ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH

ASSESSMENT OF QUALITY OF CLINICAL LABORATORY SERVICE AND CLIENTS' SATISFACTION AT PUBLIC GENERAL HOSPITALS IN ADDIS ABABA, ETHIOPIA

BY
YALEMZEWOUD AYALEW (B.Sc.)

A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF PUBLIC HEALTH.

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Abstract

Background: - Laboratory services are essential components in the diagnosis and treatment of patients infected with a variety of diseases. The laboratory infrastructure and quality remain in its nascent stages in most countries in Africa which demanded strengthening them. There are limited studies on quality of clinical laboratory services in Addis Ababa, Ethiopia.

Objectives: - To assess quality of clinical laboratory services and clients satisfaction in public general hospitals in Addis Ababa.

Methods:- A facility based quantitative study was conducted using two study instruments. The WHO-AFRO accreditation tool was used to measure the quality standard according to the WHO-AFRO score. Service quality descriptive measures were used to measure quality. On the other hand, customers' satisfaction was measured using 422 clients' exit interview in five public general hospital laboratories. Sampling proportionate to size technique was employed. Descriptive summary measures and odds ratio along with 95% CI in binary logistic regression was used to measure magnitude and association respectively.

Results:- The mean score of all five public general hospital laboratories in the observational study using WHO/AFRO accreditation checklist were 65.5%, and ranked as two stars. Whereas only 47.6% of the respondents perceived the clinical laboratory service as good quality or satisfied. Politeness and willingness of health providers,(66.1%). Professionals' neatness and physical appearance, (61.2%) were better attributes in clients' satisfaction. However, clients were highly dissatisfied by cleanliness of latrine, (47.6 %) and turnaround time, (30.5 %) of the results.

Conclusion: - The quality of laboratories in public hospitals of Addis Ababa were found to be much less than WHO/AFRO international accreditation quality standards. And satisfaction rate of clients was also low. The satisfaction was found to be much lower in turnaround time and cleanliness of latrines in laboratories.

Recommendations: - The Regional Government and Regional Office of laboratory coordinators should take measures to enhance quality of clinical laboratory services within the public general hospitals. In service trainings should also be availed to laboratory personnel. Continuous monitoring of laboratory services should be done to achieve full accreditation and maximum patient satisfaction. The Ethiopian Health Sector Development Program should have targets with regards to laboratory quality improvement. Detailed studies should also be done at national level.

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Acronyms:

WHO	World Health Organization
HIV	Human Immunodeficiency Virus
TB	Mycobacterium Tuberculosis
STIS	Sexually Transmitted Diseases
SLIPTA	Strengthen Laboratory Improvement Towards Accreditation
IQC	Internal Quality Controls
EQA	External Quality Assessment.
PT	Proficiency Testing
HTA	Health Technology Assessment
SLMTA	The Strengthening Laboratory Management Toward Accreditation
WHO-AFRO	World Health Organization Regional Office for Africa.
CDC	Centers for Disease Control and Prevention
CLSI	Clinical Laboratory and Standards Institute
TAT	Turn Around Time.
ENAO	Ethiopian National Accreditation Office
MDG	Millennium Developments Goals
AI	Avian Influenza

1. Introduction

1.1 Background

Laboratory services are essential components in the diagnosis and treatment of patients infected with the human immunodeficiency virus (HIV), malaria, mycobacterium tuberculosis (TB), sexually transmitted diseases (STI), and other infectious diseases(1). However, service quality or access to reliable laboratory testing remains limited in many resource-limited countries (2,3). This can result in delayed diagnosis, misdiagnosis, and ineffective and inappropriate treatment and can eventually lead to increased morbidity and mortality.

Consequently, there is an urgent need to strengthen laboratory systems to produce quality clinical laboratory to achieve accreditation at international standards and patient's satisfaction is an invaluable tool for countries to improve the quality of laboratory services.

In observational accreditations, laboratories' capacity to detect, identify, and promptly report all diseases of public health significance in clinical and research specimens will be explored. The accreditation process further provides a learning opportunity, a pathway for continuous improvement, a mechanism for identifying resource and training needs – which are all measures of progress (1).

Studies on clients' satisfaction reveal satisfaction trends; identify the various factors associated with satisfaction and pin point strategies to resolve problems (4, 5, 6). Such studies are also important and useful quality improvement tools for clinical laboratory, health care organizations, and business in general. Most clinical laboratories in the United States require assessing their clients' satisfaction in order to maintain their accreditations (7).

This study aims to assess the quality of public health laboratory service and patients' satisfaction.

1.2 Statement of the Problem:

Access to reliable diagnostic testing facilities is among the major challenges in Africa contributing to the delay or lack of appropriate and timely response to outbreaks and quality patient care. Despite the growing threat from emerging and re-emerging pathogens including HIV, TB and malaria as well as Avian Influenza (AI), the majority of an estimated 12 million annual deaths in Sub-Saharan Africa remain uninvestigated. Laboratory investigations continue to be undervalued as evidenced by lack of skilled manpower for quality-control and reproducible laboratory testing (8,9).

Other major barriers for laboratory capacity in Africa include: lack of funds, weak health infrastructure, lack of basic essential equipment and laboratory consumables, scarcity of educators and training programs, inadequate logistical support, insufficient monitoring of test quality, less commitment of laboratory testing and inadequate representation of laboratory personnel in health policy development and implementation of public health interventions(10).

Many factors have also been cited as contributing to limited laboratory access and poor service quality including lack of laboratory supplies, limited numbers of skilled personnel, lack of educators and training programs, inadequate logistical support, insufficient monitoring of test quality, decentralization of laboratory facilities and lack of government standards for laboratory testing (11). There were also a culture of mistrust and poor communication between laboratory personnel and clinical staffs which contributed to low morale within the technical profession.

Poor quality laboratory services have the greatest impact on the poorest people who use the service because they have the largest burden of ill-health (12). Therefore, the objective of this study is assessing the quality of clinical laboratory service in respect to WHO-AFRO quality standards and patient satisfaction.

1.3 Rationale of the study

Studies in Ethiopia (13,14 , and15) assessed the quality of clinical laboratory services but none had adequately addressed quality of clinical laboratory service in Addis Ababa, Ethiopia. Findings in this study can be used for patients and health providers of clinical laboratory in various kinds of hospitals, regulatory bodies and policy makers in various MOH organizations.

Using this research we are determining level and identifying factors that affect quality of clinical laboratory service at public health facility. The identified factors at the end of this research important for policy makers and regulatory bodies to make an appropriate action to be improved through target laws and policies. Quality laboratory services are important for implementing of different effective therapeutic interventions and research activities by the regulator. Regulators have to be consistently informed on the need to sustain quality of care for patients.

The characteristics of patients in different hospitals should be identified and different effective method to improve quality of services should be outlined. Patients need to be benefited from highest quality of clinical laboratory services. Moreover, they should be protected from misdiagnosis, wrong treatment and prolonged illness.

Health care providers should also be trusted by the service they deliver, they should also attempt to reduce patient defaulting that might be attributed to poor quality service. Our health facilities need to get international recognitions on best practices and stimulate for innovation

2. Literature Review

2.1 WHO/AFRO Observational Study

WHO stated that efficient and reliable laboratory services and networks were essential and fundamental components of effective, well functioning health systems; however, few developing countries had quality standards which were affordable and easy to implement and monitor (16). WHO went on to say it was clear that high quality laboratory testing was critical for patient care, prevention, disease surveillance & outbreak investigations (16). CDC & WHO issued a statement in 2008 regarding laboratory quality systems, calling for countries with limited resources to consider a staged approach towards laboratory accreditation. It was also suggested that national laboratory standards establish minimum requirements for all laboratories. National reference laboratories were encouraged to meet international standards (16). In 2009, CDC collaborated with WHO and other partners to launch a five step laboratory accreditation process in the presence of government health officials from 13 African countries. The process was named WHO/AFRO Laboratory Accreditation System (16).

Good laboratory practice is defined as " a quality system concerned with the organizational process and the condition under which non-clinical health and environmental safety are planned, performed, monitored, recorded, archived and reported" the purpose data for of good laboratory practice to promote developments of the quality of test data for accurate clinician decision making and provide a tool to ensure a sound approach to the managements of laboratory (17)

A well functioning national laboratory system is made up of components of leadership, organizational structure, policy and regulations, testing services, referrals and networks, infrastructure, human resources, reagents and equipment procurement and supply, information management, financing, quality and bio-risk management systems within each laboratory (11).

Laboratories spent decades improving analytical quality by establishing internal quality controls and external quality assessment. The analytical phase begins when the patient specimen is prepared in the laboratory for testing, and it ends when the test result is interpreted and verified.

Not processing a specimen properly prior to analysis or substances interfering with assay performance can affect test results in the analytical phase (18). Establishing and verifying test method performance specifications as to test accuracy, precision, sensitivity, specificity, and linearity are other areas where errors can occur in the analytical phase of laboratory testing. The role of external quality assessment and proficiency testing is to provide reliable information allowing laboratories to assess and monitor the quality status of internal procedures and processes (18).

Considerable resources have been invested in recent years to improve laboratory systems in resource-limited settings. A review of published reports, interview of major donor organizations and conducted case studies of laboratory systems in 3 countries to assess how countries and donors have worked together to improve laboratory services indicated while infrastructure and the provision of services have shown improvement, implementation of national laboratory plans were inconsistent, human resources were limited, and quality laboratory services rarely extend to lower tier laboratories (eg, health clinics, district hospitals). Coordination within, between, and among governments and donor organizations were reported to be problematic. Laboratory standardization and quality control were improving but remained challenging, making accreditation difficult (19).

The study in Tanzania in 35 representative laboratories from the public and private sector included test-specific equipment, ancillary equipment, reagents and consumables, physical facility attributes such as internal finishing, office and storage space, security, electrical and water supply systems, temperature control, general laboratory supplies, laboratory safety, data management, the human resources availability and capacity, quality management systems, training and laboratory management. The findings of this study revealed inadequate modern or automated equipment, inadequate human resources both in numbers and skill sets, an irregular reagent and supply chain and poor physical facilities, inadequate data capture and its management and almost no implementation of quality management systems (20).

The quality of clinical service measured through WHO /AFRO checklist in sub Saharan region remain poor. No detailed research was done in Addis Ababa, Ethiopia which claimed for the conduct of this research (9).

Exploration of key Elements of Quality for laboratory in observational study using WHO/AFRO checklist showed it has three broad categories which will be subsequently described in brief.

1. Resource management.

I. Facility and Safety section – has 43 points out of total 258 points. It includes size and layout of laboratory, separation of patient care and testing area, work station set up, testing environment appropriateness, authorized access or access control, proper storage area cold or room temperature, proper waste disposal, hygiene or disinfection procedure, bio-safety cabinet, post exposure prophylaxis's policy and procedure, accessibility of safety manual, safety inspection, standard safety equipment, personal protective equipment, preventive measure for personnel, safety occurrence log book, bio safety training and safety training personnel.

II. Organization and Personnel section - This has 20 points from total of 258 points. It includes work load, schedule and coverage, duty roster, organizational chart, external and internal reporting system. Quality management system oversight, personnel filing system, staff competence assessment and training laboratory staff and staff meeting.

III. Equipments section – This section has 30 points from the total 258 points. It includes operator manual, adherence to equipment protocol and calibration, equipments records, service maintenance, preventive maintenance, spare part availability, maintenance records, contingency plan, communication on effective way of quality management system and laboratory testing service.

IV. Purchasing and Inventory section - – This section also has another 30 points from the total of 258 points. It covers inventory and budgeting system, service suppliers' performance review; manufacture supplier list, budgetary projection, management review supply request, order

tracking, inspection and documentation, inventory control system, stock count, waste minimization, disposal of expired products and laboratory testing service.

2. **Process management**

I. Process control, External and Internal quality assessment section – This section has 33 points out of total of 258 points. It covers guidelines for patient identification, specimen collection, labeling and transportation, sample receiving procedure, proper storage, Specimen packing, transportation time frame, Specimen tracking, procedure manual, reagent log book, verification of reagent shipments, New lot numbers, internal quality control before result release, quality control result review, monitoring and corrective action. Environmental condition review, performance assessment system, test accuracy and completion.

II. Documents and Records section - It covers 25 points out of total 258 points. This section includes laboratory quality manual, documents and information control system, documents and records accessibility and updating, Laboratory policy [document and record control, conflict interest, communication, review of contracts, advisory service, purchasing and inventory control, internal audit, continual improvements, preventive action, corrective action, personal files and training, SOP, calibration equipment competency assessments, authorization and accommodation. etc] standard operation procedure, as well as data file and archived results accessibility.

III. Information managements section – It also covers 18 points out of 258 points. It includes test result reporting system, testing result records, testing personnel, analytic system, results cross checking system, archived data labeling and storage, information and data backup system, test result report and test result communication.

IV. Clients managements and customer service section – It has 8 points out of the total 258 points. It covers that advice and training by qualified staff, laboratory hand book for clients and communication policy on delay in service, evaluation tools and follows up.

3. Improvement managements

I. Managements reviews section – It covers 17 points out of points the total 258 including work plan and budget, quality management system improvement measure and communication system on laboratory operation.

II. Internal audit section –has 10 points out of the total 258. Internal audit and audit recommendation action plan and follow up.

III. Corrective action section – It covers 12 points out of the total 258 points including compressive occurrence report, trouble shouting, documentation cause analysis of corrective actions, discordant results tracking and corrective action.

IV. Occurrence/Incidence/ Improvement managements section – has 12 points from the total of 258 points including graphical tools, quality indicators improvement activities, performance improvements, checking effectiveness of quality improvements of laboratory performance.

2.2 Patients satisfaction

Avedis Donabedian defined quality of care as the kind of care, which is expected to maximize an inclusive measure of patient welfare, after taking into account the balance of expected gains and losses associated with the process of care in all its segments (21). According to the World Medical Assembly, physicians and health care institutions have an ethical and professional obligation to strive for continuous quality improvement of services and patient safety with the ultimate goal of improving both individual patient outcomes as well as entire population health (21). Health technology assessment is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner, with the aim of formulating safe and effective health policies that are patient focused and seek to achieve the highest value (21).

The healthcare systems of most developed nations face a common challenge: substantial gap existed between the best possible care and the care routinely delivered. Numerous studies done including the one by the Institute of Medicine (IOM) in the United States report provided compelling and persuasive evidence that care is not consistently safe, timely, effective, equitable,

efficient or patient-centered. A landmark study published in 2003 reported that Americans receive recommended care 54.9% of the time (22).

On the other hand, another study recently conducted by the Common Wealth Fund of adult patients in six countries - Australia, Canada, Germany, New Zealand, the United Kingdom and the United States underscored the pervasive challenges of providing high-quality care (23)

A patient satisfaction surveys provided feedback to hospital management and staff regarding the quality of services rendered. The survey becomes routine activity as part of Aminu Kano Teaching Hospital. Overall, 83% of the patients were satisfied with the services received from Aminu Kano Teaching Hospital, while the remaining 17% were dissatisfied. Specifically, 88%, 88%, 87% and 84% of the patients were satisfied with patient provider relationship, in-patient services, hospital facilities and access to care. However, 30% and 27% of the patients were dissatisfied with waiting time and cost of treatment respectively. Patients and their relatives complained about delayed appointments, missing folders, missing laboratory results and long appointments (24)

Similarly reducing medical errors has become an international concern. Population-based studies from a number of nations around the world have consistently demonstrated unacceptably high rates of medical injury and preventable deaths. Clinical teams must feel empowered to change the way in which they deliver their services, promoting effective clinical risk management. Process analysis, implementation of evidence-based practices, and a clear accountability system are effective tools not only for decreasing error rates, but also for improving effectiveness (25).

A cross sectional study in Eastern Ethiopia was conducted at a public general hospital on 429 patients and 54 clinical service providers showed that, most of the patients (87.6%) were satisfied with the laboratory services. The lowest and highest (2.48), (4.27) rate satisfaction were on cleanness of latrine to collect specimens and availability of laboratory staff on working hours respectively (26).

Key Elements of Quality in client satisfaction.

As mentioned earlier key elements of quality include satisfaction related to customer service when contacted billing office at the time paying and laboratory personnel's knowledge and explanation on the test procedures at the time of collecting specimen required for your medical test, the cleanliness of the room where blood is drawn, friendliness and communication of the phlebotomist, professionalism of the phlebotomist who is the person who drew your blood,

professional neatness and physical appeal of health provider, cost of each test service, politeness and willingness of health providers, turnaround time or waiting time of the results.

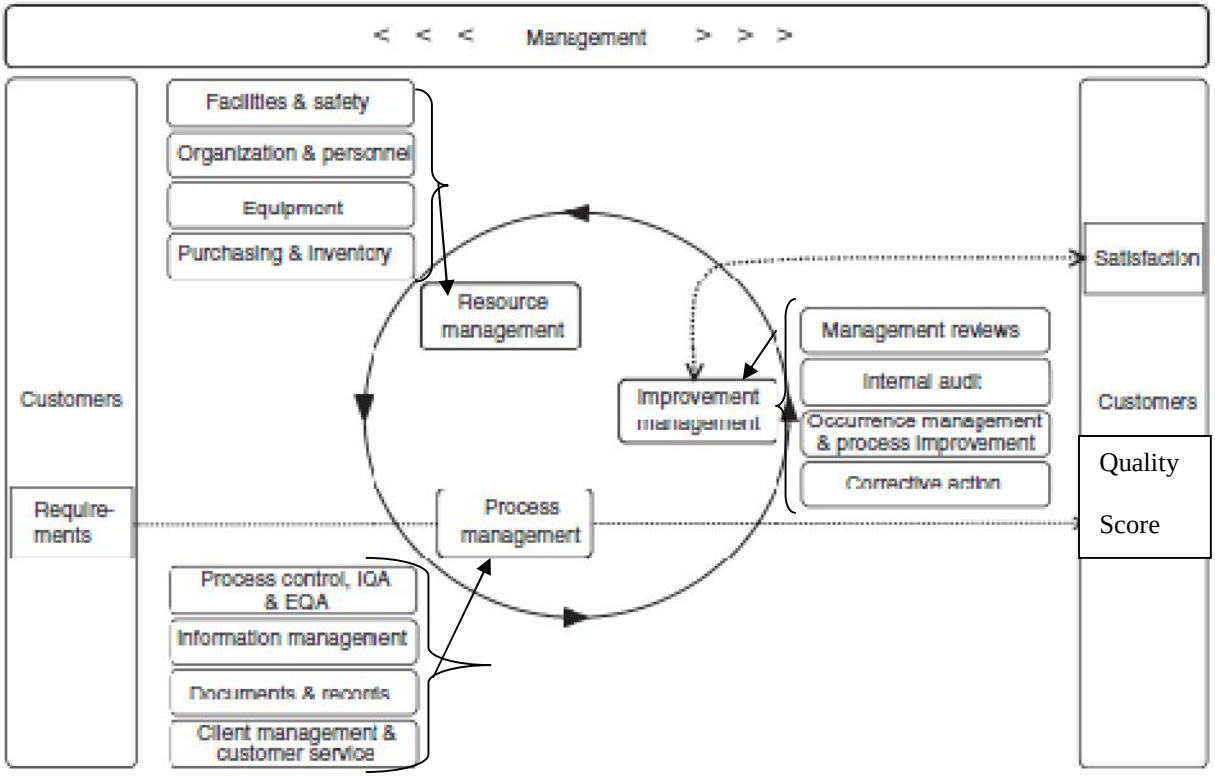

Figure 1: Analysis fame work used for analysis of point distribution quality score of clinical laboratory service.

The quality cycle can be divided into three stages starting with resource management, (Structure), followed by process managements and then improved management. To each stage four section of SLIPTA checklist were allocated. The list of four allocated SLIPTA checklist and the point it worth from the total 258 points were described above (27) The composite quality score from 12 quality measurements categorized into three categories that is resource managements which has 123 out of 258. Includes facility and safety, organization and personnel, equipments and purchasing and inventory section. Composite quality score in process management's categories cover 84 points out of total 258 points. It includes process control, IQA and EQA, information managements, documents and records, and customer service and clients managements. Improved managements was the last category in the composite quality score which cover 51 points from the total 258 points

3. OBJECTIVE

3.1 General Objective:

The general aim of this study was to assess quality of clinical laboratory service delivery and patients' satisfaction in public general hospitals in Addis Ababa, Ethiopia.

3.2 Specific objectives:

3.2.1 To determine the level of quality of clinical laboratory service according to WHO/AFRO laboratory quality standard guidelines.

3.2.2 Assess the level of satisfaction among laboratory service users.

3.2.3 To identify factors associated with client's satisfaction on quality of clinical laboratory services.

4. Methodology

4.1 Study design

A facility based cross sectional study design with quantitative approach was used to assess the quality of clinical laboratory service and client satisfaction in public hospital's laboratory of Addis Ababa City Administration.

4.2 Study area and period

This study was conducted in Addis Ababa, the Capital City of Ethiopia. Addis Ababa lies at an average altitude of 2,300 meters above sea level and covers 527 square kilometers with the population density of 5,165.1 persons per square kilometer. According to the Addis Ababa City Administration Health Bureau 2012 report, there were a total of 43 hospitals (government, private and NGOs) and 53 health centers (50 governmental and 3 NGOs). There were also more than 600 private health facilities (Higher clinics+ Medium clinics + other type). All of these 96 health facilities give clinical laboratory services in the city (28). The study was carried out in the five public general hospitals laboratory units only, namely Minilik II Memorial Hospital, Ras Desta Dametew Memorial hospital, Yekatite 12 Memorial Hospital, Empress Zewuditu Memorial Hospital, and Gandhi Memorial Hospital which are under the auspices of the Addis Ababa City Administration Health Bureau.

4.3 Source population:

All public hospital laboratories and their clients in Addis Ababa, Ethiopia were considered as source population for this study.

4.4 Study population

All laboratories and their clients in public hospitals under the auspices of the Addis Ababa City Administration were considered as study population. Study participants were medical laboratory quality officers or delegates as quality officer at the time of data collection in each hospital laboratory and clients of the laboratories of these hospitals.

4.5 Sample size determination

There were two major components of the study. The observation component of the study administered WHO/AFRO checklist to investigate the level of the laboratory qualities in the study hospitals. On the other hand, a client exit interview was conducted to assess client satisfaction. The sample size for the later component of the study was calculated using a single population proportion formula with an assumption of 95% confidence level, 5% margin of error and 50 % proportion since the prevalence of patient satisfaction regarding clinical laboratory service was not known. Finally, 10% non-response rate was also considered.

$$N = \frac{(Z_{\alpha/2})^2 p(1-p)}{d^2} = \frac{(1.96)^2 * 0.5 * 0.5}{(0.05)^2} = 384$$

Where:

n = total sample size

$Z_{\alpha/2}$ = (the value of 95% confidence level from the table) which is 1.96.

p = (Proportion of patients satisfaction regarding to clinical laboratory service) = 50%, because it is unknown prevalence in Addis Ababa. Finally, 10% non-response rate was also considered.

d = (Margin of error) = 5%, 1- p = (Proportion of failure). Then, 10% contingency (38 patients who seeks clinical laboratory service.) were added to the calculated sample size of 384 and resulted in 422 laboratory clients who were interviewed in the study.

4.6 Sampling procedures

The observation study using the WHO/AFRO checklist designed for such a purpose of laboratory quality assessment was administered in five public general hospitals in Addis Ababa City Administration. Meanwhile, systematic random sampling was employed to select clients for client exit interview. The number of laboratory clients in each of the hospitals was determined from the same previous year and month registries. The sample size was proportionally allocated according to the size of laboratory clients in each health facility. Observed sizes were divided by allocated size to determine the sampling interval. One of them was randomly selected from the first batch coming to facilities' laboratory and subsequent interviewees were determined by adding the sampling interval. The client exit interview was conducted during July 15 – 30, 2013

4.7 Schematic Presentation of Sampling Procedure

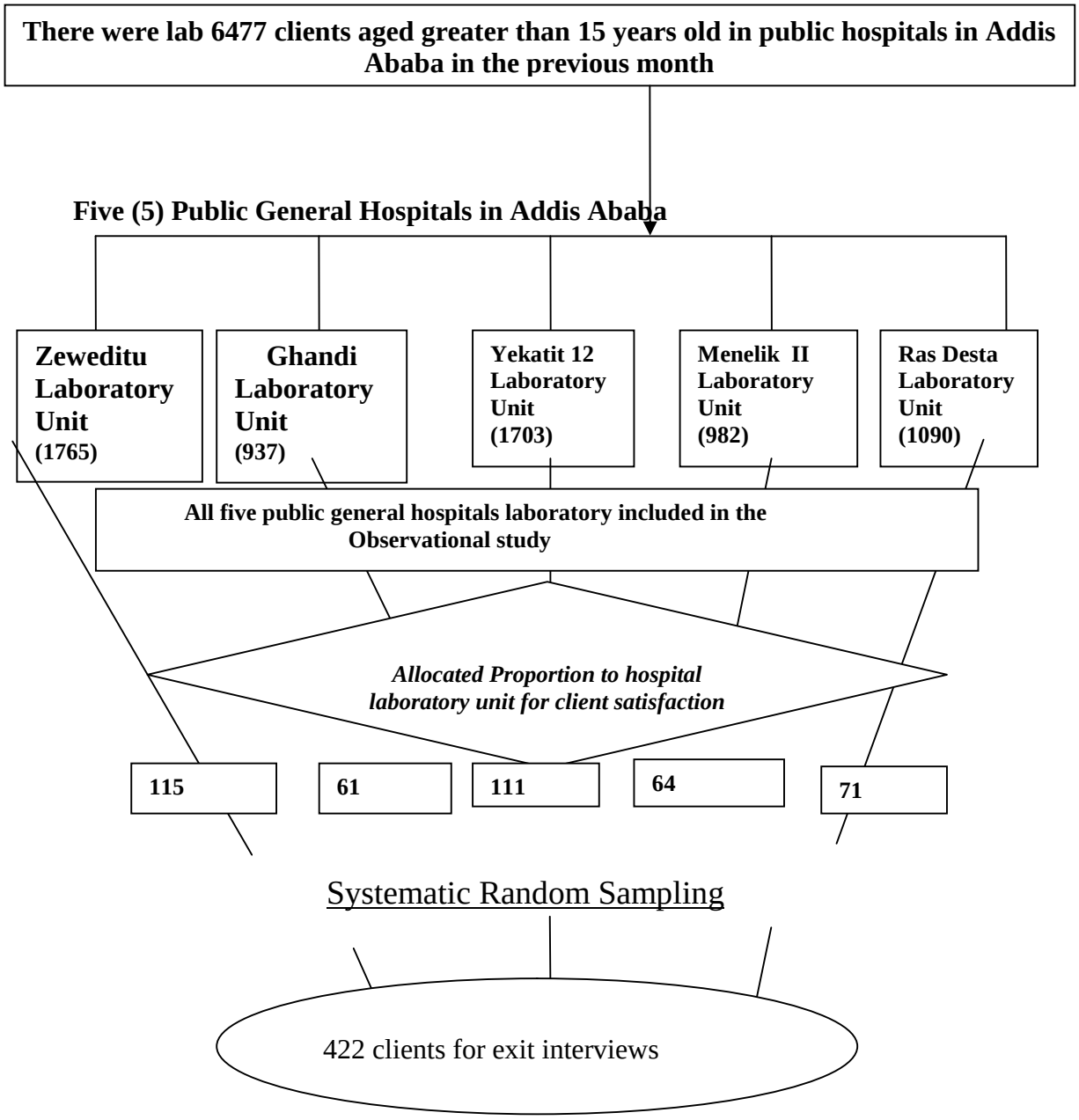

Figure 2: Schematic presentation of sampling procedure

4.8 Inclusion and Exclusion criteria

All public general hospital's laboratory units in Addis Ababa City Administration that have clinical laboratory services and their clients were included. Clients above the age of 15 years old that agreed to be interviewed participated in the study. This study did not include clients who were severely sick and had communication problems.

4.9 Study variables

4.9.1 Dependent variables

WHO-AFRO quality measurement checklist score - is measured by the composite indicator calculated using the checklist comprising 12 sections provided on the basis of 111 clauses and 258 total possible points. Each item has been assigned a weighted value of 2, 3, 4, or 5 points based on complexity and/or relative importance. Incomplete fulfillment of an item can be scored as "partial" and awarded a single point, with written explanation. All other subsequent values from 2 to 5 were also given depending on the relative weights they got to the answers of the 111 clauses. Some clauses in the checklist are "tick lists" and require the satisfactory presence of all sub items listed below the main heading to receive full credit. Finally, Assessed score compare with WHO standards level. On the other hand, the dependent variable for the clients exit interview tools was patient satisfaction.

4.9.2 Independent variables

The checklist for the observation study includes questions on Organization and personnel**,** Facilities and Safety**,** Purchasing and Inventory, Equipment**,** Process Management**,** Documents and Records. Information Management**,** Event Management**,** Monitoring and Assessment, Service and Satisfaction and, Continual Improvement.

Meanwhile, patient satisfaction exit interview include socio demographic characteristics including age, sex, educational status, marital status; religion, Occupation, ethnicity**,** waiting time (TAT), keeping privacy and confidentiality**,** cost of the service**,** politeness of service providers, professionals neatness and physical appearance of health provider, friendliness of

health provider, cleanliness of latrines, cleanness of blood drawing room, explanation and knowledge about the service, billing office service quality status.

4.10 Data collection

Pre-tested and standardized WHO/AFRO checklist in English version was used for the observational study. The questionnaire was adapted by the principal investigator of the study after reviewing relevant literatures for the client exit interview. The client exit interview questionnaire was first developed in English and translated in to Amharic language and then back to English to ensure the consistency of translation. Five diploma laboratory technicians with an experience in data collection were selected and employed for client exit interview and trained for a day. On the other hand, laboratory technologists working as quality officers in each of the study hospitals were employed for the observational study. In addition to this, each quality officer was supervisor of patient's satisfaction data collectors in each hospital.

4.11 Data Quality Assurance

The questionnaires were pre tested in a hospital where the actual study was not conducted. To increase the quality of the data, first training were given for data collectors for one day by the principal investigator on the objectives, relevance of the study and on methods of interviewing. The interview was conducted in a separate place (a place where the respondent feels free to express her/his feelings and ideas, that was used to maximize the data accuracy). To ensure completeness of information, first supervisors critically saw each completed form which was followed by the scrutiny of the principal investigator to check completeness of the information before receiving the filled questioners from each data collector on daily basis. The data from each general hospital were checked for completeness, accuracy, clarity, and consistency. Double entry was performed to assure quality of data. All completed questionnaires were safely stored to ensure privacy and confidentiality.

4.12 Data process and analysis

Data entry, coding and cleaning were done by principal investigator using Epi Info 3.5.1 soft ware program. It was then exported to SPSS version 16 software for data analysis. Data were checked and cleaned up by running frequencies, sorting and listing variable for consistency. Data collected using the WHO/AFRO checklist was used to perform descriptive analysis to measure laboratory quality standards. The WHO/AFRO step wise approach was used as a standard against which the findings of this study were compared. A composite score was calculated from this standard tool. It was then categorized according to pre-defined levels.

The investigator compared the percentage using the standard levels which were labeled between 1-5 stars. The scoring allows the checklist to assign the laboratory a zero to five star rating. The WHO-AFRO SLIPTA checklist star rating was as follows: 0–137: 0 stars, 138–160: 1 star, 161-185: 2 stars; 186–211: 3 stars, 212–236: 4 stars and 237–258: 5 stars. When the star rating represent diagrammatically it seems like figure-3.

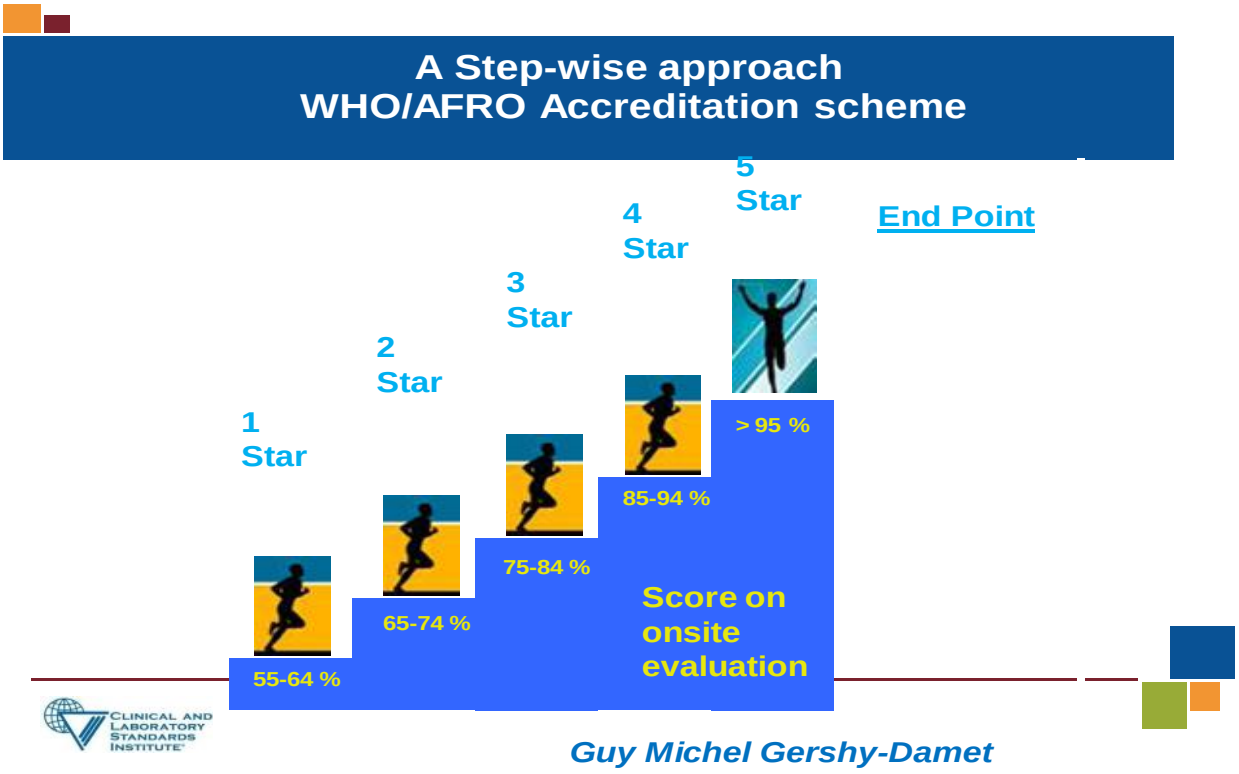

Figure.3: WHO/AFRO Accreditation Standard

Similarly, data analysis on patient satisfaction was analyzed using SPSS 16 software. A 5 point likert scale was changed into three point likert scale. The three point likert scales were coded as poor, medium and good to measure various issues related to satisfaction. A composite indicator on satisfaction was generated and binary coded to assess the association between it and the various covariates included in the study. The quality of laboratory service above the median, (2.00) were categorized as good quality of laboratory service and below the median (2.00) were categorized as poor quality service. The frequency distributions of each of the characteristics were run. While the percentage, mean and median of good, medium, poor rating was calculated. Cross tabulation and binary logistic regression of the various characteristics with satisfaction on quality of clinical laboratory service were done.

The overall associations between each of the covariates and patient satisfaction were checked using Chi-square test. P-value less than 0.05 were considered as statistically significant. Moreover, crude and adjusted odds ratio along with their 95% confidence intervals in binary logistic regression model was employed to assess the strength and significance of associations between the various socio-demographic characteristics and the satisfaction on clinical laboratory service quality.

4.13 Operational Definition of terms

Assessment: is a process to make a judgment about health service care system based on understanding of the situation through a survey.

Clinical laboratory: includes a facility where microbiological, serological, hematological, parasitological, clinical chemistry or other examinations are performed on specimens derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

Quality: is the degree to which actual performance or achievement of the health service system corresponds to set standards by WHO-AFRO.

Service quality: An assessment of how well a delivered clinical laboratory service based on the quality score using SLIPTA checklist and Level of patient's satisfactions. The level of service quality was measured quantitatively through patient satisfaction and checklist assessment score.

Standards: are performance specifications, if the service delivered would lead to the highest possible quality in the system.

Accreditation (ISO 15189) - Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Client /patient/ satisfaction: overall client's perception towards the clinical laboratory services delivered.

Conformity assessment: is demonstration of specific requirements related to a product, process system, person or body is fulfilled.

4.14. Ethical consideration

Written ethical clearance was obtained from the Research Ethics Committee (REC) of the School of Public Health, Addis Ababa University and formal letter was written to the Addis Ababa Health Bureau. It was then approved by the Research Ethics Committee of Addis Ababa Health Bureau and study hospitals, respectively. Consent was secured from the Addis Ababa City Administration Health Bureau and study hospitals prior to data collection. Hospital administrators wrote letter of support to their respective laboratory units. Verbal consent was also secured from each study participant after the purposes of the study were made clear. The information was kept confidential. Privacy of the respondents was kept by conducting the interview privately. The information collected from respondents in each laboratory unit was kept by removing identifiers and placing data in a safe place which were used for the purpose of the study only.

4.15 Dissemination of results

The thesis report shall be submitted for the graduate school of AAU as a partial fulfillment of the requirements for Master of Public Health. The findings of the study will be presented at the School of Public Health, College of Health Sciences. Besides, the findings will also be presented in national and international workshops and conferences on laboratory safety and quality. The report will also be shared with Addis Ababa Regional Health Bureau and study hospitals. Publication in a reputable scientific journal was considered.

5. Result

5.1 Laboratory Service Quality Standard Assessment.

There were total of 12 essential quality measurements sections. The total mean quality score in five public general hospitals laboratory in Addis Ababa, Ethiopia was 169, (65.5%). It is graded as II star when compared against WHO/AFRO standard. The eight quality measurement sections that scored above 55% were written in sequence from high to low quality score. And those quality sections that scored highest result were in process control, internal and external quality control section 28, (85%) followed by the quality score observed in facility and safety section 35, (82%). The quality score in clients managements and customer service, and organization and personnel sections were 6 (75%), 14, (70%) respectively. Among all quality measurements section documents and records and equipment 16.6 (67%) and 20(67%) scored each equally. Quality score in purchasing and inventory section and managements review were 19, (64%) and 9.8, (58%) respectively. The quality scores for all of the units mentioned above were above 58%.

On the other hand, the quality scores in four quality measurements section were scored below 55%, which was considered as low quality score against WHO/AFRO quality standard. Those quality sections were corrective action section 6, (50%), information management 8.2 (46%), occurrence/Incidence/ improved managements 4.8 (40%), auditing 1.6 (16%) and Lowest scored out of the total quality measurement section was scored in auditing section, (16%).

Overall quality score of the five public general hospitals were 169, (65.5%). Highest quality score 182, (72.8%) were recorded in Gandhi Memorial Hospitals and Zeweditu Memorial Hospital Laboratory equally. Both were graded as II star against WHO/AFRO SLIPTA checklist standard. Minilike II hospitals Laboratory were scored 180, (70%) and graded as II star. Whereas quality score in Ras Desta Dametew hospital laboratory were scored 147, (59%) and graded as I star. The least score 137 (52%) were scored in Yekatite 12 hospital laboratory and its score graded as Zero star. Average quality score in all five public general hospital laboratories were 65.5% and graded as II star against WHO/AFRO standards.

Table 1: The distribution of WHO/AFRO accreditation mean and percentage scores by 12 quality measurement items in the public general hospitals of Addis Ababa, Ethiopia, 2013

12 essential quality measurement	Total Point	Minlike.	Zewdtu	Yekatit.	Gandi	Ras Desta	Mean (%)
Section 12: Facility and safety, (21 item)	43	39	39	21	38	38	**35 (82%)**
Section 3: Organization & Personnel, (8 item)	20	16	16	10	14	14	**14 (70%)**
Section 5: Equipment, (15 item)	30	24	22	15	23	17	**20 (67%)**
Section 7: Purchasing & Inventory, (15 item)	30	21	26	13	24	12	**20, (67%)**
Section 1: Documents & Records, (10 item)	25	18	18	13	18	14	**16.2, (65%)**
Section4: Client Management& Customer Service (4 items).	8	7	6	5	7	5	**6, (75%)**
Section 8: Information Management,(10 item)	18	7	6	10	11	7	**8.2, (46%)**
Section 9: Process IQC &EQC (13 item)	33	27	29	22	30	32	**28, (85%)**
Section 2: Management Reviews,(5 item)	17	11	11	11	9	7	**9.8, (58%)**
Section 6:Internal Audit, (2 item)	10	2	2	2	2	0	**1.6 (16%)**
Section 11: Occurrence/Incident Management & Process Improvement, (3 item)	12	3	5	8	4	4	**4.8, (40%)**
Section 10: Corrective Action,(4 item)	12	5	7	5	8	5	**6, (50%)**
Total assessment score for each hospital laboratory.	**258**	**180, (70%)**	**182, (70.5 %)**	**137, (52 %)**	**182, (70.5%)**	**147, (56%)**	**169, (65.5%)**

Under resource management categories the observed total mean quality score and its percentage was 87 point out of 123, (71.5%). Among four allocated quality measurements section the highest quality scores (82%) were observed in facility and safety section. The second highest mean quality score and least variability was observed in organization and personnel section. In similar manner the mean quality score observed in equipment section and purchasing and inventory were 14, (67%) and s 20, (64%) respectively. The minimum quality score (64%) were observe in purchasing and inventory section. None were statically different among the four quality measurements section allocated as structure or resource management categories. Chart-1.

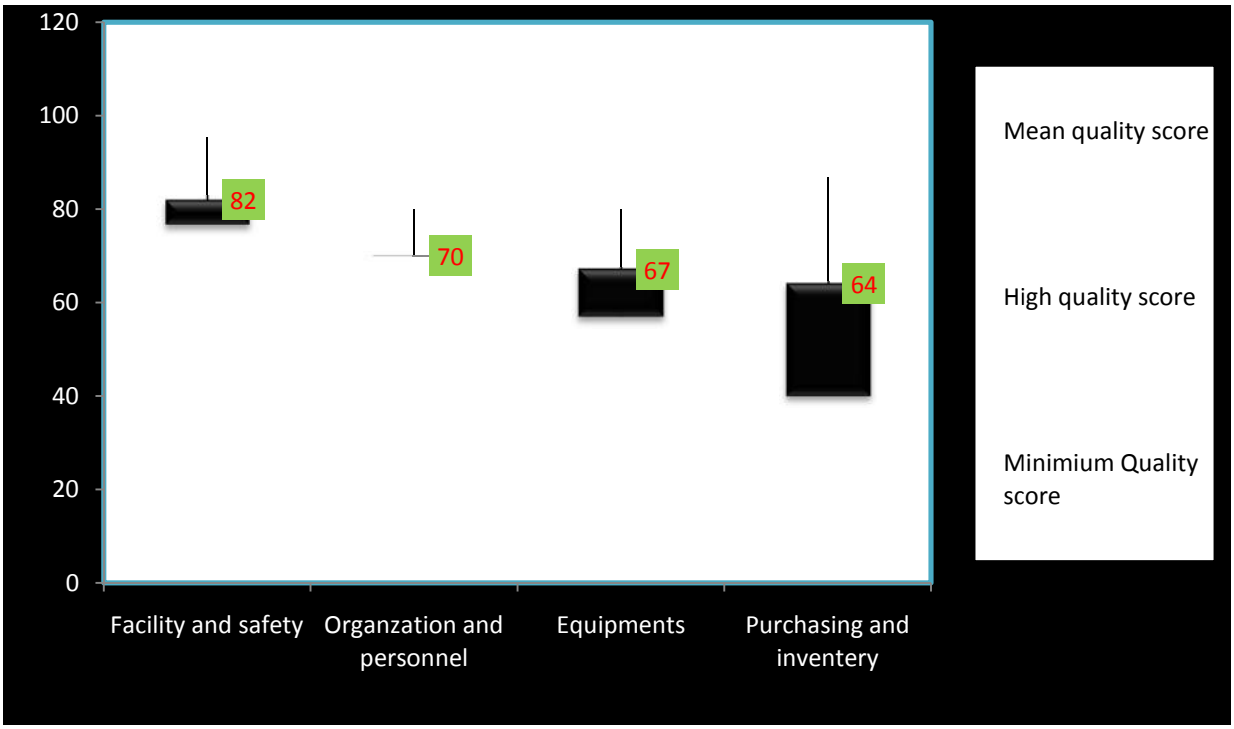

Chart 1: Resource management categories and its mean score, lower and upper limit in public general hospitals in 2013.

The process management section includes process IQC and EQC, clients' management and customer service, documents & records and information management. From the total quality measurements process managements had 37 items worth 84 points or covers (36.8%) of the total WHO/AFRO checklist. Mean assessment score of process management were scored 57.4 out of 84 points or (68.3%). The highest mean quality score and highest range or difference between four sections of process managements were, 85% and 29% respectively was seen in process,

internal and external quality control section. Followed by the second highest assessment score was recorded in client's management and customer service 6, (75%). And then 16.8, (67%) were observed in documents and records. Mean quality score recorded in process managements category was little lower than the quality scored recorded in resource managements category (chart-2).

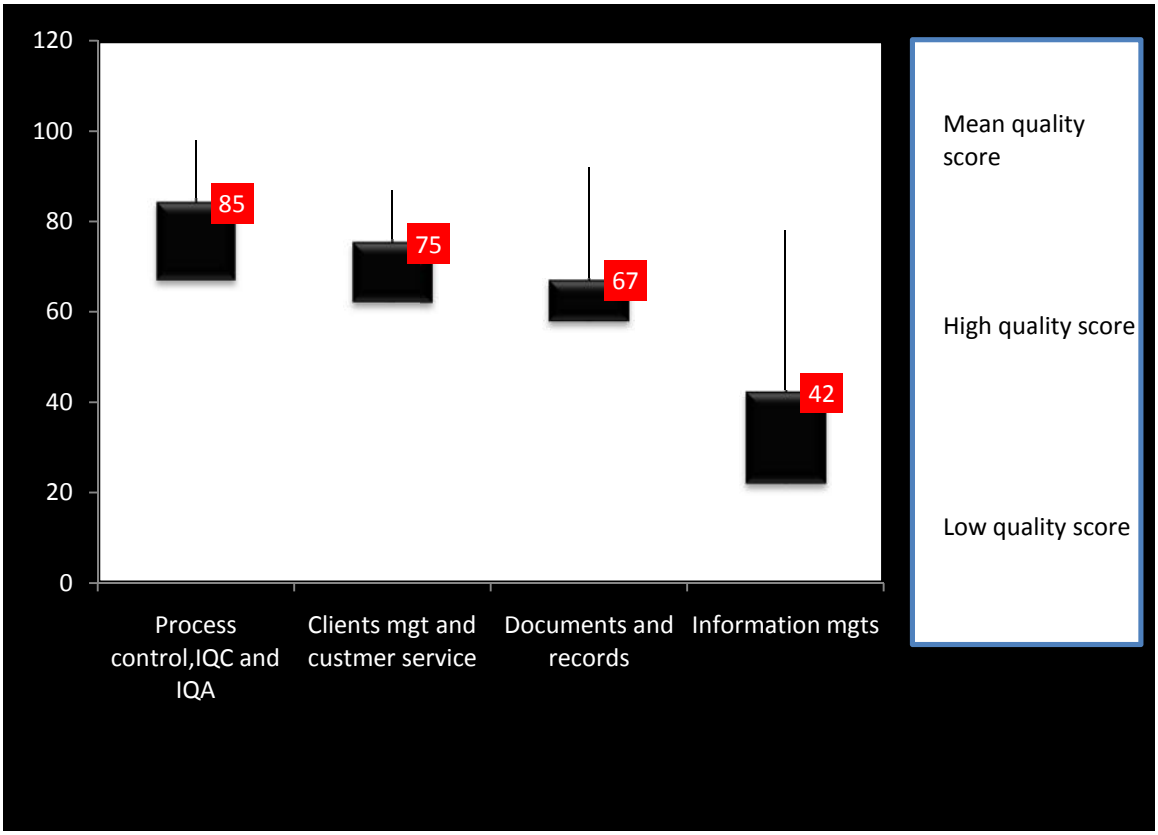

Chart 2: mean minimum and maximum scores of process management of laboratories of public general hospitals, 2013

The four essential components for qualities monitoring section in improved managements categories included management review, internal audit, occurrence/incident management and, corrective action. The mean assessment score of improved management were 22.2 (43.5%). The highest score 9.8, (58%) was observed in management review section and significantly different as compared to internal audit but not significantly different as compared to occurrence/incident management section and corrective action section.

Highest variability of quality score observed in corrective action section across different hospitals among four allocated quality measurements section. The mean score of corrective action were 6, (50%). Whereas lowest assessment scores 16% were observed in internal audit section. Least quality score were observed in improved management (43.5%) Chart-3.

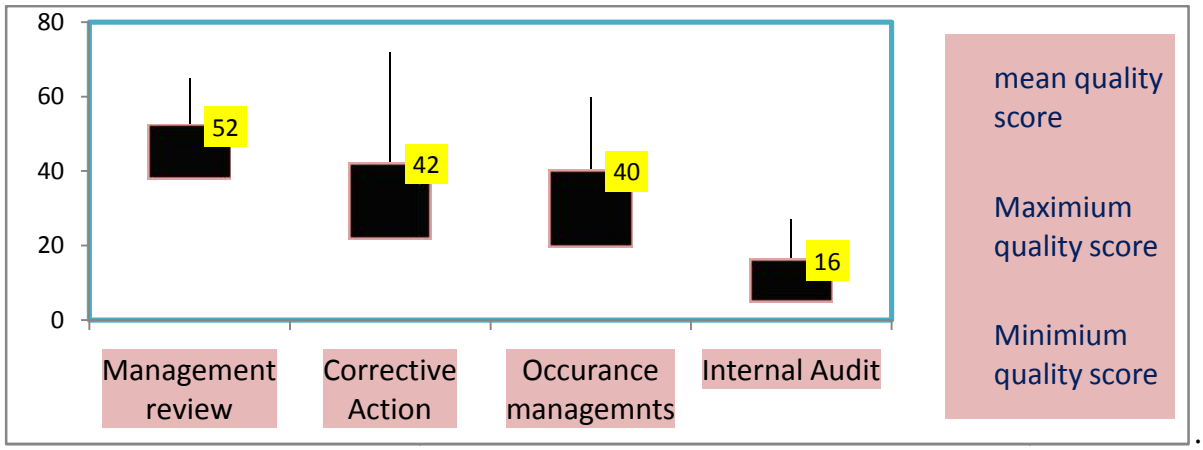

Chart 3: Mean quality score and its min and maximum values for the improvement management section in public general hospitals, Addis Ababa, Ethiopia 2013.

In summary, among the three Donabedian Model (resource management, process management, and improved management) the average quality score in resource management categories were 88, (71.5%) which was greater than process managements score 68.3% and improved managements 22.2, (43.5%). The least quality score was observed in improved management's categories from the three Donabedian Model. Overall mean quality score assessments in WHO/AFRO checklist in total of five public general hospitals were 169 (65.5%). Chart-4.

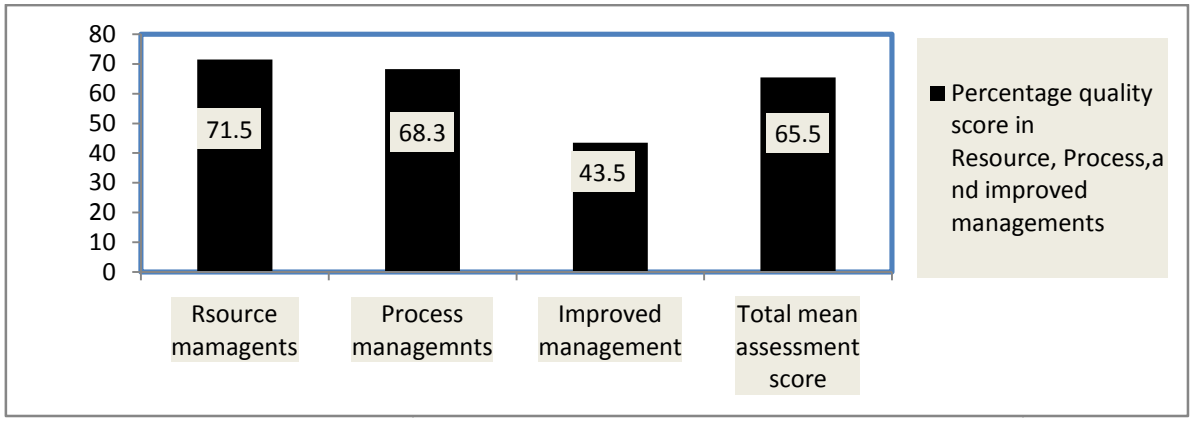

Chart: 4 Overall Quality Assessment score using WHO/AFRO checklist to determine the level of laboratories quality standards in public general hospital, Addis Ababa, Ethiopia, 2013

5.2 Assessment patient satisfaction on laboratory service qualities in Addis Ababa Hospitals

5.2.1 Socio-demographic characteristics of study participants.

The response rate was 100% (422). The mean and median ages of the patients recruited for the study were 33.75+12.79 and 31 years old respectively. Nearly half of the participants 210 (49.8%) were in the age group of 15 - 30 years, followed by 115 (27.3%) who were aged between 31-40 years of age, the rest of the participants were above 41 years old (Table-2). More than half of the respondents 223 (54.3%) were females. Regarding to marital status of the participants, 221 (52.4%) were married and 201 (47.6%) were not currently in union.

More than three fourth of the participants 366 (86.7%) were literates and the rest 56 (13.3) were not able to read and write at the time of the study. Patient attained secondary and above level of education comprised 261 (61.9%) while around one third of the participants 162 (38.4%) had attained primary level. Over one- third, 155 (38.4%) of study participants were from Amhara ethnic group followed by Oromo nationals 125 (29.6%), where as the rest of them, 135 (32%) were Guargie and Tigraways. The majority of study participants 216 (50.2%) were Orthodox Christians followed by Muslim 88 (20.9%) (Table-2).

In addition to this, when we see the composition of study participants by their occupational status about 199 (47.2%) of them were employees in private, governmental and non-governmental organization institutions and 47 (11.1%) were merchants and 82 (19.4%) were housewives while the remaining 40 (9.5%) were jobless. Most of the respondents 115, (27.3%) and 111, (26.3%) were clients of Zeweditu and Yektite 12 memorial hospital laboratory facilities respectively. While, 73 (16.3%) clients were recruited from Ras Desta Memorial hospital and 62 (14.7%) were from Minilike II memorial hospital laboratories (Table-2).

Table-2: The distribution of study participants from the laboratory units of five public general hospitals in Addis Ababa by their various socio-demographic characteristics, 2013.

Characteristics	Frequency	Percent (%)
Age		
< 30	210	49.8
31-40	115	27.3
41-50	50	11.8
>51	47	11.1
Sex		
Male	193	45.5
Female	223	54.5
Marital Status		
Married	221	52.4
Not currently in union	201	47.6
Educational Status		
Illiterate	56	13.3
Primary education	105	24.9
Secondary education	162	38.4
Tertiary education	99	23
Ethnic group		
Amphora	162	38.4
Oromo	125	29.6
Tigray	66	15.6
Guragie	69	16.4
Religion		
Orthodox	216	51.2
Catholic	55	13
Protestant	63	14.9
Muslim	88	20.9
Occupation		
House wife	82	19.4
employees	199	47.2
Merchant	47	11.1
Un employed	40	9.3
Student	54	12.8
Public general hospitals		
Ras Desta	73	17.3
Zeweditu	115	27.3
Gandhi	61	14.5
Yekatite 12	111	26.3
Minilike II	62	14.7

5.2.2 Magnitude of Patient satisfaction on Laboratory Quality Standards.

Regarding the politeness and willingness of health providers 93 (22%), 189 (44%) of the respondents were very satisfied and satisfied respectively on the other hand 22 (5.3%) and 6 (1.4%) of the clients were somewhat dissatisfied and very dissatisfied respectively. The rest, 115 (27%) were neutral or undecided. The mean and the median score were 2.59 and 3.0 respectively.

In relation to the cost of the service, out of the total participants who responded 112 (26.5%) and 156 (37%) reiterated that the laboratory service cost were very good (very cheap) and good (cheap) respectively. On the other hand, nearly one third of the participants 128 (20.3%) were neutral and the rest of around 28(6.6%) reported the cost was reported to be expensive raising dissatisfaction with the cost of service.

Quality related variable of waiting time or turnaround time for laboratory test result showed 71 (16.8%) and 86 (20.4%) of patients who were very satisfied and satisfied respectively. While, 136 (32.3%) were neutral or undecided and 129 (30.5%) were dissatisfied or perceived poor laboratory service quality. The mean and the median score of turnaround time was 2.07 and 2 respectively. Moreover, (51%) of patients perception on the service given by billing office were satisfied and very satisfied. While 49 (11.6%) were dissatisfied and the rest (37.4%) were neutral. On the other hand, 199 (47.2%) of the respondents were very satisfied and satisfied concerning the knowledge and explanation about the service procedure and (22.7%) were dissatisfied, the rests 127 (30.1%) were neutral.

From the total participants 249 (59%) believed that privacy and confidentiality were maintained. Almost one-third of the respondents 135 (32%) were responded as neutral or not sure and the remaining 38 (9%) responded that privacy and confidentiality were not maintained. Patients' response on professionals' neatness and appearance showed that out of total participants 109 (25.6%) and 150, (35.5%) perceived very good and good respectively, whereas 120 (28.4%) reported as neutral. The remaining 43 (10.2%) were dissatisfied with professional neatness and appearance.

On the other hand, in regards to friendliness and communication of health providers 102 (24.2%), 154 (36.5%) of participants were very satisfied and satisfied respectively where as 38 (9%) of the participants were dissatisfied. About 128 (30.3%) of the participants were neutral.

Patients perception on cleanliness of blood drawing area 215 (51.0%) of them were satisfied and 44 (10.4%) were dissatisfied while the remaining 163 (38.6%) were neutral. In response to latrine cleanliness 201 (47.6%) were dissatisfied while 74 (17.4%) were satisfied where as the other 147 (34.8%) of them were neutral. Similarly, regarding with the knowledge and explanation of health personnel about the service 199 (47.2%) were satisfied and 96 (22.7%) were dissatisfied while 127 (30.1%) were neutral. Overall this study showed that 221 (52.4%) of clients of public hospitals revealed that the current quality of clinical laboratory services were perceived as poor while the remaining 201 (47.6%) of the respondents felt that laboratory services were good quality.

Table 3: Laboratory service satisfaction level of clients in different quality variable in laboratory units of public general hospital in Addis Ababa, 2013 (n=422)

Factors	**Frequency**	**Percentage (%)**
Politeness of the provider		
Very polite	93	22
Polite	189	44.1
Fair, neutral	115	27.3
Not polite	28	6.6
Cost of service		
Very good	112	26.5
Good	156	37
Fair, neutral	128	20.3
Not good	26	6.2
Turnaround time		
Very fast	71	16.8
Fast	86	20.4
Fair, neutral	136	32.3
Long time	101	23.9
Very long time	28	6.6

Privacy and confidentiality.		
Yes, maintained	249	59
Neutral, I am not sure	135	32
No ,Its not maintained	38	9
Professional appearance and neatness		
Very good	109	25.8
Good	150	35.5
Fair, neutral	120	28.4
Not good	33	7.8
Worst	10	2.4
Friendliness of the provider:		
Very satisfied	102	24.2
Satisfied	154	36.5
Fair, neutral	128	30.3
Dissatisfied	38	9
Cleanliness of blood drowning area :		
Very satisfied	67	15.9
Satisfied	148	35.1
Fair, neutral	163	38.6
Dissatisfied.	44	10.4
Knowledge and explanation:		
Very satisfied	62	14.7
Satisfied	137	32.5
Fair, neutral	127	30.1
Dissatisfied	87	20.6
Very dissatisfied	9	2.1
Cleanliness of latrine :		
Very satisfied	17	4
Satisfied	57	13.5
Fair, neutral	147	34.8
Dissatisfied	160	37.9
Very dissatisfied	41	9.7

Service given by billing office :		
Very satisfied	67	15.9
Satisfied	148	35.1
Fair, neutral	158	37.4
Dissatisfied	33	7.8
Very dissatisfied	16	3.8
Clinical laboratory quality service:		
Poor	221	52.4%
Good	201	47.6%

Chart 5 below indicated that service quality satisfaction level of clients were different across different study hospitals, the maximum satisfaction of (73.8%) was observed in Gandhi Memorial Hospital while the minimum service quality satisfaction level of clients being recorded in yekatite hospital (31.5%). On the other hand clinical service quality was above 70% in all study hospitals except Ras Desta hospital and Yekatite 12 hospital which showed only 56% and 52% in observational WHO/AFRO tools. Clients satisfaction (Y) have positive relation with WHO/AFRO quality score (X), in linear logistic regression, Y = 0.92X – 42, it indicate that when quality score increased by one unit clients satisfaction will be increased by 0.92 times.

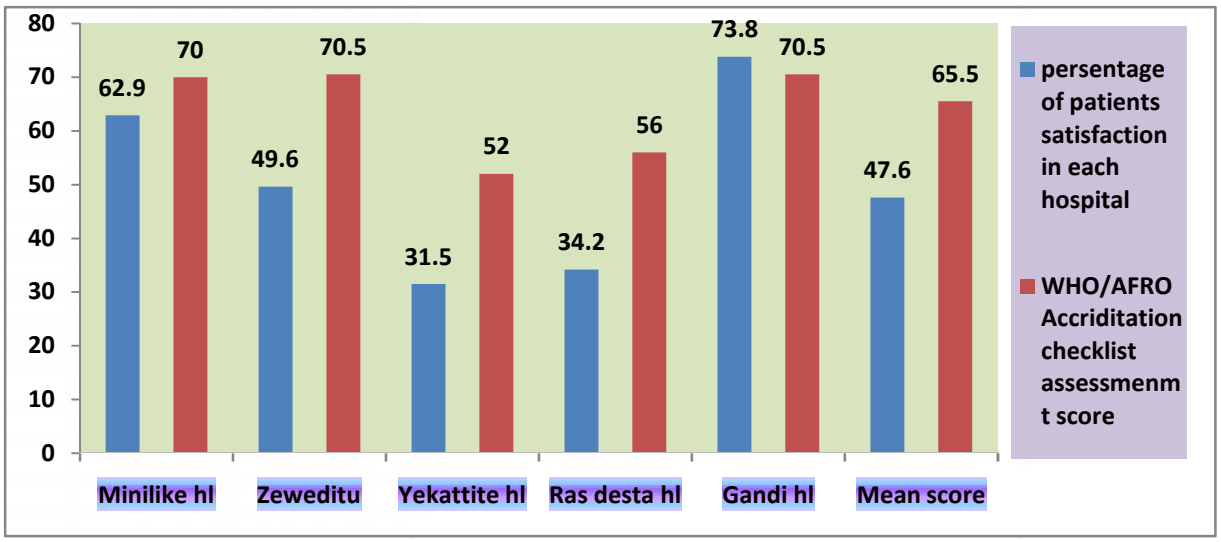

Chart 5: Patients' satisfaction level and overall mean quality score of clinical laboratory service in laboratories of public general hospitals, 2013.

The average quality score of each study hospital's laboratory according to the WHO/AFRO checklist were 70%, 70.5%, 70.5%, 56%, 52%, in Minilike II, Zeweditu, Gandhi, Ras Desta, and Yekatite 12 memorial hospitals laboratories respectively. The average quality score for all five public general hospitals were 65.5% which is in the category of Star I (one) according to WHO/AFRO quality standard. On the other hand, the percentage of satisfaction by service users were 31.5%, 34.2%, 49.6%, 62.9%, 74%, in Yekatite 12, Ras Desta, Zewditu , and Minlike II and Gandhi memorial hospitals laboratories, respectively.

5.2.3 Bivariate association between socio-demographic variables and patient satisfaction among laboratory service users

Table 3 showed the pattern of laboratory service satisfaction by selected socio demographic characteristics. There were no association between patients' age and overall satisfaction on the quality of clinical laboratory facilities in public hospitals of Addis Ababa (p=0.46). However, the overall satisfaction increased as the age of clients increased. The sex of clients was found to be marginally significantly associated with over all clinical laboratory service quality in this study (p=0.05). The satisfaction level were 121 (52.2%) and 82(42.2%) among female and male clinical laboratory clients respectively of public hospitals in Addis Ababa. There was no significant association between educational status of clients and lab service quality satisfaction (p=0.30) though it seems that the satisfaction decreased as the educational status of clients increased except for the little surge among those clients attained tertiary level of education. There was marginal statistical significance in the association between lab service quality satisfaction and marital. The level of satisfaction was 115 (52%) among clinical lab clients while it was only 86 (42.8%) among those who were not in marital union during the time of the study.

However there were no significant associations between religion, ethnicity and occupation with clinical laboratory service quality satisfactions in public hospitals of Addis Ababa. Clinical lab service satisfaction was a bit higher among Amhara nationals 84 (51.9%), 111(51.4%) among Orthodox Christians and 46 (56.1%) among house wives in general public hospitals of Addis Ababa. Meanwhile lab service satisfaction was significantly different across different study hospitals in Addis Ababa (p<0.01). Satisfaction was higher in Ghandi memorial hospital with a level of 45 (73.8%) and lower in Yekatite 12 memorial hospital with a level of 35 (31.5%).

Table 4: The bivariate association between socio-demographic factors and clinical laboratory service quality satisfaction among patients in public general hospitals in Addis Ababa, Ethiopia, 2013(n=422).

Characteristics	**Quality Status**			**P –value**
	Poor	**Good**	**Total**	
Age				
< 30	111 (52.9%)	99 (47.1%)	219	0.455
31-40	55 (47.8%)	60 (52.2%)	115	
41-50	26 (52%)	24 (48%)	50	
>51	29 (61.7%)	18 (38.3%)	47	
Total	221 (52.4%)	203 (47.6%)	422	
Sex				
Male	111 (57.5%)	82 (42.5%)	193	0.052
Female	114 (48%)	121 (52%)	229	
Total	221 (52.4%)	201 (47.6%)	422	
Educational Status				
Illiterate	28 (50%)	28 (50%)	56	0.299
Primary education	55 (52.4%)	50 (47.6%)	105	
Secondary education	93 (57.4%)	69 (42.6%)	162	
Tertiary education	45 (45.5%)	54 (54.5%)	99	
Total	221 (52.4%)	201 (47.6%)	422	
Marital Status				
Married	106 (48%)	115 (52%)	221	0.057
Not currently in union	115 (57.2%)	86 (42.8%)	201	
Total	221 (52.4%)	201 (47.6%)	422	
Ethnic group				
Amhara	78 (48.1%)	84 (51.9%)	162	0.115
Oromo	63 (50.4%)	62 (49.6%)	125	
Tegeraye	35 (53%)	31 (47%)	66	
Guragie	45 (65.2%)	24 (34.8%)	69	
Total	221 (52.4%)	201 (47.6%)	422	

Religion				
Orthodox	105 (48.6%)	111 (51.4%)	216	0.305
Catholic	32 (58.2%)	23 (41.8%)	55	
Protestant	32 (50.8%)	31 (49.2%)	63	
Muslim	52 (59.1%)	36 (40.9%)	88	
Total	221 (52.4%)	203 (47.6%)	422	
Occupation :				
House wife	36 (43.9%)	46 (56.1%)	82	0.108
Employees	99 (49.7%)	100 (50.3%)	199	
Merchant	30 (63.8%)	17 (36.2%)	47	
Unemployed	25 (62.5%)	15 (37.5%)	40	
Student	31 (57.4%)	23 (42.6%)	54	
Total	221 (52.4%)	203 (47.6%)	422	
Public general hospitals				
Ras Desta	48 (65.8%)	25 (34.2%)	73	0.00
Zeweditu	58 (50.4%)	57 (49.6%)	115	
Gandhi	16 (26.2%)	45 (73.8%)	61	
Yekatite 12	76 (68.5%)	35 (31.5%)	111	
Minilike II	23 (37.1%)	39 (62.9%)	62	
Total	228 (52.4%)	201 (47.6%)	422	

5.2.4 Factors associated with client's satisfaction on quality of clinical laboratory services.

In the above section the overall associations between socio-demographic variables including age, sex, marital status, educational status, ethnic group, religion and Occupation with clients' satisfaction on quality of clinical laboratory services were found to be statistically not significant. However the statistical insignificance between socio-demographic variables and clients satisfaction might be attributed to the confounding effect of one socio-demographic variable over another. This section is therefore devoted to assess the multivariate analysis of the association between different factors with clients' satisfaction.

None of the socio-demographic variables were found to be statistically significantly associated with lab service quality satisfaction after the effect of other variables were controlled in this

study. The purpose of the following descriptions is to reveal the strength of associations between the various demographic variables with laboratory service quality satisfaction. The odds of laboratory service quality satisfaction was AOR=1.05: 95% Cl (0.64, 1.7) times higher among clients aged 31-40 years compared with younger ones below the age of 30 years. On the other hand, the likelihood of laboratory service quality satisfaction were AOR=0.84: 95% CI (0.44, 1.75) and AOR=0.65:95% CI (0.31, 1.38) among clients aged 41-50 and those aged 51 years and more respectively compared to clients below the age of 30 years.

Female clients were AOR=1.23: 95% CI (0.79, 1.91) times more likely to be satisfied with clinical laboratory services in public hospitals compared to male patients. The likelihood of lab service quality satisfaction were AOR=0.78: 95% CI (0.38, 1.63), AOR=0.59: 95% CI (0.28, 1.21) and AOR=0.94: 95% CI (0.43, 2.10) among clients attained primary, secondary and tertiary level of education, respectively compared with those who did not have any formal education in public hospitals of Addis Ababa.

However, the odds of laboratory service satisfaction in public hospitals in Addis Ababa were 23% lower among clients who were not in marital union [AOR=0.77, 95% CI: 0.51, 1.17] compared to those clients who were married at the time of the study.

On the other hand, the likelihood of lab service quality satisfaction in public hospitals of Addis Ababa were AOR=0.93: 95% CI: (0.56, 1.54), AOR=0.86: 95% CI (0.47, 1.60) and AOR=0.56: 95% CI (0.30, 1.01) among clients from Oromo, Tigray and Guragie ethnic groups compared to those belong to Amhara ethnic groups. Meanwhile, the likelihood of service quality satisfaction were AOR=0.75: 95% CI (0.4, 1.43), AOR=0.98: 95% CI (0.53, 1.82) and AOR=0.94: 95% CI (0.50, 1.62) among Catholic, Protestant and Muslim clients compared to those confessing in Ethiopian Orthodox Church.

Moreover, the likelihood of lab service satisfaction among employees, merchants, unemployed and students were AOR=0.89: 95% CI (0.47, 1.68), AOR=0.58: 95% CI (0.24, 1.31), AOR=0.62: 95% CI (0.26, 1.49) and AOR=0.82: 95% CI (0.36, 1.87) respectively compared with house wives clients of public hospitals in Addis Ababa.

Table-5: Multivariate association between socio-demographic variables and overall satisfaction of clinical laboratory service clients in public general hospital in Addis Ababa, 2013 (n=422).

Factors	Quality-Status		Crude OR (95% CI)	Adjusted OR (95% CI)
	Poor	Good		
Age				
< 30	111	99	1.00	1.00
31-40	55	60	1.22 (0.78, 1.93)	1.05(0.64, 1.7)
41-50	26	24	1.04 (0.56, 1.92)	0.84 (0.44,1.75)
51^{+}	29	18	0.70 (0.36, 1.33)	0.65(0.31, 1.38)
Sex				
Male	111	82	1.00	1.00
Female	110	119	1.46 (0.99, 2.15)	1.23 (0.79, 1.91)
Educational Status				
Illiterate	28	28	1.00	1.00
Primary	55	50	0.91 (0.48, 1.74)	0.78 (0.38, 1.63)
Secondary	93	69	0.74 (0.40, 1.37)	0.59 (0.28, 1.21)
Tertiary	45	54	1.20 (0.62, 2.31)	0.94 (0.43, 2.10)
Marital Status				
Married	106	115	1.00	1.00
Not in union	115	86	0.69 (0.47, 1.01)	0.77 (0.5, 1.17)

Ethnicity				
Amhara	78	84	1.00	1.00
Oromo	63	62	0.91 (0.57,1.46)	0.93 (0.56, 1.54)
Tegraye	35	31	0.82 (0.46, 1.46)	0.86 (0.47, 1.60)
Guragie	45	24	0.50 (0.28, 0.89)	0.56 (0.30, 1.01)
Religion				
Orthodox	105	111	1.00	1.00
Catholic	32	23	0.68(0.37, 1.24)	0.75 (0.4, 1.43)
Protestant	32	31	0.92 (0.52, 1.61)	0.98 (0.53,1.82)
Muslim	52	36	0.66 (0.40,1.08)	0.94 (0.50, 1.62)
Occupation				
House wife	36	46	1.00	1.00
Employees	99	100	0.79 (0.47, 1.3)	0.89 (0.47, 1.68)
Merchant	30	17	0.44 (0.21, 0.93)	0.58 (0.24, 1.31)
Unemployed	25	15	0.47 (0.22, 1.02)	0.62 (0.26, 1.49)
Student	31	23	0.58 (0.29, 1.16)	0.82 (0.36, 1.87)

6. Discussion

The study aimed at measuring the quality of clinical laboratory services according the WHO/AFRO standard and assesses the laboratory service satisfaction among clients of public hospitals under the auspices of Addis Ababa City Administration Health Bureau. This study is the first of its kind in Ethiopia in general and Addis Ababa in particular just because of combined tools were used to assess clinical laboratory service quality.

Mean quality score and its percentage were 169 (65.5%) which was graded as 2-star according to the WHO/AFRO standard (1). The quality score documented in this study was low to start the accreditation process which requires a 5-star grade. This result may be because of the inadequate representation of laboratory units in the administrative structure of ministry of health which incapacitated the medical laboratory service strengthen and obtain accreditation (29). However, it is evident that a quality laboratory service enhances quality of medical care through improving diagnosis of all diseases of public health importance such as TB, HIV/AIDS, malaria for the successful attainment of the MOH prevention and control programs. Quality laboratory service has also significant contribution to measure the achievements millennium development goals (MDGs).

The total quality score in the resource management categories was greater than the total quality score in process managements and the in improved managements. Mean total quality score in the improved managements categories were much less than WHO/AFRO international quality standard to be qualified for accreditation application. The reason may be quality section allocated in improved managements were professional working in the laboratories of hospitals did not have adequate knowledge about accreditation concepts and have no culture of making internal audit, occurrence managements, corrective action and information management (30). Furthermore, the above quality sections not included in the curriculum of medical laboratory professionals.

The findings of this study were better than the baseline quality score assessment which found a grade of zero star for each of hospital laboratory units done by regional laboratory office (30).The increase in lab quality standard in public hospitals of Addis Ababa might be attributed

to the stepwise laboratory improvement program towards accreditation through the nine months improvements project under Addis Ababa Regional Laboratory Office. Moreover, repeated evaluation might have raised awareness about way of achieving accreditation and importance of producing quality service for the community.

However, out of twelve quality measurement items four of them including internal Audit (16%), occurrence management (40%), corrective action (46%) and information management (42%) were found to be below the lowest WHO/AFRO standard score (1). This could be related to various factors. Ethiopia recently accepted WHO/AFRO stepwise laboratory improvement program for implementation which started from the scratch though the above quality measurements sections were not yet included in the curriculum. Furthermore, there has not been strong commitment of practice on quality improvements section like audit, occurrence management in developing countries. Similarly, Ethiopian National Accreditation Office (ENAO) launched only two years ago (February, 2010) to enhance accreditation which is the main instrument to build high quality service at facility level and national level at large (31).

Six of the quality measurement sections were scored between 58% and 75%. The quality score recorded in client's management and customer service section were 75%. Equipments section and Purchasing and Inventory section scored 67% each. The organization and personnel section scored 70%. Documents and records sections scored 64% and managements reviews section were cored 64% and 58% respectively. However, all of the above section scored below the expected threshold of 95% for a five star grade according to WHO/AFRO standard (1). The main reasons are still inadequate coverage in the laboratory schools curricula and absence of in service training in respective laboratories of public hospitals.

The highest mean quality score of 85% was observed in process control, internal and external quality controls section which is under the category of resource managements. The second highest score in facility and safety section was also 82% which is under the category of process managements. It was the highest score among all others section because the two section more important for infection prevention, reliable results and had been practiced for long time as

compared to the others quality measurement sections. On the other hand, they are all below the 95% threshold which could be attributed to the capacity of personnel and units in the hospital.
The overall public general hospital laboratory quality score were found to be much less than WHO/AFRO international quality standards. There is only one disease specific (Polio lab in EHNRI) and only one integrated service provider (AHARI) accreditation laboratory in Ethiopia (31).

On the other hand, the overall clinical laboratory service satisfaction in this study was 47.6% which was low compared to a study in Eastern Ethiopia (87.6%) (32), and also lower than the study conducted among student run medical clinics in Eastern Nigeria in which satisfaction level was (88.2%)(33). This might be due to less empowerment of laboratory personnel to make timely corrective action, lack of skill and positive attitude to bring about change in laboratory service.

The finding of highest satisfaction of lab clients' on lab professionals' politeness and hospitality and the cost of the service was in line with a study in Eastern Ethiopia (26). Because costs of laboratory service in governmental hospital was cheaper than privately owned hospitals laboratories. In a similar manner, more than half of the respondents were satisfied on professionals' neatness and physical appearance, communication and friendliness of health provider, maintaining privacy and confidentiality, almost similar or little less satisfaction observed the above study finding (26). The reason for finding might be due to the fact that professional having been undergoing similar trainings.

Less than half (47% and 41%) of the respondents were satisfied on the knowledge and explanation about the procedure and service given by billing office. About 37.2% of them were satisfied by the turnaround time which was in line with the study done in Northern Nigeria in which (30%) of the patients were dissatisfied by the waiting time (33). This might be attributed to the workload of lab technology professionals. Clients were very much dissatisfied by the cleanliness of latrine which might be related to behavioral and logistical issues in health facilities under study. The regulatory body does not visit lavatories quite frequently. However, the Policy guide in this line demanded that laboratory working environment shall be kept organized and

clean, with safe procedure for handling of specimen and waste materials to ensure patient and staff protection from unnecessary risks at all times (34).

A study showed that 70% of all medical decision had been influenced by medical laboratory service (35). Poor laboratory practice could increase inaccurate results that lead to wrong diagnoses, inappropriate treatment and prolonged illness or death. It is evident that the quality of laboratory services is a major factor which directly affects the quality of health care. Therefore it requires urgent attention to enhance quality of laboratory service and exploring the relation between health laboratory quality score over level of patient's satisfaction. Accreditation should be promoted and it should create satisfaction. Accreditation or maximum quality standard without creating client satisfaction or satisfaction without accreditated (reliable) service is not considered as full quality service. That why the study used mix of observational and clients satisfaction to measure service quality.

The multivariate analysis of this study in client exit interview revealed that all of the socio-demographic characteristics, such as age of the respondent, religious, ethnic group, occupation and educational status of the clients did not have any independent statistically significant association with clinical laboratory service satisfaction. The study in Eastern Ethiopia (26) documented a similar finding.

7. Strengths and limitations of the study

The study could be considered as a baseline for subsequent works in the area as it is the first in our country in respect to observational tools but not client's satisfaction. Use of the WHO/AFRO observation checklist to measure laboratory service quality standards and patient exit interview to assess their satisfaction and non-response rate were 100% could also be considered as strength of this study

On the other hand, not including provider satisfaction and laboratory services provider unit in primary health care government owned laboratories, specialized diagnostic centers and privately owned lab services might be cited as a limitation of the study.

8. Conclusions

The total mean laboratory service quality score of public general hospital was 65.5% and graded as 2-Star according to WHO/AFRO standard. The highest score were observed in process control, internal and external quality assurance section followed by facility and safety section and client's managements and customer service sections. However, lower scores were observed in occurrence management, corrective action, management review, information managements section. The least scores were scored in internal audit. All 12 essential quality measurements were found to be below 95% which was the lowest minimum WHO/AFRO standard to get 5-star.

Moreover, overall client's satisfaction among laboratory clients in public hospitals was only 47.6%. Better clients' satisfaction was observed with regard to politeness and providers hospitality and cost of lab services. However, the least clients' satisfaction was observed in cleanliness of latrine, turnaround time and billing office service.

9. Recommendations

The Regional Health Bureau should strive to increase the quality of laboratory services in public hospitals in Addis Ababa. Priorities should be given to sections of the lab service which were found to be weak in this study which include, internal audit, occurrence management, corrective action, management review section and information managements sections. Improving the costume of practicing and included in the curriculum in professional developments process.

The level of patient satisfaction should also be given top priority by enhancing cleanliness of latrine and reducing turnaround time. Lab technologists should also be given training on how to entertain their clients to enhance adherence in treatment of patients. Further detailed studies at national and regional levels including the private sector and primary health delivery care units are also recommended.

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11.1 Annex I: Declaration

I, the undersigned, declared that this is my original work, has not been presented for a degree in this or any other university, and all the resource of material used for this has been fully acknowledged.

Name……..

Place…….

Date of submission……

This thesis has been submitted for examination with my approval as a University advisor.

Name……..

Signature……

11.2 Annex II: English version of participant's information sheet, consent form and questionnaire:

1.1. Title: - A cross sectional study to assess the quality of clinical laboratory services in all five public general hospitals in Addis Ababa, Ethiopia from June, 2013.

1.2. Back Ground: - Laboratory services are essential components in the diagnosis and treatment of patients infected with the human immunodeficiency virus (HIV), malaria, Mycobacterium tuberculosis (TB), sexually transmitted diseases (STI), and other infectious diseases. Presently, the laboratory infrastructure and quality for all types of clinical laboratories remain in its nascent stages in most countries in Africa. Consequently, there is an urgent need to strengthen laboratory systems and services quality. The establishment of a process by which laboratories can achieve accreditation at international standards is an invaluable tool for countries to improve the quality of laboratory services.

1.3. Aims of the Study: - To assess quality of clinical laboratory service delivery in all public general hospitals and examine clients satisfaction on the service in Addis Ababa, Ethiopia.

1.4. Benefits for participants: - Study participant receive no monetary benefit from this study. However, knowledge gained from this study may help for the improvement of quality of clinical laboratory service for the future.

1.5. Risk and Complication: - There is no considerable risk for the study subject in participating the study.

1.6. Confidentiality: - Study participant`s research finding will be confidential. They will be identified by participant identification number. No personal information will be disclosed to party or will not appear in any report from this study.

1.7. Assurance of principal investigator:-This is my signature below to confirm you that I take over the responsibility for the scientifically and technical conduct of the research project and for provision of the progress reports for all stakeholders of the research project.

Yalemzewoud Ayalew (PI), Signature…….Date…….

Note: If you have any questions about this study, You should feel free ask now or at any time through the study by contacting: Address: yalemzewoud Ayalew

E-mail:yalem.ayalew@yahoo.com.

Tell,No:-251911762761

School of Public Health Collage of Health Sciences

Addis Ababa University, Addis Ababa, Ethiopia.

2. Participants' Consent Form

I have been informed about the study which plan to determine level of clinical laboratory service in all five public general hospital of Addis Ababa, Ethiopia. Namely Ras Desta general hospital, Gandhi memorial, Zewditu, Yekatite 12 and Minilike general hospital. The objective and application of the study were briefly explained to me and kept confidential. Moreover, I have been well informed of my right to refuse information.

Decline to cooperate and drop out of the study if I want and none of my action will have any bearing at all on my overall health care. It is therefore with full understanding of the situation that I agreed to give the informed consent voluntarily to the research to give my information for the mentioned study.

Participant code…….…….signature……Date……

Addis Ababa University Collage of Health science School of public health questioners for the demographic characteristics, Assessments of factors affecting quality clinical laboratory service, In Gandhi memorial, Yekattit Zewedtu, Ras Desta dametew and Minilik general hospitals in Addis Ababa, Ethiopia.

Facility Name…….Year……ParticipantCode…..……ParticipantAddress…….

Telephone…….Signature……DataCollectorName……date…….signature……..

3. Questionnaire of client exit interview in English version

Number	**Independent factors**	
101	Age	No……
102	Sex	A. male B. female
103	Can you read and write?	A. Yes B. No
103	Educational status	Grade in number…….
104	Marital status	A. Single A. Married B. Divorced C. Widowed D. Others
105	Ethnic groups	A. Amhara B. Oromo C. Guragae D. Tigraway E. Others
106	Religion	A. Orthodox B. Muslim C. Protestant D. Other

107	Occupations	A. Private employ B. Governmental employ C. House wife D. Merchants E. Un employed F. Student
Factors affecting quality clinical laboratory service satisfaction.		
108	Politeness and willingness of health of the provider	A. Very polite B. Polite C. Fair, (Neutral), D. Not polite E. Worst
109	Cost effectiveness of laboratory service/tests/	A. Very good B. Good C. Fair,(Neutral), D. Not good E .worst
110	Turnaround time of the result?	A. Very fast B. Fast C. Fair,(Neutral) D. Long E. Very long.
111	Privacy and confidentiality is maintained	A. Yes B. No C. undecided

112	How satisfied were you with the professional neatness and physical appeal of the phlebotomist (the person who drew your blood)?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied
114	How satisfied were you with the friendliness and communication of the phlebotomist?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied
115	How satisfied were you with the cleanliness of the room where you had your blood drawn?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied
116	How helpful were laboratory personnel in knowledge and explanation the procedures for collection of the specimen required for your medical test?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied
117	How satisfied were you with the cleanliness of latrine?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied
118	How satisfied were you with customer service when you contacted our billing office?	A. Very Satisfied B. Somewhat Satisfied C. Undecided D. Somewhat Dissatisfied. E. Very Dissatisfied

11.3 Annex III: Amharic version of the participant information Sheet, Consent form and questionnaire.

11.3 የተሳታፈዎች መረጃ ቅፅ

በአዲስ አበባ ዩኒቨርስቲ ጤና ሣይንስ ኮሌጅ የህብረተሰብ ጤና አጠባበቅ ት/ቤት የድር ምረቃ ማሞያ ጥናት ለይ ለመሳተፍ ፈቃደኝነት መጠየቂያ ቅፅ

11.3 የጥናቱ ረእስ፡ - በአዲስ አበባ የመንግስት ሆስፒታል ላይ የሚሰጠው የላቦራቶሪ አገልግሎት ጥራት ደርጃ ማወቅ ፡፡

11.31 የጥናቱ አላማ ፡-

ጥናቱ የሚካሀደው በአዲስ አበባ ከተማ አስተዳደር በሚገኙ የመንግስት ሆስፒታሎች ላቦራቶሪ ክፍል ውስጥ ሲሆን የዚህ ጥናት ዋና ዋና አላማዎች በላቦራቶር ክፍል ውስጥ በሚሰጠው አገልግሎት ጥራት ላይ ተፅዕኖ የሚያሳድሩትን መንስኤዎች እና የጥራቱን ደረጃ እንዲሁም የድነብኛ የእርካታ ደረጃ ማወቅ ነው፡፡ ይህም በከተማው ውስጥ የሚሰጠውን የአገልግሎት ጥራት ደረጃ ከፍ ለማድረግ ለሚደረገው ጥረት ይርዳል፡፡

11.32 አጠቃላይ መረጃ ፡ -

በጥናቱ በመሳተፍዎ ከልብ እያመሰገንን ከመወሰንዎ በፍት ይህንን ቅጺ በትክክል አንብቡ ወይም ሲነበብልዎ በትትክክል ያዳምጡ እንዲሁም ግልጺ ያልሆነልዎትን ነገረ በነፃነት ይጠይቁ፡፡

11.33 መግቢያ ፡ -

በዘመናዊ ህክምና ውስጥ የላቦራቶሪ አገልግሎት ለማከም ፡በሽታን ለመለየት ፡ ለክትትል እና መዳኑን ለማርጋገጥ የሚያገለግል እጅግ በጣም ጠቃሚ አገልግሎት ነው፡፡የላቦራቶሪ አገልግሎት ጥራት ደረጃ በአፈሪካም ሆነ በኢትዮጵያ ዝቅተኛ እንደሆነና ተከታታይ ጥናትና ድጋፍ አስፈላጊ እንደሆነ ብዙ ጥናቶች ያሰረዳሉ፡፡

11.34 ለጥናቱ ተሳታፈዎች ያለው ልዩ ጥቅም

በጥናቱ ላይ ለሚሳተፉ ፍቃደኛ ተሳታፈዎች ምንም አይነት የገንዘብ ክፈያ የለውም፡፡ነገረ ግን ጥናቱ በከተማው ውስጥ የሚሰጠውን የአገልግሎት ጥራት ደረጃ ከፍ ለማድረግ ስለሚረዳ ወደፊት ከሚሰጠው ጥሩ አገልግሎት እንደ ማነኛውም ህብረተሰብ ተጠቃሚ ይሆናሉ፡፡

11.35 በጥናቱ ተሳታፈዎች ላይ ያለው ጉዳት እና ተዛማጅ ችግረ

በዚህ ጥናት ላይ በመሳተፈዎ ሊደረስብዎ የሚችል አንድም ጉዳት የለም፡፡

11.36 የመረጃ ሚስጥራዊ አጠባበቅ

ከዚህ ሌላ ላረጋግጥልዎ የምፈልገው እርስዎ የሚሰጡት ማንኛውም መረጃ ሚስጥራዊነቱ የተጠበቀ እና ለዚህ ጥናት ዓላማ ብቻ የሚውል መሆኑን ነው፡፡ ሥምዎም አይጻፍም፡፡ በጥናቱ የመሳተፍ፣ ያለመሳተፍ ወይም የማይፈልጉትን ጥያቄ ያለመመለስ መብትዎ የተጠበቀ ነው፡፡

11.37 የፈቃደኝነት ማረጋገጫ ቅፅ

ይህ የስምምነት ቅፅ ከቃለ መጠይቁ በፊት በጥናቱ ተሳታፊ ስምምነትን የሚያረጋገጥ ነው፡፡
1. የጤና ተቋሙ ስም፡ .....

11.38 የቃለ መጠይቁ መለያ ቁጥር፡

እንደምን አደሩ/ዋሉ? እኔ ስሜ..... ይባላል፡፡ በአዲስ አበባ የኑቨርስቲ ጤና ሣይንስ ኮሌጅ በህበረተሰብ ጤና አጠባበቅ ት/ቤት የጥናት ቡድን አባል ነኝ፡፡ በመጀመሪያ ስለሰጡኝ ጊዜ በጣም አመሰግናለሁ፡፡

ከእርስዎ ጋር ለጥናቱ አጭር የቃል ምልልስ እንደምናደርግ ላስገነዝብዎ እወዳለሁ፡፡ ሥልጥናቱ አጠቃላይ ዓላማና ሁኔታ በማነብልዎ ጊዜ በጥንቃቄ ያድምጡኝ፡፡የዚህ ጥናት ዋና ዋና አላማዎች በዚህ በላቦራቶር ክፍል ውስጥ በሚሰጠው አገልግሎት ጥራት ላይ ተፅዕኖ የሚያሳድሩትን መንስኤዎች እና የጥራቱን ደረጃ እንዲሁም የድነብኛ የእርካታ ማወቅ ነው፡፡ ይህም በከተማው ውስጥ የሚሰጠውን የአገልግሎት ጥራት ደረጃ ከፍ ለማድረግ ይርዳል ፡፡ ለዚህም የጥናቱ ተሳታፊ እንዲሆኑ በአጋጣሚ ተመርጠዋል፡፡

በጥናቱ ቃለ ምልልስ አለመስማማትዎ በእርስዎ ወይም በቤተሰብዎ በምታገኙት አገልግሎት ላይ ምንም ዓይነት ተፅዕኖ አይኖረውም፡፡ ቢሆንም የእርስዎ ተሳትፎ በመሰል ሆስፒታሎችና ተመሳሳይ ተቋማት ውስጥ የሚሰጠውን አገልግሎት ጥራት ላይ ተፅዕኖ የሚያሳድሩትን መንስኤዎች እና የጥራቱን ደረጃ እንዲሁም የድነበኛ እርካታ ጥናት ለማሟላት ነው፡፡ አሁን በጥናቱ ላይ ለመሳትፍ በቅድሚያ ፈቃደኝነትዎን ይግለፁልኝ፡፡

☐ ፈቃደኛ ነኝ ☐ ፈቃደኛ አይደለሁም

ፈቃደኛ ከሆኑ አመስግኖ በስምምነታቸው ቅጽ ላይ እንዲፈርሙ ማድረግ፡፡
ፈቃደኛ ካለሆኑም ማመስገን እና ማሰናበት፡፡

የስምምነት ቅፅ

መጠይቁ የተደረገበት ቀን፡ የተሳታፊ ፊርማ፡
የቃለመጠይቁ ውጤት 1. የተሟላ 2. ተቀባይነት ያጣ 3. በከፊል የተሟላ 4. ሌላካለ (ይጥቀሱ)

መረጃ ሰብሰባ (ቃለ ተቀባይ) ሥም..... ፊርማ.....የተረጋገጠበት ቀን.....
የጥናቱ ዋና ባለበት ሥም፡ ያለምዘውድ አያልው:: ስልክ ቁጥር ፡ 0911 76 27 61
ኢ-ሜይል፡ yalem.ayalew@yahoo.com

በአዲስ አበባ ዩኒቨርስቲ ጤና ሣይንስ ኮሌጅ የህበረተሰብ ጤና አጠባበቅ ት/ቤት:: ከ15 አመት በላዬ በሆኑ በላቦራቶር አገልግሎት ተጠቃሚ ሰወች ላይ የአገልግሎት የጥራት ደረጃ ሁነታ ለማወቅ የሚደረግ የዳሰሳ ጥናት፡፡

ክፍል 1፡ የማህበራዊና ኢኮኖሚያዊ ሁኔታን የሚዳስሱ መጠይቆች

ተ.ቁ	ጥያቄዎች	አማራጭ መልሶች
101	ዕድሜዎት ስንት ነው?	በሙሉ አመት.....
102	ጾታ?	1. ሴት 2. ወንድ
103	ማንበብ እና መፃፍ ይችላሉ?	አወ የለም
104	የትምህርት ደረጃዎ?	የትምህረት ድረጃ/በክፈል .....
105	የጋብቻ ሁኔታ ምንድን ነው?	ı. ያላገባ/ች 2. ያገባ/ች 3. የተለያየ/ች ፣የተፋታ/ች 4. አግብታ ቧላ/ሚስት የሞተባት

106	ብሔርሰብዎ ምንድን ነው?	1. አማራ 2. ኦሮሞ 3. ትግሬ 4. ጉራጌ 5. ሌላ ከሆነ (ይጥቀሱ)
107.	ሐይማኖትዎ ምንድነው?	ı. አርቶዶክስ ተዋህዶ 2. ካቶሊክ 3. ፕሮቴስታንት 4. እስልምና 5. ሌላ ከሆነ (ይጥቀሱ)
108.	የሚተዳሩበት ዋና የሥራ ዓይነት	1. የቤት እመቤት 2. የመንግሥት ሠራተኛ 3. የግል ተቀጣሪ 4. ነጋዴ 5. ሥራ አጥ 6. ተማረ 7. መንግስታዊ ያልሆነ ድረጅት
109	የባለሙያው ስነ ምግባረ/ትህትና/ምን ይመስላል?	1. በጣም ጥሩ 2. ጥሩ 3. ደህና 4. ጥሩ ያልሆነ 5. በጣም ጥሩ ያልሆነ
110.	ለላቦራቶሪ ምረምራ የከፈሉት ገንዘብ ከምረምራው ጥራትና ብዛት ጋረ ያለው መመጣጠን ምን ያህል እርክቶዎታል?	1. በጣም ጥሩ 2. ጥሩ 3. ደህና 4. ጥሩ ያልሆነ 5. በጣም ጥሩ ያልሆነ
111.	የላቦራቶሪ ውጠት በደረሰበት ስአት ያለውት እርካታ ከየትኛው ዬመደባል?	1. በጣም ፈጣን 2. ፈጣን 3. ደህና 4. የዘገየ 5. በጣም የዘገየ
112	የግል የህክምና ውጠት ወዬም ሚስጥረወት ተጠብቀል ብለው ያምናሉ?	1. አወ 2. አልተጠበቀም 3.እረግጠኛ አዬደለሁም (ዐልወሰንኩም)
113	ደም በወሰደልህ/ናሙና በሰጠህው ባልሙያ ናሙና አያያዝ ላዬ ምን ያህል እርክተህል?	1. በጣም ጥሩ 2. ጥሩ 3. ደህና 4. ጥሩ ያልሆነ 5. በጣም ጥሩ ያልሆነ

114	ደም በወሰደልህ/ናሙና በሰጠህው ባልሙያ ጋረ ምን ያህል ተግባብተሀል?	1. በጣም ተግባብቻለሁ 2. ተግባብቻለሁ 3. ደህና 4. አልትግባባሁም 5. በጣም አልትግባባሁም
115	በለቦራቶሪ ደም መውሰጃ ክፈል ጽዳት ምን ያህል ተደስተዋል?	1. በጣም ተደስተዋል 2. ተደስተዋል 3. ደህና 4. አልተደስትኩም 5. በጣም አልተደስትኩም
116	በላቦራቶሪ የአገልግሎት ክፍል ናሙና ለመስጠት ሲስተነግዱ ምረምራውን አስመልክቶ በተደረገልዎት ገለጻ ምን ያህል ተጠቅመዋል?	1. በጣም ጥሩ 2. ጥሩ 3. ደህና 4. አልተጠቀምኩም 5. በጣም አልተጠቀምኩም
117	የንት በቱን ጥዳት እንዳት አገኙት?	1. በጣም ንጹህ 2. ጥሩ ንጸህ 3. ደህና 4. ቆሻሻ 5. በጣም ቆሻሻ
118	የላቦራቶሪ የአገልግሎት ክፍያ ለመክፍል ሲስተነግዱ በአገኙት አገልግሎት ምን ያህል ተደስተዋል?	1. በጣም ተደስቻለሁ 2. ተደስቻለሁ 3. ደህና 4. አልተደስትኩም 5. በጣም አልተደስትኩም

11.4 Annex IV: WHO/AFRO accreditations tools

AUDIT SCORING

This Stepwise Laboratory Improvement Process Towards Accreditation Checklist contains 111 main sections (a total of 334 questions) for a total of 258 points. Each item has been awarded a point value of 2, 3, 4 or 5 points—based upon relative importance and/or complexity. Responses to all questions must be, "yes", "partial", or "no".

- Items marked "yes" receive the corresponding point value (2, 3, 4 or 5 points). All elements of a question must be present in order to indicate "yes" for a given item and thus award the corresponding points.

  NOTE: items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching item.

- Items marked "partial" receive 1 point.

- Items marked "no" receive 0 points.

When marking "partial" or "no", notes should be written in the comments field to explain why the laboratory did not fulfill this item to assist the laboratory with addressing these areas of identified need following the audit.

Audit Score

Section	Total Points	Audited Score
Section 1: Documents & Records	25	
Section 2: Management Reviews	17	
Section 3: Organization & Personnel	20	
Section 4: Client Management & Customer Service	8	
Section 5: Equipment	30	
Section 6: Internal Audit	10	
Section 7: Purchasing & Inventory	30	
Section 8: Process Control and Internal & External Quality Assessment	33	
Section 9: Information Management	18	
Section 10: Corrective Action	12	
Section 11: Occurrence/Incident Management & Process Improvement	12	
Section 12: Facilities and Safety	43	
TOTAL SCORE	258	

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 142 pts)	(143 – 165 pts) 55 – 64%	(166 – 191 pts) 65 – 74%	(192 – 217 pts) 75 – 84%	(218 – 243 pts) 85 – 94%	(244 – 258 pts) ≥95%

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the item must be satisfactorily present to indicate

	Y	P	N	Comments	Score
1.0 DOCUMENTS & RECORDS					
1.1 LaboratoryQualityManual Is there a current laboratory quality manual, composed of the quality management system's policies and procedures, and has the manual content been communicated to and understood and implemented by all staff?					4
	Tick for each item				
The quality manual includes the following elements:	Y	N			
Structure defined per ISO15189, Section 4.2.4					
Quality policy statement that includes scope of service, standard of service, objectives of the quality management system, and management commitment					
Description of the quality management system and the					
Reference to supporting procedures, including technical procedures					
Description of the roles and responsibilities of the laboratory manager, quality manager, and other personnel responsible for ensuring					
Documentation of at least annual management review and approval.					
Standard: A quality manual should be available that summarizes the laboratory's quality program, includes policies that address all areas of the laboratory service, and identifies the goals and objectives of the quality program. The quality manual should include policies (processes and procedures) for all areas of the laboratory service and should address all of the quality system essentials (QSE). ISO 15189: 4.2.3, 4.2.4					
1.2 Document and Information Control System Does the laboratory have a system in place to control all documents and information (internal and external	Y	P	N		2
Standard: A document control system should be in place to ensure that records and all copies of policies/procedures are current, read by personnel, authorized by proper authorities, reviewed annually, and immediately prior versions filed separately as per national policy. There must be a procedure/policy on document control. Documents must be uniquely identified to include title, page numbers, and authority of issue, document number, versions, effective date, and author. There must be a procedure/policy on document control. Documents must be uniquely identified to include tile, page numbers, and authority of issue, document number, versions, effective date, and author. ISO 15189: 4.3.1, 4.3.2 and 4.3.3					
1.3 DocumentandRecords Are documents and records properly maintained, easily accessible and fully detailed in an up-to-date Master List?	Y	P	N		2
Standard: An up-to-date Master List that comprehensively details all laboratory documents, policies, and procedures should be readily accessible in either hard copy or electronic form. These should be retrievable within a timely manner. If documents and records are maintained in electronic form they should be backed up on CD or other media. ISO 15189: 4.3.2 (b,c): "Procedures shall be adopted to ensure that… b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained; c) only currently authorized versions of appropriate documents are available for active use at relevant locations."					
1.4 LaboratoryPoliciesandStandard OperatingProcedures Are policies and standard operating procedures	Y	P	N		5

functions current, available and approved by authorized personnel? ISO15189 4.3.2					
Policies and/or SOPs that:	Tick for each item Yes	 No			
Document&RecordControl Defines the writing, checking, authorization, review, identification, amendments, control & communication of revisions to - and retention & safe disposal of - all documents and records. Standard ISO15189: 4.3.1, 4.13.1-3					
Conflict of Interest Defines the systems in place to identify and avoid potential conflicts of interest and commercial, financial, political or other pressures that may affect the quality and integrity of operations . Standard ISO15189: 4.1					
Communication Defines the systems in place to ensure effectiveness of the quality management systems ISO15189: 4.1.6					
Review of Contracts (Supplier and Customer) Defines the maintenance of all records, original requests, inquiries, verbal discussions and requests for additional examinations, meetings, and meeting minutes. Standard: ISO 15189: 4.4					
Examination by Referral Laboratories Defines the 1) evaluation, selection, and performance monitoring of referral laboratories, 2) packaging and tracking of referred samples, 3) and reporting of results from referral labs Standard: ISO 15189: 4.5.1					
Purchasing and Inventory Control Defines the processes for 1) requesting, ordering and receipt of supplies, 2) the selection of approved suppliers, 3) acceptance/rejection criteria for purchased items, 4) safe handling; 5) storage; inventory control system; 6) monitoring and handling of expired consumables Standard: ISO 15189: 4.6					
Advisory Services Defines the required qualifications and responsibility for providing advice on: 1) choice of examinations; 2) the use of the services; 3) repeat frequency; 4) required type of sample; 5) interpretation of results; and 6) maintenance of records of communication with lab users ISO 15189: 4.7					
Resolution of Complaints and Feedback Defines how 1) complaints and feedback shall be recorded, 2) steps to determine whether patient's results have been compromised, 3) investigative and corrective actions taken as required, 4) timeframe for closure and feedback to the					

complainant Standard: ISO15189: 4.8				
Identification and Control of Nonconformities Defines the 1) types of nonconformities that could be identified, 2) how/where to record, 3) who is responsible for problem resolution; 4) when examinations are to be halted, 5) the recall of released results and 6) person responsible for authorizing release of results after corrective action has been taken Standard: ISO15189: 4.9				
Corrective Action Defines 1) where to record, 2) how to perform root cause analysis, 3) who will be responsible for implementing action plans within the stipulated timeframes, and 4) monitoring the effectiveness of these actions in overcoming the identified problems. Standard: ISO15189: 4.10				
Preventive Action Defines what tools will be used, where the action plan will be recorded, who will be responsible for ensuring the implementation within an agreed time frame and the monitoring of its effectiveness Standard: ISO15189: 4.11				
Continual Improvement Defines what quality indicators will be used and how action plans for these areas will be recorded, evaluated, and reviewed for effectiveness of improvement Standard: ISO15189: 4.12				
Quality and Technical Records Defines what are quality and technical records, how amendments would be done, traceability, storage, retention and accessibility of all hard and electronic records Standard: ISO15189: 4.13				
Internal Audits Defines the internal audit process, including roles and responsibilities, types of audits, frequency of audits, auditing forms to be used, what will be covered, and identification of personnel responsible for ensuring closure of any nonconformances raised within the agreed timeframe and effectiveness of corrective actions implemented. Standard: ISO15189: 4.14				
Management Review Defines frequency, agenda (in line with 4.15.2 a-m), key attendees required, and plan that will include goals, objectives, action plans, responsibilities, due dates and how decisions/actions taken will be communicated to the relevant persons Standard: ISO15189: 4.15				
Personnel Records/Files				

Defines organizational plan, personnel policies, what is required in a personnel file (minimum in line with ISO 15189 Section 5.1.2) and location of personnel files Standard: ISO15189: 5.1				
Personnel Training Defines staff appraisals, staff orientation, initial training, refresher training, continuous education program, recommended and required trainings, and record-keeping of training Standard: ISO15189: 5.1.4, 5.1.6, 5.1.9				
Competency Assessment Defines the methods, ongoing competency testing and training, and criteria used to assess competency of personnel Standard: ISO15189: 5.1.11				
Authorization Defines the level of authorization for all tasks, roles and deputies for all staff Standard: ISO15189: 5.1.7				
Accommodation and Environmental Conditions Defines any specific environmental and accommodation requirements, and the responsibility, monitoring, controlling, and recording of these requirements. Standard: ISO15189: 5.2.5				
Equipment Defines what records are to be maintained in equipment file, the minimum information required on equipment label; action to be taken for defective equipment and maintenance frequency; and access control Standard: ISO15189: 5.3				
Calibration of Equipment Defines frequency; the use of reference standards where applicable; what is required on the calibration label or calibration record and what action to be taken if calibration fails ISO15189: 5.3				
Pre-examination Procedures (Handbook) Defines Specimen Collection, sample and volume requirements; unique identification, special handling; minimum requirements for completion of a requisition form, transportation and receipt of samples ISO15189: 5.4.2 and 5.4.3				
Specimen Storage and Retention Defines pre- and post-sampling storage conditions, stability and retention times ISO 15189: 5.7.2				
Examination SOPs Defines all sub-clauses of ISO15189 Section 5.5.3 (a-q)				

ISO15189:2007 5.5.3					
Equipment Validation/Verification Defines methods to be used, how the lab ensures that equipment taken out of the control from the lab is checked and shown to be functioning satisfactorily before being returned to laboratory use, validation/verification acceptance criteria and person responsible for final authorization for intended use ISO15189: 5.5.2					
Interrupted Services Defines backup procedures for equipment failure, power failure, unavailability of consumables and other resources					
Examination Validation/Verification Defines methods to be used, acceptance criteria, and person responsible for final authorization for intended use ISO15189: 5.5.2					
Quality Assurance Defines the use of IQC and EQC, setting up of ranges, monitoring performance and troubleshooting guidelines ISO15189 5.6					
Reporting of Results Defines the standardized format of a report (in line with ISO15189: Section 5.8.3), methods of communication, release of results to authorized persons, alteration of reports and reissuance of amended reports. ISO 15189: 5.8.					
Patient Confidentiality Defines the tools used to ensure patient confidentiality and access control to laboratory facilities and records (electronic and paper records) ISO 15189: 5.8.13					
Laboratory Safety or Safety Manual Defines the contents to be included. ISO 15190 7.5					
Standard: Standard Operating Procedures (SOPs) should be established and maintained up-to-date for all tasks performed within the laboratory, safety and waste disposal, document control, specimen collection and processing, inventory control, procurement, and quality assurance. SOPs should be reviewed for accuracy and relevance on an annual basis. All policies and procedures should be approved by an authorized person.					
1.5 PolicyandSOPsAccessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff?	Y	P	N		2
Standard: All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory. ISO15189: 5.5.3 & 4.3.2 Part C					
1.6 PoliciesandSOPsCommunication Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities?	Y	P	N		2

Standard: Policies, processes, programs, procedures and instructions shall be documented and communicated to all relevant staff and management must ensure that these documents are understood by staff and implemented. ISO 15189: 4.2.1					
1.7 DocumentControlLog Are policies and procedures dated to reflect when it was put into effect and when it was discontinued?	Y	P	N		2
Standard: The document control log or other documentation should capture the date the policy/procedure went into service, schedule of review, the identity of the reviewers, and the date of discontinuation. ISO 15189: 4.3.1, 4.3.2 Part (e) and (f): 4.3.2 - "Procedures shall be adopted to ensure that e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use; and f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use.					
1.8 Discontinued PoliciesandSOPs Are invalid or discontinued policies and procedures removed from use and retained or archived for the time period required by lab and/or national	Y	P	N		2
Standard: Discontinued policies/procedures should be retained or archived in a separate file or place clearly marked to avoid use for the period of time required by laboratory and/or national policy. ISO 15189: 4.3.1, 4.3.2 Part (e) and (f) – see above					
1.9 DataFiles Are test results and technical and quality records archived in accordance with national/international	Y	P	N		2
Standard: Copies or files of results should be archived. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional or local requirements. SO 15189: 5.8.6, 4.13.2, 4.13.3					
1.10 ArchivedResults Accessibility Are archived records and results easily retrievable in a timely manner?	Y	P	N		2
Standard: Archived patient results must be easily, readily, and completely retrievable within a timeframe consistent with patient care needs. ISO 15189: 5.8.6, 4.13.2					
SECTION 1: DOCUMENTS & RECORDS Subtotal					25 2

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
2.0 MANAGEMENT REVIEWS					
2.1 WorkplanandBudget Does management develop and implement a workplan and develop a budget that supports the laboratory's testing operations and maintenance of the quality system?	Y	P	N		2
Standard: Laboratories should be involved in the development of the work plan and budget for their activities. The workplan should reflect the findings of management reviews in its goals, objectives, and actions. Not all labs will have budgetary authority as higher levels of management may have direct control for budget-making. If the laboratory does not develop these guiding documents itself, it must communicate with upper management effectively about these areas, including providing a forecast of needs. ISO 15189 4.1.5 Part (a) and (h) "Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of					
2.2 Review of Quality and Technical Records Does the laboratory supervisor routinely perform a documented review of all quality and technical records?	Y	P	N	Partial score Some of the elements are essential for One Star	5
	Tick for each item				
Does the supervisor's review include the following?	Y	N			
Follow-up of action items from previous reviews					
Status of corrective actions taken and required preventive actions					
Reports from personnel					
Changes in volume and type of work the laboratory undertakes					
Changes in the suitability of biological reference ranges					
Changes in the client handbook					
Environmental monitoring log sheets					
Specimen rejection logbook					
Equipment calibration and maintenance records					
IQC records across all test areas					
Outcomes of PTs and other forms of Inter- laboratory comparisons					
Monitoring of turnaround time					
Quality indicators					
Outcomes from recent internal audit records					
Results of assessment(s) or audits by external bodies					

Customer complaints and feedback					
Occurrence/incidence logs nonconformities and corrective action reports					
Results of improvement projects					
Operational procedures (for potential sources of non-conformance and opportunities for improvement)					
Evaluation of performance of referra laboratories					
Evaluation of supplier performance					
Document Review					
Documentation of review and action planning with staff for resolution and					

Standard: There must be documentation that the laboratory manager/supervisor or a designee reviews the quality program regularly. The review must ensure that recurrent
problems have been addressed, and that new or redesigned activities have been evaluated.

2.3 Annual Review of Quality Management Systems Does the laboratory management annually perform a review of all quality systems	Y	P	N		5
Does the management review meeting include the following?	Tick for each item				
	Yes	No			
Follow-up of action items from previous management reviews					
Status of corrective actions taken and required preventive actions					
Reports from managerial and supervisory personnel					
Changes in volume and type of work the laboratory undertakes					
Changes in the suitability of biological reference ranges					
Changes in the client handbook					
Environmental monitoring log sheets					
Specimen rejection logbook					
Equipment calibration and maintenance records					
IQC records across all test areas					
Outcomes of PTS and other forms of Interlaboratory comparisons					
Turnaround time					
Quality indicators					
Outcomes from recent internal audit records					

Results of assessment(s) or audits by external bodies					
Customer Complaints and Feedback					
Reports from managerial and supervisory personnel					
Occurrence/incidence logs, nonconformities and corrective action reports					
Results from improvement projects					
Operational procedures (for potential sources of non-conformance and opportunities for improvement)					
Evaluation of performance of referral laboratories					
Evaluation of supplier performance					
Documentation of review and action planning with staff for resolution and					
Standard: There must be documentation that the head of laboratory or a designee reviews the quality program at least once every 12 months. The review must ensure that recurrent problems have been addressed, and that new or redesigned activities have been evaluated. ISO 15189: 4.15					
2.4 QualityManagement System ImprovementMeasures Does the laboratory identify and undertake quality improvement	Y	P	N		3
Standard: The monthly and annual reviews of the quality management system must be used as opportunities for identifying nonconformities and areas for improvement. Action plans for improvement shall be developed, documented and implemented, as appropriate.					
2.5 Communications System on Laboratory Operations Does the laboratory communicate with upper management regularly regarding personnel, facility,	Y	P	N		2
Standard: The laboratory must have a system in place for communicating with management regarding laboratory operations and effectiveness of the quality management system. The communication and follow-up must be documented ISO15189: 4.1.6					
SECTION 2: MANAGEMENT REVIEW Subtotal					17

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
3.0 ORGANIZATION & PERSONNEL					
3.1 Workload, Schedule and Coverage Do work schedules show task assignments & coordination of work for adequate lab staff coverage?	Y	P	N		2
Standard: Work schedules show who is in the laboratory and when they should be available. Work schedules are normally provided to hospital management showing laboratory coverage. There shall be enough staff resources adequate to cover the work as required and tasks should be prioritized, organized, and coordinated based upon personnel skill level, workloads, and the task completion timeframe ISO 15189 5.1.5 "There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system."					
3.2 DutyRosterAndDailyRoutine Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and which indicates that only authorized personnel perform specific tasks?	Y	P	N		2
Standard: A duty roster designates specific laboratory personnel to specific workstations and workstation tasks list the tasks associated with a specific workstation. E.g. personnel X assigned to hematology (duty roster) expected to perform specific tasks (workstation tasks). Daily routines should be prioritized, organized and coordinated to achieve optimal service delivery for patients. ISO 5.1.7 "Laboratory management shall authorize personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system."					
3.3 OrganizationalChartand External/InternalReportingSystems Are lines of authority and responsibility clearly defined for all lab staff, including the designation of a supervisor and deputies for all key functions?	Y	P	N		2
Standard: An up-to-date organizational chart and/or narrative description should be available detailing the external and internal reporting relationships for laboratory personnel. The organizational chart or narrative should clearly show how the laboratory is linked to the rest of the hospital and laboratory services where applicable					
3.4 Quality Management System Oversight Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality	Y	P	N		3 1
Standard: There should be a quality manager (however named) with delegated authority to oversee compliance with the requirements of the quality management system. This quality manager should report directly to the level of laboratory management at which decisions are made on laboratory policy and resources. ISO 15189: 4.1.5 Part (i)					
3.5 Personnel FilingSystem Are Personnel Files present?	Y	P	N	Only some elements required	3 1
If files are present, do they document or contain the following:	Tick for each item Yes	No	N/A		
Employee Orientation					
Education & Training (e.g., degrees/certificates)					
Previous experience and work history (e.g. CV)					
Written job description with documentation that staff member received and signed a copy of their job description	Y			One Star	
Letter of employment or appointment					

Review of job-relevant SOPs	Y				
Documented review of safety manual, evidence of safety training					
Review of procedure for employees to communicate concerns about test quality and laboratory safety					
Registration with professional board					
Training record documenting trainings received, vendor training received on-site					
Periodic Performance Review – including Observation, Competency Assessment,					
Documentation of employee recognition (i.e., employee of the month, letter of commendation, etc.)					
Human Resource (HR) Data – (vaccination status, accidental exposure during work injuries, accident history, leave days taken, etc.)					
Standard: Personnel files should be maintained for all current staff. Documentation should include job description, qualifications, training, experience, competency assessment records, periodic performance review records, and records of vaccination, injuries, or workplace accidents.					
3.6 StaffCompetencyAssessmentand Training Is there a system for competency assessment of personnel (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?	Y	P	N		3
Standard: Newly hired lab staff should be assessed for competency before performing independent duties and again within six months. All lab staff should be regularly assessed for testing competency at least once a year. Staff assigned to a new section should be assessed before fully assuming independent duties. When deficiencies are noted, retraining and reassessment should be planned and documented. If the employee's competency remains below standard, further action might include supervisory review of work, re-assignment of duties, or other appropriate actions. Records of competency assessments and resulting actions should be retained in personnel files and/or quality records. Records should show which skills were assessed, how those skills were measured, and who performed the assessment. ISO 15189: 5.1.11: "The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary."					
3.7 LaboratoryStaffTraining Does the laboratory have adequate training policies, procedures, and/or training plans, including cross-training within the laboratory team, one-on-one mentoring, and/or off-site external training?	Y	P	N		2
Standard: In line with national laboratory training plans, each laboratory should have functional training policies and procedures that meet the needs of laboratory personnel through both internal and external training. ISO 15189: 4.12.5, 5.1.6, 5.1.9					
3.8 StaffMeetings Are staff meetings held regularly?	Y	P	N		3
Do meetings include the following items?	Tick for each item				
	Yes	No	N/A		
Follow-up of action items from previous staff meetings					
Discussion about problems and complaints					
Review of documentation					
Communication on reviewed/revised/redundant					

	Systemic and or recurrent problems and issues addressed, including actions to prevent recurrence				
	Review of results from prior corrective actions				
	Discussion and evaluation of improvement topics/projects				
	Feedback given by staff that have attended meetings, training,				
	Recognition of employees for exemplary performance (i.e., employee of the month, letter of commendation, etc.)				
	Relay of reports and updates from lab attendance at meetings with clinicians (the use of lab services and/or attendance at clinical rounds)				
	Recording and monitoring of meeting notes for progress on issues				
Standard: "Laboratory management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system. "The laboratory should hold regular staff meetings to ensure communication within the laboratory. Meetings should have recorded notes to facilitate review of progress over time.					
SECTION 3: ORGANIZATION & PERSONNEL Subtotal					20 7

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
4.0 CLIENT MANAGEMENT & CUSTOMER SERVICE					
4.1 Advice and Training by Qualified Staff Do staff members with appropriate professional qualifications provide clients with advice and/or training regarding required types of samples, choice of examinations,	Y	P	N		2
Standard: Professionally-qualified staff should provide advice on sample type, examination choice, frequency, and results interpretation. ISO 15189:4.7; 4.12.5					
4.2 Laboratory Handbook for Clients Is there a laboratory handbook for laboratory users that includes information on services offered, quality assurance, laboratory operations, sample collection, transport and agreed turnaround times?	Y	P	N		2
Standard: The laboratory should provide its clients with a handbook that outlines the laboratory's hours of operation, available tests, specimen collection instructions, packaging and shipping directions, and expected turnaround times. ISO 15189: 4.7, 4.12.5, 5.5.6					
4.3 Communication Policy on Delays in Service Is timely, documented notification provided to customers when the laboratory experiences delays or interruptions in testing (due to equipment failure, stock outs, staff levels, etc.) or finds it necessary to change examination	Y	P	N		2
Standard: There shall be a policy for notifying the requester when an examination is delayed. Such notification shall be documented for both service interruption and resumption as well as related feedback from clinicians. This does not mean that the clinical personnel are to be notified of all delays of examination, but only in those situations where the delay could compromise patient care. ISO 15189: 5.8.11					
4.4 Evaluation Tool and Followup Is there a tool for regularly evaluating client satisfaction and is the feedback received effectively utilized to improve services?	Y	P	N		2
Standard: The laboratory should measure the satisfaction of client clinicians and patients regarding its services, either on an ongoing basis or through episodic solicitations. ISO 15189: 4.8, 4.15.2 Part (b)					
SECTION 4: CLIENT MANAGEMENT & CUSTOMER SERVICE Subtotal					8

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
5.0 EQUIPMENT					
5.1 Adherence to Proper Equipment Protocol Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?	Y	P	N		2
Standard: Equipments should be properly placed as specified in user manual away from the following but not limited to water, direct sunlight, vibrations, in traffic and with more than 75% of the base of the equipment sitting on the bench top to avoid tip-over. ISO 15189: 5.3.3 "Each item of equipment shall be uniquely labeled, marked, or otherwise identified."					
5.2 Equipment and Method Validation/ Verification and Documentation Are newly introduced equipment and methods validated/verified on-site and are records	Y	P	N		2
Standard: Newly introduced methods or equipment should be validated onsite to ensure that their introduction yields performance equal to or better than the previous method or equipment. Validation may be done versus the method or equipment being replaced or the prevailing gold-standard. An SOP should be in place to guide method					
5.3 EquipmentRecordMaintenance Is current equipment inventory data available on all equipment in the laboratory?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Name of equipment					
Manufacturer's contact details					
Condition received (new, used, reconditioned)					
Serial number					
Date of purchase					
Date when put "out of service"					
Date of entry into service					
Standard: Records shall be maintained for each item of equipment used in the performance of examinations. Such equipment list must include major analyzers as well as ancillary equipment like centrifuges, water baths, rotators, fridges, pipettes, timers, printers, computers.					
5.4 EquipmentMaintenanceRecords Is relevant equipment service information readily available in the laboratory?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Service contract information					
Contact details for service provider					
Decontamination Records					
Performance and maintenance records					
Last date of service					
Next date of service					
Current location					
Standard: Maintenance records must be maintained for each item of equipment used in the performance of examinations… These records shall be maintained and shall					

available for the lifespan of the equipment or for any time period required by national, regional and local regulations. ISO 15189: 5.3.4					
5.5 Obsolete Equipment Procedures Is non-functioning equipment appropriately labeled and removed from the laboratory & storage areas?	Y	P	N		2
Standard: The laboratory must have procedures for proper retirement of obsolete equipment and should be removed from the laboratory to free work and storage areas. The equipment shall be properly decontaminated before being removed from the lab ISO 15189: 5.3.7					
5.6 Adherence to Equipment Calibration Protocol Is routine calibration of laboratory equipment (including pipettes, centrifuges, balances, and thermometers) scheduled, as indicated on the	Y	P	N		2
Standard: All equipment in the laboratory that require calibration must be calibrated according to the schedule, which at minimum must meet the manufacturer's recommendations. This shall cover major analyzers as well as ancillary equipments like pipettes, thermometers, balances, centrifuges, timers, balances ISO 15189: 4.2.5, 5.3.2					
5.7 Equipment Preventive Maintenance Is routine preventive maintenance performed on all equipment and recorded according to SOPs/log sheet?	Y	P	N		2
Standard: Preventative maintenance by operators must be done on all equipment used in examinations including centrifuges, autoclaves, microscopes, safety cabinets ISO 15189: 4.2.5, 5.3.2					
5.8 Equipment Service Maintenance Is equipment routinely serviced according to schedule by qualified and competent personnel and is this information documented in appropriate logs?	Y	P	N		2
Standard: All equipments must be serviced at specified intervals by a qualified service engineer either through service contracts or otherwise. Service schedule must at minimum meet manufactures requirements ISO 15189: 4.2.5, 5.3.2					
5.9 Equipment Parts for Repair Are parts available to perform minor repairs as per manufacturer's instructions?	Y	P	N		2
Standard: ISO 15189: 5.3.2 "Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned."					
5.10 Equipment Malfunction - Response and Documentation Is equipment malfunction resolved by the effectiveness of the corrective action program and the associated root cause analysis?	Y	P	N		2
Standard: All equipment malfunctions must be investigated and documented on corrective action reports. Where user cannot resolve the problem, a repair order must be initiated					
5.11 Equipment Repair Monitoring and Documentation Are repair orders monitored to determine if the service is completed? Does the laboratory verify and document that it is in proper working order before being put it back into service?	Y	P	N		2
Standard: All equipment should receive thorough documented checks to ensure proper functioning before being returned into service, following its absence from the laboratory.					
5.12 Equipment Failure - Contingency Plan	Y	P	N		2

Are there back-up procedures for equipment failure (including SOPs for handling specimens during these times, identification of a back-up lab for testing, and referral procedures)?					
Standard: Contingency plans must be in place, in the event of equipment failure, for the completion of testing. In the event of a testing disruption, planning may include the use of a back-up instrument, the use of a different testing method, the referral of samples to another laboratory, or the freezing of samples until testing is reestablished. ISO 15189: 5.3.1 "The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample					
5.13 Manufacturer's Operator Manual Are the equipment manufacturer's operator manuals readily available to testing staff, and where possible, available in the	Y	P	N	If available, otherwise SOPs are adequate and should count as partial. One Star	2
Standard: Operator manuals must be readily available for reference by testing staff. ISO 15189: 5.3.5					
5.14 Communicationon Effectivenessof QualityManagementSystem Are equipment specifications and maintenance needs routinely communicated to	Y	P	N		2
Standard: Laboratory management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system. ISO 15189: 4.1.6					
5.15 Laboratory Testing Services Has the laboratory provided uninterrupted testing services, with no disruptions due to equipment failure in the last year (or since the last assessment)?	Y	P	N		2
Standard:					
SECTION 5: EQUIPMENT Subtotal					30 3

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further

	Y	P	N	Comments	Score
6.0 INTERNAL AUDIT					
6.1 InternalAudits Are internal audits conducted at intervals as defined in the quality manual and do these audits address areas	Y	P	N		5
	Tick for each item				
	Yes	No			
Are audits being carried out by persons who are not involved in lab activities in the section being audited?					
Are the personnel conducting the internal audits trained and					
Is cause analysis performed for nonconformities/noted					
Are internal audit findings documented and presented to the laboratory management and relevant staff for					
6.2 Audit Recommendations and Action Plan&Followup Are recommendations for corrective/preventive actions made based on audit findings; is an action plan	Y	P	N		5
Standard: Internal audits should be conducted at least annually. Investigation of individual problems may not reveal trends or patterns. Errors and incident reports should be reviewed periodically to determine whether systemic problems are responsible for errors and/or incidents. Laboratory management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.					
SECTION 6: INTERNAL AUDIT Subtotal					10 0

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
7.0 PURCHASING & INVENTORY					
7.1 Inventory and Budgeting System Is there a system for accurately forecasting needs for supplies and reagents?	Y	P	N	One Star	2 / 2
Standard: The Laboratory must have a systematic way of determining its supply and testing needs through inventory control and budgeting systems that take into consideration past patterns, present trends, and future plans: ISO 15189: 4.6.4 "The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list those approved." ISO 15189: 5.1.4 (i) "Provide effective and efficient administration of the medical					
7.2 Service Supplier Performance Review Are supply & reagent specifications periodically reviewed and are approved suppliers identified?	Y	P	N		2
Standard: All suppliers of services used by the laboratory must be reviewed for their performance. Those that perform well must be identified and listed as approved suppliers. Results of these reviews must be documented					
7.3 Manufacturer/SupplierList Is an up-to-date list of approved manufacturers/suppliers available and includes their complete contact	Y	P	N		2
Standard: Each laboratory should keep a comprehensive and up-to-date list of approved manufacturers/suppliers that includes full contact details to expedite ordering, tracking, and follow-up.					
7.4 BudgetaryProjections Are budgetary projections based on personnel, test, facility and equipment needs, and quality assurance procedures and materials?	Y	P	N		2
Standard: ISO 15189: 5.1.4 (i) "Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible					
7.5 Management Review of Supply Requests Does management review the finalized supply requests?	Y	P	N		2
7.6 OrderTracking,Inspection,and Documentation Are all orders tracked until delivery and inspected, receipted, and labeled with date of receipt when the orders are checked in?	Y	P	N		2
Standard: All incoming orders should be inspected for condition and completeness, receipted and documented appropriately and the date received in the laboratory and the expiry date for the product should be clearly indicated. ISO 15189: 4.6.1 and 4.6.3					
7.7 InventoryControlSystem Is an inventory control system in place?	Y	P	N	One Star	2 / 1
Criteria and procedures for	Tick for each item: Yes	No			
Acceptance and rejection of consumables		P			
Recording of lot number, date of receipt, received by and date		P			

Storage of consumables	Y				
Standard: There laboratory shall have an inventory control system for supplies that monitors receipt, storage and use of consumables ISO 15189: 4.6.1, 4.6.3 CAP GEN 61900					
7.8 LaboratoryInventorySystem Are inventory records complete and accurate, with minimum and maximum stock levels denoted?	Y	P	N		2
Standard: The Laboratory inventory system shall reliably inform the Laboratory of how much at minimum must be kept in the laboratory to avoid interruption of servic due to stock outs and how much at maximum must be kept by the lab to prevent expiry of reagents					
7.9 Usage Rate Tracking of Consumables Is the consumption rate	Y	P	N		2
Standard: The inventory control system must allow the Laboratory to track rate of usage of consumables ISO 15189: 4.6.3					
7.10 InventoryControlSystem–Stock Counts Are stock counts routinely	Y	P	N		2
Standard: The laboratory must routinely perform stock counts as part of its inventory control system ISO 15189: 4.6.3					
7.11 StorageArea Are storage areas set up and monitored appropriately?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Is the storage area well-organized and free of clutter?					
Are there designated places labeled for all inventory items?					
Are hazardous chemicals stored appropriately?					
Is adequate cold storage available?					
Are storage areas monitored as per prescribed storage conditions?					
Is the ambient temperature monitored routinely?					
Is storage in direct sunlight avoided?					
Is the storage area adequately ventilated?					
Is the storage area clean and free of dust and pests?					
Are storage areas access-controlled?					
Standard: CAP GEN 62000 & 62100					
7.12 Inventory Organization and Wastage Minimization Is First-Expiration-First-Out (FEFO)	Y	P	N		2
Standard: To minimize wastage from product expiry, inventory should be organized in line with the First-Expiry-First-Out (FEFO) principle. Place products that will expire first in front of products with a later expiry date and issue stock accordingly to ensure products in use are not past their expiry date. Remember that the order in which					
7.13 Disposal ofExpiredProducts Are expired products labeled and disposed properly?	Y	P	N		2
Standard: Expired products should be disposed of properly. If safe disposal is not available at the laboratory, the manufacturer/supplier should take back the expire stock at the					
7.14 ProductExpiration Are all reagents/test kits in use (and in stock) currently within the manufacturer- assigned	Y	P	N	One Star	2 2

stability?					
Standard: All reagent and test kits in use, as well as those in stock, should be within the manufacturer-assigned expiry dates. Expired stock should not be entered into use and					
7.15 Laboratory Testing Services Has the laboratory provided uninterrupted testing services, with no disruptions due to stock outs in the last year or since last assessment?	Y	P	N		2
Standard: Testing services should not be subject to interruption due to stock outs. Laboratories should pursue all options for borrowing stock from another laboratory or referring samples to another testing facility while the stock out is being addressed.					
SECTION 7: PURCHASING & INVENTORY Subtotal					30 5

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
8.0 PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY ASSESSMENT					
8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample	Y	P	N	One Star	2 / 2
Standard: "Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management and made available to those responsible for primary sample					
8.2 Are adequate sample receiving procedures in place?	Y	P	N	Some elements required.	3 / 1
	Tick for each item				
	Yes	No	N/A		
Are specimens labeled with patient ID, test, and date, time of collection, date of collection and authorized requester?	Y			One Star	
Are all test requests accompanied by an acceptable and approved test requisition	Y			One Star	
If not a 24 hour lab, is there a documented method for handling of specimens received					
Are all samples that are either received or referred to a higher level laboratory accompanied by a sample delivery					
Are received specimens evaluated according to acceptance/rejection					
Are specimens logged appropriately upon receipt in the laboratory (including date, time, and name of receiving officer)?	Y			One Star	
When samples are split, can the portions be traced back to the primary sample?					
Is a two-identifier system in use and is each sample assigned a unique identifying					
Are procedures in place to process "urgent" specimens and verbal requests?					
Are specimens delivered to the correct workstations in a timely manner?					
Standard :ISO 15189: 5.4.1, 5.4.5, 5.4.7, 5.4.8, 5.4.10, 5.4.11, 5.4.13					
8.3 Are specimens stored appropriately prior to testing?	Y	P	N	One Star	2 / 2
Are specimens disposed of in a safe					
Standard: "Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results." Specimens should be stored under the appropriate conditions to maintain the stability of the specimen. Specimens no longer required should be disposed of in a safe manner, according to Biosafety regulations.					
8.4 Are specimens packaged appropriately according to local and or international regulations and transported to referral laboratories within acceptable	Y	P	N	One Star	2 / 2
Standard: All samples shall be transported to the laboratory in such a manner as to prevent contamination of workers, patients, or the environment.					

ISO Safety Standard 15190: Clause 26 CAP GEN 40511, 40512						
8.5	Are referred specimens tracked properly using a logbook or tracking form?	Y	P	N		2
Standard: "The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all samples that have been referred to another laboratory" The referral log must be reviewed routinely for outstanding results and turnaround times						
8.6	Is complete procedure manual available at the workstation or in the work area?	Y	P	N	One Star	3 3
Standard: "All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory." ISO 15189: 5.5.3						
8.7	Is there a reagent logbook for lot number and dates of opening that reflects verification of new lots?	Y	P	N		2
Standard: "Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable."						
8.8	Is each new lot number, new shipment of reagents, or consumables verified before use?	Y	P	N	One Star	2 2
Standard: "Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable."						
8.9	Is internal quality control performed, documented, and verified before releasing patient results?	Y	P	N	One Star	3 3
Standard: The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions ISO 15189: 4.2.2, 5.6.1						
8.10	Are QC results monitored and reviewed (biases, shifts, trends, and Levy-Jennings charts)? Is there documentation of corrective action when quality control results exceed the acceptable	Y	P	N		3
Standard: "The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results."‹ As part of the Laboratory internal quality control systems L-J charts shall be used to monitor quantitative tests on a daily basis and reviewed routinely.						
8.11	Are environmental conditions are checked and reviewed accurately?	Y	P	N	One Star	2 2
		Tick for each item				
Are the following environmental conditions checked daily?		Yes	No	N/A		
Room temperature						
Freezers						
Refrigerator						
Incubators						
Water Bath						

Standard: "The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results."						
	Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action	Y	P	N	One Star	2 2
Standard: SMILE, Johns Hopkins University, Baltimore, MD, Pro 71-07, May 20, 2010. "Acceptable ranges or criteria must be defined, with documentation of action taken in response to out of range temperatures."						
8.12	Does the laboratory participate in external Proficiency Testing (PT) or exercise an alternative performance assessment system when	Y			One Star	3 3
	Are the following criteria	Tick for each item Yes	No	N/A		
	Are blinded characterized samples routinely distributed for testing to					
	Do PT samples come from providers who are accredited or approved?					
	Are PT specimens handled and tested the same way as patient specimens?					
	Is cause analysis performed for unacceptable PT					
	Is corrective action documented for unacceptable					
Standard: The laboratory should handle, analyze, review, and report results for proficiency testing in manner similar to regular patient testing. Investigation and correction of problems identified by unacceptable proficiency testing should be documented. Acceptable results that show bias or trends suggest a problem should also be investigated. ISO 15189: 4.2.2, 5.6.4, 5.6.5, 5.6.7						
8.13	Are test requests checked with test results, thereby assuring the accuracy and completion of all tests?	Y	P	N		2
Standard: "Authorized personnel shall systematically review he results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorized the release the results." A standard procedure should be followed for crosschecking all results. In instances where there is a LIS (laboratory information system) daily printing of the pending reports list should be done routinely to cross-check the completion of all tests within the defined turnaround times.						
SECTION 8: PROCESS CONTROL and INTERNAL & EXTERNAL QUALITY ASSESSMENT Subtotal						33 22

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
9.0 INFORMATION MANAGEMENT					
9.1 TestResultReportingSystem Are test results legible, technically verified by an authorized person, and confirmed against patient	Y	P	N	One Star	2 2
Standard: Results must be written in ink, written clearly with no mistakes in transcription. Cancellation must follow Good Lab Practices. The persons performing the test must indicate verification of the results. There must be signature or identification of person authorizing the release of the report.					
9.2 TestingPersonnel Are testing personnel identified on the requisition and record?	Y	P	N		2
Standard: The person who performed the procedure must be identified on the report for purposes of audit trail. ISO 15189: 5.4.7 "All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded."					
9.3 TestResultRecords Are test results recorded in a logbook or electronic record in a timely manner?	Y	P	N	One Star	2 2
Standard: In line with maintaining agreed turnaround times, the Laboratory shall perform and record test results in a timely manner and confidentiality of reported an stored result					
9.4 AnalyticSystem/MethodTracing When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing?	Y	P	N		2
Standard: It is important that the laboratory has the ability to trace specimen results to a specific analytical system or method. Proficiency testing specimens would also fall under					
9.5 ResultCross-checkSystem Is there a system for reviewing for transcription errors?	Y	P	N		2
Standard: The laboratory must have a system for cross-checking of results before release to requesters in order to identify and correct errors ISO 15189: 5.8.3 "Results shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information."					
9.6 Archived Data Labeling and Storage Are archived results (paper or data- storage media) properly labeled and stored in a secure location accessible only to authorized personnel?	Y	P	N		2
Standard: All patient data, paper, tapes, disks should be properly labeled and stored securely in places accessible only to authorized personnel. ISO 15189: 5.8.3 Annex B 6.4.					
9.7 InformationandDataBackupSystem Are there documented procedures to prevent the loss of test result data in the event of hardware/software failure, fire or theft?	Y	P	N		2
Standard: The laboratory should have a procedure to protect essential data in the event of equipment failure and/or an unexpected destructive event. These procedures could include flood and fire safe storage of data, periodic backing up and storing of information, and off-site storage of backup data. ISO 15189: 5.8.3 Annex B 3.3.					
9.8 TestResultReport Is the laboratory result report(s) in a standard form	Y	N	P	One Star	2

acceptable by its customers?					1
Indicate for each item	Tick for each item				
	Yes	No			
Is the laboratory issuing the report clearly identified?	Y			One Star	
Does the report contain the patient's name, address, and the hospital/destination of the report?	Y			One Star	
Is the name of the person requesting the test indicated on the report?					
Is the type of sample received and the test requested included in the					
Are the date and time for specimen collection, receipt of specimen, and release of report indicated?					
Does the report indicate biological reference ranges for each test?					
Is the result reported in SI units where applicable?					
Is there space for interpretation of results when applicable, and for indication of when specimens are received and unsuitable	Y			One Star	
Does the result contain the name of the person authorizing release of the report and the signature of the person accepting responsibility for its content?					
9.9 TestResult Are test results validated, interpreted and released by appropriately-authorized personnel?	Y			One Star	2 2
SECTION 9: INFORMATION MANAGEMENT Subtotal					18 7

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further

	Y	P	N	Comments	Score
10.0 CORRECTIVE ACTION					
10.1 Are all laboratory-documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent	Y	P	N	There must be at least a description of what happened and what was done to prevent it from happening again.	5 1
Standard: "Laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained." ISO 15189: 4.8					
10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis?	Y	P	N		2
Standard: "Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions.Corrective action shall be appropriate to the magnitude of the problem and commensurate with possible risks." "The laboratory shall document, record and, as appropriate, expeditiously act upon results from these comparisons. Problems or deficiencies identified shall be acted upon and records of					
10.3 Is corrective action performed on all non-conforming aspects of the quality management system documented?	Y	P	N		3
Indicate for each item	Tick for each item				
	Yes	No			
Are results withheld, if indicated by the level of control violated? ISO 4.9.1 part d					
Have these been recalled and corrected, if results have been released? ISO 4.9.1 part f					
Is this approved by an authorized person, when testing resumes? ISO 4.9.1.part g					
Standard: "Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinicians." ISO 15189:4.9					
10.4 Are discordant results tracked and appropriate corrective action taken?	Y	P	N		2
Standard: "Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem." ISO 15189: 4.10.1					
SECTION 10: CORRECTIVE ACTION Subtotal					12 1

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
11.0 OCCURRENCE / INCIDENT MANAGEMENT & PROCESS IMPROVEMENT					
11.1 Are graphical tools (charts and graphs) used to communicate quality findings and identify trends?	Y	P	N		2
Standard: "Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend-and risk-analyses and external quality assurance."Use of graphical displays of quality data communicates more effectively than tables of numbers. Examples of graphical tools commonly used for this purpose include Pareto charts, cause-and-effect diagrams, frequency histograms, trend graphs, and flow charts. ISO 15189: 4.11.2 , Note 1					
11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential	Y	P	N		5
11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance?	Y	P	N		3
11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab					2
Standard: "Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contributing These indicators should be compared against a benchmark from an acknowledged guideline." " Laboratory management, in consultation with the requesters, shall establishes turnaround times for each of its examinations. A turnaround time shall reflect clinical needs." Key indicators of quality must be monitored regularly and evaluated for opportunities to improve testing services. Indicators should be drawn from pre-analytic, analytic, and post-analytic phases and reflect activities critical to patient outcomes, those that correspond to a large proportion of the laboratory's patients, or areas that have been problematic in the past. These indicators should be compared against a benchmark from an acknowledged guideline. ISO 15189: 4.12.4, 5.8.11					
SECTION 11: OCCURRENCE/INCIDENT MGT, & PROCESS IMPROVEMENT Subtotal					12 0

For each item, please circle either Yes (Y), Partial (P), or No (N). All elements of the question must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

	Y	P	N	Comments	Score
12.0 FACILITIES & SAFETY					
12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal	Y	P	N		2
Standard: The laboratory floor plan should be configured to promote high quality work, personnel safety, and efficient operations. ISO 15189: 5.2.2 CAP GEN 60000					
12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?	Y	P	N	One Star	2 2
Standard: "There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination." Client service areas (i.e., waiting room, phlebotomy room) should be distinctly separate from the testing areas of the laboratory. Client access should not compromise 'clean' areas of the laboratory. For Biosafety reasons, microbiology and TB testing should be segregated in a separate room(s) from the general laboratory testing. ISO 15189: 5.2.6					
12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?	Y	P	N		2
Are the following criteria met:	Tick for each item				
	Yes	No	N/A		
Does the equipment placement/layout facilitate optimum					
Are all needed supplies present and easily accessible?					
Are the chairs/stools at the workstations appropriate for bench height and the testing operations being performed?					
Is reference material readily available (critical values and required action, population reference ranges, frequently called numbers?					
Standard: Age-and sex-specific reference intervals (normal values) must be verified or established by laboratory. If a formal reference intervals study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference ranges, and retain documentation of this evaluation.					
12.4 Is the physical work environment appropriate for testing?	Y	P	N	One Star	2 2
Is the workplace:	Tick for each item				
	Yes	No	N/A		
Free of clutter? ISO 15190: 13.0					
Adequately ventilated? ISO 15190: 6.3.3					
Free of excess moisture? ISO 15190: 6.3.2					
Adequately lit? ISO 15190: 6.3.1					
Climate-controlled for optimum equipment function? ISO 15190: 6.3.2					
Are filters checked, cleaned and/or replaced at regular intervals, where air-conditioning is installed?					

Are wires and cables properly located and protected from					
Is there a functioning back-up power supply					
Is critical equipment supported by uninterrupted power source (UPS)					
Is equipment placed appropriately (away from water hazards, out of					
Is a contingency plan in place for continued testing in the event of prolonged electricity disruption?					
Are appropriate provisions made for adequate water supply, including deionized water (DI) or distilled					
Is clerical work completed outside the testing area?					
Is major safety signage posted and enforced including NO EATING, SMOKING, DRINKING?					
Standard: The laboratory space should be sufficient to ensure that the quality of work, the safety of personnel, and the ability of staff to carry out quality control procedures and documentation. The laboratory should be clean and well organized, free of clutter, well-ventilated, adequately lit, and within acceptable temperature ranges. Emergency power should be available sensitive instruments, temperature controlled storage, and other essential equipment to prevent damage and disruption due to unexpected power fluctuations and outages. Sensitive instruments should be equipped with surge controls. Distilled and de-ionized water should be available, if required.					
Is the laboratory properly secured from unauthorized access with appropriate signage?					2
Standard: The access of unauthorized persons to the laboratory should be strictly limited to avoid the unnecessary contact of individuals with contaminated areas, reagents, or equipment. Unnecessary traffic also disturbs workflow and can distract staff members. ISO 15189: 5.2.7					
12.6 Is laboratory-dedicated cold and room temperature storage free of staff food items, and are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	Y	P	N		2
Standard: Staff food items should be stored in separate locations dedicated to that purpose, not in laboratory storage areas, particularly cold storage. Laboratory reagents and blood products should be stored separately when refrigerated or frozen. ISO 15190: 11.1					
12.7 Is the work area clean and free of leakage & spills, and are disinfection procedures conducted and documented?	Y	P	N	One Star	2 2
Standard: The work area should be regularly inspected for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all bench tops and working surfaces should be disinfected at the beginning and end of every shift. All spills should be contained immediately and the work surfaces disinfected. ISO 15189: 5.2.10					
12.8 Is a certified and appropriate Biosafety cabinet (or an acceptable alternative processing procedure) in use for all specimens or organisms considered to be highly contagious by airborne routes? (Biosafety cabinet should be recertified	Y	P	N	If required by testing activities. One Star	2 2
Standard: A Biosafety cabinet should be used for to prevent aerosol exposure to contagious specimens or organisms. For proper functioning and full protection, Biosafety cabinets require periodic maintenance and should be serviced accordingly. ISO 15190: 16					

12.9 Is a laboratory safety manual available, accessible, and up-to-date?	Y	P	N		3
	Tick for each item				
Does the safety manual include guidelines on the following topics?	Yes	No	N/A		
Blood and Body Fluid Precautions					
Hazardous Waste Disposal					
Hazardous Chemicals / Materials					
MSDS Sheets					
Personal protective equipment					
Vaccination					
Post-Exposure Prophylaxis					
Fire Safety					
Electrical safety					
Standard: A safety manual shall be readily available in work areas as required reading for all employees. The manual shall be specific for the laboratory's needs . The Safety Manual shall be reviewed and updated at least annually by laboratory management. ISO 15190: 7.4					
12.10 Is sufficient waste disposal available and is waste separated into infectious and non-infectious waste, with infectious waste autoclaved, incinerated, or buried?	Y	P	N	One Star	2 2
Standard: Waste should be separated according to biohazard risk, with infectious and non-infectious waste disposed of in separate containers. Infectious waste should be discarded into containers that do not leak and are clearly marked with a biohazard symbol. Sharp instruments and needles should be discarded in puncture resistant containers. Both infectious waste and sharps containers should be autoclaved before being discarded to decontaminate potentially infectious material. To prevent injury from exposed waste, infectious waste should be incinerated, burnt in a pit, or buried.					
12.11 Are hazardous chemicals / materials properly handled?	Y	P	N	One Star	2 2
	Tick for each item				
	Yes	No	N/A		
Are hazardous chemicals properly labeled?					
Are hazardous chemicals properly stored?					
Are hazardous chemicals properly utilized?					
Are hazardous chemicals properly disposed?					
Standard: All hazardous chemicals must be labeled with the chemical's name with hazard markings clearly indicated. Flammable chemicals must be stored out of sunlight and below their flashpoint, preferably in a still cabinet in a well-ventilated area. Flammable and corrosive agents should be separated from one another. Distinct care should always be taken to handle hazardous chemicals safety in the workplace. Used, outdated, old, or discolored chemicals should be discarded appropriately—some items can be poured down the sink, while others will require additional steps for their safe disposal. ISO 15190: 17.1 and 17.3					
12.12 Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized?	Y	P	N		2
Standard: All syringes, needles, lancets, or other bloodletting devices capable of transmitting infection must be used only once and discarded in puncture resistant containers that are not overfilled. Sharps containers should be clearly marked to warn handlers of the potential hazard and should be located in areas where sharps are commonly used.					
12.13 Is fire safety included as part of the laboratory's overall safety program?	Y	P	N		2
	Tick for each item				
	Yes	No	N/A		
Are all electrical cords, plugs, and receptacles used appropriately and in good repair?					
Is an appropriate fire extinguisher available, properly placed, in working condition, and routinely inspected? ISO 15190: 19.7					

Is an operational fire warning system in place in laboratory with periodic fire drills?					
Standard: Electrical chords and plugs, power-strips, and receptacles should be maintained in good condition and utilized appropriately. Overcrowding should be avoided and chords should be kept out of walkway areas. An approved fire extinguisher should be easily accessible within the laboratory and be routinely inspected and documented for readiness. Fire extinguishers should be kept in their assigned place, not be hidden or blocked, the pin and seal should be intact, nozzles should be free of blockage, pressure gauges should show adequate pressure, and there should be no visible signs of damage. A fire alarm should be installed in the laboratory and tested regularly for readiness and all staff should participate in periodic fire drills.					
12.14 Are safety inspections or audits conducted regularly and documented?	Y	P	N		2
Standard: Safety inspections or audits, using a safety checklist, should be conducted periodically to ensure the laboratory is a safe work environment and identify areas for redress and correction. ISO 15190 7.3.1 and 7.3.2					
12.15 Is standard safety equipment available and in use in the laboratory?	Y	P	N	One Star	2
	Tick for each item				
	Yes	No	N/A		
Biosafety cabinet(s) ISO 15190: 16					
Covers on centrifuge(s)					
Hand-washing station ISO 15190: 12.7					
Eyewash station/bottle(s) and showers where applicable ISO 15190: 12.10					
Spill kit(s)					
First aid kit(s) ISO 15190: 12.9					
Standard: It is the responsibility of laboratory management to ensure the laboratory is equipped with standard safety equipment. The list above is a partial list of necessary items. Biosafety cabinets should be in place and in use and all centrifuges should have covers. Hand washing stations should be designated and equipped and eyewash stations (or an acceptable alternative method of eye cleansing) should be available and operable. Spill kits and first aid kits should be kept in a designated place and checked regularly for readiness. ISO 15190: 5.2					
12.16 Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and	Y	P	N	One Star	2
Standard: Management is responsible to provide appropriate personal protective equipment—gloves, lab coats, eye protection, etc. — in useable condition. Laboratory staff must utilize personal protective equipment in the laboratory at all times. Protective clothing should not be worn outside the laboratory. Gloves should be replaced immediately when torn or contaminated and not washed for reuse. ISO 15190: 12					
12.17 Are laboratory personnel offered appropriate vaccination//preventive measures?	Y	P	N	One Star	2
Standard: Laboratory staff should be offered appropriate vaccinations--particularly Hepatitis B. Staff may decline to receive the vaccination, but should sign a declination form to be held in the staff member's personnel file. ISO 15190: 11.3					
12.18 Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures?	Y	P	N	One Star	2
Standard: The laboratory must have a procedure for follow-up of possible and known percutaneous, mucus membrane, or abraded skin exposure to HIV, HBV, or HCV. The procedure should include clinical and serological evaluation and appropriate prophylaxis. ISO 15190: 9					
12.19 Are occupational injuries, medical screening or illnesses documented in the safety occurrence log?	Y	P	N		2
Standard: All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented. ISO 15190: 11.3					

12.20 Are drivers/couriers and cleaners working with the laboratory trained in Biosafety practices relevant to their job	Y	P	N		2
Standard: All occupational injuries or illnesses should be thoroughly investigated and documented in the safety log or occurrence log, depending on the laboratory. Corrective actions taken by the laboratory in response to an accident or injury must also be documented. ISO 15190: 9					
12.21 Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including the training of other staff?	Y	P	N		2
Standard: A safety officer should be designated to work with the laboratory manager to implement the safety program, monitor the ongoing safety conditions and needs of the laboratory, coordinate safety training, and serve as a resource for other staff. This officer should receive safety training. ISO 15190: 17.2					
SECTION 12: FACILITIES & SAFETY Subtotal					43

11.5 Annex v: ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical Conduct of the research project and for provision of required progress reports as Per terms and conditions of the Research Publications Office in effect at the time of Grant is forwarded as the result of this application.

Name of the student: Yalemzewoud Ayalew Desta

Date._____ Signature _____

Approval of the primary Advisor

Name of the primary advisor:_____

Date._____ Signature _____