for laboratory testing services in Malawi. For the first day of the workshop, a large group of stakeholders were invited to attend, including clinicians, nursing staff, program staff, development partners, and laboratory staff from different specialties and levels of the system. See appendices A, B, and C for a list of the participants, objectives, and timetable for day 1.

The focus of the first day was to allow as many stakeholders as possible to share their opinions and visions for the laboratory system. It was also an opportunity for the same people to be involved in decision making, which would ensure that all needs were met and a commitment was made to establish the standardization process.

CREATING A VISION FOR STANDARDIZATION

The participants were first introduced to the concept and benefits of standardization for the supply chain and also for the clinical and programmatic advantages. After the introductions, the participants that represent different cadres and levels of the health system gave a brief presentation explaining how they see the laboratory system now and the perceived gaps in national laboratory testing services. Laboratory personnel from central, district, and blood transfusion services; program staff from HIV, TB, and malaria programs; nursing and medical staff; and development partners made presentations.

DETERMINING TEST MENUS

The plenary session was used to stimulate decisions about what tests should be available at each level of the system. The larger group was split into smaller groups and allocated a level of the system to determine the testing menus appropriate for the level. Each group was given a table to guide the process. The table was designed using the WHO Laboratory Recommendations by Level document (see references) and included all the tests currently included in the EMLS (see appendix D for worksheet provided to groups). The groups expanded this list to address the current gaps in testing services identified during the plenary session. The different groups then shared the new list and the larger group gave inputs and reached consensus on the tests to be provided at each level of the laboratory network.

STANDARDIZATION WORKSHOP (DAYS 2–5)

During the following four days of the workshop a smaller group of key laboratory staff were tasked with setting techniques to the test menus, selecting equipment necessary to provide the tests, and listing the products needed to perform automated, semi-automated, and manual tests. See appendix E for the list of participants and appendices F and G for the objectives and timetable for days 2–5 of the workshop.

SETTING TECHNIQUES

In setting the techniques, the larger group was divided into the three levels of the system—central, district, and health center—to select appropriate techniques for each level. To maintain consistency in terminology when describing the techniques, the whole group then reviewed each level. All the participants took time and care to ensure the tests and techniques listed were consistent and appropriate for the situation in Malawi.

SELECTING EQUIPMENT

After setting the tests and techniques, the participants were given a list of example operational criteria that could be used to guide the selection of equipment. When selecting equipment, many factors need to be considered, including the technical specifications, supply chain considerations, infrastructure requirements, availability of service engineers, and costs associated with procuring and operating the machine.

The participants were asked to consider each criterion and determine if each criterion was critical, important, or desirable for Malawi, then to decide if any criteria should be deleted or added. After the criterion for critically evaluating equipment or analyzers were set, the participants used this information to evaluate the equipment currently in use in Malawi for biochemistry, hematology, and CD4. See the appendix H for the list of criterion used to evaluate the equipment.

The participants were first asked to consider whether or not to continue using the current equipment; it is costly and resource intensive to replace all equipment in a country with a new product unless it is absolutely necessary. After the participants evaluated the current equipment and if it was determined that the existing equipment did not meet the country's needs, the scope was then broadened to other equipment that was being used elsewhere in the southern African development community.

This process showed the participants the multitude of factors that influence the selection of equipment, including technical specifications, existing infrastructure in the country, and availability of service engineers to overall program requirements.

IDENTIFYING THE PRODUCTS REQUIRED

After the tests, techniques, and equipment were selected, the participants were then tasked with listing the other smaller equipment, consumables, and reagents needed to conduct each test. Without all the required products, it is not possible to perform a test; so it was essential that the participants list every item required, including general items such as gloves, lancets, and test tube stands. In identifying the products, the participants were referred to the draft laboratory standard operating procedures (SOPs) that include supply and equipment lists.

In addition, the participants were asked to use the CMS catalogue when listing the products, first to determine if the product was already included in the CMS list and then to ensure that the product name was correct and complete. Participants were asked to note missing products and name changes; using the lists, the CMS catalogue could be updated later.

RESULTS

VISION FOR LABORATORY TESTING SERVICES

The plenary session for sharing ideas and visions for the laboratory services in Malawi was a highly interactive session that created fruitful discussions. The presentations highlighted some of challenges in providing testing services in Malawi, such as a lack of data, trained staff, and difficulties in transporting samples. With these challenges, the participants discussed new initiatives that were being introduced, such as the introduction of laboratory assistants at health centers. The initiatives would expand the testing capabilities of these lower-level facilities and put into place the plan to procure motorbikes for some district hospitals to facilitate sample transportation and information dissemination. The challenges and new initiatives helped create a realistic and current vision for laboratory testing services in Malawi.

Medical and laboratory staff from the central- and district-level facilities gave specific recommendations on what laboratory tests should be added to the current testing services. The following list of recommendations is a compilation of the plenary session presentations by laboratory, nursing, and medical staff from each level.

Table 3: Recommended Additions Made by Participants to Current Services

Health Service	Recommendations
Central hospitals	Histology, cytology, hormones tests, tumor markers, TB culturing
District hospitals	Microbiology culture and sensitivity, renal function tests, liver function tests, cardiac enzymes, gastrointestinal tract tests
Health centers	Malaria- blood film, TB-Ziehl Neelsen, anemia-hemoglobin, urine/stool microscopy/HCG, syphilis screening, blood glucose
Blood transfusion service	Infrastructure—space, lighting, sink, workbench, storage, fridge
Programs	
HIV	Increase CD4 testing—currently underutilizing the CD4 machines—average of 16 tests/machine/day.
TB	Increase number of microscopy sites Increased availability of staff—locally trained microscopists for urban and rural health centers Motorbikes on Global Fund proposal for sample transport
Malaria	Increase in microscopes and microscopists, evaluating possibility of introducing rapid diagnostic testing

STANDARDIZATION RESULTS

TESTS MENUS

The larger plenary group was divided into smaller groups that would decide on tests for each level of the system. Each group was tasked with one level—central, district, or health center. The groups created a comprehensive list of tests to be offered at their level of the system. In deciding which tests to offer at the central level versus the district level, the participants considered the infrastructure available and the capacity of the medical staff at the particular facility to interpret and appropriately act on the results. The testing menus were reviewed and expanded, taking into account the presentations in the plenary session.

Table 4 lists the updated test menu for hematology by level. As shown, the tests for hematology chosen for the district and central hospitals are very similar except that the central level offers a few more specialized tests. This was the case for most testing categories because there are minimal differences between the central and district hospitals. However, the table shows that the health centers offer a small number of tests and only very basic testing services, which reflects the staffing capacity and infrastructure of these facilities. For a complete list of tests by level, refer to appendix I.

Table 4: Test Menu for Hematology by Level

Central Hospital	District Hospital (including community hospital)	Health Center
<i>Hematology</i>	<i>Hematology</i>	<i>Hematology</i>
Full blood count	Full blood count	Hemoglobin
Differential count manual	Differential count manual	White blood cell count
Sickle cell screening	Sickle cell screening	
Sickle cell confirmatory test	Sickle cell differential test	
Hemoglobin	Hemoglobin	
Prothrombin Time	Prothrombin Time	
Activated Partial Thromboplastin Time	Activated Partial Thromboplastin Time	
Fibrinogen test	Erythrocyte Sedimentation Rate	
Erythrocyte Sedimentation Rate	Reticulocyte count	
Reticulocyte count	CD4 count	
Lupus erythromatous	CD4 %	
CD4 count		
CD4 %		

TECHNIQUES

Techniques were determined for each type of test, for each level of the system, based on the capacity of the staff at that level of the system and the infrastructure available to support the technique. See table 5 for a list of the techniques chosen for hematology for each level of the system. Again, note that the difference in techniques and capabilities between the central and district level laboratories is minimal, but the techniques used at the health center are usually simple, rapid tests. See appendix J for the full list of standard techniques.

Table 5: List of Techniques for Hematology

Test Menus	Techniques		
	Central Hospital	District Hospital	Health Center
Haematology			
Full blood count	Haematology analyzer	Haematology analyzer	
Differential count	Manual	Manual	
White blood cell count			HemoCue
Sickle cell screening	Sodium metabisulphate	Sodium metabisulphite	
	Sodium dithionate	Solubility	
Sickle cell confirmatory test	Electrophoresis		
Hemoglobin	HemoCue	HemoCue	HemoCue
PT	Automated machine	Tube method	
APTT	Automated machine	Tube method	
Fibrinogen test	Automated machine		
ESR	Westergreen	Westergreen	
Reticulocyte count	Brilliant cresol blue	Brilliant cresol blue	
	New Methylene blue	New Methylene blue	
	Automated machine		
Lupus erythromatous	Latex agglutination		
CD4 Count	Flowcytometry	Flowcytometry	
CD4 %	Flowcytometry	Flowcytometry	

EQUIPMENT

Selecting the equipment to include on the standardized list is a challenging activity because many factors must be considered and often participants have different priorities based on their own situation. It is important that participants understand they need to select the equipment that is the best for the majority of facilities but may not be the best machine for every situation.

The equipment chosen to be included on the standardized list in Malawi was carefully evaluated and compared with other similar equipment. The participants established the criterion for evaluating the equipment. See appendix H for a list of operational considerations. The participants identified the criterion, such as ongoing supplier service, including training of users, ready availability of service engineers, and regular maintenance, as very important considerations and often one of the deciding factors in choosing a machine. See appendices K, L, and M for the evaluation of CD4, hematology, and biochemistry equipment currently in use in Malawi.

Through discussion with participants and valuable input from development partners, the participants selected the following equipment for biochemistry, hematology, and CD4, as listed in table 6. Most of equipment selected by the participants is already in use in the country; this simplifies the implementation of the standards.

However, some equipment was selected with conditions; the Partec Cyflow SL3 was one of those. While this analyzer is used in many facilities in Malawi, many laboratory staff are not happy with the performance of this machine. Participants could not confirm the exact reasons for the challenges with this equipment but it may be a lack of adequate training and stockouts of reagents due to poor planning and poor maintenance within the laboratory. If these reasons are correct, any equipment

may fail; therefore, efforts should be made to increase training, improve availability of reagents, and service all machines.

Some new equipment was also selected for the standard list that is not currently in use in the country. On evaluating the existing equipment if none of them fulfilled some important criterion set by the participants—such as poor maintenance and service provision or unaffordable operating costs—the scope was expanded to consider equipment not currently used in Malawi but that is used in the region. One example is the hematology analyzer for central-level labs. The existing equipment used for hematology at the central level either had unreliable servicing, high service costs, or was too expensive to operate. Therefore, a new analyzer needed to be considered. The reputation and regional experience with the Sysmex XT 1800 had shown this to be a good, reliable machine; local experience with the Sysmex KX21 had demonstrated that the suppliers provided good service and maintenance. See appendix N for a standardized list of equipment.

Table 6: List of Standard Equipment

Type of Analyzers	Central	District
Biochemistry	Humastar 180 / Humalyte ISE	Humalyzer 3000
	Keylab	
Haematology	Sysmex XT 1800	Sysmex KX21
	Sysmex KX21	
CD4	EPICS	Partec Cyflow SL3
	Partec Cyflow SL3	FACS Count

PRODUCTS

The participants selected the products that were required to perform each test using the agreed-upon technique and the equipment selected. On compiling this list of products, the participants were referred to both the draft SOPs and the current CMS catalogue; they guided the decisions and helped identify any discrepancies or gaps in either of these documents.

The total list of reagents and consumables required for all tests, at all levels, is approximately 385 products. Currently, the CMS list includes only 250 products. It was found in compiling this list that many of the items were missing from the CMS catalogue and many were duplicated but with slightly different names. Updating the CMS catalogue will be critical as all facilities refer to it when placing orders.

RECOMMENDATIONS AND IMPLEMENTATION PLAN

Standardization offers benefits and opportunities for Malawi that outweigh the challenges associated with the process of achieving standardization. Commitment from the MOH and support from all development partners in-country to implement the standards will be necessary if this process is to become a reality in Malawi.

The participants were asked to consider how the new standardized list might be implemented in the laboratories of Malawi. The participants identified the list of activities in the following list as the next steps needed to implement standardization. The participants identified a small technical group that will be responsible for pursuing the next steps and the USAID | DELIVER PROJECT advisors will be available to provide assistance. In summary, the next steps were identified as follows.

1. *Finalize, by level, the standardized list of tests, techniques, equipment, consumables, and reagents,*

To ensure that the list is complete and addresses all needs, all participants and other experts and development partners need to edit the draft standardized list of tests, techniques, equipment, consumables, and reagents developed during the workshop. A smaller technical group consisting of all central laboratory managers will coordinate the process of reviewing and finalizing this list.

2. *Send a final list to the Deputy Director for HTSS Diagnostics Department for approval.*

After the standardized list is finalized, to make it into an official policy, it must be presented to the Deputy Director for HTSS Diagnostics Department for MOH approval. The smaller technical group will be responsible for preparing this document.

3. *Liaison with the procurement unit to assist in implementing standardization.*

One of the major challenges to implementing standardization is compliance with the procurement laws. Generally, procurement laws require open international competitive bidding when procuring equipment or products. Therefore, laboratory staff are usually required to provide specifications to the procurement unit and they cannot specify the preferred brand. Standardization cannot occur if the procurement of equipment is only based on specifications. Discussions with the procurement unit indicate that, in Malawi, it is possible to single-source under the current procurement guidelines if the process is transparent and there is adequate justification. Standardization itself is a justification for single sourcing.

4. *Disseminate the new standards to laboratory staff and refresher trainings to staff at all levels to ensure they have the skills to provide the tests (collaborate with HUTAP).*

For the new standards to become a reality across the national laboratory services, the new standards must be communicated to all laboratory staff and all staff must have the skills to follow the standards. Dissemination of the new standards should occur at the same time that all laboratory staff are receiving refresher trainings.

5. *Provide an orientation of the new standards for laboratory services for all stakeholders, including clinicians, nursing staff, and development partners.*

In addition to communicating the new standards to the laboratory staff, it is also necessary to orientate the new standards with clinicians, nursing staff, and development partners. This also provides an opportunity to encourage medical staff to use the laboratory services and support the strengthening of the laboratory system.

6. *Incorporate the standard techniques and analyzers into the training programs.*

The current training curriculum for laboratory technologists, technicians, and assistants must be reviewed to ensure that it is in line with the new standards. Where required, it will also be necessary to procure the standard equipment if the equipment is not currently available for training. It is essential that new graduates are adequately trained in using the standardized equipment.

7. *Form a standardization committee.*

A standardization committee should be responsible for overseeing the process of implementation and for regularly updating the national standards. The committee should include a representation of clinicians, program and laboratory staff, and implementing partners. The role of this committee will be to meet once or twice a year to review the list and incorporate the latest in technologies and best practices in the field. This committee will review requests for additions or deletions to the standardized list and they will be responsible for reviewing technical documents and evaluating new technologies and equipment to determine if they are appropriate for inclusion on the list.

8. *Form a laboratory commodities sub-committee.*

It is recommended that a sub-committee to the Laboratory Technical Working Group be formed; it would be responsible for the laboratory commodities. This group will be responsible for monitoring the availability of laboratory equipment, reagents, and consumables and will also identify gaps in funding and resources needed to ensure a continued supply of these essential laboratory supplies.

9. *Strengthen the CMS for procuring and maintaining laboratory supplies.*

The CMS has challenges in forecasting for laboratory supplies, preparing specifications for procurement, and maintaining adequate stock levels of laboratory supplies. Some of the reasons for this are a lack of understanding within CMS of the laboratory commodities and also a failure in communication between the CMS and the laboratory staff. Technical assistance from the project and/or partners should be provided to CMS to update the CMS catalogue; this will ensure that each product is appropriately listed and the specifications for each item are clear and complete.

A logistics management information system and inventory control system must be designed and implemented to collect data for forecasting needs, ensure rational ordering of products from all facilities, and guide facilities in maintaining adequate stock levels of essential reagents and products.

10. *Review annually the standardized list.*

The standardized list of tests, techniques, equipment, and products must be reviewed annually. This will allow flexibility to changes in technology, service provision by suppliers, and changes in testing protocols and best practices. Each year, the MOH should convene a small technical group of both laboratory and medical staff to thoroughly review the standardized list. The roles and responsibilities of this group should be documented and included in the standardization policy.

Table 7: Next Steps for Implementation of Standardization

Activity	Date	Responsible
Draft standardized list of tests, techniques, equipment, consumables, and reagents by level to be edited by all participants and coordinated by a smaller technical group of central laboratory managers.	June 15, 2009	Standardization TWG (all central-level managers)
Final list to be sent to the Deputy Director for HTSS Diagnostics Department for approval and formal documentation.	June 30, 2009	Standardization TWG (all central-level managers)
Liaison with procurement unit to assist in implementation of standardization.	June 30, 2009	USAID DELIVER PROJECT—local laboratory advisor
Dissemination of new standards to laboratory staff and refresher trainings to staff at all level to ensure they have the skills to provide the tests.	July 30, 2009	USAID DELIVER PROJECT in collaboration with HUTAP
Orientation of stakeholders including clinicians, nursing staff, and development partners of the new standards for laboratory services.	July 30, 2009	USAID DELIVER PROJECT
Incorporation of the standard techniques and analyzers into training programs.		undetermined
Formation of a Standardization committee	Sept. 2009	USAID DELIVER PROJECT
Strengthening of CMS in procuring and maintaining laboratory supplies.	ongoing	USAID DELIVER PROJECT
Annual reviews of the standardized list.		Standardization TWG (all central-level managers)

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APPENDICES

Appendix A: Standardization Workshop Participants - Day 1

Appendix B: Goals and Objectives for Day 1

Appendix C: Timetable for Day 1

Appendix D: Malawi Essential Medical Laboratory Services (EMLS) Package

Appendix E: Standardization Workshop Participants - Day 2-5

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Appendix H: Operational Considerations for Equipment Selection

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Appendix K: Evaluation of Existing CD4 Equipment

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Appendix N: Standardized List of Equipment (Analyzers)

APPENDIX A: STANDARDIZATION WORKSHOP PARTICIPANTS - DAY I

No.	Name	Place of Work	Title	Contacts	
				Telephone	Email
1	Alwin B Mbene	Mzuzu Central Hospital	Laboratory Manager		
2	R Mwenda	Ministry of Health	DDHTSS (D)		
3	B D Mvula	Mzuzu Central Hospital	Lab Officer		
4	L I Zungu	Ministry of Health	Supervisor		
5	D Butao	USAID DELIVER	Lab Logistics Advisor		
6	J Mwaisemba	CHSU - EPIDEMIOLOGY	Principal Epidemiologist		
7	M A Nazombe	Mzuzu Central Hospital	Lab Technologist		
8	M M'bang'ombe	MOH - EPIDEMIOLOGY	Disease Surveillance		
9	G B Samuti	TB Program	CRL Officer		
10	A H C Kawonga	Medical Council	Registrar		
11	D Mpinda	QECH	Lab Technologist		
12	T N Soko	QECH	Chief Nursing Officer		
13	Evance Moyo	USAID DELIVER	ALMIS Associate		
14	Tinei Chitsike	USAID DELIVER	HIV/AIDS Logistics Advisor		
15	M Kazipe Phiri	MCHS	Senior Lecturer		
16	S G Santula	Ntcheu DHO	Laboratory Manager		
17	Thom Mfuno	MBTS	Laboratory Manager		
18	W S Rubeni	Ntaja Health Center	Senior Medical Assistant		-
19	Yohane Mello	Ntaja Health Center	Laboratory Microscopist		-
20	Patrick Chagwa	Malamulo College	Lab HOD		-
21	Mabel Chinkhata	Kamuzu Central Hospital	Chief Nursing Officer		
22	Dr Jessie Mlotha	Kamuzu Central Hospital	Chief Dental Surgeon		
23	Gervase Gamadzi	Kamuzu Central Hospital	Laboratory Manager		
24	Enoch Gama	UNC	QA/QC Coordinator		-
25	Rose Dzimadzi	Mzuzu Central Hospital	Hospital Director		
26	G M Banda	Nguludi Hospital	Administrator		
27	T K Nyirenda	MANET			
28	Carol Porter	HUTAP	Director		
29	Jayne Waweru	USAID DELIVER	Country Director		
30	Veronica Chirwa	Clinton Foundation (CHAI)	Deputy Country Director		
31	Rosezoil Rioja	Clinton Foundation (CHAI)	Lab System Mentor		
32	David Mwalilino	Mzimba District Hospital	Lab Technologist		
33	Christine Phiri	Central Medical Stores	Principal Pharmacist		
34	Nancy Matemba	Mzimba District Hospital	District Nursing Officer		
35	Dr Doris Kayambo	Mzimba District Hospital	DMO		
36	Bertha Chikuse	Ntcheu DHO	District Nursing Officer		
37	Thom Ngwira	Mzuzu Central Hospital	Chief Nursing Officer		
38	Dorica Chirwa	HTSS (Pharm)	Logistics Officer		
39	Joseph Bitilinyu	QECH	Laboratory Manager		
40	Chimwenwe Mvula	MOH - Clinical Directorate	ADCS		
41	Bibiana Angarita	HUTAP	Lab Coordinator		
42	Mwai Makoka	MOH - HIV Unit	HIV Fellow		
43	Zengani Chirwa	MOH - HIV Unit	T/A Care & Treatment		
44	B Chilima	CHSU	DDPHS		

45	John Zoya	Malaria Program	ITN Coordinator	████████	████████████████
46	Laphiod Chisuwo	Mangochi DHO	EMLS Supervisor	████████	████████████████
49	Abel Phiri	CHSU	Lab Technician	████████	
50	S C Kadzombe	Ntcheu DHO			
51	E Mabunya	Mzimba District Hospital			
52	J Misinde	Mzuzu Central Hospital			
53	H Feluzi	Zomba Central Hospital	Principal Lab Technologist	████████	
54	M S Wayile	QECH			
55	I C Mwandira	Mzuzu Central Hospital			

APPENDIX B: GOALS AND OBJECTIVES FOR DAY I

**Malawi Ministry of Health
Standardization Workshop for Laboratory Commodities, Day 1
27th April 2009**

Goals and Objectives

Goal:

Participants will begin the process of standardizing testing services in Malawi.

Objectives:

By the end of this workshop, participants will have:

1. Understood the concept of standardization and the benefits it will have on laboratory services
2. Shared their visions for the testing services in Malawi
3. Set the tests for each level of the system
4. Committed to the process of standardization

APPENDIX C:TIMETABLE FOR DAY I

**Malawi Ministry of Health
Standardization Workshop for Laboratory Commodities,
Day 1
27th April 2009**

Schedule

Monday 27/04/09	
8:30 – 9:30	Opening Session
9:30 – 10:00	Introduction to Standardization & Logistics
10:00 – 10:15	Break
10:15– 10:45	Benefits of standardization
10:45– 11:15	Maputo Declaration
11:15 – 12:15	Panel Session - Vision for Lab services in Malawi
12:15-1:15	Lunch
1:15 – 2:15	Panel Session - Vision for Lab services in Malawi
1:15-3:00	Group activity 1 – Set tests by level
3:00 – 3:15	Break
3:15 – 5:00	Group activity 1 presentations and Consensus

APPENDIX D: MALAWI ESSENTIAL MEDICAL LABORATORY SERVICES (EMLS) PACKAGE

Laboratory Tests	Urban Health Centers		District Hospitals		Central Level
	Send Out	On Site	Send Out	On Site	
Haematology					
Hemoglobin		√		√	√
Total WBC and differential				√	√
Blood Bank					
Blood transfusion screening				√	√
Microbiology					
TB Microscopy		√		√	√
HIV screening		√		√	√
Urine microscopy		√		√	√
Stool microscopy		√		√	√
Antenatal syphilis screening		√		√	√
Parasitology					
Malaria Microscopy		√		√	√
Biochemistry					
Urine Chemistry		√		√	√
Blood Glucose				√	√
CSF Analysis					
Microscopy (?cell count)				√	√
Indian Ink				√	√
Gram stains				√	√
ZN stains				√	√
Protein				√	√
Glucose				√	√

APPENDIX E: STANDARDIZATION WORKSHOP PARTICIPANTS - DAY 2-5

<i>Name</i>	<i>Place of Work</i>	<i>Title</i>	<i>Contacts</i>	
			<i>Telephone</i>	<i>Email</i>
Bibiana Angarita	HUTAP	Lab Coordinator	████████	██████████
Patrick Chagwa	Malamulo College	Acting HOD	████████	████████████████
Evance Moyo	USAID DELIVER	ALMIS Associate	████████	██████████
Manuel Nazombe	Mzuzu Central Hospital	Lab Technologist	████████	██████████████
Alwin Mbene	Mzuzu Central Hospital	Laboratory Manager	████████	██████████████
Abel Phiri	PHL (CHSU)	Lab Technician	████████	██████████████
Dorica Chirwa	MOH	Logistics Officer	████████	██████████
Enoch Gamah	UNC	QA/QC Coordinator	████████	██████████████
Laphiod Chisuwo	Mangochi DHO	Lab Supervisor	████████	██████████████
Henry Feluzi	Zomba Central Hospital	Principal Lab Technologist	████████	-
Demister Mpinda	QECH	Lab Technologist	████████	██████████
David Mwalilino	Mzimba District Hospital	Laboratory Manager	████████	██████████████
Scotch Santula	Ntcheu DHO	Laboratory Manager	████████	██████████
M Kazipe Phiri	MCHS	Senior Lecturer	████████	██████████████
B D Mvula	Mzuzu Central Hospital	Lab Officer	████████	██████████████
R Mwenda	MOH – HTSS	DD HTSS - Diagnostics	████████	██████████
J Bitilinyu	QECH	Laboratory Manager	████████	██████████████
I L Zungu	MOH	Diagnostics Officer	████████	██████████████
D Butao	Lab Logistics Advisor	Lab Logistics Advisor	████████	██████████
G Gamadzi	Kamuzu Central Hospital	Laboratory Manager	████████	-
Dr B Chilima	CHSU	Deputy Director	████████	██████████████
Patrick Msipa	USAID DELIVER	Lab Logistics Advisor		██████████████
Sarah Anderson	USAID DELIVER			██████████████
H Chimphepo	HTSS – PAM	Deputy Head of Dept		-
Carlo Porter	HUTAP	Director	████████	██████████████
Rozezoil Rioja	Clinton Foundation (CHAI)	Lab System Mentor	████████	██████████████

APPENDIX F: GOALS AND OBJECTIVES FOR DAY 2-5

**Malawi Ministry of Health
Standardization Workshop for Laboratory Commodities, Day 2-5
28th April – 1st May 2009**

Goals and Objectives

Goal:

Participants will standardize the techniques, equipment and laboratories products used in Malawi.

Objectives:

By the end of this workshop, participants will have:

1. Agreed on technique and priority equipment by level to fulfill test menus.
2. Identified the products that correspond to the agreed testing technique and equipment by level that will become the standard list.
3. Developed next steps for standardization.

APPENDIX G: TIMETABLE – DAY 2-5

Schedule - Standardization Workshop for the Ministry of Health, Malawi, 28th April – May 1st 2009

Tuesday, 28/04/09	Wednesday, 29/04/09	Thursday, 30/04/09	Friday, 01/05/09
8:00 – 9:00	8:00 – 10:00	8:00-10:00	8:00-10:00
Ice breaker / Review Monday activities	Group activity 3	Group activity 4	Group activity 4 presentation and consensus
9:00 – 9:30			
Supply chain considerations			
9:30 – 10:00			
Review of Techniques			
10:00 – 10:30	10:00 – 10:30	10:00 – 10:30	10:00-10:30
Break	Break	Break	Break
10:30 – 12:00	10:30 – 12:00	10:30 – 12:00	10:30 – 12:00
Group activity 2	Group activity 3	Group activity 4	Group activity 4
12:00 – 1:00	12:00 – 1:00	12:00 – 1:00	12:00-1:00
Lunch	Lunch	Lunch	Lunch
1:00 – 2:00	1:00 – 2:00	1:00 – 3:00	1:00 – 3:00
Group activity 2 presentations and consensus	Group activity 3	Group Activity 4	Next Steps
3:00-3:15	3:00 – 3:15	3:00-3:15	3:00-3:15
Break	Break	Break	Break
3:15 – 4:00	3:15 – 5:00	3:15-5:00	3:15-5:00
Group activity 2 presentations and consensus	Group activity 3 presentation and consensus	Group activity 4	Wrap up and closing
4:00 – 5:00			
Operational considerations for equipment selection			

APPENDIX H: OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION

OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION			
Criteria	Critical	Important	Desirable
Equipment assessed, in-country, CDC ,WHO etc.. and report available	X		
Equipment uses existing regular power supply	X		
Operator manual available in appropriate language	X		
Technical manual available in appropriate language	X		
Training offered on installation	X		
Supplier installs and commissions equipment	X		
Equipment in current production	X		
Services engineers available	X		
Machine will run as single platform		X	
Equipment can run stat (ad hoc) samples		X	
Machine has stable calibration settings		X	
Machine can store test results		X	
Machine can store QC results		X	
Few operator initiated maintenance activities		X	
Technology has been used elsewhere		X	
Reagent with shortest shelf life in kit is > 6 months		X	
Equipment fits in existing space		X	
Existing generator can support equipment		X	
Complements existing equipment		X	
Does not require additional accessories		X	
Reagents and supplies of equipment can be stored in existing space		X	
Works well in existing temperature range		X	
Minimal sample preparation before running on the machine		X	
Machine is self calibrating		X	
Machine can be switched off when not in use		X	
Throughput within range		X	
Machine can interface with computer		X	
Local agent available for product support		X	
Equipment comes with 5-10 years spares guarantee from manufacturer		X	
Supplier has regional presence		X	
Equipment has essential spares kit e.g. operator replaceable tubes, valves, filters etc		X	
Existing cold chain distribution can accommodate equipment reagents		X	
Existing cold storage can accommodate reagents		X	
Open system		X	
Training on use of equipment less than 1 week			X
Reagents ready to use (no reagent preparation required)			X
Load and walk away system			X
Equipment can run sample batches			X
Machine can be upgraded			X
Equipment can self diagnose			X
Equipment used in the region			X
Similar equipment in existence and use in-country			X
Machine has in-built printer			X
Bulk reagents used on machine (20 liter containers)			X
Equipment has no unique consumables e.g. sample cups, cuvettes			X
Purchase price			
Cost of start up kit			
Cost of accessories			
Cost of consumables to run 1000 tests			
Cost of Quality Control materials specific to equipment required for 1000 Tests run			
Supplier lead time for supply of equipment			
Supplier lead time for supply of reagents and consumables			
Cost of Service Contract			
Volume of Reagent/s required to run 1 test 1000 times			

APPENDIX I: STANDARDIZED LIST OF TESTS BY LEVEL

CENTRAL HOSPITAL	DISTRICT HOSPITAL (incl. Community Hospital)	HEALTH CENTER
<i>Haematology</i>	<i>Haematology</i>	<i>Haematology</i>
FBC	FBC	Hemoglobin
Differential count	Differential count	WBC count
Sickle cell screening	Sickle cell screening	
Sickle cell confirmatory test	Sickle cell differential test	
Hemoglobin	Hemoglobin	
Prothrombin Time	Prothrombin Time	
APTT	APTT	
Fibrinogen test	ESR	
ESR	Reticulocyte count	
Reticulocyte count	CD4 %	
Lupus erythematous	CD4 %	
CD4 Count		
CD4 %		
<i>Blood Bank</i>	<i>Blood Bank</i>	<i>Blood Bank</i>
ABO grouping	ABO grouping	ABO grouping
Rh grouping	Rh grouping	Rh grouping
Cross match testing	Cross match testing	
Direct Coombs test	Direct Coombs test	
Indirect Coombs test	Indirect Coombs test	
Du Test	Du Test	
<i>Microbiology</i>	<i>Microbiology</i>	<i>Microbiology</i>
TB Microscopy - Z-N	TB Microscopy - Z-N	TB Microscopy - Z-N
TB Microscopy - Fluorescence	TB Microscopy - Fluorescence	Gram stain
Culture and sensitivity	Culture and sensitivity	Wet prep
Blood	Blood	
Pus swabs	Pus swabs	
Stool	Stool	
Urine	Urine	
Sputum	Sputum	
CSF	CSF	
Aspirates	Aspirates	
Cervical	Cervical	
Eye	Eye	
Nasal	Nasal	
Ear	Ear	
Throat	Throat	
Wet prep	Wet prep	
HVS	HVS	
Urine	Urine	
Cell Count	Cell Count	
CSF	CSF	
Aspirates	Aspirates	
India ink	India ink	

Gram Stain	Gram Stain	
KOH	KOH	
Wayson stain	Semen Analysis	
Occult Blood		
Mycology silver stain		
Mycology Lactophenol blue		
Mycology Grocotts'		
Parasitology	Parasitology	Parasitology
Malaria RDT	Malaria RDT	Malaria RDT
Malaria microscopy	Malaria microscopy	Malaria microscopy
Urine chemistry	Skin Snips for microfilaria	Trypanosoma
Urine microscopy	Urine microscopy	Filaria - blood film
Stool microscopy	Stool microscopy	Urine
Skin Snips for microfilaria	Trypanosoma/ Borelia testing	Stool
Filaria - blood film	Filaria - blood film	
	Urine chemistry	
<i>Serology</i>	<i>Serology</i>	<i>Serology</i>
Cryptococcal antigen test	Cryptococcal antigen test	HIV test Rapid
HIV test (ELISA)	HIV test Rapid	Syphilis (TPHA) test
HIV test Rapid	Syphilis (TPHA) test	Hepatitis B Rapid
Syphilis (TPHA) test	Hepatitis B Rapid	Hepatitis C Rapid
Hepatitis B Rapid	Hepatitis C Rapid	Pregnancy Test
Hepatitis C Rapid	Pregnancy Test	Pregnancy Test
Measles	Pregnancy Test	
Rubella		
ASOT		
Rheumatoid Factor		
Pregnancy Test		
Pregnancy Test		
<i>Biochemistry</i>	<i>Biochemistry</i>	<i>Biochemistry</i>
Acid phosphatase	Acid phosphatase	Urine Chemistry
Albumin	Albumin	Blood Glucose
Alkaline phosphatase	Alkaline phosphatase	
Amylase	Amylase	
Blood gases	Blood glucose	
Blood glucose	Calcium	
Calcium	Chloride	
Cholesterol	Cholesterol	
Creatine kinase	Creatine kinase	
Creatinine	Creatinine	
CSF protein	CSF protein	
CSF glucose	CSF glucose	
CSF globulin	CSF globulin	
Direct bilirubin	Direct bilirubin	
GGT	GGT	
Glycosylated Hb	Indirect bilirubin	
Immunoglobulin Electrophoresis	Lactic Acid	
Indirect bilirubin	LDH	
Iron	Phosphorus	
Lactic Acid	Potassium	
LDH	SGPT (ALT)	

Magnesium	SGOT (AST)	
Phosphorus	Sodium	
SGOT (AST)	Total bilirubin	
SGPT (ALT)	Total protein	
Total bilirubin	Triglycerides	
Total protein	Urea	
Triglycerides	Uric acid	
Urea		
Uric acid		
Thyroid Hormones T3		
Thyroid Hormones T4		
FSH		
TSH		
Tumor Markers		
Prostate Antigen		
Carcinogenic Embryonic Antigen		
Alpha fetoprotein		
Sodium		
Lithium		
Potassium		
Chloride		
<i>Histology / Cytology</i>	<i>Referred Tests</i>	<i>Referrals</i>
Hematoxylin-and-Eosin	Histological samples	HIV EID (DBS preparation)
Pap stain	EID HIV DNA-PCR	CD4 -collection of samples
Prussian stain	Hormones	
ZN	antibody screening & identification	
<i>Molecular biology</i>		
PCR - DNA		
PCR - RNA (viral load)		

APPENDIX J: STANDARDIZED TECHNIQUES BY LEVEL

Test Menus	Techniques		
	CENTRAL HOSPITAL	DISTRICT HOSPITAL	HEALTH CENTER
<i>Haematology</i>			
FBC	Haematology analyser	Automated	
WBC			HaemoCue
Differential count	Manual	Manual	
Sickle cell screening	Sodium metabisulphate	Sodium metabisulphite	
	Sodium dithionate	Solubility	
Sickle cell confirmatory test	Electrophoresis		
Hemoglobin	HaemoCue	HemoCue	HaemoCue
PT	Automated machine		
APTT	Automated machine	Tube method	
Fibrinogen test	Automated machine		
ESR	Westergreen	Westergreen	
Reticulocyte count	Brilliant cresol blue	Brilliant cresol blue	
	New Methylene blue	New Methylene blue	
	Automated machine		
Lupus erythromatous	Latex agglutination		
CD4 Count	Flowcytometry	Flowcytometry	
CD4 %	Flowcytometry	Flowcytometry	
<i>Blood Bank</i>			
ABO grouping	Tube method/Tile method	Tube method/Tile method	Tile method
Rh grouping	Tube method	Tube method	Tile method
Cross match testing	Tube method	Tube method	
Direct Coombs test	Tube method	Tube method	
Indirect Coombs test	Tube method	Tube method	
Du Test	Tube method	Tube method	
<i>Microbiology</i>			
TB Microscopy - Z-N	ZN Stain	ZN Stain	ZN Stain
TB Microscopy - Fluorescence	Auramine O Stain	Auramine O Stain	
<i>Culture and sensitivity</i>			
Blood	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	Co2	Co2	
Pus swabs	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	Co2	Co2	
Stool	Aerobic	Aerobic	
Urine	Aerobic	Aerobic	
Sputum	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
CSF	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Aspirates	Aerobic	Aerobic	

Test Menus	Techniques		
	CENTRAL HOSPITAL	DISTRICT HOSPITAL	HEALTH CENTER
	Anaerobic	Anaerobic	
	CO2	CO2	
Cervical	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Eye	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Nasal	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Ear	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Throat	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
<i>Wet prep</i>			
HVS	Direct microscopy	Direct microscopy	
Urine	Direct microscopy	Direct microscopy	
<i>Cell Count</i>			
CSF	Counting chamber	Counting chamber	
Aspirates	Counting chamber	Counting chamber	
India ink	Direct microscopy	Direct microscopy	
Gram Stain	Microscopy	Microscopy	Microscopy
KOH	Microscopy	Microscopy	
Wayson stain	Microscopy		
Occult Blood	Microscopy		
Mycology silver stain	Tablet		
Mycology Lactophenol blue	Microscopy		
Mycology Grocotts'	Microscopy		
<i>Parasitology</i>			
Malaria Rapid	Rapid - Chromatography	Rapid - Chromatography	Rapid - Chromatography
Malaria microscopy	Microscopy	Microscopy	Microscopy
Urine chemistry	Multistix	Multistix	
Urine	Microscopy - sedimentation	Wet prep Microscopy - sedimentation	Wet prep Microscopy - sedimentation
Stool	Microscopy - formal -ether concentration	Microscopy - formal -ether concentration	
	Microscopy - direct - normal saline	Microscopy - direct - normal saline	Microscopy - direct - normal saline
	Microscopy - direct - iodine	Microscopy - direct - iodine	Microscopy - direct - iodine
Skin Snips for microfilaria	Microscopy - direct - normal saline	Microscopy - direct - normal saline	
Filaria - blood film	Microscopy	Microscopy	Microscopy
Trypanosoma/ Borelia testing		Microscopy - Field stain A & B	Microscopy - Field stain A & B
<i>Serology</i>			
Cryptococcal antigen test	Latex agglutination	Latex agglutination	
HIV test	Semi/Fully automated - ELISA		
HIV test Rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography

Test Menus	Techniques		
	CENTRAL HOSPITAL	DISTRICT HOSPITAL	HEALTH CENTER
Syphilis (TPHA) test	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Hepatitis B Rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Hepatitis C Rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Pregnancy Test	Latex agglutination	Latex agglutination	Latex agglutination
Pregnancy Test	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Measles	ELISA		
Rubella	ELISA		
ASOT	Latex agglutination		
Rheumatoid Factor	Latex agglutination		
Biochemistry			
Acid phosphatase	Auto analyzer	Auto analyser	Multistix
Albumin			
Alkaline phosphatase			
Amylase			
Blood gases			
Blood glucose			Hemocue
Calcium			
cholesterol			
Creatine kinase			
Creatinine			
CSF protein			
CSF glucose			
CSF globulin			
Direct bilirubin			
GGT			
Glycosylated Hb			
Immunoglobulin Electrophoresis			
Indirect bilirubin			
Iron			
Lactic Acid			
LDH			
Magnesium			
Phosphorus			
SGOT (AST)			
SGPT (ALT)			
Total bilirubin			
Total protein			
Triglycerides			
Urea			
Uric acid			
Thyroid Hormones T3			
Thyroid Hormones T4			
FSH			
TSH			
<i>Tumor Markers</i>			
Prostate Antigen			
Carcinogenic Embryonic Antigen			
Alpha fetoprotein			

Test Menus	Techniques		
	CENTRAL HOSPITAL	DISTRICT HOSPITAL	HEALTH CENTER
Sodium			
Lithium			
Potassium			
Chloride			

APPENDIX K: EVALUATION OF EXISTING CD4 EQUIPMENT

OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION						
Criteria	CD4 Equipment					
	Cyflow SL3	EPICS	FACS Calibur	FACS Count	Cyflow Counter	
THROUGHPUT (tests/day)				50-70	100-150	
CRITICAL						
Equipment assessed, in-country, CDC ,WHO etc.. and report available	Y	Y	Y			
Equipment uses existing regular power supply	Y	Y	Y	Y	Y	
Operator manual available in appropriate language	Y	Y	Y	Y	Y	
Technical manual available in appropriate language	Y	Y	Y	Y	Y	
Training offered on installation	Y	Y	Y	Y	Y	
Supplier installs and commissions equipment	Y	Y	Y	Y	Y	
Equipment in current production	Y	Y	Y			
Services engineers available	Y	Y	Y	Y	Y	
IMPORTANT AND DESIRABLE						
<i>Technical</i>						
Machine will run as single platform	I	Y	Y	N	Y	
Equipment can run stat (ad hoc) samples	I	N	Y	Y	Y	
Machine has stable calibration settings	I	Y	Y	Y	N	
Machine can store test results	I	Y	Y	Y	Y	
Machine can store QC results	I	Y	Y	Y	Y	
Few operator initiated maintenance activities	I	N	Y	Y	N	
Minimal sample preparation before running on the machine	I	Y	Y	Y	Y	
Machine is self calibrating	I	N	N	N	N	
Throughput within range	I	Y	Y	Y	Y	
Machine can interface with computer	I	Y	Y	Y	Y	
Reagents ready to use (no reagent preparation required)	D	Y	Y	Y	Y	
Load and walk away system	D	N	Y	Y	N	
Equipment can run sample batches	D	Y	Y	Y	N	
Machine can be upgraded	D	Y	Y	Y	Y	
Equipment can self diagnose	D	Y	Y	Y	N	
Machine has in-built printer	D	N	Y	Y	N	
<i>Supply Chain</i>						
Reagent with shortest shelf life in kit is > 6 months	I	Y	Y	Y	Y	
Reagents and supplies of equipment can be stored in existing space	I	Y	Y	Y	Y	
Existing cold chain distribution can accommodate equipment reagents	I	Y	Y	Y	Y	
Existing cold storage can accommodate reagents	I	Y	Y	Y	Y	
Open system	I	N	N	N	N	
Does not require additional accessories	I	N	Y	N	Y	
Bulk reagents not used on machine (20 liter containers)	I	Y	Y	Y	Y	
Equipment has no unique consumables e.g. sample cups,cuvettes	I	N	Y	Y	Y	
Supplier lead time for supply of equipment (months)	I					
Supplier lead time for supply of reagents and consumables (months)	I					
<i>Service & Maintenance</i>						
Machine can be switched off when not in use	I	Y	Y	Y	Y	
Local agent available for product support	I	N	Y	Y	N	
Supplier has regional presence	I	Y	Y	Y	Y	
Equipment comes with 5-10 years spares guarantee from manufacturer	I				N	
Equipment has spares kit e.g. replaceable tubes, valves, filters etc	I	Y	N	N		
<i>Appropriate for country setting</i>						
Equipment fits in existing space	I	Y	Y	Y	Y	
Existing generator can support equipment	I	Y	Y	Y	Y	
Complements existing equipment	I	Y	Y	Y	Y	
Works well in existing temperature range	I	N	N	N	Y	
Training on use of equipment less than 1 week	I	N	Y	Y	Y	
<i>Experience with use of machine</i>						
Technology has been used elsewhere	I	Y	Y	Y	Y	
Equipment used in the region	I	Y	Y	Y	Y	
Same equipment in existence and use in-country	I	Y	Y	Y	Y	
ADDITIONAL CRITERIA						
<i>Price</i>						
Purchase price (US\$)			\$75,000	\$60,000		
Cost of start up kit						
Cost of accessories						
Cost of consumables to run 1000 tests						
Cost of Quality Control materials specific to equipment required for 1000 Tests run						
Cost of Service Contract						
<i>Program (system) needs</i>						
Sample Stability		48 Hours	5 Days			
Sample transport				48 hrs room temp	6 hrs cold chain	
Equipment meets any program plans to increase testing						

APPENDIX L: EVALUATION OF EXISTING HEMATOLOGY EQUIPMENT

OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION								
Criteria	Haematology Equipment							
	Mindray 3000	Mindray 5500	ABX Pentra 60	ACT 8	ACT 5	Sysmex KX21	Micros 60	Huma-count
THROUGHPUT tests/day)								
CRITICAL								
Equipment assessed, in-country, CDC, WHO etc... and report available	Y	Y	Y	Y	Y	Y	Y	Y
Equipment uses existing regular power supply	Y	Y	Y	Y	Y	Y	Y	Y
Operator manual available in appropriate language	Y	Y	Y	Y	Y	Y	Y	Y
Technical manual available in appropriate language	Y	Y	Y	Y	Y	Y	Y	Y
Training offered on installation	Y	Y	Y	Y	Y	Y	Y	Y
Supplier installs and commissions equipment	Y	Y	Y	Y	Y	Y	Y	Y
Equipment in current production	Y	Y	Y		N	Y	Y	Y
Services engineers available	Y	Y	N	Y	Y	N	Y	Y
IMPORTANT AND DESIRABLE								
<i>Technical</i>								
Machine will run as single platform	I	Y	Y	Y	Y	Y	Y	Y
Equipment can run stat (ad hoc) samples	I	Y	Y	Y	Y	Y	Y	Y
Machine has stable calibration settings	I	Y	Y	Y	Y	Y	Y	Y
Machine can store test results	I	Y	Y	N	N	N	Y	N
Machine can store QC results	I	Y	Y	N	N	N	Y	N
Few operator initiated maintenance activities	I	Y	Y	N	Y	Y	Y	Y
Minimal sample preparation before running on the machine	I	Y	Y	Y	Y	Y	Y	Y
Machine is self calibrating	I	N	Y	Y	N	N	N	N
Throughput within range	I	Y	Y	Y	Y	Y	Y	Y
Machine can interface with computer	I	Y	Y	Y	Y	Y	Y	Y
Reagents ready to use (no reagent preparation required)	D	Y	Y	Y	Y	Y	Y	Y
Load and walk away system	D	N	Y	N	N	N	Y	N
Equipment can run sample batches	D	N	Y	N	N	N	Y	N
Machine can be upgraded	D	Y	Y	Y	Y	Y	Y	Y
Equipment can self diagnose	D	Y	Y	N	N	N	Y	N
Machine has in-built printer	D	N	Y	N	N	N	Y	N
<i>Supply Chain</i>								
Reagent with shortest shelf life in kit is > 6 months	I	Y	Y	Y	Y	Y	Y	Y
Reagents and supplies of equipment can be stored in existing space	I	Y	Y	Y	Y	Y	Y	Y
Existing cold chain distribution can accommodate equipment reagents	I	Y	Y	Y	Y	Y	Y	Y
Existing cold storage can accommodate reagents	I	Y	Y	Y	Y	Y	Y	Y
Open system	I	N	N	N	N	N	N	N
Does not require additional accessories	I	N	N	Y	Y	Y	Y	Y
Bulk reagents not used on machine (20 liter containers)	I	Y	N	N	Y	Y	N	N
Equipment has no unique consumables e.g. sample cups, cuvettes	I	N	N	Y	N	N	N	Y
Supplier lead time for supply of equipment	I							
Supplier lead time for supply of reagents and consumables	I							
<i>Service & Maintenance</i>								
Machine can be switched off when not in use	I	Y	Y	Y	Y	Y	Y	Y
Local agent available for product support	I	Y	Y	N	Y	Y	N	Y
Supplier has regional presence	I	Y	Y	Y	Y	Y		
Equipment comes with 5-10 years spares guarantee from manufacturer	I	N	N	N	N	N	Y	N
Equipment has spares kit e.g. replaceable tubes, valves, filters etc	I	Y	Y	Y	Y	N	N	Y
<i>Appropriate for country setting</i>								
Equipment fits in existing space	I	Y	Y	Y	Y	Y	Y	Y
Existing generator can support equipment	I	Y	Y	Y	Y	Y	Y	Y
Complements existing equipment	I	Y	Y	Y	Y	Y	Y	Y
Works well in existing temperature range	I	Y	Y	Y	Y	Y	Y	Y
Training on use of equipment less than 1 week	I	Y	Y	Y	Y	Y	Y	Y
<i>Experience with use of machine</i>								
Technology has been used elsewhere	I	Y	Y	Y	Y	Y	Y	Y
Equipment used in the region	I	Y	Y	Y	Y	Y	Y	Y
Same equipment in existence and use in-country	I	Y	Y	Y	Y	Y	Y	Y
ADDITIONAL CRITERIA								
<i>Price</i>								
Purchase price								
Cost of start up kit								
Cost of accessories								
Cost of consumables to run 1000 tests								
Cost of Quality Control materials specific to equipment required for 1000 Tests run								
Cost of Service Contract								
<i>Program (system) needs</i>								
Sample Stability				48 hrs	6 hrs			
Sample transport				room temp	cold chain			
Equipment meets any program plans to increase testing								

APPENDIX M: EVALUATION OF EXISTING BIOCHEMISTRY EQUIPMENT

OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION										
Criteria	Biochemistry Equipment									
	Pentra ABX	Humastar	Spinlab	Keylab	CX5	Humalyzer	Nova 5	Pelong	Biolyte	
THROUGHPUT tests/day)										
CRITICAL										
Equipment assessed, in-country, CDC ,WHO etc... and report available		Y		Y	Y	Y	Y			
Equipment uses existing regular power supply	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Operator manual available in appropriate language	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Technical manual available in appropriate language	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
Training offered on installation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Supplier installs and commissions equipment	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Equipment in current production	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Services engineers available	Y	Y	Y	N	Y	Y	Y	N	Y	Y
IMPORTANT AND DESIRABLE										
<i>Technical</i>										
Machine will run as single platform	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Equipment can run stat (ad hoc) samples	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Machine has stable calibration settings	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Machine can store test results	I	Y	Y	Y	Y	Y	Y	Y	Y	N
Machine can store QC results	I	Y	Y	Y	Y	Y	Y	Y	Y	N
Few operator initiated maintenance activities	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Minimal sample preparation before running on the machine	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Machine is self calibrating	I	N	Y	Y	Y	N	N	Y	Y	Y
Throughput within range	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Machine can interface with computer	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Reagents ready to use (no reagent preparation required)	D	Y	Y	Y	Y	Y	Y	Y	Y	Y
Load and walk away system	D	Y	Y	Y	Y	N	N	N	N	N
Equipment can run sample batches	D	Y	Y	Y	Y	N	N	N	N	N
Machine can be upgraded	D	N	NS	NS	NS	Y	Y	N	Y	Y
Equipment can self diagnose	D	Y	Y	Y	Y	Y	Y	Y	Y	Y
Machine has in-built printer	D	Y	N	N	Y	N	Y	Y	Y	Y
<i>Supply Chain</i>										
Reagent with shortest shelf life in kit is > 6 months	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Reagents and supplies of equipment can be stored in existing space	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Existing cold chain distribution can accommodate equipment reagents	I	Y	Y	Y	Y	Y	Y	NA	NA	NA
Existing cold storage can accommodate reagents	I	Y	Y	Y	Y	Y	Y	NA	NA	NA
Open system	I	Y	N	N	Y	N	Y	N	N	N
Does not require additional accessories	I	N	Y	Y	Y	NS	Y	Y	N	Y
Bulk reagents not used on machine (20 liter containers)	D	Y	N	Y	Y	Y	Y	Y	Y	Y
Equipment has no unique consumables e.g. sample cups, cuvettes	D	N	N	Y	N	Y	Y	Y	Y	Y
Supplier lead time for supply of equipment (months)										
Supplier lead time for supply of reagents and consumables (months)										
<i>Service & Maintenance</i>										
Machine can be switched off when not in use	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Local agent available for product support	I	N	Y	Y	N	NS	Y	N	Y	Y
Supplier has regional presence		Y	Y	Y	Y	Y				
Equipment comes with 5-10 yrs spares guarantee from manufacturer	I	Y	NS	Y	Y	Y	Y	N	N	N
Equipment has spares kit e.g. replaceable tubes, valves, filters etc	I	Y	Y	Y	Y	Y	Y	Y	N	Y
<i>Appropriate for country setting</i>										
Equipment fits in existing space	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Existing generator can support equipment	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Complements existing equipment	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Works well in existing temperature range	I	Y	Y	N	Y	Y	Y	Y	Y	Y
Training on use of equipment less than 1 week	I	N	Y	Y	Y	Y	Y	Y	Y	Y
<i>Experience with use of machine</i>										
Technology has been used elsewhere	I	Y	Y	Y	Y	Y	Y	Y	N	N
Equipment used in the region	I	Y	Y	Y	Y	Y	Y	Y	Y	Y
Same equipment in existence and use in-country	I	N	Y	Y	Y	Y	Y	Y	N	N
ADDITIONAL CRITERIA										
<i>Price</i>										
Purchase price							\$8,000			
Cost of start up kit										
Cost of accessories										
Cost of consumables to run 1000 tests										
Cost of Quality Control materials specific to equipment required for 1000 Tests run										
Cost of Service Contract										
<i>Program (system) needs</i>										
Equipment meets any program plans to increase testing					48 hrs	6 hrs				
Sample transport					room temp	cold chain				

APPENDIX N: STANDARDIZED LIST OF EQUIPMENT (ANALYZERS)

	Central	District
<i>Chemistry</i>	Humastar 180 / Humalyte ISE	Humalyzer 3000
	Keylab	
<i>Haematology</i>	Sysmex XT 1800	Sysmex KX21
	Sysmex KX21	
<i>CD4</i>	EPICS	Partec Cyflow SL3
	Partec Cyflow SL3	Facs Count

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