QUALITY OF SELECTED IMMUNOLOGICAL AND IMMUNOHEAMATOLOGICAL TESTS IN CLINICAL LABORATORIES IN KIAMBU COUNTY, KENYA

LILLY ALICE MURUGI NJUE MSc. (Molecular Medicine)

P97/20977/2020

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF DOCTOR OF PHILOSOPHY IN MEDICAL LABORATORY SCIENCES (IMMUNOLOGY) IN THE SCHOOL OF HEALTH SCIENCES, KENYATTA UNIVERSITY

APRIL 2025

DECLARATION

This thesis is my original work and has not been presented for an award of a degree or other award in any University.

Name: Lilly Alice Murugi Njue

Reg. No: P97/20977/2020

Signature: ..... **Date:** 7th April 2025

Supervisors:

This thesis has been submitted for examination with our approval as the University supervisors.

1. Dr. Margaret Muturi

Department of Medical Laboratory Sciences

Kenyatta University

Signature: ..... **Date:** 07-04-2025

2. Dr. Nelson Menza

Department of Medical Laboratory Sciences

Kenyatta University

Signature: ..... **Date:** 7/4/2025

3. Dr. Stanley King'e Waithaka

Department of Medical Laboratory Sciences

Mount Kenya University

Signature: ..... **Date:** 07/04/2025

DEDICATION

I dedicate this work to my supportive late father-in-law, Mr. James Njau Gitau; my husband, Mr. John Kiranga Njau; my children, Joy Wanjiru and Benjamin Njau; my mother, Mrs. Eudias Wanjiku Njue and my lovely nephews; Alvin Karani and Eugene Njau who are my great pillars of strength and support.

ACKNOWLEDGEMENTS

I am deeply grateful to God for everything. My heartfelt appreciation goes to my supervisors, Dr. Margaret Muturi, Dr. Stanley King'e Waithaka, and Dr. Nelson Menza, for their inspiration, support, and guidance in completing this thesis. I also extend my gratitude to my Ph.D. classmate, Mrs. Susan Githii, for her invaluable input and collaboration.

I am indebted to the laboratory personnel and healthcare workers who provided the data for this study and appreciate their sacrifice. Special thanks go to the laboratory staff in Kiambu County, including sub-county heads Dorcas Karanja, Jennifer Njagi, and Nicholas Muraguri. I also acknowledge the supportive staff at the Kenya Medical Training College Nairobi Campus Medical Laboratory Science Department, particularly Dr. Nyamai Munyoki, Davies Ndegwa, Elloys Sigei, and Japheth Walutila.

I sincerely thank the National Commission for Science, Technology, and Innovation (NACOSTI) for permitting me to conduct this research. Special appreciation goes to Dr. Beatrice Nesidai Kithuka for believing in my ability to complete this work. I am also grateful to my data analyst, Emily Nyanumba, for her dedication during data analysis.

A special mention goes to my elder sister, Dolly D. Mavutta, for her unwavering support. My appreciation also extends to Kiambu County Chief Medical Laboratory Technologist, Mr. David Nduati. Lastly, I thank my family and friends for their intellectual, emotional, physical, and spiritual support. Your contributions are truly valued. God bless you all.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS:	Acquired Immune Deficiency Syndrome
AMR:	Analytical Measurable Range
ASOT:	Anti-Streptolysin O Test
CBC:	Complete Blood Count
CBO's:	Community based organizations
CL:	Confidence Level
CLIA:	Clinical Laboratory Improvement Amendment
CQI:	Continuous Quality Improvement
CRP:	C-reactive protein
CV :	Coefficient of Variation
DNA:	Deoxyribonucleic Acid
EDL's:	Essential diagnostic list
EID:	Early Infant Diagnosis
ELISA:	Enzyme-Linked Immunosorbent Assay
EQC:	External quality control
GCLP	Good Clinical Laboratory Practice
GHI:	Global health Initiative
FGD:	Focused group Discussions
HB:	Haemoglobin
HB A1c:	Glycated haemoglobin
HBSAG:	Hepatitis B Surface Antigen
HBV:	Hepatitis B Virus
HC:	Health Centre

HCG:	Human chorionic gonadotropin
HIV:	Human Immunodeficiency Virus
ICC:	Intra-class Correlation Coefficient
IgM:	Immunoglobulin Mu
IT:	Information Technology
ISO:	International Standard of Operation
KEMRI:	Kenya Medical Research Institute
KMPDB:	Kenya Medical Practitioners and Dentist Board
KMTC:	Kenya Medical Training College
KMLTTB:	Kenya Medical Laboratory Technicians and Technologists Board
KNH:	Kenyatta National Hospital
LM's:	Laboratory Managers
LQMS:	Laboratory Quality Management System
MDGS:	Millennium Developmental Goals
MLT:	Medical Laboratory Technologist
NACOSTI:	National Commission for Science, Technology and Innovation
NGO's:	Non-Governmental Organizations
NPHLS:	National Public Health Laboratories
OEE:	Overall Equipment Effectiveness
PDT:	Pregnancy determination test
PHC:	Primary Health Care
POC:	Point of care
PPP:	Private Public Partnerships

PSA:	Prostatic surface Antigen
QA:	Quality Assurance
QC:	Quality Control
RA:	Rheumatoid Arthritis
RF:	Rheumatoid Factor
RICT:	Rapid Immuno-chromatological Test
SAT:	Salmonella Antigen Test
SOPs:	Standard operating procedure
SLTA:	Strengthening Laboratory towards accreditation
TAT:	Turnaround Time
TLA:	Total Laboratory Automation
TTP:	Total Testing Process
TQC:	Total Quality Control
TB:	Mycobacterium tuberculosis
UHC:	Universal Health Coverage
UK:	United Kingdom
VDRL:	Venereal disease research laboratory
WHO:	World Health Organization
WTTM:	Weighted Tube Touch Moment

ABSTRACT

Laboratories play an indispensable part in preventing and controlling diseases by ensuring availability of well-timed and accurate results for the treatment and management of patient's conditions by providing essential diagnostic information that guides treatment decisions and overall patient care; ranging from diagnosis of disease, Monitoring Disease Progression, Guiding Treatment Decisions, Assessing Organ Function, Screening and Preventive Care, Quality Control and Assurance and Patient Education and Counselling. This obligation spread out to giving disease surveillance statistics. Despite the critical role that immunological and hematological play in patient diagnosis and management, there is limited research on the quality of these tests in relation to the skills and competencies of laboratory personnel in Kiambu County, Kenya. Existing literature may focus on general laboratory practices or specific testing methodologies but often overlooks the interplay between personnel competency and test quality. To guarantee the production of high-quality laboratory information medical diagnostic laboratories need to adopt Good Clinical Laboratory Practices (GCLP). However, many diagnostics laboratories in limited resources settings do not receive enough technical and financial support. Participation in quality management undertakings is often costly for many regular clinical diagnostic laboratories; hence, most level two (2) and three (3) laboratories do not participate. This study aimed at evaluation of the quality of diagnostic results generated by clinical laboratories in Kiambu County by the assessment of accuracy, reliability and precision of test results from standard Immunological and haematological control samples from partaking laboratories. Laboratory personnel qualifications, training, and proficiency while conducting the tests was evaluated and healthcare workers' opinions on the quality of the laboratory services were also assessed. This study was a multi-site descriptive cross-sectional study involving a total of 38 laboratories from entirely all levels, and 76 laboratory workers. Five focused group discussions were conducted with the healthcare workers. Data to compare the difference of haematological profiles was analysed using Mann Whitney U test while comparison between the profiles was tested using Kruskal-Wallis test. The reliability of each single cell type was done using Mann Whitney U test. Laboratory personnel competency was analysed using content analysis method of the interviews, documentation and observation if they were following the guidelines. Healthcare workers' views were analysed using thematic analysis. The analysis of the findings was done at 95% confidence level ($P<0.05$). The findings showed that the comparison of laboratory results none of the comparisons show a statistically significant difference between the control and the laboratory results, with all ($P<0.005$) Individual hematological profiles the all the p values were greater than 0.005($P>0.005$) therefore the results showed a significant difference with those of the control. The immunological tests the CD4 cell count were precise together with CRP results. The laboratory personnel were competent and skilful. Most healthcare workers had a good perception on the laboratory services quality. Customer satisfaction surveys should be done regularly in each laboratory and ways of reducing the dissatisfaction level designed and implemented promptly.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

International Standard of Operation (ISO) defines quality as the number of features of an article that bear on its ability to meet the stated and inferred requirements. It is associated with consistency, which is, repeatedly providing the same product or service, thereby making the outcome more predictable. Quality assurance implies creating certain, guaranteeing the realization of quality (Ibrahim, 2020). Exactness of test results, improved assurance of patients, physicians, and communities at large in the relation to laboratory testing, is a product of ensuring laboratory quality standards are met which in turn inform the management of the patient (Okezue *et al.*, 2020).

Medical diagnostic laboratories are at the Centre of preventing and controlling diseases through provision of timely and accurate results for patient management, these results are also useful for disease surveillance, which helps to preserve lives (Plebani, 2024; Younes, 2020; Tadeu and Geelhoed, 2018; Pellings, 2015). Quality laboratory service is a very fundamental part of the healthcare system (Shumbenj, 2020). Most recently, healthcare establishments in Africa have ordered the quality of laboratory services by executing quality management systems (QMSs) through constructing quality improvement actions in their organizations (Girma, et al., 2020). To identify reasons for the poor laboratory services and also the gaps that need further improvements especially in sub-Saharan African countries, evaluation of the extent of application of laboratory quality management systems is very vital. It is apparent the need for quality diagnostic services is necessary, however, the

admittance to quality and dependable laboratory services in this area has remained a major setback because of limited resources (Nayupe *et al.*, 2023). The strength of any healthcare system is greatly influenced by the availability of its workforce their abilities, proficiencies and their value systems. Thoroughly educated and competent laboratory technologists guarantee precise and consistent results are obtainable for prevention, diagnosis, care and treatment of various diseases (Fonjungo *et al*., 2013). Measurable variables for Quality assurance (QA) in a clinical laboratory include the quality of teaching and education of the laboratory workers, the apparatus in use, the specimen quality, and the techniques' suitability (Giavarina & Lippi, 2017; Plebani, 2020). When the laboratory services are not available, healthcare workers depend on medical signs and indications to treat their patients, which may be inaccurate since signs and symptoms of diseases are non-specific that is why quality laboratory services to patients are very importance and also because misdiagnosis may cause improper use of drugs, avoidable hospital admissions and deprived patient management and public health consequences (Odhiambo *et al*., 2023). The safety of the patient is inclined to the rate of recurrence and gravity of errors occurring in the healthcare systems (Plebani, 2020; Lippi, 2017).

Studies have reported that the health care systems in the Sub-Saharan Africa (SSA) are the worse than any other part of the world at large (Tessema *et al*., 2022; WHO, 2020). Specifically, it is documented that many laboratories turn to inferior work which is disorganized and dubious resulting in erroneous diagnosis of patients (Ishengoma *et al.,* 2009; Kenya *et al*., 2012). In spite of the efforts put in place of forming the board for accreditation and licensing (MOH, 1999; MOH/KMLTTB,

2005) there is still a major challenge to compliance and validity of several documented assays, especially those that don't obligate to funded programs or performance policies for instance TB and HIV/AIDS in Kenya (Ondoa *et al*., 2017; Njoroge, 2014; Legido *et al.*, 2013). Medical diagnosis that is inaccurate and unreliable has increased the opinion that laboratory testing is not necessary and this may lead to substandard patient care. Some of the major setbacks of quality laboratory services in under-developed locations include infrastructure that are weak, qualified personnel unavailability, and lack of putting into practice of laboratory policies, strategic ideas and integrated national quality management systems (Carter, 2017, Vitoria *et al.*, 2009, Biadgo *et al.*, 2019).

C-reactive protein (CRP) was earliest discovered by Tillett and Francis in 1930. They gave the name CRP because it was initially identified as a substance in the serum of patients having acute inflammation that countered with the "c" carbohydrate antigen of the capsule of pneumococcus. CRP is a pentameric protein produced by the liver, whose level augments when there is inflammation process in the body. Being an acute-phase reactant protein it is predominantly prompted by the cytokine IL-6 action on the gene responsible for the transcription of CRP during the acute phase of an inflammatory/infectious process (Khanmiri *et al*.,2023).Studies have shown that CRP has shown some protective properties in animal studies on lung tissue in alveolitis through reducing neutrophil-mediated damage to the alveoli and protein leakage into the lung(Nehring *et al*.,2017).

When CRP test is compared to the erythrocyte sedimentation rate, which is an indirect test for inflammation, the levels of CRP increase and decrease rapidly with the commencement and elimination of the inflammatory stimulus, respectively. Persistently high CRP levels can be seen in chronic inflammatory conditions like chronic infections or inflammatory arthritis such as rheumatoid arthritis, Cancer indication and in cases of heart attack prediction (Buch *et al.*, 2024:Schwartz *et al.*,2017).

Current research proposes that patients with elevated basal levels of CRP are at a higher risk of diabetes mellitus, hypertension and cardiovascular disease (Schakelaar *et al.*,2023). And therefore, CRP is becoming one of the commonly requested tests in clinical laboratories since also it is a useful test to screen for diseases and as a measure of the efficiency of treatment (Plebani,2023;Brown *et al.*, 2023).

CD4 T cells do a wide-ranging of functions both in innate and adaptive immune system(MacLeod *et al.*,2006). Inside the adaptive immune system, they are best known for their role as T helper (Th) cells, including Th1, Th2, Th17, and regulatory T-cell (T_{reg}) subclasses. Considerably, CD4 T cells authorize dendritic cells (DC) to permit optimal instructing of CD8 T cells, deliver crucial signals for immunoglobulin isotype class switching, stimulate bactericidal action of phagocytes, recruit neutrophils, stimulate angiogenesis, and secrete cytokines, additionally to possibly having direct cytotoxic functions (MacLeod *et al.*, 2009). Correspondingly, CD4 T cells give the impression to have noteworthy plasticity, permitting subsets to changeover amongst one another, enlarging their functional impact. The CD4 cell

count is of great importance especially to help healthcare workers manage HIV/AIDS condition which is a disease of great medical importance (McBride and Striker,2017). In recent studies CD4 has also been indicated with exhaustion especially in patients with various types of Cancers (Miggelbrink *et al.*,2021).

External quality assessment (EQA) also known as proficiency testing is an assessment carried out by an external independent organization on the performance of a number of laboratories with the provided proficiency testing panels to screen each laboratory's outcomes and identify the ones that need training or corrective processes to increase their performance (Milinković *et al*., 2018; Zima 2017). It also refers to a technique that permits testing being carried out by a laboratory, testing location or distinct operator to be likened to that of a source external of that laboratory (WHO, 2016).

External Quality Assurance (EQA) is one of the excellent ways to monitor the outcome of individual laboratories in relation to the performance outcomes of other laboratories under scrutiny (Plebani & Sciacovelli, 2017). EQA is very necessary for monitoring laboratory performance and ensuring quality laboratory service standards are maintained, it is also a valued benefit for becoming aware of and evaluating technology in use, detecting flaws in laboratory performance; they are also tools for improvement and targeting training requirements (Duan *et al*., 2019; Carter, 2017). Continually striving to identify and enhance the results of the quality indicators by doing remedial actions over a period of time will without doubt aid to increase the quality of laboratory services and health care of the patients (Van Hoof et al., 2022).

The World Health Organization (WHO) vouch for especially in malaria endemic countries those in Sub Saharan to apply comprehensive external quality assessment (EQA) as an emphasis of EQA which ensures that Malaria diagnosis is quality in this region (WHO, 2016; Yitbarek *et al*., 2016). The precision of microscopy is analytically reliant on the quality of blood smear provision and the staining procedures for the reason that ill-prepared and/or stained blood films openly decreases interpretation accuracy irrespective of the professional analysis skill (Kalinga *et al*., 2020; Dhorda *et al*., 2020).

Even with the availability and well-known importance of External Quality Assurance programs for testing and monitoring immunological tests only a few African laboratories engage with the several well renowned international external quality monitoring institutions in comparison with other non-African Countries (Ondoa *et al*., 2020; Younes, 2020). The most important user of laboratory services is well thought-out to be the patient and the clinician (Wesolowski and Roseff, 2024). Today with the world focus on customer satisfaction which is a multidimensional and all-embracing idea; various variables can directly or indirectly have an effect on customer satisfaction and hence influencing customer allegiance during the course of the customer cycle of life (Shokouhyar *et al*., 2020). Customer satisfaction monitoring and evaluation is important and a valuable tool for ensuring clinical laboratories and health care institutions increase the quality of their services (Di Fazio *et al*., 2023; Van Hoof *et al*., 2022; Alain *et al*., 2021). Based on literature good quality is a factor decided by the producer and has an effect on the item's and service consumption by

the user. Service quality has a helpful and noteworthy influence on purchase decision (Feinberg and Wooton 2020).

Clinical laboratory division in public and private hospitals and primary health centres measures quality using several indicators one of them being trust (Abebe *et al*., 2023). Trust has been observed as a key influencer of purchasing ability of consumer of product and services (Amin *et al*., 2020; Rupprecht *et al*., 2020). Since the healthcare workers are the immediate customers for most laboratory services (Rusanganwa *et al*., 2020), the perfect situation, they should rely on quality laboratory information for making confirmation their medical decisions (Nkengasong *et al*., 2018; Tuijn 2014), however, it is not always the case because the healthcare workers have a formed mind-set on the dependability of laboratory results (Abebe *et al*., 2023). Physician's indicates that reliability of laboratory result is the most important measure of quality (Abebe *et al*., 2023; Wu *et al*., 2020). Reliability as a measure of quality is demonstrated by the exceptional performance on an on the outside authentication fixed that is completely self-governing of the in-house validation process, attention of the sensitivity, specificity, and general precision of an analytical method (Wu *et al*., 2020). For laboratories to enhance the quality of results with efficiency they undertake accreditation which is the practice that guarantees that certification carry out are executed (Kavak *et al*., 2020).

Accreditation also assists the involved laboratories to increase technical methods, attain reasonable benefit and help rise the marketplace stake (Gawor *et al*., 2021). To attain accreditation, it is necessary to successfully implement the laboratory quality

management system (LQMS) (Okezue *et al*., 2020). Some of the requirements for accreditation also include having well trained laboratory staff and the training needs of the staff are evidence based and assessed by evaluation of their competency and evaluated through the staff performance in order to sustain the laboratory as a world class type of service. Financial resources and motivated staff are important to attaining quality service in any institution (Beyanga *et al*., 2018). While benchmarking for services improvement quality indicators are paramount (Willmington *et al*., 2022).

Furthermore, quality has been identified as one of the keys to ensuring continuous improvement of healthcare services (Breyer *et al*., 2019). In clinical laboratories specifically expounding Laboratory quality management system (LQMS) are necessary to help understand the present-day standard necessities of quality system application and looking after to increase the quality of service of the laboratories and aid certification (Okezue *et al*., 2020). Decline in quality services could be due to the failure of implementation of quality management systems and therefore the necessity for accreditation which ensures unceasing improvement. Continuous improvement is a crucial part of quality and so consequently for each and every organization that is concern about quality should be able to establish institutional values of continuous quality improvement (CQI) on the way to accreditation and ensuring the quality health care is attained (Rusanganwa *et al*., 2019) Routine shortcomings examination and preparation for improvement by means of a system approach is prerequisite for and ensuring that in-service training of quality management is made mandatory for

the personnel working within the laboratories at all levels are necessary in order to achieve CQI (Ong *et al*., 2020).

In Kenya according to Kenya Medical Technicians and Technologists Board (KMLLTB) classification schedule, April 2016 laboratories have been classified into six (6) classes based on the tests done and the techniques available, staffing level and the availability of basic requirements. The lowest level is the class B (Dispensary/medical Clinic), Class C (health Centre clinics/medical Centre),Class D District Hospital/Nursing Homes), Class E (County Hospital/Primary) Class F (Referral, Teaching and Research Hospitals) class G (International and National Referral and Clinical Research Laboratory) in this study the laboratories that were involved only included Level C,D and E (MOH/KMLLTB,2024)

Laboratory personnel play a crucial role in the accuracy and reliability of immunological and immunohematological tests. Their skills, training, and overall competency can significantly impact the outcomes of these tests, as well as the procedures followed during testing, which includes safe work performs, sample or data collection, preparation of specimen, quality equipment's and reagents, valuation and examination, recording and reporting, infection control, quality management, critical thinking skill, communication and collaboration, and skilled practice this are domains that are used to evaluate the competency any laboratory personnel all over the world (Kumar *et al*., 2024).

1.2 Statement of the Problem

Laboratory guidelines on quality assurance measures have been developed for specific laboratory tests in funded programs like HIV/AIDS, TB and Malaria however there is a challenge for other tests that lack funding(Sexton *et al.*,2020)). The result of this is that most laboratories, especially tertiary and privately owned cannot verify that their results are accurate. There is inadequate information concerning the participation of diagnostic medical laboratories on internal and external quality control and the quality of the laboratory results. How often laboratory errors occur and how many erroneous results are received by healthcare workers, and further their perception on the quality of laboratory results offered to them in Kenya have not been documented. The impact of these errors on the patients is not well known either. Furthermore, the competency and skill of the laboratory personnel, who are the key players in the diagnosis, have not been well identified too. To specify and overcome these difficulties, this study identified the inconsistency of results produced using diverse diagnostic machinery and techniques for immunology and haematological and then revealed the effects of these on the general quality of results.

1.3 Justification

To meet the diagnostic needs of patients, the Ministry of Health must provide quality medical laboratory services for everyone and ensure that healthcare workers are up to date with patient care practices. Kenya National Accreditation Service has come in handy but unfortunately it focuses on verifying a conformity evaluation of a section's competency to perform particular tasks rather than the overall performance of the laboratory. It is possible for a laboratory to be accredited only in some section because

of the cost of acquiring the accreditation. Furthermore, findings on participation of clinical laboratories on quality control programs and activities has not been documented in Kenya and whether they are available or not is not well known. Errors on in diagnosis may seriously impact patients. The laboratory personnel's competence gives the best chance for implementing quality. Competency is developed by education and training, and competent laboratory staff who are highly motivated. The patient and the healthcare workers are the primary consumers of laboratory services. This study was done in a number of clinical laboratories in Kiambu County, the County with the greatest number of KMLTTB listed laboratories. The results of this study revealed apparent gaps, the central requirements for implementation of quality laboratory systems and the required corrective measures.

1.4 Research Questions

1. What is the difference between the test results from external quality control materials for haematological tests and those obtained from a selection of clinical laboratories in Kiambu County?
2. What is the precision of selected immunological test results obtained from selected clinical laboratories from Kiambu county of Kenya?
3. How proficient and skilful are laboratory personnel toward quality laboratory services delivery in Kiambu County?
4. What are the healthcare workers' views on the quality of laboratory services in Kiambu County?

1.5 Study Objectives

1.5.1 General Objective

To evaluate the quality of selected immunological and immunohaematological tests in clinical laboratories in Kiambu County, Kenya.

1.5.2 Specific Objectives

1. To compare the difference between the test results from external quality control materials for haematological tests obtained from a selection of clinical laboratories in Kiambu County.
2. To assess precision of selected immunological tests obtained from a selection of clinical laboratories in Kiambu County.
3. To evaluate laboratory personnel proficiency and skilfulness toward quality laboratory services delivery in Kiambu County.
4. To evaluate the healthcare workers' views on the quality of laboratory services in Kiambu County.

1.6 Significance of the study

The quality of immunological and haematological tests, along with the skill and competency of laboratory personnel, are critical components in ensuring accurate diagnosis and effective treatment of various medical conditions. In Kiambu County, Kenya, the significance of this study lies in its potential to identify gaps and areas for improvement in clinical laboratory practices, ultimately enhancing healthcare outcomes.

Accurate immunological and Haematological is vital for the diagnosis and management of diseases such as bacterial infections, viral infections, parasitic infections, cancers, heart disorders, autoimmune disorders, and haematological conditions. High-quality testing reduces the risk of diagnostic errors, which can lead to inappropriate treatments and poor patient outcomes. The study results will ensure that patients receive reliable diagnoses and appropriate care. The competency of laboratory personnel plays a crucial role in the accuracy of test results. Skilled and well-trained personnel are essential for correctly performing complex immunological and immune cells differential counting.

Improved laboratory practices lead to better disease surveillance and control, ultimately contributing to the overall health and well-being of the population. By highlighting areas for improvement, the study can inform policy decisions and resource allocation to strengthen laboratory services in the region. The findings provided valuable insights for improving diagnostic accuracy, enhancing patient care, and strengthening public health systems in the region. Furthermore the study findings are helpful in informing policy decisions, and guiding future research. It is crucial to understand that these findings have their potential to positively influence health outcomes and inform strategic planning in the field of laboratory Medicine.

1.7 Scope of the study

This study assessed the quality of selected immunological and haematological tests and the skill and competency of laboratory personnel in clinical laboratories in Kiambu County, Kenya. It evaluated the accuracy, reliability, and consistency of

commonly performed tests. The study also assessed the qualifications and proficiency of laboratory personnel by evaluating their educational background, ongoing professional development, and practical skills through direct observation and interviews. Additionally, it will investigate laboratory practices and infrastructure, focusing on equipment maintenance, quality control measures, and adherence to safety protocols to identify gaps that may impact test quality and personnel performance.

By exploring the relationship between test quality, personnel competency, and patient outcomes, the study determined how diagnostic accuracy influences treatment and health outcomes. The ultimate goal was to provide actionable recommendations to improve laboratory practices, enhance personnel training, and to improve patient care in Kiambu County, by ensuring reliable diagnostics and better healthcare delivery.

1.8 Limitations and delimitation of the study

These study was piloted in laboratories wherever the personnel gave their informed consent therefore those who did not consent their views were not included in the study. The study also was purposively limited to Kiambu County in selected healthcare facilities with the assumption that it would be a representation of the situation of all the laboratories in the country and that they would be a representation of the situation in the county too. The laboratory performed the panel of tests just once and therefore the assumptions that all other runs would give similar results. Only the current laboratory manager and one laboratory personnel per facility were selected to provide information and perform the tests hence the limitation to those individuals' opinions and performance despite the fact that other personnel and managers could

have a varied opinion if it was another staff. The tests done depended on individual laboratories with their available methods and so the methods varied from laboratory to laboratory. Although other personnel inside the similar facility may have had varied views regarding quality, interviewing all the workers in any selected health facility was impossible. Only selected laboratories were observed and not all for the observation checklist and the assumption was that those observed were a representative of all the others. Focused group discussions by the healthcare workers varied in numbers from 5-20 members and the training specialties from facility to facility and also only a representative participated and therefore also then the opinions and deductions could be varied and subjective biased and objective.

CHAPTER TWO

LITERATURE REVIEW

2.1 Background information of Medical Laboratory

Clinical diagnostic laboratories accomplish a very serious role in the healthcare system (Alharbi *et al*., 2023). Approximately 60–70% of clinical decisions made are enabled by objective medical data received from clinical diagnostic laboratories (Mcpherson, 2017) nevertheless, confirmation supporting this claim is not well illustrated and laboratories are still deficient of visibility, notwithstanding their indisputable need on patient upkeep and public health (Olver *et al*., 2023).

One of the critical importance's of clinical diagnostic laboratories is provision of timely and accurate results for patient management, which are also useful for prevention and control of diseases (Gulati *et al*., 2022; Tripathi *et al*., 2020; Lippi and Plebani, 2020). In fact, clinical diagnostic laboratories are usually the first to identify, and by the end of the day isolate a first-time microorganism or a re-emerged pathogen (Ball *et al*., 2024). This mandate extends to support disease surveillance when the laboratory confirms the presence of the queried cases (Xu *et al*., 2017; Aarestrup and Koopmans, 2016). The drug prescription choice on the best treatment for the patient is largely dependent on the microbial isolates obtained from the laboratory diagnosis. Infection control guidelines are also developed based on population susceptibility data obtained from the clinical diagnostic laboratories from which the antimicrobial resistance trends at any given point in time are determined, which powers in addition the development of working standard treatments practices (Gandra, 2016). It is worth to note that by the use of molecular investigation of world-wide collections of

microbial isolates contributes to an understanding of evolutionally progression, the circulating resistant strains and the environmental and genetic components (Gagneux, 2018; Aarestrup and Koopmans, 2016; Gandra, 2016).

Another role of clinical laboratories is to assist other health departments in meeting regulatory requirements (Church& Naugler, 2019;RA,2017). This pattern shift has been motivated by administrators and financiers seeking to realize resource effectiveness and to follow practice to the requirements of automation as well as the adoption of automatic medical registers (Waring *et al*., 2020). Meeting regulatory requirement is difficult for an organisation because often knowledge in laboratory quality-management systems is not always given emphasis to at the native public health organization, specifically in those facilities that deliver only accepted tests to upkeep on-site patient care (Cornish *et al*., 2021; Wilson *et al*., 2018).

The National Public Health Laboratories (PHL's) gives to the local laboratory systems by giving both quality-assurance knowledge and technical support, classical quality control instruction manual, standard operating procedures(SOPs), and also in-house proficiency-testing program that are helpful in ensuring quality performance of various laboratories under them (WHO, 2020) This local laboratory system helps to improve quality of testing performed in area public health agencies, particularly country public health clinics (Manual, 2021). Other important roles of both national and regional PHLs comprise training of working laboratory workers and accommodating postdoctoral scholars and medical student and also PHLs work as

provender to the national laboratories, such as the Centers for Disease Control (CDC) and deterrence (Lehmann *et al*., 2018).

It is as well essential to note that practicing clinical microbiologists working in clinical laboratories, together with healthcare workers, play a critical role which is the detection of microbial agents linked with bioterrorism in partnership with the government, national organizations and law execution agencies they support to define when a bioterrorism event has happened (Pal *et al*., 2017). The crucial responsibilities of the clinical microbiology laboratory are to be conversant with the likely agents of bioterrorism when there is a risk of bioterrorism and to be ready to use the Level A laboratory algorithms aimed at the recognition of these bioterrorism microbial agents (Walper, 2018).

The final point operational and affordable laboratory techniques are a foundation stone of any Country's capability to examine biological happenings in mandate to put on evidence-based control of identified diseases and from the laboratories to prevent and control the unintended or cautious release of pathogens to the environment (WHO, 2017). This is achieved by development and improvement of methods to systematically manage bio risk in laboratory settings by use of known national governing frameworks (WHO, 2022; Studzinski & Pasteur, 2020). They ensure that the laboratory workers are also harmless and safe at work environment and facility to inhibit accidental or deliberate discharge of infectious agents to safeguard laboratory personnel, patients, community and the surroundings (Ishaque *et al*., 2021; Cornish *et al*., 2021). Clinical laboratories cultivate and use appropriate training or capability

development programmes and relevant materials to comprehend, implement and apply bio-risk management policies within their set-up (Bowolaksono *et al*., 2021).

2.2 Competences and availability of medical laboratories services

Medical diagnostics laboratory services are delivered by a wide variety of players in Kenya, who include private or individual owned facilities, faith-based and public health facilities Community-Based Organizations (CBOs) and Non-Governmental Organizations (NGOs), (Kingangi, 2018). Kenya Medical laboratory technicians and technologist board (KMLTTB) is the regulatory Organ that helps register and regulate all these facilities, it is well documented that the public health systems account for about 51% of the laboratory facilities in Kenya (Maina *et al*., 2019). Medical laboratories are grouped into various categories which include level 1, that are dispensary facilities, level 2 that are the health Centres, level 3 that were formerly the sub-district hospitals, level 4 that were the former district facilities, level 5 the previous provincial and level 6 that are national otherwise referral facilities (Karijo *et al*., 2021; MOH/ KMLTTB, 2002; Njoroge *et al*., 2014).

The classification is essentially the devolving administrative structures transferring from the national and county levels despite the fact that this has caused a lot of teething problems which are being addressed (Kimathi, 2017). Classification by the KMLTTB categories them into five levels which are founded on facility size, the classification level of hospital covering the laboratory facility that is connected with, and the government processes (Bahati *et al*., 2021).

Several studies done in East African region, to investigate laboratory capacities and capabilities like one done in the Tanga region of Tanzania and another in Kenya involving private and government practice, including socioeconomic perspectives, indicated that for a laboratory to deliver quality laboratory services it requires competent laboratory management in place and good leadership (Ishengoma *et al*., 2009; MOH/AMREF, 1999; Njoroge, 2014) and that the laboratories need managers who can effectively use available resources in the changing healthcare environment (Sayed *et al*., 2018). These leadership skill of utilizing limited resources in the laboratory is required to actualize beneficial changes in the high level and complex healthcare settings and produce effectiveness across all the disciplines; although, most laboratories managers are not skilled to function as effective laboratory managers (Renner *et al*., 2019).

In yet another study done in Kenya to investigate the capacity of laboratories indicated that the testing and reporting capacity was still very low and therefore in order to improve reliability and reporting of routine laboratory test recording then it was necessary to allow right of entry monitoring and exploitation of laboratory testing from corner to corner of the Nation (Bahati *et al*., 2021) this is in contrast with the report by WHO of the demarcated three classifications of essential diagnostic list (EDL) for Universal Health Coverage(UHC) at Primary Health Care(PHC), where they stated that entirely the common basic tests were offered in the different checked out facilities in three counties of Kenya. However, they pointed out that for the specific disease and infectious diseases particular tests there were detectable gaps in their obtainability. On top of the common infrastructural, technical,

human resource deficiencies, it was disclosed that merely in 3% of the facilities studied to be specific, the more advanced ones, all the actual disease molecular-based and infectious diseases particular tests were available (Samuel *et al*., 2020).

2.3 The Laboratory Services Quality Systems

It has been reported that quality assurance involves to the entire diagnosis process, which starts and finishes with the patient (Konieczka and Namiesnick, 2018; WHO, 2016; Mitre, 2016; Shahangian *et al*., 2009). The quantifiable variables of quality of laboratory services includes the training and the quality of training and the learning of laboratory workers, how suitable are the methods under use, the quality of the reagents, samples, and apparatus (Giavarina & Lippi, 2017; Plebani, 2020). It has been highlighted in clinical pathology, that a product or service is quality if the result is precise, it is done on the exact specimen from the defined patient, it has been delivered on time, it is correct, and also when it has been correctly interpreted (McPherson, 2017; Rahman, 2014; CLSI, 2004). The term accuracy is used to make reference to results of a single analyse measurement being able to show agreement of its closeness between the results obtained and the true value's requirements implementation (Dean, 2019; UK Standard of Microbiology, 2015; Federal regulation, 2010; Westgard, 2008).

The establishment of the $63 billion global health initiative (GHI) which give emphasis to health systems strengthening (HSS) that are geared towards tackling essential health areas, which includes the abandoned tropical diseases, mother to child health, family planning services and HIV/AIDS management (Nkengasong, *et al*.,

2018), though studies in some African countries show that the supporters of health systems have a great influence on choice of where first funds will be channelled to as well as how much money will be allocated, despite hard work to involve the government in formulation of health policies (Nagemi & Mwesigwa, 2020). It has been documented that in resource-poor settings that the laboratory systems and services are often neglected, but it is well known that to end this funding comes in handy to help overcome this challenge, even though finances and budget are the least talked about issue in laboratory policy formulation and system strengthening in sub-Saharan African countries (Ondoa *et al*., 2017). Worth noting is that in majority of Sub-Saharan African countries the clinical laboratory are not accredited and for the ones that are, there is a solid relationship in the middle of country definite accredited laboratory density and per-capita health disbursements (Schroeder and Amukele, 2015).

Studies have strongly correlated accreditation to improved quality of laboratory systems which is usually as a result of enhanced reliability of test results (Okezue *et al*., 2020) and therefore it is necessary to sustainably found quality improvement advantages at facility level with the nation-wide methodologies comprising admittance to a national accreditation authority, implementation of national quality standards and regulatory structures (Odhiambo *et al*., 2023). Despite a noteworthy improvement of quality performance being observed during the whole process of accreditation as in many studies observed yet another study found that, in-adequate experienced laboratory personnel was the main challenge acknowledged in the accreditation process. Consequently, a fitting, workload-based employment

organisation has been recommended in order to develop, increase and put up with medical diagnostic laboratory quality standards in settings with limited resources (Getahun *et al*., 2019).

In the year 2009 program Strengthening Laboratory Management toward Accreditation (SLMTA) was established (WHO, 2019; Nkengasong *et al*., 2018) whose primary mandate is to provide quality management teachings to over hundreds of laboratory workers. Using multiple workshop implementation models SLMTA program aims to work on the collective workforce information gaps in resource-limited settings (Gopolang *et al*., 2021). As a success it is worth noting that SLMTA after working with 1368 laboratories internationally of these 191 (7.16%) of these laboratories have been ISO15189 accredited by the year 2019 (Gopolang *et al*., 2021). Additionally, the fundamental strategy known to progress global health and required to influence the Millennium Development Goals (MDGs) in relation to quality of health services is through provision of accurate and appropriate diagnostic testing (Land *et al*., 2019).

It is worth acknowledging that some countries in Sub Sahara Africa(SSA), for instance Uganda, normally track universal laboratory standards for example the International Organization for Standardization (ISO 15189), Good Clinical Laboratory Practices (GCLP) and Clinical and Laboratory Standards Institute (CLSI), though, the extent to which public laboratories follow to these guiding principles has not yet been evaluated and additionally despite the value of these same practices for their

positive effect on quality of laboratory services in this part of Africa (MOH Uganda, 2019).

An increase in SSA populations and national economies growth has resulted in an ever-increasing middle level population in need of excellent health care services and sufficient diagnostic laboratory services which are at present being looked for in other countries with additional innovative health care services (Kruk *et al.*, 2018). These middle-class populations seeking further and more cutting-edge health care services and diagnosis will empower the establishment of more workable better quality laboratory services and the requirement for acceptable clinical diagnostic and laboratory services will endure to rise throughout the subsequent few years in order to meet the demand (Land *et al.*, 2019). The management of the quality systems includes the use of procedure variables which include safety and proper scheduling which are part of pre-analytical phase (Cadamuro *et al.*, 2018), and hygiene; analytical phase factors like the ease of use of standard operating procedures (SOPs) and post-analytical phase factors like records, calibration, and proper waste discarding (Alghamdi *et al.*, 2021).

In Kenya laboratory service quality was made possible by adoption in the year 2010 the Strengthening Laboratory Management toward Accreditation (SLMTA) program whose aim was to direct laboratory quality enhancements preceding to official approval by the national accreditation body, Kenya National Accreditation Service (Makokha *et al.*, 2022). Audits were done at the commencement and conclusion of the teaching using the SLIPTA checklist to evaluate strong points, flaws, and

improvement made, and centered on the evaluations, clinical diagnostic laboratories were counted from Zero (0) to five (5) stars (SLMTA, 2021; Rusanganwa *et al*., 2018). Laboratories that scoring three (3) stars and beyond were allowed to go ahead to request for commencement of the formal accreditation assessment process (SLMTA, 2021).

Deliberate laboratory quality assurance in Kenya is autonomously managed by KENAS (Bahati *et al.,* 2021) which is a separate entity from KMLTTB, whose major role is to is to regulate of clinical laboratory services in Kenya, KMLTTB is mandated with five central accountabilities: indexing or examination of college students taking up careers in medical laboratory sciences; registration and licensing of all laboratory staff in Kenya; developing policy guidelines for the implementation of the Continuing Practice Development (CDP); and regulation of all In vitro Diagnostics (IVDs) intended for laboratory testing. Most importantly, KMLTTB regulates the conduct, practices and licensing of laboratory dealings in Kenya which is contrary to other recognizable duties notable in other SSA countries and Latin America where the regulatory body does that and also ensures quality of laboratory services (Mazziota, 2009).

Good management of the quality systems has led to good service quality (Fenandes, 2020). The rate of submission to established standards by accreditation organizations using their run-through variables which include the general dimensions of the laboratory and the accessibility of basic amenities like housing which are benchmarks well-thought-out compulsory by regulatory bodies in the delivery of quality service

inside clinical laboratories have been used as the measures of assessment (Makokha *et al*.,2021;Samwel *et al*., 2020; Karthiyayini & Rajendran 2017; Njoroge, 2014). A study done in accredited laboratories in Kenya found out that the key eight (8) factors acknowledged to have been of a great involvement in ISO accreditation encompassed as follows in their order of significance as teamwork, surroundings, organizational structure, staff preparation, communication of findings, QMS documentation and governance (Ombewa, 2018).

Total Quality Management (TQM) put into practise by ISO accredited medical laboratories in Kenya as scrutinized comprised systems founded approach, realistic decision making, technique approaches, organization management assurance, employee participation and constant preparation, constant improvement, and realistic founded judgements in which are in agreement with other departments across the health sector (Ombewa, 2018; Erhard *et al*., 2021). Thirty-two (32) laboratories participated in these Total quality management program and fully adopted total quality management practices, the conclusions were that the participants agreed that the program had a positive influence on the quality and effectiveness of the medical diagnostic laboratories. Those that had fully adopted program had also an ensured attainment of viable benefit which included client satisfaction and a progressive public perception in the decision making on the services offered to them (Ombewa, 2018).

2.4 Quality Control of Laboratory Equipment and Reagents

It has been confirmed that bad quality laboratory services cause needless costs, desolation in human lives and misery, and also erroneous information generation and data in disease occurrence owing to wrong diagnosis (Mesganaw et *al*., 2023). The consequences include misuse of antibiotics for unsuitable medical conditions which may lead to the occurrence of drug resilient microorganisms for example the multi-drug-resistant TB (Gregson *et al*., 2021). In addition, patient well-being is also influenced by the rate of recurrence and gravity of mistakes that take place in the health care organization (Layne *et al*., 2019).

Worth noting is that laboratory automation increases results integrity and decreases manipulation of the same by the staff; it also reduces method development time, turnaround time (TAT), occupational hazards, and, of course, it is associated to economic benefit (Archetti *et al.,* 2017). Therefore, many laboratories have adopted automation (Lippi & Da Rin, 2019). Quality control (QC) of equipment and reagents comprises suitable instrument choice and making sure proper setup, standardization, and instituting of required maintenance mechanisms (Miller & Nichols, 2020). The key factors that influence the selection of a haematology analyser include reliability, cost of the analyser, availability, and turnaround time (Rastogi *et al*., 2022). On the other hand, this is not always possible since quality implementation involves all parts of health systems, as well as government guidelines and resource distribution.

Documented reagent lot-to-lot assessments are commended by approval organizations to guarantee that the performance of separately reagent lot meets necessary criteria for

quality of the patient's outcomes this broad-spectrum approach is consist of carrying out frequent quality control (QC) and the sick evaluation sandwiched amid the from the past and fresh reagent lots and assessing in contrast to a pre-defined standard (To *et al*., 2021). It was also illustrated by a study done in Tanzania and 39 other African countries, up to and including Tanzania, that there was no single clinical diagnostic laboratory that acquired the least necessities for international laboratory standards (Beyanga *et al*., 2018). Worth noting is the Maputo Declaration of 2008 that commended that for the reinforcement of laboratory systems there is a need for partnership between laboratories, governments and supportive partners (Nkengasong *et al*., 2018). This is to be achieved using quality indicators which are well defined that being any degree of the system whereby information gathered in identified season are analyzed to regulate the development of the well-known system (WHO, 2017). Examples of these quality pointers which have been proven to quantity laboratory progress includes participation in the external quality assurance schemes, sum total of consumer grievances, sample turn-around time, number of disallowed samples, equipment interruption and the frequency of contamination of blood culture sample (Nkengasong *et al*., 2018).

2.5 Haematology Analysers

The current situation in many laboratories at various hospitals is that they use haematology systems from different companies which employ not the same technology mechanism; the mechanism may include light absorbance, light scatter or fluorescence to analyze the blood cells (Sayed *et al*., 2018). Studies have revealed that a number of automated techniques are not standardized, and reference ranges are

method/instrument particular therefore the patient results could be compromised by the dissimilarities in technology moreover diverse automated methods use different dyes with varying sensitivities to identify the cells hence reference ranges should be instrument specific., as they vary significantly amid different makes of instruments reference (Briggs,2009).

Worth noting is that there is also speedy growth of the range of parameters produced on automated haematology counters which is partially determined by technological improvements from instrument manufacturers and is also partly determined by shortcomings in existing technology, whereby an existing methodology is not satisfactorily precise, sensitive or reproducible (Sayed *et al*., 2018). Haematology auto analyzers have both 3 parts and 5 parts differential capability (Briggs, 2009). The 3 part differential leukocyte counters, and automated platelet counters were the ones initially brought into the market in 1970's (Brugnara,2015) however they have slowly being faced out by the novel 5-part analyser system uses state-of-the-art imaging technology to count the white blood cells (WBCs) and perform a 5-part differentiation, with the cells being classified into neutrophils, lymphocytes, monocytes, eosinophils, basophils, pathological WBCs (blasts and immature granulocytes), among others (Ragav *et al*.,2021).

2.6 Quality control of Immunologic Tests and Immune-Parameter Tests

Immunological tests make use of an antigen to identify the existence of antibodies to a specific pathogen or antibody to identify the pathogen's antigen in the clinical samples (Britannica T, 2021). The term used frequently to refer to the diagnostic identification

of antibodies in serum is serology normally formed in response to an infection in the body (Whitman *et al*., 2020). These tests methods consist of Rapid diagnostic kits, immunoassays, and precipitation, they are known to be comparatively simple to do; for that reason, majority of laboratories carry out them, for they are fast and cost-effective in contrast to other tests (Filchakova *et al*., 2022).

A common done immunological test in many diagnostic modern laboratories is Flow cytometry which identifies, classifies, and computes a particular specific cell's several physical appearances, that include the dimensions and granularity of cell surface markers, simultaneously as they flow in suspension from a sample (Adan *et al*. 2017). Flow cytometry also defines blood cell counts, including CD4, CD8, HLA typing, and sperm investigation (Mckinnon, 2018). Other immunological tests in use comprise of C-reactive protein (CRP), which remains a more dependable test than the Erythrocyte Sedimentation Rate (ESR) when checking for an inflammatory progression in a patient (Harrison, 2015). CRP is important in diagnosing conditions like sepsis, especially in neonates, and urinary tract infections (Herwald& Egesten, 2021, Mushi *et al*., 2019) and also a variable biomarker (Fazal, 2021). It is good to note that quite a number of constituents of plasma are elevated in the initial few days' subsequent to tissue damage through inflammation, infection, or trauma (Hannoodee & Nasuruddin, 2020). The liver is the main producer of "acute phase reactants" together with other substances like proteins, glycoproteins, lipoproteins which indicate an inflammatory process (Khalil & Al-Humadi, 2020). Cytokines, chemokines, adipose-cytokines, solvable cell receptors, and immune initiation markers perform an essential part in immune reaction and can be responsible for predictive value because they mirror

underlying conditions and disease states by showing deviation from normal (Aziz *et al*., 2019).

The importance of performing immunological tests cannot be underrated, recently with the pandemic of covid-19 the Tumor Department of Union Hospital associated to Tongji Medical College of Huazhong University of Science and Technology and Renmin Hospital of Wuhan University who had managed numerous of COVID-19 infected individuals and gathered wealthy clinical knowledge for the period of the diagnosis and management, bring into being that there were typical modifications in blood routine and immunological pointers of COVID-19 infected persons. The research was done to additional shed light on the laboratory features of the disease, and to direct the clinical medical workers to increase the level of diagnosis and management using serological tests (Yuan *et al*., 2020).

2.7 External Quality control of Immunological Tests

External quality assurance (EQA) similarly acknowledged as proficiency testing is a scheme for independently inspection of the laboratory's routine operations using an outside organization or facility for assessment of applicant performance compared to already well-known measures through means of inter laboratory assessment especially also from known reputable laboratory (Badrick *et al*., 2022). The first external Quality Assurance (EQA) scheme in diagnostic immunology was initiated in 1982 in Korea, which was aimed at proficiency testing for HBsAg and for Treponema pallidum serological tests (Cha & Cho, 2002). They represent a vital approach for relating diagnostic test performance amongst laboratories (Badrick *et al*., 2022, Haselmann,

2020) to enable accuracy and confidence in the results obtained (Stavelin & Sandberg, 2023; CLSI/NCCLS,2004). This will also help obtain a consistent assessment if the laboratory performance attains the obligatory expertise ordinary for patient care, and for facilitating to synchronize investigations techniques (Markey *et al.*, 2019) and to increase the quality of serological analysis (Ast *et al*., 2021).

Proficiency testing has also been defined as the laboratory testing performance through inter-laboratory test assessments determination (Durgut, 2021; Mazziotta, 2009). Inter-laboratory assessment is the establishment, performance, and assessment of tests on the equivalent or comparable test items by double or added laboratories in harmony with already determined circumstances (Perich *et al*., 2020) and it has been evidenced that involvement over time has the prospective to progress participant performance (Ast *et al*., 2021) because it is an important mechanism for attaining synchronization, and consequently an extraordinary quality, of diagnostic procedures. Studies have shown that EQA according to the concept is in control for independent confirmation of laboratory competency and it validates to the community, customers, accreditation bodies, supervisors, and administration that procedures are under control and offers technical self-assurance in the service that the laboratories make available (Stavelin & Sandberg, 2023).

Studies have clearly demonstrated that manual testing techniques have contributed to heightened discrepancies of test results, undoubtedly signifying that the absence of synchronization that is desirable to guarantee quality of serological analysis (Plebani, 2020). For instance, a recent study done on anti-SARS-CoV-2 serological analysis

indicated that prior to application of those results on medical decision making and for approximation of sero-prevalence on people level or even taking on control guidelines to present-day stresses, an optimization and synchronization of tests in use was urgently necessary (Grzelak *et al*., 2020).

In yet another study also pointed out that, for the initial time, experimental EQA scheme exposed a noteworthy variance between testing modalities of the various Ig classes, this could assist laboratories come to be cognizant of intra laboratory and assay detailed limitations as a precondition for an optimized diagnosis (Haselmann *et al*., 2018). This finding have agreed with ISO/IEC 17043:2010 EQA reports that found out that the participants had gaps identified, during the process of verification of trueness of serology tests but after identification of the gaps, the corrective actions were identified of prior to successful implementation of corrective actions (Coucke *et al*., 2020).

2.8 Skill and Competency of Laboratory Personnel

Medical laboratory technologists (MLT) often define themselves as being part of a unseen profession, which make reference to the opinion of little acknowledgment and low outward impact (Grant, 2016). In Canada, the MLT range of operation comprises obtaining and testing patient samples, engaging and deducing suitable measures of quality control (Health Professions advisory Council 2008) and communicating the results to the clinician who had asked for the test. There is an impulse to change from application management to laboratory care. In relation to the aspect of laboratory Care is comprehensive in range and comprises vigilant accountable and oral management

of resources from all-inclusive, value-based perspective (Dickerson *et al.,* 2017). Worth noting is that the National Committee for laboratory stewardship in recent times defined the key components of laboratory stewardship programs (Dickerson *et al*., 2017). The commendations included that laboratory workers at all levels become part of the laboratory developed stewardship programs.

In relation to resource usage interventions, laboratory personnel are exceptionally positioned to talk about laboratory use approvals and support renovated test collation habits by other health care specialists. According to literature review to identify the skill and Competency of laboratory personnel there were identified eighty six (86) capabilities across eleven (11) domains of laboratory personnel, which includes safe work performs, sample or data collection, preparation of specimen, quality equipment's and reagents, valuation and examination, recording and reporting, infection control, quality management, critical thinking skill, communication and collaboration, and skilled practice this are domains that are used to evaluate the competency any laboratory personnel all over the world (Kumar *et al*., 2024).

Clearly pointed out is that sub-Saharan Africa, laboratory services are one of the areas that is greatly neglected of healthcare delivery (Bates *et al*., 2006); it is affected by shortages of staff, absence of teaching, scarce equipment, deprived communication, and little staff optimism (Odoa *et al*., 2017; Schneidman *et al*., 2014). The absence of sustained medical and professional growth impedes progress in laboratory services (Bates *et al*., 2006). Reported in a study done in Tanga, Tanzania, merely 14 (17%) of the eighty-four (84) persons found employed in the laboratories existed as

technologists with an advanced requirement of a certificate or a diploma (Ishengoma *et al*., 2009), detonating that health laboratories are extremely compromised in sub-Saharan Africa (Shumbej, 2020). This state of affairs is comparable to the one in Uganda where from corner to corner of the facilities that were evaluated that revealed that, an additional total of laboratory technicians at Health Centre (HC) level four by 30% and laboratory subordinates remained in extra by 90%.

There remained an unavailability of laboratory technologists with merely 50% of the positions occupied at general hospitals consequently only about 87.5% of middle level laboratories had steered official onsite training equated to 51.2% in the non-middle level laboratories. Worth noting also a smaller amount than half of Health Centre (HC) level three laboratories led official onsite training; hospital laboratories did not do the training concerning the usage and looking after equipment. Nearly entire HC level three laboratories were supervised through administration concentrated on HIV/AIDS. The study also identified that the lack of financial resources, heavy workload and absence of supervision was the most important limitations to human workforce reinforcement (Kiwanuka *et al*., 2020). This kind of situation in many Sub-Saharan African countries will definitely cause an undesirable consequence on the quality of laboratory services (Odoa *et al*., 2017).

Similarly in yet another study done in Sokoto, Nigeria, in single tertiary organization, documented that out of 95 laboratory personnel, more than two-thirds of them had not at all any in-service training on Laboratory Quality Management (Kaoje *et al*., 2017), this discoveries are in total consensus with an evidenced study done in Addis Ababa

Ethiopia where 133 out of 213 (62.4%) had obtained on job training (Mesfin *et al*., 2017). Agreeing to theory, personnel with the greatest chance of executing quality are competent workers (Dolan *et al*., 2022). Competency is advanced by learning and preparation. A study conducted in a different place found that competent laboratory staff calls for a high level of motivation (Bates and Maitland, 2006). It is a requirement for laboratory professionals to keep up their knowledge and understanding of the most current advances in laboratory testing Kasvosve *et al*., 2014) and continuing professional development (CPD) schemes can address this prospect. In yet another study done the anticipated 400, 283 (70% reply rate) persons contributed to the assessment.

Among them, 153 (54%) had little CPD involvement and 199 (70%) were cognizant of CPD learning actions in their individual nation. Highlighted also was them with diploma credentials joined additional CPD programs ($P < .001$) than them with basic degrees and master's degrees. Cognizance of CPD programs was related with a greater level of CPD involvement ($P = .0001$). Job satisfaction was considerably connected with high levels of CPD involvement ($P = .02$). Other influences related with great level of participation in CPD programs comprised cost of the programs ($P = .03$), support by employer ($P = .0005$), and information of lawful CPD necessities ($P = .002$) (Ndlovu *et al*., 2024).

A study done in response to the challenge of HIV disease burden in South Africa, laboratory personnel were trained in order to strengthen laboratory structures to make available sufficient and quality laboratory services for improved control of Human

Immunodeficiency Virus infection. African Centre for Integrated Laboratory Training (ACILT) was put into place with an assignment to educate personnel from Nations with HIV disease burden in abilities necessary to make stronger maintainable laboratory systems. The study evaluated the conveyance of recently expanded information and skilfulness to fellow laboratory employees, and to ascertain empowering and hindering influences on their application and the conclusions were that ACILT had accepted progressive influence on empowering the laboratory capability, laboratory workers and considerable cost reserves. ACILT's venture formed a multiplier influence whereby national laboratory systems, employees and governance gained training profits. This laboratory education centre with a global following funded to increase current laboratory services, organizations and linkages for the HIV widespread and is at this time being pursued after for COVID-19 analysis that has diseased 41,332,899 persons worldwide (Shrivastava *et al*., 2021; Shrivastava *et al*., 2016).

Also studies have recommended that active participation of laboratory workers in study projects is correspondingly supportive in adding applicable evidence required for the reception of innovative diagnostic technologies (Davies *et al*., 2017). As stated earlier in developing countries, getting involved in CPD programs is a noteworthy trial for laboratory workers, comparatively because of their inadequate accessibility (Gebregzabher *et al*., 2023; Kasvosve *et al*., 2014). The greatest selected by the laboratory personnel for professional growth is quality systems essentials for medical laboratories (Gebregzabher *et al*., 2023; Greaves et al., 2019), executing a quality management system and methods to isolate and prevent causes of laboratory error

techniques (Kasvosve *et al.*, 2014). Quality management programmes done in Botswana showed that the quality score improved in 29% by the means of a quality enhancement procedure directed by work plan application, quality management system records, the institution of fresh proficiency testing and in-house quality control programmes, and improvement of workers proficiencies in practical and quality management done by means of teaching (Zohoun *et al*., 2021).

When there is a QA/QC technical mentor in the laboratories they help with technical support for diagnosis; nevertheless, it is not always the case in resource-limited situations (Petti et al., 2016). The quality of medical laboratory procedures is determined by practical skills, quality management systems and the laboratory workers rate of motivation. The technical competency of workers performs a significant part in guaranteeing firm observance to the many techniques of the total testing procedure as well demarcated by the quality management system (Simundic *et al*., 2020). In order to attain proficiency, laboratory specialists need both aimed at education and a suitable working setting to turn their learned information into technical abilities however there is a critical scarcity of well-educated laboratory personnel in sub-Saharan Africa (Ondoa *et al*., 2020).

In Kenya as in many African countries we have healthcare workers educated in a number of specialties of laboratory medicine, such as haematology, clinical microbiology, blood transfusion medicine, medical biochemistry and cytopathology and they are also known as clinical pathologists (Muzyka *et al.,* 2021). These specialists provide knowledge and leadership, through making sure that the quality of

the pre-analytical, analytical and post-analytical phases of analysis are in place and also guaranteeing that serious data about the severity and prediction of diseases centred on test results is well documented and delivered precisely. Consequently, they ensure that patients are begun and continued on the accurate medication (Wilson *et al*., 2018). The actual situation in the United States and United Kingdom, is that the pathology workers differ amid three to five per 100 000 populations (Metter *et al*., 2019).

A speedy picture inspection led by ASLM discloses acute shortcomings in the medical pathology occupation in ten nations of sub-Saharan Africa. To begin with, the simple meaning of this occupation is frequently not properly understood, with the greatest assessment respondent's actuality merely cognizant of anatomic pathologists' on the other hand not medical pathologists. With the statistics from the College of Pathologists in East, Central and Southern Central Africa indicating a predisposition in the direction of anatomical pathology (60%) paralleled to clinical pathology (18%) of the 119 certified pathologists (Saleh *et al*., 2019).

A current record of pathologists by national professional councils gives the impression that in many countries; very extremely specialized professionals stand not sufficiently enumerated or certified and accredited in their corresponding nations (Muzyka *et al*., 2021). Furthermore, the proportion of pathologists (notwithstanding of their specialty) is 5–350 more inferior to the proportions witnessed in the United States, interpreting keen on deficiencies of additional 4000 pathologists for a nation similar to Ethiopia or further than 6000 for a nation comparable to Nigeria. In most

African countries tested, the sum of pathologists is lesser than the required number in level 2 and level 3 hospitals bearing in mind these facilities is where their services are needed more. This disclosure suggests that the clinical pathologists would need to attend to patients in more than a single facility to decrease the availability lack of workers.

For instance, 61 pathologists in Ethiopia must support an entire of 400 hospitals (Wilson *et al*., 2018). From similar evaluations it is worth noting that the sum of clinical microbiologists (a sub-field of clinical pathology), next to 50% globally. Such statistics are worrying and increases alarms about the sustainability and influence of present worldwide and nationwide hard work to found diagnostic capability for prevention and control of antibiotic resistance in the Africa. The starter of innovative clinical diagnostic expertise such as point-of-care analysis at the community level or next generation sequencing at the reference laboratories will require expert laboratory medicine workers who have the capacity to guarantee the accurate usage and clarification of diagnostic tests for better-quality patient care and public health consequences. Together, this information highlights acute shortage in overall and clinical pathology, especially in sub-Saharan African nations (Sayed *et al*., 2019).

Finally, to note that many clinical laboratory programmes that have executed novel technology have not successfully reinforced the development of practical skills with suitable education and enticements to their laboratory technologists working in these facilities. Owing to this to absence of exposure and partial education on novel laboratory technology (automation), laboratory skilled worker can view new

technology as extra work as an alternative of being capable of doing additional work more proficiently. Of course, the laboratory scale-up postures trials if technologies are employed lacking backup as well as teaching of the laboratory personnel (Sayed *et al*., 2019; Marinucci *et al*., 2013).

2.9 Occurrence of Laboratory Errors

Clinical diagnostic laboratory sequence of operation includes pre-analytical, analytical, and post-analytical phases which are a process that begins with a patient and ends with a patient, these processes are referred to Total testing process (Bakan and Bakan, 2021). Studies have pointed out that laboratory mistakes can happen at any stage of the workflow in the pre-analytical phase, analytical phase or the post-analytical phase of the Total Testing Process (Asmelash *et al*., 2020). Pre-analytical errors take account of all errors that occur before examination of the sample. Approximately of the pre-analytical errors comprise hemolysis of sample, inadequate sample, improper labelling, improper request form, coagulated blood sample and or even tube damaged in separators (Shah *et al*., 2021). Statistically errors occurring in the laboratory are associated to increased patient hospital admissions and frequency of primary and following visits to the hospital (Fenta and Ali, 2020). What is complicating the situation further is the invention of blood collection tubes that are complex devices than the ones commonly known and formally used by laboratory personnel.

The present-day blood sample gathering tube might comprise several substances that may affect development of clot, which may also act together with the tube and stopper

surface and bring together undesirable substances to the samples, or at times may adsorb substances from the sample. This was pointed out in a study done to evaluate the extent of somewhat untrue raise or reduction of serum electrolytes precisely sodium, potassium, ionized calcium and lithium concentrations in several blood gathering tubes from diverse companies, It remained obvious that clot activators existing in collection tubes affected the serum lithium concentration henceforth snowballing additional the frequency of pre-analytical errors consequently furtherance in interfering with the reliability of laboratory results (Saharia & Mangaraj, 2020). It is documented that that approximately 93% of laboratory mistakes take place in the course of the pre-analytical testing phase (Jagannatha *et al*. 2019). The reason for these occurrences is that despite the development of protocols to prevent errors from happening in the pre-analytical phase, wholly the stages involved in this phase are reliant on individuals and thus it is not possible to prevent them in the laboratory, hence these errors are still observed (Shah *et al*., 2021).

The effect of these pre-analytical errors moves into the analytical and the post-analytical time reason being in the analytical stage where investigation is done, poor samples coming into the laboratory despite the conformity with quality control, calibration of equipment's, quality cannot be assured (Asmelash *et al*., 2020). The most common post-analytical errors have been identified as lack of reporting of test results, stay in reporting the findings, inappropriate calculation, life-threatening results not reported or overdue, and results directed to the mistaken patient (Walz and Darcy, 2013). In order to have a precise and trustworthy results, recognition and avoidance of errors is a necessity in all the total testing process (Shah *et al*., 2021).

Chances of occurrence of errors are higher in pre-analytical stage as compared other two stages. Thus, it is always compulsory to make proper guiding principle or protocol guidebook to lessen mistakes in this stage and it is correspondingly an essential stride to realize Total Quality Control (TQC) (Shah *et al*., 2021). Supported yet in another study done in several countries in Africa which found out great occurrence of pre- and of post-analytical medical diagnostic laboratory mistakes, additionally, the findings disclosed that the characteristic finishing point of the laboratory requisition forms was not good and there were noteworthy records of sample refusals (Asmelash *et al*., 2020). This is in also in agreement with some other studies done in 2012 where partaking laboratories pointed out that the most important sources of error were clerical mistakes which are part of the pre analytical phase (Ibrahim *et al*., 2012).

In several other studies asserted that out errors in the laboratories informed that 61.9% of mistakes happened in the pre-analytical stage, 15% in the analytical stage, and 23.1% in the post-analytical stage. In agreement with yet a not the same study, that indicated that 13%-32% of laboratory mistakes occurred in the diagnostic testing stage (Jagannatha *et al*., 2019; Sepulveda *et al*., 2019). Moreover, another study done in Ethiopia also agrees that pre-analytical and post-analytical errors happened more repeatedly than analytical errors, most of which are avoidable. The amplified pre-analytical mistakes point out the involvement of other health specialists specifically out of the 1124 (58.5%) laboratory errors that were detected, of which 807 (71.8%) were pre-analytical, 85 (7.6%) analytical, 232 (20.6%) post-analytical mistakes as stated earlier from previous studies (Tola *et al*., 2022). It has been noted that vigilant

process analysis performance discloses more errors (Jagannatha *et al*., 2019); therefore, a more laborious and deliberate methodology for error uncovering and grouping should be able to detect analytical errors as it is the case of this study.

In yet another study done to establish the occurrence of pre-analytical mistakes, indicated that the range was beginning 2.7% to 43.7%. It demonstrated that the noteworthy dissimilarity amid these discoveries may be having been credited to the disparity in the quantity of QIs, proposal of the study, sample size and the general laboratory performance. Still contrasting with other revisions led by Sharaki *et al*. (2014) that exposed great occurrence of pre-analytical mistakes which might have been because of the difference in the study strategy, QIs data gathering technique and explanations of operations and the lowermost occurrence of pre-analytical mistakes could be owing to diverse approaches of data gathering, the being there committed employees and the participation of the laboratory in the progression of accreditation (Asmelash *et al*., 2020).

Several studies have concluded that the post-analytical phase, which is the very last stage of laboratory testing, is progressively being acknowledged as a last period in to take full advantage of quality and efficiency of laboratory information (Plebani, 2024). Therefore, it is necessary to improve the laboratory final reporting by closing the gaps of the total testing cycle by ensuring the reports are accurate and their notice to consumers is done in an excellent manner (Tola *et al*., 2022). The synchronization of this last post-analytical phase is rather difficult, generally because it demands for communication that consists of sections and individuals speaking dissimilar languages

and varied opinions, comprising laboratory personnel, doctors or healthcare workers as they are referred to in various institutions, information technology professionals, and patients at large. Worth noting lately, growing attention has been voiced in assimilated diagnostics, well-defined as coming together of imaging, pathology, and laboratory tests with progressive information technology (Plebani, 2024).

To be precise, perfect interpretation of results improves patient management choices and improves quality of care this could be achieved by a conjoint laboratory, radiology and pathology diagnostic reportage arrangement that join in message, sentry imaginings and molecular diagnostic records to an incorporated system (Plebani, 2024; Shah *et al*., 2021).

There have been advances in identification and reporting of laboratory errors and now the shift and focus is on structures based methodology to addressing the analytical procedure as a substitute of basically concentrating on whether the diagnosis was accurate or else erroneous (Bates and Singh, 2018). The last few years' research has revealed better understanding of diagnostic errors and how frequently they occur the damages they cause and the contributing factors to their cause. Three approaches have been proposed most promising in this respect which includes use of 'trigger tools' towards recognizing from electronic health registers cases at a greater risk of error of diagnosis and misdiagnosis the other one is the use of consistent patients investigators to learn the rate of error in both clinical and laboratory practice and finally motivating in cooperation the patients and the healthcare workers to willingly inform any errors

they come across, and looking for ways of enabling this practice (Sabati *et al*., 2019; Graber, 2013).

It is well known that there is no one clinician's or even laboratory personnel have information and decision making sufficient to guarantee an accurate diagnosis, particularly because diagnosis changes across time and place and it consist of interactions among many team members and that is why the emphasis are more on the multidisciplinary approach to identify errors and come up with the most appropriate solutions on how best to reduce these errors (Bates and Singh, 2018) Several research studies have emphasized the prominence of accounting aimed at the several interaction of numerous important factors, together system such as failures in communication, harmonization, or teamwork or the absence of healthy policies and processes and individual such as let-downs in data collection or explanation, overconfidence in diagnostic conclusion, and absence of information on the syndrome one is dealing with (Sabati *et al*., 2019). Interestingly a study done in United States (US) found out that errors were mostly occurring in the US laboratories even though they have abundant experience in quality control (Ibrahim *et al*.,2012) Which is in contrast with the findings in sub-Saharan African countries where more errors were not analytical in nature but clerical errors, which accounted for the pronounced most common of the laboratory errors.

2.10 Healthcare Workers' Views on the Quality of Laboratory Services

The primary customer of laboratory services is considered to be the patient and the clinician. Based on literature (KEBS, 2007; Price, 2005), good quality is not a factor

decided by the provider but by the item's end user for intake or services this is a based on a description on the quality evaluation of the medical diagnostic laboratory department in community hospitals and primary health centers in northeast Ethiopia which used several indicators (Abebe et al., 2023). Since the healthcare workers are the immediate customers for most laboratory services (Rusanganwa *et al*., 2020), in the best-case situation, they rely on quality laboratory information when deciding on medical evidence-based deductions; nevertheless, this is not every time the scenario (Nkengasong *et al*., 2018; Tuijn 2014). Reason being that the healthcare workers form an attitude on the quality or soundness of results (Abebe *et al*., 2023), this is because the healthcare workers consider the quality or reliability of results to be the greatest significant element [32.3%], followed closely by routine test turnaround time (Abebe *et al*., 2023).

In research done in Ethiopia on Healthcare workers and laboratory personnel in respect to malaria work evidenced that about 61% (67/110) of the physicians and 50% (13/26) of laboratory specialists were gratified with the quality of laboratory effort. Those physicians who ordered laboratory malaria diagnosis grounded on comprehensive medical judgment were additionally content (AOR=3.12, 95% CI = 1.06 to 9.13) in contrast with their contemporaries, despite the fact that those who belief laboratory malaria diagnostic result as merely consistent were 68.0% (AOR=0.32, 95% CI = 0.13 to 0.83) a smaller amount of probable to be content than the referent individuals. Laboratory personnel with no restrictive issues for laboratory diagnosis were 30.6 times (AOR=30.6, 95% CI = 1.83 to 511.8) extra content with the service equated with individuals who had restrictions in their health facility (Bogale *et*

al., 2020) Nevertheless, in another study in Mozambique, observed that the facilities lacking laboratories claimed that that unavailability amplified the probability of costly referrals, delays, and even deaths (Tadeu & Geelhoed, 2018).

In a study done by Kaonje *et al*., 2017, in Sokoto, Nigeria highlighted that nearly all the healthcare workers in tertiary health Centres had received erroneous results one time or another. Established customers' contentment is an essential component of quality and a vital tool for upgrading the health systems (Gonzalez, 2019). Contented physicians are more probable to use laboratory tests regularly; this is because satisfaction is a measure of quality and a significant instrument for development (Abebe *et al*., 2023). Disclosed accreditation standard as well enable customer satisfaction because for a laboratory to be accredited it is required to produce quality results and ensure there are competence personnel (ISO 15189 International standard).

Physicians require reassurance of laboratory accountability on test list of options, truthful collection manual, request forms and guarantee of working with knowledgeable workers, authenticated technique and decent procedure control (Hailu *et al*., 2020). Studies have showed that healthcare workers' ordering conduct and management mediations are subjective to the delivery of information and collaborations amongst laboratory and clinical health personnel. Absence of information is an obstacle to operational healthcare service. Better-quality communication between laboratory and clinical health personnel possibly will have a positive consequence to the requisition and usage of laboratory diagnostic services and, ultimately, quality of patient care (Thakur *et al*., 2023). Quality diagnostic

services would reduce errors which may possibly cost a human life expectancy, produce a negative impression on an organization's repute, in turn lead to income loss, and open entrances for costly court cases (Berry *et al*., 2021).

To overcome these difficulties, healthcare organizations need to device an approach that benefits healthcare service workers to lessen waste, discrepancy, and labour inequity in the service processes (Ahmed, 2019). This study is designed to establish the healthcare workers' views on laboratory services in Kenya and to recognize the weakness they identify in the laboratory quality system, the crucial gaps present, and their possible solutions.

2.11 Gaps in Laboratory Capability and Diagnostic Accuracy

In order to deliver quality care in health facilities precise and well-timed diagnosis is paramount. It is essential to identify a disease before effective treatment is commenced. The diagnostic ability of a health care system is consequently a significant factor in the attainment of universal health coverage (UHC), which depend on the finding of large amounts of people with curable conditions within a community (Wilson *et al*., 2018). Enormous gaps at the diagnosis phase usually exist for crucial diseases, these includes tuberculosis (TB), diabetes mellitus, HIV/AIDS, hepatitis C (HCV), and hypertension, leaving a lot of people not diagnosed and therefore delayed treatment and even misdiagnosis and definitely this challenges presents an impediment to evidence based policy decision-making, and it has a undesirable effect on an health outcome of an individual (Markby *et al*., 2023).

Studies have revealed that a lot of low and middle-income countries (LMICs) are deprived of enough laboratory diagnostic capability, with noteworthy inadequacy in needed infrastructure, provisions and equipment, skilful workforces, quality management systems and information management just to mention a few (Nkengasong *et al*., 2018), these have represented challenges in admittance to high quality guaranteed laboratory services. For instance, a misdiagnosis of an infection like plasmodium species for a bacterial infection established on signs and symptoms alone may in turn, due to such a mistaken often lead to an inappropriate recommendation of antibiotics in resource inhibited settings where optimal microscopy is not accessible (Makanjuola & Taylor, 2020). A study done in Ethiopia showed that there was below quality performance of malaria microscopists predominantly in species proof of identity and differentiation and also underprivileged to moderate capacity of laboratories (Nega *et al*., 2020).

Setting up, sustaining, and displaying the accuracy of laboratory diagnosis is a major setback in sub-Saharan Africa owing to the nonexistence of skill and resources to introduce systematic in-house quality checks, exterior reference centres, and dependable documentation processes (Makanjuola &Taylor, 2020; Kamau, 2013) in addition in a study done in Kenya and Ethiopia showed that there was no single laboratory that had adequate quality management systems instituted (Mesfi, 2017; Njoroge, 2014). Though the situation is quite different in south Africa where a study highlighted that majority of the clinical diagnostic laboratories were accredited meaning that it is a positive suggestion of a well-implemented QMS, although even so there were challenges exposed that were encountered by the medical technologist-

privately owned laboratories which still remains non-accredited meaning poor implementation of Quality Management Systems within these facilities (Khadambi *et al*., 2021) It has been noted that the struggle and price of setting up and maintaining a quality-assurance system cause a small number of laboratories in Africa to produce precise results (Makanjuola & Taylor, 2020).

In fact a study done in Logos Nigeria showed that only two (10%) of the laboratories that were assessed were evaluated high for quality performance especially those laboratories which had automated equipment and broader range of services had upper quality appraisals (Adewoyin *et al*.,2019) the study identified noteworthy excellence gaps in work-force, procedure control systems, user oriented service, laboratory inspections systems and utilization of quality control instruments, the study recommended that all this gaps needed to be addressed (Adewoyin *et al.,* 2019). According to a study done in Ethiopia it established that poor internal quality control measures and the lack of result confirmation systems have a control on the provision of quality laboratory services (Mesfin *et al*., 2017).

In fact, a study done in several other Sub- Saharan countries revealed that there is weak laboratory authority leadership in several such countries and there is no board of directors of laboratories in existence. The study also disclosed that and laboratories were not directly positioned under the power of the Ministry of Health consequently inhibiting proper synchronization of laboratory services and restraining the domain of operation of the laboratory in comparison to the additional health divisions (Ondoa *et al*., 2020). It has been noted lack of clear obligation of managerial role contrasted with

technical duties and directives between executives and nationwide public health institutions and general reference laboratories also inhibits the inclusive growth and implementation of guidelines associated to several aspects of clinical diagnostics (Attal *et al*., 2019). The various aspects of diagnosis that have been identified to have a challenge of development and enforcement of regulations includes In Vitro Diagnostics (IVD) assessment and listing, classification and bringing up-to-date of rank definite least testing packages, laboratory staff recruitment rules or characterization and application of quality standards (Ondoa *et al*., 2020).

According to the WHO as well as the Kenya National Malaria Strategy 2009–2017 recommended teaching of laboratory staff in the selected centers of excellence in order to expand the capacity of individual microscopy practice (Wanja *et al*., 2017); nevertheless, it was noted that when trained worker coming back to health facility laboratories, they frequently face several other trials such as bad quality reagents, broken down equipment's, heavy amount of work and absence of dependence of the results by physicians (Rusangwa *et al*., 2019). These trials can add to the minimal progresses in the performance of the laboratory personnel after training.

Previous studies done in many sub-Saharan Africa countries have established that, healthcare workers base their diagnosis on in most times medical signs and symptoms without the help of backing of elementary diagnostic tests (Petti *et al.,* 2016; Kamau, 2013). This is because few healthcare workers have confidence on the assurance of the results produced to them. A study carried out in several counties in Kenya indicated that merely high-class private laboratories attending the resource rich

attained the total quality practice criteria (Njoroge, 2014). It is therefore necessary to closely evaluate the standard of quality of laboratory findings being generated in clinical diagnostic laboratories in Kenya, to find out if a lack of compliance with quality guidelines affects the quality of results based on previous studies.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Area

This was a multi-site study in which subjects were part of selected laboratories in Kiambu County in Kenya. The County lies *between latitudes 00 25'and 10 20'South of the Equator and Longitude 360 31'and 370 15'East*. According to the 2019 census, there is a total population of 2,417,735 in the county: 1,187,146 males, 1,230,454 females, and 135 intersex persons. There are 796,241 households with an average household size of 3.0 persons per household and a population density of 952 people/km^2. Its main economic activities include Agriculture-(Coffee, Tea), Trade, and Manufacturing Industries. Kiambu county is divided into twelve sub-counties including Limuru, Kikuyu, Kabete Lari, Gatundu South, Gatundu North, Githunguri, Kiambu, Kiambaa, Ruiru, Juja, and Thika Town as shown in the map below (Figure 3.1). This County was purposely selected because it has the most registered clinical laboratories in the Country (KMLTTB, 2021.) It was also the first to have the County Health Act in place (Kiambu County Health Magazine 2017, May page 2-3). In terms of infrastructure, Kiambu County currently has 400 Health facilities, of which 108 belong to the County government. There is also a significant improvement in upgrading of several health Centres level 4 statuses, with each sub-county having a referral hospital Kiambu County health strategic investment plan 2014-2019 (Nyongesa *et al*.,2013).

Figure 3.1: Map of Kiambu County, Kenya

3.2 Study Design

This was multi-site descriptive cross-sectional study done in selected laboratories, healthcare workers, and laboratory personnel in Kiambu County, Kenya. The medical laboratories were grouped based on categorization in the study of health laboratories, the KMLTTB classification (MOH/KMLTTB, 2002). To ensure comprehensive categorization, this study adopted three-tier criteria, which merged the Kenya government categories private and faith-based. The 38 laboratories in the study county were also grouped into seven strata according to ownership (private, faith-based, or government) and socioeconomic status before being randomly selected from each stratum (Njoroge, 2014; Ishengoma *et al*., 2009).

3.3 Study Population

The study population included healthcare workers and laboratory personnel working in selected health facilities in Kiambu County.

3.3.1 Inclusion Criteria

The research included clinical laboratories in Kiambu County performing haematological done through a complete blood count for white blood cell indices like monocytes, lymphocytes, neutrophils, basophils, eosinophils and platelets, the immunological tests, CD4 count and C-Reactive proteins. Those laboratories conducting a minimum threshold of specified immunological and haematological per month to ensure sufficient data for analysis. The operational status was the laboratories that have been operational for at least one year to ensure stability and consistency in practices.

The laboratory personnel were technicians and technologists working in these clinical laboratories that perform immunological and haematological. Also, those laboratories with availability of patient records and test results for the selected tests to analyse diagnostic accuracy and patient outcomes were included.

The healthcare workers included in this study were those who were willing to participate through filling an informed concept form and willing to allow the researcher to investigate the laboratory service provision who were employees having worked in the facility for more than three months.

3.3.2 Exclusion Criteria

The research excluded clinical laboratories in Kiambu County not performing haematological that is done through a complete blood count for white blood cell indices like monocytes, lymphocytes, neutrophils, basophils, eosinophils and platelets, the immunological tests, CD4 count and C-Reactive proteins. Those laboratories not conducting a minimum threshold of specified immunological and haematological per month to ensure sufficient data for analysis were excluded. The operational status was the laboratories that have been operational for at least less than one year to ensure stability and consistency in practices therefore those that were not operational that period was also excluded.

The laboratory personnel were technicians and technologists working in these clinical laboratories that perform immunological and haematological. Also, those laboratories with lacking the patient records and test results for the selected tests to analyse diagnostic accuracy and patient outcomes were excluded.

The healthcare workers excluded in this study were those who were not willing to participate through filling an informed concept form and not willing to allow the researcher to investigate the laboratory service provision and those employees having worked in the facility for less than three months in the facility.

3.4 Sample Size Determination

Yamane's (1967) formula was used because the sample population was less than 1000 laboratory personnel and known registered clinical laboratories; the information was obtained from the County health administration office with consent

For laboratory personnel

$$n = \frac{N}{1+N(e)^2}$$

Where;

N is the population size, n is the sample size, and e is the level of precision

For laboratory personnel

N=population size (280)

E=margin error (0.1)

n =sample size (74) rounded off to 80

So, the sample size for laboratory personnel was 80

For laboratories

N= population size 38

$=38/1+38(0.1)^2$

= 38 laboratories

Sample size for the number of focused group discussion was based on the concept of theoretical redundancy (Krueger, 2002) therefore 5 FGDs comprising 8-12 members were conducted at each facility serving the 4 Classes of laboratories in total the healthcare workers were (49).

3.5 Sampling Techniques

The laboratories were purposively sampled ensuring that every level of laboratory was selected both private and public facilities were represented. Purposive sampling was adopted based on the possibility study for primary healthcare laboratories in Kenya (MOH/AMREF, 1996) and on the KMLLTB classification of Laboratories. The three (3) level five hospitals in the County were sampled which houses Class E laboratories; from the twelve (12) sub-counties hospitals each sub-county level 4 eight (8) public was selected and (8) private level 4 hospitals housing class D laboratories were sampled and eight (8) Public health Centre and eight (8) private level three hospitals housing class C laboratories and lastly class B laboratories which are the dispensaries and private clinics laboratories. Clinical personnel working in the selected facilities were purposively sampled. Those who were selected to participate in the focus group discussions were the ones who were easily represent each cadre of users of laboratories in the facilities. Purposeful sampling was adopted for medical personnel who are users of laboratory services by ensuring at least the FGD were not from the same sub-county, 5 focused group discussions were held for healthcare workers in the various categories of the selected facilities.

3.6 Laboratory procedures

The preparation and dispatch of Quality Control (QC) samples in a clinical laboratory involved several steps to ensure that the samples for Heamatology,CD4 and CRP were prepared, tested, and sent out accurately and efficiently. The preparation of the QC materials was done according to the standardized protocols.

3.6.1 Preparation of Quality Control Sample for CD4+ T-lymphocyte Count

Fresh screened whole blood prepared by drawing predetermined CD4 value from a single donor was mixed thoroughly to ensure homogeneity (Younes, 2020). The blood was separated into normal (sample-A) and low (sample-B) EQA provisions. Normal EQA material was organized to coincide with Kenyan CD4 T- cell counts (753±227 cells/µl for adult males). Low counts were made by diluting with phosphate buffer saline (PBS) until a required low CD4 count was attained (100-300 cells/µl range).

3.6.2 Preparation of Quality Control Sample for Haematology

Screened whole blood samples were gotten from the national blood transfusion Centre using the protocol (Anido 1975) from a single donor mixed and dispensed in screw-capped external thread vials, then pre-labelled as blind samples. Pre-analysis of the EQC was done at KMTC haematology laboratory using the three part analyser and the results were recorded for the absolute white blood cell count and platelets and for the comprehensive five categories of white blood cells determined by the using the 5 part analyser ”Sinnowa” at national blood transfusion centre (Anido 1975).

3.6.3 Preparation of External Quality Control samples for C-reactive protein diagnosis

Blind standard serum samples for C-reactive protein (Acute Phase Protein) were prepared by spiking pooled serum and the value was pre-determined by testing in duplicates and the average value obtained before dispensing homogenous1ml of the same in 2ml screw capped serum containers samples which were used as controls.

3.6.4 Dispatch of Quality Control Materials

All dispatch included prepared QC material verified for homogeneity and stability through random selection of representative final with the management and operation instruction sheets; results report form with a distinctive participant identifier, the submission deadline date, and safety information (Appendix II and III) were delivered by the principal investigator.

3.7 Data Collection Tools

Questionnaire, focus group discussions and laboratory personnel competency checklists and observation checklists were the tools used for data collection.

3.7.1 Questionnaire

Similar Close ended, self-administered questionnaires were developed and issued to the participating laboratory staff (Appendix IV). Triangulation was used to verify each participating laboratory technologist's competency by issuing a competency checklist to their respective laboratory supervisor/managers (Appendix XI).

3.7.2 Focused group discussions (FGD)

Five focused group discussions were conducted and moderated by the principal investigator, two (2) groups had 8 healthcare workers, one (1) had 10 healthcare workers, the remaining two (2) had 11 healthcare workers, and 12 healthcare workers respectively in different health facilities at all the clusters of the health facilities selected. The Focus Group discussions (FGD) gave participants free will to express their state of mind in order to acquire data representative the purpose of the study. To

inform on their attitudes, perceptions, and views concerning the laboratory quality service delivery, the interview guide questions were as indicated in Appendix (VI) which informed five themes which were created to include, Frequency of laboratory tests request, views on the Validity of the laboratory tests, Trust of healthcare workers in the laboratory results, Clinician's opinion on the competency of the laboratory personnel and opinion on the attitude of laboratory personnel. The FGD sessions lasted between one hour to one and half hours. By the conclusion of each discussion, the conclusions were summarized and disseminated to the participants (participant scrutiny), for authenticating the findings and snowballing the reliability of the study (Birt *et al*., 2016) and were recorded for further transcription.

3.7.3 Observation checklist

Observation data was collected in every participating laboratory using an observation checklist (Appendix VII) adapted and modified using parameters developed from an important laboratory feasibility investigation for primary health care laboratories in Kenya (MOH/AMREF, 1996) to investigate the practice characteristics which include the general laboratory outlook, security and safety, presence of accessory rooms and essential facilities, presence of displayed standard operating procedures (SOPS), the laboratory safety practices (waste disposal) and credibility and courtesy of laboratory personnel. The information was collected by ticking on the observed items compliance.

3.8 Reliability of the Tests

The reliability of research instruments for the study on the quality of selected immunological and immune cells count and laboratory personnel skill and competency in clinical laboratories in Kiambu County was meticulously ensured to produce consistent and dependable results. Test-Retest Reliability was assessed by administering the same instruments to the same subjects at different points in time. This approach verified the stability of the responses, ensuring that the instruments yielded consistent results over repeated administrations. Inter-Rater Reliability was ensured by training multiple evaluators to use the research instruments uniformly. The consistency of the results obtained by different evaluators was then compared, confirming that the tools produced similar results regardless of who administered them.

Internal Consistency was evaluated using statistical methods of Cronbach's alpha, to measure the coherence of items within the questionnaires and checklists and it was 0.9. This ensured that the items were reliably measuring the same underlying construct. Parallel-Forms Reliability was tested by creating equivalent versions of the instruments and administering them to different groups of participants. The consistency of the results across these forms confirmed the reliability of the instruments. By addressing these aspects of reliability, the study ensured that the research instruments produced consistent and dependable data, providing a solid foundation for evaluating the quality of tests and personnel competency in clinical laboratories in Kiambu County.

3.9 Quality Assurance (QA)

Quality assurance for the study on the quality of selected immunological and immune cells count tests and laboratory personnel skill and competency in clinical laboratories in Kiambu County were rigorously maintained to ensure the accuracy and reliability of the findings. Protocol Development involved creating detailed procedures for data collection, instrument administration, and data analysis. These protocols were reviewed and approved by experts to ensure they met high standards of research practice. Training Sessions were conducted for all researchers and evaluators involved in the study. This training ensured that everyone had a consistent understanding of the protocols and could apply them uniformly, minimizing variability in data collection and analysis.

Pilot Testing was performed to identify and address any issues with the research instruments and protocols. Feedback from this phase was used to refine the instruments and procedures, ensuring they were robust and effective. Continuous Monitoring was implemented throughout the study to track adherence to protocols and identify any deviations. Regular audits and supervision ensured that data collection remained consistent and accurate.

Data Verification processes were established, including double-checking data entries and cross-referencing with original sources. This step helped to identify and correct any errors, ensuring the integrity of the data. By implementing these quality assurance measures, the study maintained high standards of research integrity, ensuring the

findings were accurate, reliable, and actionable for improving laboratory practices and personnel competency in Kiambu County.

3.10 Data Analysis

Raw data from the participating laboratories and the questionnaires were entered into different Microsoft Excel spreadsheets and then imported to Statistical Package for Social Sciences (SPSS) version 26 software for analysis. Descriptive statistics mean, median, frequencies, and standard deviation were made for haematological control test results, and the comparison of the means of the controls against the results obtained from the laboratories was analysed using Mann Whitney U test while comparison between haematological profiles was done using Kruskal-Wallis test. Descriptive statistics mean, median, and frequencies were again used to define the characteristics of the laboratory personnel demography; content analysis and thematic narratives were used to analyse the competency of laboratory personnel and healthcare workers' opinions via thematic analysis. Analysis was done at a 95% confidence level ($P<0.05$). Tables, bar graphs, and histograms were used for data presentation.

3.11 Ethical considerations

Ethical clearance was obtained from Kenyatta University ethical research committee (Appendix VIII). Research permits and licenses were obtained from the National Public Health Laboratories (NPHLS) Appendix (XI), National Commission for Science, Technology, and Innovation (NACOSTI) Appendix (X), and the relevant authorities of the participating laboratories (Appendix XII), respectively. Written

informed consent was obtained from participants who consented in the study (Appendix I). There was no risk associated with participation by the healthcare workers or the laboratory personnel. Data identification codes were used in data collection and storage to maintain confidentiality. Overall, testing quality among the participating laboratories was communicated without breaching confidentiality. The laboratories benefited from the feedback, which highlighted critical errors observed in the control test results and identified areas for improvement in laboratory testing, as well as best practices that needed to be implemented.

CHAPTER FOUR

RESULTS

4.1 Characteristics of the Study Subjects

Clinical Laboratories that participated in the study were 38 selected as per sample size that confirmed they did not have active EQC activities in the tests under investigation. Out of the thirty-eight (38) sampled laboratories, 35 laboratories met the inclusion criteria. Based on KMLTTB classification of laboratories the selected laboratories fall under different classes whereby majority of the laboratories are in class C and D as shown in the table below (Table 4.1)

Table 4.1: Classes of Laboratories selected to participate in the study

Class of laboratories	Number of laboratories
Class B	0
Class C	16
Class D	16
Class E	3
Class F	0
Class G	0
Total	35

4.2 Social Demographic Information of the Laboratory Personnel

The laboratory personnel who filled the self-administered questionnaire were 76, majority being male 53.9% participants. Age group 30-39 recorded the highest number of laboratory personnel with majority having Diplomas 55.3%. Focused groups were five comprising 49 participants (mixed healthcare workers); two FGD had least participants with 8 healthcare workers as shown in Table 4.2 below.

Table 4.2: Social demographic information of the study participants

Variable	Response	Number (n)	Percent (%)
Gender	Male	41	53.9
	Female	35	46.1
Age (years)	20-29	17	22.3
	30-39	36	47.3
	40-49	16	21
	50-59	6	0.7
	60 and above	1	0.1
Marital Status			
	Single	17	22.4
	Married	59	77.6
Education Level	Certificate	2	2.6
	Diploma	42	55.3
	Higher Diploma	11	14.5
	Degree	20	26.3
	Masters and above	1	1.3
Job Position	Lab Head	18	23.7
	Supervisor	5	6.6
	Quality Assurance Staff	5	6.6
	Ordinary Staff	48	63.2
Laboratory speciality	Clinical Chemistry	1	1.3
	Haematology	6	7.9
	BTS	2	2.6
	Immunology	1	1.3
	Microbiology	3	3.9
	General	63	82.9
Work Experience	0-5 years	22	28.9
	6-10 years	23	30.3
	>10 years	31	40.8
Focused Group Discussions	Group 1	8	16.3
(mixed healthcare workers)	Group 2	10	20.4
	Group 3	8	16.3
	Group 4	11	22.4
	Group 5	12	24.4

4.3 Comparison of the difference between the control haematological results and the laboratories haematological results

Screened whole blood was tested for the eighteen basic haematological parameter as absolute value (#) or as a percentage (%) that were erythrocytes, leucocytes and platelets using haematological analyser. The comparison of the control results and laboratory results of the hematological profiles. The comparison of the control results with the laboratory results for hematological profiles were compared using Mann-Whitney U test.

Table 4.3 below shows RBC (Red Blood Cell Count) $U = 70$, $p = 0.000$ with significant difference ($p < 0.05$). HGB (Hemoglobin) $U = 35$, $p = 0.000$ with a significant difference. HCT (Hematocrit) $U = 227.5$, $p = 0.000$ with a significant difference. MCV (Mean Corpuscular Volume) $U = 350$, $p = 0.001$ with a significant difference. Similarly, MCH (Mean Corpuscular Hemoglobin) has $U = 472.5$, $p = 0.068$ implying no significant difference ($p > 0.05$). For MCHC (Mean Corpuscular Hemoglobin Concentration), $U = 385$, $p = 0.004$ implying significant difference. The RDWc (Red Cell Distribution Width - Coefficient) had $U = 245$, $p = 0.000$ which implies significant difference. For RDWs (Red Cell Distribution Width - Standard Deviation), $U = 245$, $p = 0.000$ implying a significant difference.

Table 4.3: Comparison of erythrocyte profile results between control and a selection of the laboratories mean

	Category	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2-tailed)
RBCx10^6u/L	Control	35	51	1785		
	Lab	35	20	700	70	0
HGB(g/dl)	Control	35	52	1820		
	Lab	35	19	665	35	0
HCT(%)	Control	35	46.5	1627.5		
	Lab	35	24.5	857.5	227.5	0
MCV(fL)	Control	35	28	980		
	Lab	35	43	1505	350	0.001
MCH(pg)	Control	35	31.5	1102.5		
	Lab	35	39.5	1382.5	472.5	0.068
MCHC(g/dl)	Control	35	42	1470		
	Lab	35	29	1015	385	0.004
RDWc (fL)	Control	35	46	1610		
	Lab	35	25	875	245	0
RDWs(%)	Control	35	46	1610		
	Lab	35	25	875	245	0

Table 4.4 below shows WBC (White Blood Cell Count), U = 0, p = 0.000 implying a significant difference between the control and lab samples. LYM (Lymphocytes, absolute), U = 0, p = 0.000 implying a significant difference. MID (Mid-range cells, absolute) had U = 0, p = 0.000 which shows a significant difference. GRA (Granulocytes, absolute) had U = 175, p = 0.000 implying a significant difference (N = 30 for lab). LYM% (Lymphocyte Percentage) with U = 175, p = 0.000 implying a significant difference (N = 34 for lab). Similarly, MID% (Mid-range Cell Percentage) had U = 105, p = 0.000 which shows a significant lastly, the GRA% (Granulocyte Percentage), U = 70, p = 0.000 implying a significant difference.

Table 4.4: Comparison of leucocyte profile results between control and a selection of the laboratories mean

	Category	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2-tailed)
WBCx10^3/uL	Control	35	53	1855		
	Lab	35	18	630	0	0
LYMx10^3/uL	Control	35	52	1820		
	Lab	34	17.5	595	0	0
MID x10^3/uL	Control	35	52	1820		
	Lab	34	17.5	595	0	0
GRAx10^3/uL	Control	35	23	805		
	Lab	30	44.67	1340	175	0
LYM%	Control	35	47	1645		
	Lab	34	22.65	770	175	0
MID%	Control	35	45	1575		
	Lab	30	19	570	105	0
GRA%	Control	35	20	700		
	Lab	32	49.31	1578	70	0

Table 4.5 shows PLT (Platelet Count) with U = 0, p = 0.000 implying a significant difference suggesting possible platelet loss or aggregation in labs. Similar trends are seen for PCT (Plateletcrit): U = 105, p = 0.000, MPV (Mean Platelet Volume): U = 122.5, p = 0.000 and PDW (Platelet Distribution Width): U = 140, p = 0.000.

Table 4.5: Comparison of platelet profile results between control and a selection of the laboratories mean

	Category	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2-tailed)
PLTx10^3/uL	Control	35	53	1855		
	Lab	35	18	630	0	0
PCT(%)	Control	35	50	1750		
	Lab	35	21	735	105	0
MPV(FL)	Control	35	21.5	752.5		
	Lab	35	49.5	1732.5	122.5	0
PDW(%)	Control	35	22	770		
	Lab	35	49	1715	140	0

4.4 Comparison of each laboratory results with those of the control results

Table 4.6 provides key metrics for each comparison using Mann-Whitney U test statistic. The sample size for each group (Control and Lab 1-18) is denoted by N. The control group consistently has 19 samples, while most labs also have 19, except Lab 5 (13), Lab 10 (17), and Lab 11 (17) the findings were as follows. All p-values are well above 0.05, ranging from 0.604 (Lab 5) to 1.0 (Lab 16). This indicates that none of the comparisons show a statistically significant difference between the control and the lab results. All p-values are well above 0.05, ranging from 0.781 (Lab 29) to 1.0 (Lab 23). This indicates no statistically significant differences between the control and any of the labs.

Table 4.6: Comparison of haematological control results means with each laboratory mean (1-19) results

Category	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2-tailed)
Control	19	19.95	379		
Lab1	19	19.05	362	172	0.804
Control	19	19.74	375		
Lab2	19	19.26	366	176	0.895
Control	19	19.74	375		
Lab3	19	19.26	366	176	0.895
Control	19	19.42	369		
Lab4	19	19.58	372	179	0.965
Control	19	15.79	300		
Lab5	13	17.54	228	110	0.604
Control	19	19.63	373		
Lab6	19	19.37	368	178	0.942
Control	19	19.68	374		
Lab7	19	19.32	367	177	0.919
Control	19	19.61	372.5		
Lab8	19	19.39	368.5	178.5	0.953
Control	19	19.47	370		
Lab9	19	19.53	371	180	0.988
Control	19	18.37	349		
Lab10	17	18.65	317	159	0.937
Control	19	18.79	357		
Lab11	17	18.18	309	156	0.862
Control	19	19.76	375.5		
Lab12	19	19.24	365.5	175.5	0.884
Control	19	19.82	376.5		
Lab13	19	19.18	364.5	174.5	0.861
Control	19	19.53	371		
Lab14	19	19.47	370	180	0.988
Control	19	19.66	373.5		
Lab15	19	19.34	367.5	177.5	0.93
Control	19	19.5	370.5		
Lab16	19	19.5	370.5	180.5	1
Control	19	19.87	377.5		
Lab17	19	19.13	363.5	173.5	0.838
Control	19	19.47	370		
Lab18	19	19.53	371	180	0.988
control	19	19.84	377		
Lab19	19	19.16	364	174	0.849
Control	19	19.66	373.5		
Lab20	19	19.34	367.5	177.5	0.93
Control	19	19.42	369		

Category	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig. (2-tailed)
Lab21	19	19.58	372	179	0.965
Control	19	19.08	362.5		
Lab22	18	18.92	340.5	169.5	0.964
Control	19	19	361		
Lab23	18	19	342	171	1
Control	19	19.84	377		
Lab24	19	19.16	364	174	0.849
Control	19	19.92	378.5		
Lab25	19	19.08	362.5	172.5	0.815
Control	19	19.53	371		
Lab26	19	19.47	370	180	0.988
Control	19	19.63	373		
Lab27	19	19.37	368	178	0.942
Control	19	19.68	374		
Lab28	19	19.32	367	177	0.919
Control	19	20	380		
Lab29	19	19	361	171	0.781
Control	19	19.42	369		
Lab30	19	19.58	372	179	0.965
Control	19	19.68	374		
Lab31	19	19.32	367	177	0.919
Control	19	19.55	371.5		
Lab32	19	19.45	369.5	179.5	0.977
Control	19	19.37	368		
Lab33	19	19.63	373	178	0.942
Control	19	18.79	357		
Lab34	18	19.22	346	167	0.903
Control	19	18.89	359		
Lab35	18	19.11	344	169	0.952

4.5 Comparison of the haematological profiles across the laboratories

The Kruskal-Wallis test initially confirmed significant differences in the distributions of the three blood cell types (Erythrocytes, Leucocytes, Platelets) across the 35 labs ($H=39.57H = 39.57H = 39.57$, $p < 0.001$), The post-hoc pairwise comparisons provide clarity on which specific groups differ, using a significance level of 0.05, adjusted for multiple comparisons via Bonferroni correction as shown in the Table 4.7 below.

Table 4.7: Inter-haematological profile results variation across a selection of laboratories

Groups	Test Statistics	Std Error	Std Test statistic	Sig.	Adj. Sig.[a]
Erythrocytes-Leucocytes	-7.111	5.244	-1.356	0.175	0.525
Erythrocytes - Platelets	-14.222	5.244	-2.712	0.007	0.02
Leucocytes - Platelets	-2.711	5.244	-1.356	0.175	0.525

4.6 Evaluation of precision of the immunological tests' results

The immunological tests' that were done were CRP and CD4 counts. Out of the 38 selected laboratories 10 facilities were doing CRP and 3 laboratories were doing CD4..The control mean for CRP was 1.06ug/L and the average mean derived from ten sampled laboratories was 1.084 ug/L with a standard deviation of 0.2633 as shown in Figure 4.1 below. Out of the 3 laboratories doing CD4 count two were quantitative and one was qualitative as shown in Table 4.8 below

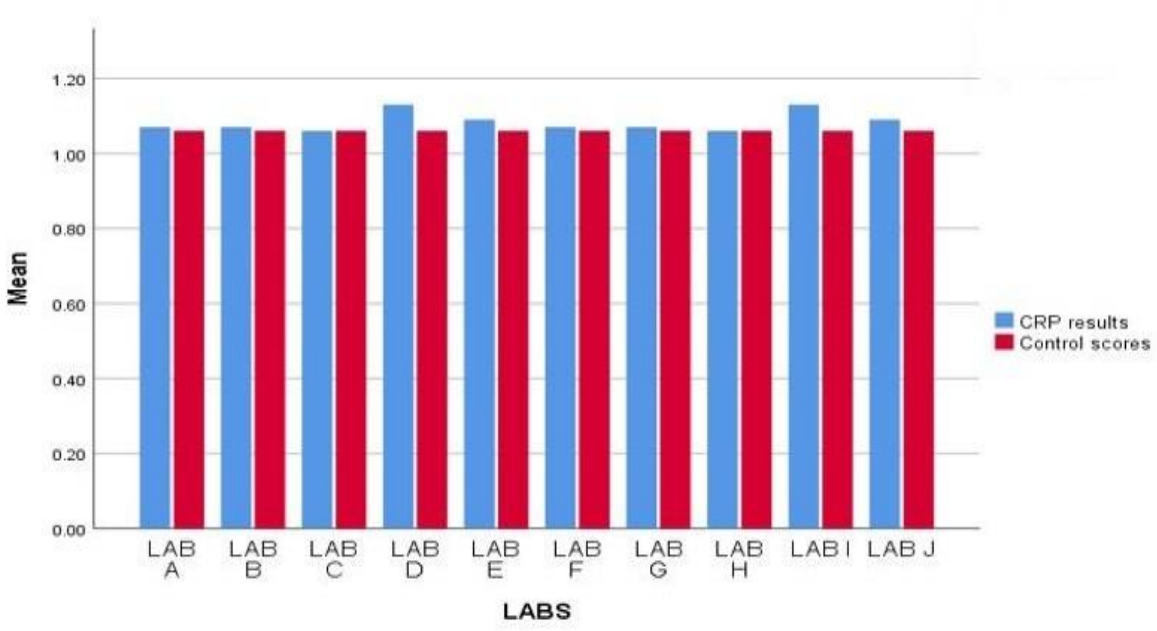


Figure 4.1: Precision of C-reactive proteins scores from the different laboratories

Table 4.8: Precision of CD4 cell count from the clinical laboratories

	Normal CD4 count(cells)	Low CD 4 count (cells)
Control	572	164
LAB A	667	164
LAB B	597	101
LAB C	>250	< 250

4.7 Assessment of laboratory personnel skill and competency towards quality service delivery

4.7.1 Continued education of laboratory personnel

Table 4.9 shows majority of laboratory staff in the study had plans to pursue further education 96.1%. However, only a 35.5% were enrolled in an education program. Among those that received training, 65.6 % had training on laboratory quality management, which lasted for one week (73.7%). The most attended trainings were seminars and workshops.

Table 4.9: Laboratory personnel's engagement in various continued education activities

Variable	Response	Number (%)
Plan to Pursue Education	No	3 (3.9)
	Yes	73 (96.1)
Enrolled in Education Program	Yes	27 (35.5)
	No	49 (64.5)
In-Service Training on Quality Management	Yes	50 (65.8)
	No	26 (34.2)
Number of Times in Two Years	Once	29 (38.2)
	Twice	13 (17.1)
	Many times	4 (5.3)
	None	30 (39.5)
Category of In-Service Training	Conference	5 (6.6)
	Seminar	25 (32.9)
	Workshop	16 (21.1)
	School environment	7 (9.2)
	None	17 (22.4)
Duration of Training	1-7 days	56 (73.7)
	1-3 weeks	9 (11.8)
	1-6 months	3 (3.9)
	1-3 years	8 (10.5)

4.7.2 Job satisfaction of the laboratory personnel

Majority (84.2%) of the participants reported that understaffing was a challenge; the facilities had approximately 1-5 employees. Also, 59.2% of the participants felt overworked throughout. These findings are further confirmed by the number (88.2%) of laboratory requests received per day to the number of completed by day (72.4%) against the number of laboratory employees per facility. Despite being over worked, almost all participants were happy with their jobs, and the few who were unhappy gave reasons like low pay, delayed salaries, being overworked, and a toxic

environment. However, 97.4% of participants acknowledged that the wage they receive is not commensurate with the work at their level. A good number termed low salary payment as the main reason for workload and delayed promotions despite being qualified and having good work experience, as shown in Table 4.10 below.

Table 4.10: Job satisfaction of the laboratory Personnel

Variables	Response	No. (%)
Would you say that employees generally feel overworked?	Yes	45 (59.2)
	No	10 (13.2)
	Sometimes	21 (27.6)
In your view, is it critical to hire more staff in this laboratory?	Yes	64 (84.2)
	No	12 (15.8)
Are you happy with the job that you do?	Yes	72 (94.7)
	No	4 (5.3)
If no, please specify	Not applicable	71 (93.4)
	Low pay	1 (1.3)
	A lot of work	2 (2.6)
	Salary delays	1 (1.3)
	Toxic environment	1 (1.3)
Is the salary you receive commensurate to the work at your level?	Yes	2 (2.6)
	No	74 (97.4)
If no, choose the reason why	Not applicable	22 (28.9)
	Low pay	28 (36.8)
	No promotion	11 (14.5)
	More workload	12 (15.8)
	Salary delays	1 (1.3)
	Many job risks	2 (2.6)
In your experience, how many lab requests do you receive in a day on average?	1-10	9 (11.8)
	More than 20	67 (88.2)
Test completed in one day	All	55 (72.4)
	Some	20 (26.3)
	None	1 (1.3)
Approximate number of employees per laboratory	1-5	41 (53.9)
	6-10	13 (17.1)
	More than 10	22 (28.9)

4.7.3 Laboratory infrastructure

Only 3.9% of the respondents reported adequate working space and 50.0 % has satisfactory working space. This was backed up by the results from the observation checklist Table 4.13, good calibration and maintenance of machines, and facilitation of the performance of the quality control program. On the other hand, there was a poor timely supply (9.2%), use of new equipment to promote quality services (7.2%), and replacement of faulty equipment as shown in the Table 4.11 below.

Table 4.11: Laboratory personnel feedback on the status of laboratory infrastructure

Variable	Response	Number (n)	percent (%)
Working space adequacy	Poor	3	(3.9)
	Unsatisfactory	28	(36.8)
	Satisfactory	38	(50.0)
	Excellent	7	(9.2)
Calibration and maintenance of laboratory equipment	Poor	6	(7.9)
	Unsatisfactory	21	(27.6)
	Satisfactory	38	(50.0)
	Excellent	11	(14.5)
Timely supplies to run tests	Poor	7	(9.2)
	unsatisfactory	29	(38.2)
	satisfactory	34	(44.7)
	Excellent	6	(7.9)
New equipment necessary for quality services	Poor	6	(7.9)
	unsatisfactory	25	(32.9)
	satisfactory	34	(44.7)
	Excellent	11	(14.5)
Equipment replacement	Poor	13	(17.1)
	unsatisfactory	25	(32.9)
	satisfactory	32	(42.1)
	Excellent	6	(7.9)
Facilitation of performance of internal quality control	Poor	1	(1.3)
	unsatisfactory	19	(25.0)
	satisfactory	41	(53.9)
	excellent	15	(19.7)

4.7.4 Laboratory errors

Majority (75.0%) of the laboratory participants reported existence of errors in laboratories. caused mistakes while working in the laboratory, and 68% testified witnessing other laboratory workers doing an error. The errors witnessed ranged in all the phases, where mislabelling was the most error in the pre-analytical phase, incorrect measuring of the sample in the analytical phase and sending results to the wrong location in the post-analytical phase. 53% of the participants reported requesting further tests in case of abnormal results, and 72% reported that sometimes they consult their colleagues while conducting microbiology tests. In addition, 76% confirmed that they do not regularly participate in quality control, and sometimes they use non-calibrated, poor-quality machines. Mislabel of sample is the most common pre-analytical error, in the analytical stage it is failure to follow the SOP, at the post analytical stage is handwritten report that are illegible at 26.3%.

Further, participants reported limited support from the management, work load, and lack of external quality control as the reason they do not regularly participate in external quality control programs. These results were bucked up with the laboratory in charge of the competency checklist, as shown in table 4.12a and 4.2b below.

Table 4.12a: Laboratory error committed by laboratory Personnel

Type of error	Response	Number (%)
Laboratory Errors	Yes	57 (75.0)
	No	19 (25.0)
Pre-Analytic Phase	Not applicable	19 (25.0)
	Collecting the wrong sample	13 (17.1)
	Mislabelling the sample	22 (28.9)
	Stored sample incorrectly before testing	4 (5.3)
	Sample handling	12 (15.8)
	Improper storage of reagents	6 (7.9)
Analytic Phase	No response	33 (43.4)
	Failure to follow established procedures	9 (11.8)
	Reporting test findings with quality control out of range	12 (15.8)
	Improper gauging/dilution of the sample	16 (21.1)
	Use of expired or incorrectly stored reagents	14 (18.4)
Post-Analytic Phase	Handwritten report that is unreadable	2 (2.6)
	Referring report to the mistaken locality	9 (11.8)
	Whole loss of report	6 (7.9)
	Not distributing the report to the patient	27 (35.5)

Table 4.12b: Laboratory errors witnessed being committed by other laboratory Personnel

Type of error	Response	Number (%)
	Did not respond	28 (36.8)
	Seen other employees reporting errors	52 (68.4)
	No	24 (31.6)
Pre-Analytical Phase	Collecting the wrong sample	9 (11.8)
	mislabeling the sample	18 (23.7)
	Stored sample incorrectly before testing	3 (3.9)
	Handling test samples in a destructive environment	6 (7.9)
	Unsuitable storage of reagents	1 (1.3)
	Unfilled laboratory request form	11 (14.5)
Analytical Phase	Did not respond	37 (48.7)
	Failure to follow SOPs	18 (23.7)
	Recording test findings with quality control out of range	15 (19.7)
	Improper gauging/dilution of the sample	5 (6.6)
	Use of expired or incorrectly stored reagents	1 (1.3)
Post-Analytical Phase	Did not respond	34 (44.7)
	Swapping patient information	12 (15.8)
	Handwritten report that is unreadable	14 (18.4)
	Conveyance of report to the wrong place	2 (2.6)
	Whole loss of report	5 (6.6)
	Not distributing the report to the patient	9 (11.8)

4.7.5 Competency rating of Laboratory personnel by the laboratory supervisors

Most of the laboratories supervisors rated the personnel working under them as very good and Excellent in verbal skills and general performance as shown in Figure 4.2 below.

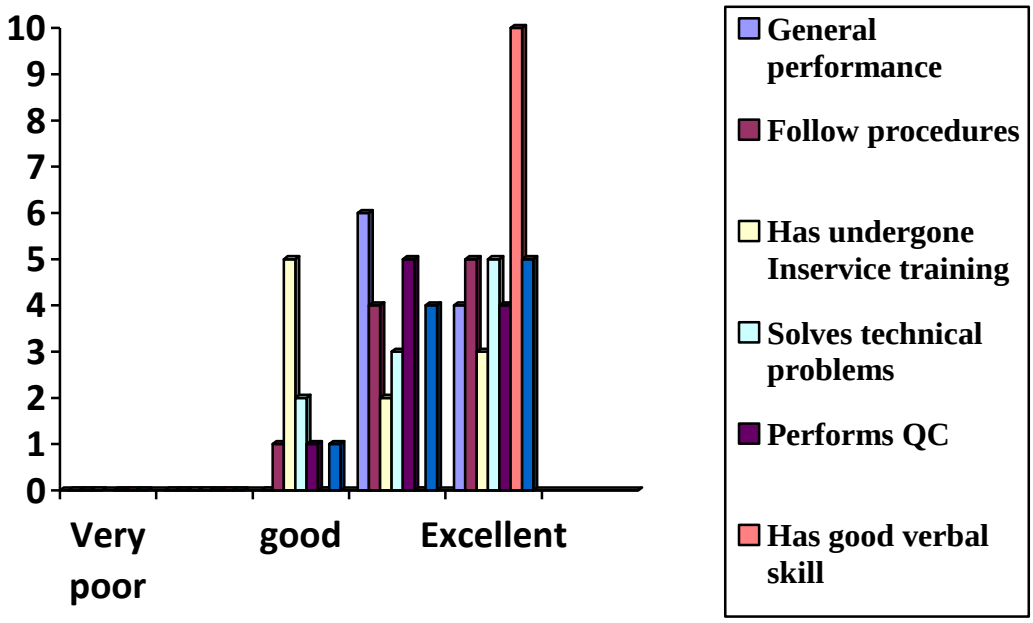


Figure 4.2: Laboratory supervisor's competency rating of the laboratory personnel

4.7.6 Conformance of laboratory personnel to set standards by World Health Organization in the sampled laboratories

The level of compliance is generally above 68% for all the variables apart from the lack of the availability of accident record book which was at 40% from observation recorded below in the table 4.13.

Table 4.13: Conformance to the guidelines set by World Health Organization for clinical laboratories

Variable	Number	Percent (%)
General Outlook of the Laboratory		
Main working room with enough spacing	16	68
Smooth floor, non-slippery	19	80
Adequate ventilation	19	80
Lockable cupboards	16	68
Two sinks with running tap water	18	76
Mains power of 12-volt, batteries recharged, or solar system	23	96
Electrical power points	23	96
Security and Safety		
Metal bars on window vents	21	88
Secure, lockable door	35	100
Accessory Rooms		
Waiting bay	23	96
Wash room	23	96
Store	20	84
Essential Facilities		
Running water or aspirator bottle	35	100
Availability of water	35	100
Flush toilets or latrines	23	96
Separate toilet facilities for patients and staff	21	88
Presence of Displayed SOPs		
Display of SOPs	16	68
Display of equipment calibration worksheet	15	60
Laboratory Safety Practices (Waste Disposal)		
Waste disposal	19	80
Fire extinguishers/buckets	15	68
Laboratory coats	23	96
Gloves	35	100
First aid kit	17	72
Accidents record book	9	40
Credibility and Courtesy		
Clean and neat premises	21	88
Clean and neat personnel	23	96
Politeness, respect, friendliness	23	96

4.8 Health workers views on the quality of laboratory services

Five focused group discussions comprising healthcare workers who comprised the doctors, clinical officers, nutritionists, public health workers and nurses were conducted in various Kiambu County facilities in order to assess the perception of healthcare workers on the quality of laboratory service. Themes were created and the results were analysed as follows using thematic analysis.

4.8.1 Frequency of laboratory tests request by the healthcare workers

Almost all healthcare workers frequently requested laboratory tests in the County, citing the importance of the results for confirmation of their diagnosis. They reported that laboratory results are crucial and necessary for clinical judgment, especially in times of emergencies. The healthcare workers also stated that in some chronic diseases and infections they require the laboratory findings for the purpose of monitoring the progression of a disease and the effectiveness of treatments in order to change the course of action or still remain with the current treatment. Other healthcare workers said that they requested the laboratory test because the patients themselves were more confident with the diagnosis if tests were done on them; however, some stated that the tests are not always available, especially those working in public facilities.

> "*I frequently request laboratory tests, primarily because many patients express a strong desire to verify their conditions through objective results. This insistence often stems from a need for reassurance and clarity regarding their diagnosis. While clinical presentations guide my initial assessment, I find that patient expectations play a significant role in my decision to order tests (Karuri Level 4 hospital,Banana,7th November 2023*)".

> "*When patients feel involved in their care and see that their concerns are taken seriously, it enhances their appreciation for the treatment process, especially after receiving medication based on confirmed results. Therefore, while clinical indicators are essential, the patient's perspective and desire for validation are equally important in guiding my requests for laboratory tests (Wankan hospital Juja 14th November 2023)".*

The healthcare worker emphasizes that patients often seek objective evidence of their health status, which highlights their need for reassurance and clarity. This desire for validation not only informs the clinician's decisions but also enhances patient engagement and satisfaction in their care. By acknowledging the importance of patient involvement and feedback, the clinician fosters a collaborative relationship that ultimately leads to better treatment outcomes and patient adherence to recommended therapies. This approach underscores the significance of considering both clinical indicators and patient perspectives in healthcare decision-making.

4.8.2 Trust of healthcare workers in the laboratory results

Most healthcare workers trusted the results they received from the laboratory; however, a few said there were particular tests they didn't always trust which sometimes they use clinical presentation alone to manage their patients despite the laboratory results findings. Most healthcare workers did not have time to discuss the received test results with the laboratory personnel, especially in public facilities, due to high work load and long ques unless there were significant discrepancies. Few healthcare workers stated that in their facilities there was no discussion channels put in place in the facilities to discuss the patient's results with the laboratory personnel. A great number of healthcare workers were satisfied with the results they received.

> *"I am satisfied with the laboratory results I receive though I don't have the time to discuss the results with the laboratory personnel unless a very urgent or pressing issue".*

This finding shows that the health care workers have a lot of confidence with the results they receive from the laboratories.

4.8.3 Healthcare workers' views on the Validity of the laboratory tests

Almost all the healthcare workers stated that they had received wrong results at one time or another, especially results that have been mislabelled and required typing. They mentioned areas that are most misdiagnosed, included microscopy and serology tests in relation to testing errors.

Several healthcare workers sited having received PDT negative results, and after a CT scan of the patient state, they established the presence of a pregnancy. Most were comfortable with the test methods and reagents, though a few felt that some reagent kits were below standard.

> "*Not once not twice have I received wrong results from the laboratory but I don't blame them, sometimes the just don't have the right reagents and also they are humans and human is to error and error is to human (Gatundu level 5 hospital and 21st Nov 2023)"*

These findings agree that human error in diagnosis is a common occurrence however this does not change the perception of the meet workers on laboratory personnel.

4.8.4 Healthcare workers' opinion on the Competency of laboratory personnel

A significant number of healthcare workers felt that most of the laboratory personnel were competent to perform their duties in relation to accuracy and reliability of results; however, they felt that the medical field is growing and they should be

conversant with the new guidelines, continue with medical education, and familiarize themselves with the basic normal to avoid serious errors that could be fatal for their patients.

> *"Someone cannot be trained for 3 years and work in the same place for 10 years and be incompetent (Karuri level 4 hospital banana 7th November 2023)"*

Such statements show that the healthcare workers have a lot of confidence on the competency of laboratory workers.

4.8.5 Healthcare workers' opinion on the attitude of laboratory personnel

Healthcare workers felt that the conduct and attitude of laboratory employees were above average; most were cooperative with them and were often available to discuss issues and inquires made and provide timely updates on laboratory test results for effective and efficient patient management. However, few of those working in public facilities felt that a few laboratory personnel were not serious with their work, especially during emergencies and urgent test requests and sited poor ineffective problem-solving skills and take pro-active measures to address their concerns.

> "*Laboratory personnel have come a long way and the training on continuous improvement has really helped them' (Gatundu level 5 hospital)".*

The healthcare workers perceive the attitude of their laboratory counterparts to be good.

From the above findings, the Healthcare workers have a good perception on quality of laboratory services and the status of laboratories in relation to personnel skill, competency and compliance.

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Comparison of the haematological control test results with those from clinical laboratories

This study objective was to assess the reliability of haematological by comparing the EQC materials sent to various laboratories versus those obtained from the reference laboratory. The limitation of that was that the study could only be able to assess the reliability of the auto analysers by evaluating the test results obtained from different clinical laboratories using the different types of auto-analysers. Lab samples significantly differ from the control in RBC, HGB, HCT, MCV, MCHC, RDWc, and RDWs (all $p < 0.05$), with lower values in RBC, HGB, HCT, MCHC, RDWc, and RDWs, and higher MCV in labs. MCH ($p = 0.068$) is the exception, showing no significant difference, though it's close to the threshold. These findings suggest lab samples may reflect altered blood quality possibly due to processing, storage, or testing conditions compared to the control. The direction of differences (e.g., lower RBC/HGB/HCT, higher MCV) could indicate dilution, cell swelling, or equipment calibration issues in labs. Further investigation into lab-specific factors is warranted.

The lab samples significantly differ from the control across all parameters ($p = 0.000$). Lab samples exhibit lower WBC, LYM, MID, LYM%, and MID% compared to the control, suggesting potential degradation, dilution, or loss of these cell types during lab processing. In contrast, GRA and GRA% are significantly higher in lab samples, possibly due to an actual increase in granulocytes or a relative shift from the decrease

in other cell types. These consistent differences lower lymphocytes and mid-range cells, higher granulocytes point to systematic variations, potentially from lab handling, storage conditions, or equipment inconsistencies. The findings suggest lab sample quality deviates from the control, warranting further investigation into procedural or environmental factors affecting blood integrity.

This results disagreed with a study done to evaluate and compare the general equipment effectiveness (OEE), the sensitivity, specificity, and effectiveness of the high-end haematology analysers; the OEE was great and equivalent for all the haematology auto-analysers apart from one (Rastogi *et al*., 2022 Müller *et al*., 2006; Yee *et al*., 2001) some of the actual consideration were exactness and imprecision, linearity, inter-instrument associations, and the differential of white blood cell and flagging effectiveness. Haematological auto analysers generally give reliable results as they were compared for both haematological indices and differential count and with Haemoglobin levels using different methods (Yadav *et al*., 2020; Ghys *et al*., 2009).

It was in agreement with a study that was done on aquaculture to test the effectiveness of automated analysis methods as a tool for the evaluation of hematological parameters as an substitute to conventional manual methods, the finding were that automated analyses are valid diagnostic benefit for the prospect of aquaculture (Fazio, 2019).), also in agreement with Plebani study that indicated that laboratory errors had meaningfully reduced over time owing to proper use of automated analytical procedures (Plebani, 2020).

However, these results were contrasting with those done using two different equipment's specifically Sysmex XN-2000 and Horiba Yumizen H2500 whereby the results had noteworthy variances in the measurements of haematological parameters amongst the paralleled analysers (Małecka and Ciepiela 2020).

The PLT (Platelet Count) with $U = 0$, $p = 0.000$ implying a significant difference. Lab samples (mean rank = 18) have a much lower platelet count than control (mean rank = 53), suggesting possible platelet loss or aggregation in labs. Similar trends are seen for PCT (Plateletcrit): $U = 105$, $p = 0.000$, MPV (Mean Platelet Volume): $U = 122.5$, $p = 0.000$ and PDW (Platelet Distribution Width): $U = 140$, $p = 0.000$.

The lab samples significantly differ from the control across all platelet parameters ($p = 0.000$). Lab samples exhibit lower PLT and PCT, indicating fewer platelets and reduced platelet volume overall, which could result from clotting, sedimentation, or improper handling in labs. Conversely, MPV and PDW are higher in lab samples, suggesting that the remaining platelets are larger and more variable in size—potentially a compensatory effect or an artifact of processing (e.g., activation or swelling). These consistent differences point to systematic variations in lab sample quality, possibly due to storage conditions, centrifugation issues, or equipment calibration. The findings suggest lab samples deviate from the control in platelet characteristics, warranting further investigation into lab-specific factors affecting blood integrity.

Erythrocytes vs. Leucocytes: The standardized test statistic (-1.356) and p-value (0.175, adjusted 0.525) indicate no significant difference in the distributions of Erythrocyte and Leukocyte counts. The adjusted p-value far exceeds the 0.05 threshold, suggesting that the medians of these two groups are statistically similar. This aligns with the data's relatively close ranges (e.g., Erythrocyte RBC: 3.2 to 5.0; Leukocyte WBC: 0.45 to 3.9), despite some overlap in lower values.

Erythrocytes vs. Platelets: The standardized test statistics (-2.712) and p-value (0.007, adjusted 0.02) show a significant difference between Erythrocyte and Platelet distributions. The unadjusted p-value (0.007) is below the Bonferroni-adjusted threshold (0.0167), and the adjusted p-value (0.02) is below the overall 0.05 threshold, confirming statistical significance. This difference likely stems from the wide range of Platelet values (0.183 to 228) compared to the narrower Erythrocyte range (3.2 to 5.0), indicating that Platelet counts vary more dramatically across labs, possibly due to measurement variability or biological factors.

Leucocytes vs. Platelets: The standardized test statistic (-1.356) and p-value (0.175, adjusted 0.525) reveal no significant difference between Leukocyte and Platelet distributions. The adjusted p-value is well above 0.05, suggesting similar medians. While Platelets have a broader range, Leucocytes (0.45 to 3.9) share some overlap in lower values, reducing the distributional difference. The implication of this is that these metrics may be influenced by distinct factors in the Wajir East context, such as environmental conditions, health status, or lab measurement techniques (Ahmed *et al*., 2020). The lack of difference between Erythrocytes and Leucocytes, and between

Leucocytes and Platelets indicates that these cell types may share similar distributional patterns, possibly reflecting correlated biological responses or consistent measurement practices across labs. These findings can inform health interventions in regions in Kenya like Wajir East, where understanding blood cell variations may guide targeted medical support for women traders, who face significant challenges (e.g., insecurity, limited capital) as identified in the study.

It is worth noting that all the tests done in this study were done using auto-analysers, there was no laboratory that was using manual methods of analysis this is in total agreement that upgrading in technology is been witnessed in clinical laboratories and that the addition of novel parameters in automated haematology analysers permits for improved and quicker discovery of anaemias and other blood cell related abnormalities and that is why many laboratories have adopted automation in Kenya because majority of health facilities are now more concern about timely and proficient explanation of complete blood counts that allow for efficient care of the patient (Dixit *et al*., 2022). In fact, studies have shown that analytical automation is of serious significance in patient well-being with reverence to precise and quick examination result transmission (Bakan & Umudum 2021) which is an indisputable improvement in clinical laboratories as found out in this study. In the previous years, noteworthy developments in laboratory errors reduction have been realized by technological facilities, which have developed a significant part of the decrease of avoidable diagnostic mistakes by the use of total laboratory automation and workflow alterations that include process normalization that enable shorter specimen processing and reduction of turnaround time across specimen sources (Gonzalez *et al*., 2020).

The findings of this study were that the test results from the control results were accurate for most parameters apart from the MID cells and platelets. The results variation of platelets has been noted in the past studies (Zandecki *et al*.,2007) reason being the use of EDTA anticoagulant, it has been noted that the flags produced depend on the software version on the haematology analyser used, the performance in detecting the same anomalies may differ depending on which analyser is used, even those from the same manufacturer may also produce varied results (Zandecki *et al*.,2007). It is, therefore, important for the workers to be aware of the characteristics of their analyser and be able to identify and evade anomalous results even the more the importance of this study and many other EQC programs to ensure quality diagnosis (Briggs *et al*.,2008).

Worth noting is that correct reporting of blood cell counts and differential count is the principal objective of all medical diagnostic haematology laboratories (Thachil and Bates 2017). The crucial factors that guidance haematology analyser choice; include the analyser's reliability, cost, availability, and turnaround time (Rastogi *et al*., 2022). Constant assessment of the equipment with the suitable techniques is the vital factor to guarantee continuous quality of reporting in clinical diagnostic laboratories (CLSI, 2010). Equipment calibration every single six months, daily QC standards measurement, and the inter-instrument assessment within the 6-month intermission by means of patient samples of extra than 40 samples is the strategy being employed to maintain quality control (QC) though from the questionnaire of the laboratory personnel this has not been the case in this study (Selvi, and Ankanagari, 2019).

The results of MID cells in this study also did not follow a normal distribution curve, which is an expected outcome because it is possible for a haematology analyser to misidentify various cellular forms, resulting in incorrect positives (Rastogi *et al*., 2022; Chin *et al*., 2002) or they can produce spurious results (Zandecki *et al*., 2007). In particular, Basophils have been misdiagnosed using routine haematological analysers (Feriel & Genevieve, 2020; Ducrest *et al*., 2005). This is the reason that there has been a recommendation to use the microscopic evaluation of a slide, which is the method that is presently considered as the reference method because a true value for the leukocyte differential count is the actual count. Nevertheless, this method contains from several shortcomings, such as numerical, slide distribution, and morphological explanation errors (Feriel & Genevieve, 2020; Allou *et al*., 2015). Also, it has been agreed that the use of linear regression is not an excellent concordance of results in a correlation coefficient (r-value) for the reason that there could be a negative consequence of the correlation coefficient, and thus, the correlation coefficient should be interpreted with carefulness.

Furthermore, some parameters have been reported to for their poor association results with those done using peripheral blood films, such as the basophil count (Chopra *et al*., 2021). This is also in agreement to yet another study done which performed great linearity for white blood cell, and platelet counts ($r > 0.99$) and Within-run precision actuality occurring decent at all ranks for the routine cell blood count parameters (CV < 3.5%). The study also revealed the of inter-run precision was satisfactory at all levels for the analysis parameters (CV < 5%) except for eosinophil and basophil (CV% >10%). Particularly the comparison of the two equipment confirmed identical

correlation ($r > 0.94$) cell blood count and cell differential parameters except for basophil ($r = 0.72$)(Xiang *et al.*,2015). There was a suggestion that every laboratory professional should establish their own quality parameters and reference ranges, and the entire laboratory staff must be trained (Carey *et al*., 2020). Unfortunately, such conversions are major undertakings in today's down-sized laboratory, as found in this study whereby the staff shortage was evident.

There are discussions around introduction of automation to be able to address the issue of staff shortage though they are disadvantages and advantages around this great technological advancement. Studies have shown that the purchase cause small rise in equipment expenditures which is greatly recompensed by a noteworthy reduction in staff expenses. One study particularly showed that the total cost of running the laboratory decreased by 12.55% (Archetti *et al*., 2021). In the same study the findings were that the introduction of automation also improved the TAT of examinations that are not urgent while the emergency exams were still authorized within the extreme period of time obliged by the healthcare facility (Archetti *et al*., 2021).

In yet another study the findings reported that there was laboratory performance improvement after Total laboratory automation (TLA) implementation in entirely four of the key performance pointers which typically include the average turn-around time (TAT), demonstrating the time it takes to report of laboratory, reduced by 6.1%; the 99th percentile of TAT, representative the outlier rate, reduced by 13.3%; the TAT CV, signifying predictableness, reduced by 70.0%; and weighted tube touch moment (wTTM), demonstrating workers safety, enhanced by 77.6%. Grounded on these

efficiency results, financial assessment was done by means of two methods. The first approach was the use of incremental charge effectiveness proportion and wTTM to know the most affordable performance pointers. Secondly, the anticipated repayment time was also considered. Bearing in mind only staff cost saving, it was expected that 4.75 years would be required for the repayment of the initial investment. In Conclusion according to that study the TLA can meaningfully increase laboratory performance, because of the reasonably rapid repayment time, hence reduction of total hospital costs in the extended duration. Therefore, the capital investment for TLA employment is well thought-out to be very prized venture (KIM *et al*., 2022).

In yet another study to explore the introduction of automation in the pre- and post-analysis automation in the laboratory system found out that the automation did not contribute to lack of impact on the laboratory workforce, and that manual labour is not done away with in all laboratories, allowing for multiple job roles for the laboratory workforce and therefore this was a contrary opinion with the previous studies (EL-Osta, 2024). The only sample type that was sent out for analysis in this study was whole blood despite the fact that automated haematology analysers have the capacity to produce precise complete blood counts (CBC) results on almost all types of samples and so it would have been interesting to compare results outcome from various sample types and that should be a point of further study despite the fact that the most commonly requested results are for blood because it is the most significant in disease management. Though, every once in a while, the laboratory come across, approximately samples that yield no or erroneous result(s) for one or more CBC parameters despite the analyser is working appropriately and the requirements by the

company being are followed precisely. Erroneous results, which may undesirably disturb patient, care, medically undependable and need the close consideration by the laboratory workers and they must look for ways of recognizing undependable results, define the potential cause(s), and be conversant with the means to get dependable results on such samples while using auto analysers (Gulati *et al*., 2022).

Finally, users of auto-analysers should be conscious of a possible causes of lack of accurateness that can be come across when using such equipment's and in this study the laboratory personnel were very well informed on the potential cause of inaccurate results and the analytical phase and that is why most of them at 50% had the calibration and maintenance of laboratory equipment done regularly. Just like it is the recommendation of Saad *et al* that altogether laboratories ought to confirm or validate the differential counts that are generated from slide makers and digital microscope with automated cell differential counters for the reason that he suggest that manual count confirmation should only be well-thought-out if a noteworthy proportion of medically applicable abnormal cells are existing because according to the study, haematology analyser results should always preferred over all other haematological analysis method (Saad *et al*., 2020).The results from this study despite the limitation of using only one sample type and doing only one control run per laboratory the results had excellent reliability and validity as shown in the findings.

5.1.2 Determination of precision of immunological test results

The other reason for a challenge in compliance is the rationale of risk assessment in relation to what lack of quality performance would mean to the patients and to the

society at large, because this diseases risk not has high like the others fore-mentioned which have a greater risk to the society (Burcu *et al*.,2020). Some of the reasons that would have caused the variation could have been the common human errors or the reagents could have been of poor quality in those individual laboratories. The concern of poor-quality reagents was raised by the healthcare workers in this study who stated that there was poor quality of the reagents being supplied in the laboratories (Kierkegaard *et al*., 2021; Lippi and Favaloro, 2015).

5.1.3 Precision of CD4 test results

The CD4 count results were in agreement with those of the positive and negative control however only 2 laboratories out of the 39 selected laboratories were doing the CD4 count. There could be many reasons for the lack of availability of the tests, one being that majority of patients coming with HIV infection, come for help late with CD4 counts below 200, so they do not advantage from earlier ART (Sharma *et al*., 2021) or maybe because by the year 2015, all the most important guidelines endorsed treating entirely HIV-infected adults irrespective of their CD4 count (Yoshimura, 2017), however a study done as an external quality assessment of CD4+ T-Cell Count by means of in-house proficiency testing panels for CD4 count in laboratories in Addis Ababa, Ethiopia had similar outcome with of this study that the results were sensitive and reliable (Yibalih *et al*., 2019).

5.1.4 Precision of C-reactive proteins results

CRP control mean results were 1.06 ug/L and those from the laboratories were average mean of 1.084 ug/L. and a standard deviation of 0.2633 meaning that the

results were agreeable with those of the control. This findings agree with a study done to determine the Sensitive C-Reactive Protein-Based Immunoassay and the Effects of Laboratory Variables on Levels of Protein in Blood that clearly shown that this protein is highly stable even after several changes done to it like using different diagnostic methods example the enzyme immunoassay where the findings highly correlated with those obtained with an automated immunonephelometric assay. Comparable results were obtained for plasma (heparin and EDTA treated) and serum samples, and levels were unaffected by delays in sample processing and storage temperature. CRP levels were also not changed by up to seven freeze-thaw cycles (Aziz *et al.*, 2003).

Similar findings were established by yet other EQC study that was done for three years which also found out that the findings were that both the precision and accuracy of hs-CRP by an external QC program applied for 3 years in a joint epidemiological study (Nadif *et al*.,2020).

From the findings of this study however, only ten(10) out of the laboratories were doing the test out of all the 38 selected facilities, meaning there is lack of availability of required analyser for the CRP, which is a clear picture of the state of lack of the availability of resources (Mesfin *et al*., 2017; Wanjau *et al*., 2012, and Bates *et al*., 2006) and therefore some tests are not easily available and accessible in the County despite their importance. CRP is a very important test in the diagnosis of conditions like sepsis especially in neonates and urinary tract infections (Mushi et al., 2019) and also a variable biomarker for inflammation (Fazal, 2021). This findings are in contrast

with studies done in developed countries that CRP is one of the most frequently requested test in many such countries (Plebani,2023).It will therefore be necessary to do more campaigns by the immunologists to ensure frequent usage of this superior inflammatory indicator for better management of patients especially because combined use of ESR and CRP yields higher diagnostic accuracy (Lapic *et al*.,2020).
A study done to investigate the importance of CRP indicated that its sensitivity in the diagnosing infection of bacteria remained at 80.7%, specificity was 96.0%, positive predictive value at 91.9% and negative predictive value was 89.8%.Worth noting was that CRP and body temperature had greater sensitivity and specificity than white cell counts and neutrophil count in the identification of bacterial septicity. Evidenced is that for every 1-mg/l increase in CRP, the risk of bacterial infection upsurges by 2.9% the two studies documented (Karasahin *et al*., 2018; Liu *et al*., 2010).So therefore it is necessary for the ministry of health and policy makers to ensure installation of this important diagnostic tool.

This study was limited to qualified laboratory personnel who were registered with KMLTTB and therefore the performance was biased because their performance was based on skill and competence but there are many other laboratories, pharmacies, chemists or even clinics where rapid diagnosis are being performed by non-qualified personnel or even non licensed personnel and therefore there is further discussions ongoing on whether it is still okay for other professionals to perform the rapid diagnosis on patients and the findings are that similar failure proportions of in-house quality control findings with turnaround times amongst non-laboratory and expert laboratory-educated workers put forward that non-specialized laboratory-trained

personnel can correspondingly do Pont of care early diagnosis correspondingly well as expert laboratory personnel (Simmonds *et al*., 2020), this should be an area of future research to include both registered and non-registered laboratory personnel and the difference between trained and non-trained workers.

5.1.5 Laboratory personnel proficiency and skilfulness

Most of the laboratories in charge rated the staff members working under them to be competent. In addition according to the quality of the findings obtained from the performed tests, also found to be agreeing with these findings; the observation checklists also proofed that most laboratories followed the required guidelines by the licensing board and that is why they were complying which is in agreement with a study done still in various regions in Kenya to assess the quality of laboratory services (Njoroge, 2014).Studies have observed that for the clinical diagnostic laboratory, the quality of laboratory testing is greatly influenced by on the quality of personnel giving the necessary services (Howanitz *et al*.,2000).According to this study based on the sediments of the laboratory in charge that the laboratory personnel had excellent communication skill rated at 10/10 explains why there was great outcome in almost all the laboratories that were visited and also the courtesy evaluated by politeness, respect and friendliness which was at 96%. According to this study the only lacking element of quality observed, rated at 40%, was the lack of an incidence record book, although the laboratory staff knew its importance in detecting mistakes and preventing the action from happening again (Okezue *et al*., 2020). It is therefore important as part of the contribution of this study to the improvement of excellence of laboratory services to educate the laboratory personnel and the

management of the laboratories on the importance of recording the incidences they encounter in their day-to-day work.

This study also found out that some laboratories had limited resources to construct quality laboratories with adequate spaces and timely provision of supplies, which are the a major causes of poor laboratory services as have been stated in previous studies done by Mesfin *et al*., 2017; Wanjau *et al*., 2012 and Bates *et al*., 2006), who revealed that the most important issue affecting laboratory services were a shortage of resources, which was clear and evident in this study, equipment lack of function, deprived management system, scarcity of qualified staff, little staff inspiration, nonexistence of knowledge and absence of training (Kaoje *et al*., 2017). In fact some of the selected laboratories did not participate in the study because there was only one personnel working in that facility at that particular time and was on leave or otherwise. This means that even the patients visiting the facilities at that given time were not attended to and could have been referred to another facility for the service.

Most laboratories in this study did not have external quality control programmes in place at 76% and those that were available were for the diseases under surveillance this is in tandem with several studies done in many African countries that have found out that lack of resources could also contribute to the lack of internal and external quality control participation. Further studies indicate lack of participation in quality control activities could lead to poor delivery of quality laboratory services and also it has been found out that the laboratory specialists who did not perform regular in-house quality control activities are six (6) times additional probably to offer low-

quality laboratory services than those who consistently run through (Mesfin *et al*., 2017).

In addition, 76% of the laboratory personnel confirmed that they sometimes used non-calibrated, poor-quality machines. Further, participants reported limited support from the management, work load, and lack of external quality control as the reason they do not regularly participate in external quality control programs. These results were bucked up with the laboratory in charge of the competency checklist this findings are in consensus with a study conducted in Ethiopia that exposed that absence of equipment repairs, scarcity of reagents and provisions, poor laboratory administration, and absence of follow-up remained as the known influences that caused poor results in the laboratories (Desalegn, 2016). This study strongly believes if more resources were given to the laboratories the services could even be better than they are currently are.

In this study specifically the laboratory personnel were happy with the services they provide at 94.7% which contradicts a study done in Ethiopia that verified that Seventy-five (35.2%) participants supposed their laboratories did not make available quality laboratory services. The chief mentioned reasons influencing the delivery of quality services were scarcity of resources (64.3%), deprived management provision (57.3%), bad equipment quality (53.4%), and great staff amount of work (41.1%), absence of equipment standardization (38.3%) and absence of information (23.3%) (Mesfin *et al*., 2017). Some of this study findings are partly comparable to the results of this study whereby from the interviewed laboratory personnel 84% of them felt

understaffed and high workload (60%) being stated as the greatest challenge of the employees in most countries in the world similar to some in SSA (Dignos *et al*., 2023; Rays, 2020).

Similar information was obtained from the focused group discussions with the healthcare workers whereby they stated that they did not have time to discuss the results with the laboratory because of the high workload and long ques despite the revelation high workload being an elemental forecaster of job satisfaction (Srimarut and Mekhum 2020). From a certain study done there was conclusion that satisfied employees were better in performance in their duties as compared to dissatisfied employees, thus contributing significant role in the enriching of their organizations (Inayat and Jahanzab 2021).

Additionally, studies from other Sub-Saharan Africa countries exposed that most important factors affecting laboratory services were equally staff scarcities, deprived communication systems, scarce equipment, little staff morale, and absence of training (Bates et al., 2006) which this study perfectly revealed in is a similar state in Kenya which is one of the sub-Saharan Africa countries. More than 97% of the professionals in this study were not satisfied with their salaries. This agrees with studies done by (Mesfin *et al*., 2017, Odoa *et al*., 2017, Schneidman *et al*., 2014). The lack of continued medical and professional development hinders improvement in laboratory services delivery (Bates *et al*., 2006).

The results also show that almost all laboratory staff in the study had plans to pursue further education; however, only a quarter were enrolled in an education program. Among the few that received training, a good number (66%) had training on laboratory quality management, which lasted for one week. The most attended trainings were seminars and workshops this findings are similar with those of a study reported in Tanga, Tanzania, whereby only 14 (17%) of the 84 people who were employed in the laboratories were technologists with an advanced qualification, a certificate or even a diploma (Ishengoma *et al.*, 2009), implicating that health laboratories training in sub-Saharan Africa are extremely inadequate as with similar agreement with (Shumbej, 2020). The training institutions in the country should take up the responsibility of opening avenues to ensure that there are in-service trainings that are staff friendly and accommodate those who desire to pursue further education. If this does not happen there is undesirable consequence on the quality of diagnosis as illustrated by a certain study (Odoa *et al*., 2017). Similarly, a study done in Sokoto, Nigeria, in a middle level institution, disclosed that out of 95 laboratory personnel, additional than two-thirds had not obtained in-service training on Laboratory Quality Management (Kaoje *et al*., 2017), which is similar to yet another study done in Addis Ababa Ethiopia where 133 out of 213 (62.4%) had received in-service training (Mesfin et al., 2017). This major gap identified not only in Kenya but in many SSA countries as stated needs to be addressed urgently in order to ensure provision of quality laboratory services and for continuous improvement.

According to the study only 6.6% of the personnel that participated were quality assurance staff. It is known that the presence of a Quality assurance /Quality control

(QA/QC) consultant in the laboratories supports with technical provision for diagnosis; however, it is not the state of affairs in resource-limited situations (Petti *et al*., 2016) and this was evidenced in this study an so as stated earlier the training institutions should seize this opportunities and develop curriculums and further study programs that would be able to address this gap also. Though now there are confirmations of the availability of various training programs from corner to corner of diverse African countries that integrates of online learning platforms, rather than comprehensive dependence on the old-fashioned physical training programs that may grow the education scope of the current platforms. Digitalization inspired by the coronavirus disease 2019 pandemic possibly will make available opportunities to reduce the information deficiency in low- and middle-income countries (LMICs) and provide further education opportunities to many Kenyans (Rambiritch *et al*., 2021).

Furthermore, strengthening pre-service laboratory training is promising in resource-limited backgrounds, and put emphasis on its advantages (sufficient local capability, country rights and sustainability) make available a cherished basis of skilled laboratory personnel to release an at present overstrained healthcare system (Fonjugo *et al*., 2013). Yet another suggestion to mitigate the training gap is inclusion of the private public partnerships (PPP) pool the capabilities of the public and private divisions to enhance maintainable laboratory systems and advance labour force abilities in African nations as illustrated in a study (Reyes,2021;Shrivasta *et al*., 2016). The key known endeavours of the PPP initiative comprise quantifiable and scalable results to help reinforce national capabilities to construct technical expertise, progress sample referral networks, chart disease occurrence, fund proof-based health

programming, and initiate constant quality enhancement in clinical diagnostic laboratories as indicated by two studies (Kebede *et al*., 2016; Shrivasta *et al*., 2016).

According to the study 82.9% of the personnel who were interviewed were general practisers, 7.9% of them in haematology, immunology 1.3%, and 3.9% microbiology with such kind of findings the training need assessment need to be undertaken in order to know which areas of diagnosis require more staffing though according to a study done in the Government Chemist Laboratory in Kenya illustrated that even though training needs analysis was investigated, there was no consensus as to when and how often it was carried out (Nyoike *et al*.,2020). This study recommends that both out of the-job training and in-the-job training approaches should be engaged and also establishment of the factors which hindered employee training and development as stated earlier because many employees had a desire to study, but few were enrolled in actual study programs. It is of great importance to ensure that training is actualised as was recognized that there is a helpful association amongst training and progress of employees and employees' work performance at the Government Chemist Laboratory (Nyoike *et al*., 2020), and therefore this study like the one done in government agrees on the need to continue to establish the training needs and also what are the factors hindering the personnel from furthering their education.

Finally, to address the lack of ongoing activities in Quality Control and quality assurance it is good to include competency program that lists entirely investigations and techniques for each sub-specialty and grow a program where an worker can contribute in the process by picking out pieces from the test lists and roster the

implementation to take place with an onlooker at a jointly suitable time which has succeeded elsewhere (Curtin *et al*., 2020) and it will be an innovative group centred methodology for quality improvement efficiently that engages all staff and decreases adverse happenings in healthcare settings. Areas that needs to be included as stated by the Health Care Financing Administration, CLIA programs Medicare and Medicaid include direct scrutiny of routine patient test presentation, checking the report and recording of investigation results, evaluation of intermediary test findings.

Quality Control registers, proficiency analysis outcomes, and precautionary upkeep records, straight surveillance of performance of equipment's repairs and task instructions, evaluation of test performance complete testing earlier examined samples, in-house blind testing samples, or outside proficiency analysis samples; and assessment of problem-solving expertise (Maphumulo & Bhengu, 2019) this study was able to do that but it is also good to note that in many cases this does not happen and that is why regular quality assessment programs should be a priority in our nation in fact a study done in Ghana showed double noteworthy trials pointed out by respondents to comprise poor laboratory funding and hindered execution of the Ghana National Health Laboratory Policy (Kploanyi *et al*., 2023).

Though there are three vital achievement influences for medical laboratories in LMICs applying QMS explicitly organizing for change, resource obtainability, and operational project management, however Institutional pledge was recognized as the necessary of the model and is the most significant to safeguarding the quality of laboratory services (Tanasiichuku *et al*., 2023) as also seen in this study whereby the

facilitation of quality control services was at satisfaction was at 53.4%. All other laboratory services need the support from the key stakeholders because it is essential for sustainability as has been identified in the Point of Care (POC) aimed at Early infant diagnosis (EID) research which found out that it was a success because the contributors held on to the establishment of POC analysis for EID (Bianchi *et al*., 2020).

5.1.6 Laboratory errors

This study finding was that 72% of the personnel stated that they had identified errors, the tricky part of medical errors or misses has in recent times received much attention and which will probably increase (Plebani 2020). Laboratory personnel having observed errors at this high percentage is of great concern this is because errors compromise the quality of laboratory services and patient management (Kimengech, 2017; Sepulveda *et al*., 2019). These possibly will negatively influence patient care, which adds to unnecessary investigations or incorrect management, increases spans of hospital visit, and discontent with healthcare services (Dugad *et al*., 2022). Furthermore, laboratory errors made to happen by poor quality management activities can cause the patient to suffer in addition a damage of confidence by healthcare workers, hence conveying about in the reduced usage of diagnostic testing data for physicians management and a series of poor quality, for instance frequently experienced in resource-limited countries (Ong *et al*., 2020).

The findings were that pre-analytical phase was the most common at almost 70%, which is in total similarity to many other study findings (Dugad *et*

al.,2022;Green,2013;Ibrahim *et al*.,2012), with mislabelling at 28.9% being the most identified error, the mislabelling sediments were backed up by the healthcare workers stating that they had received wrong mislabelled results one time or another in the focused group discussions agreeing to Jagannatha et al that around 93% of laboratory errors happen in the course of the pre-analytical testing phase (Jagannatha *et al*., 2019) and Kimengech,2017 that pre analytic phase is prone to error which could include haemolysis of samples. In another study stated that 61.9% of errors happened in the pre-analytical phase, 15% in the analytical phase, and 23.1% in the post-analytical phase. In a different study, 13%-32% of laboratory errors happened in the analytical testing phase (Jagannatha *et al*., 2019; Sepulveda *et al*., 2019).

Vigilant procedure analysis during performance exposes additional errors (Jagannatha *et al*., 2019); therefore, a more laborious methodology for error revealing and arrangement should be able to identify analytical mistakes, and external quality assessment like this study is one of the ways that has been identified as an indicator for quality at the performance in error identification and backed up by (Madhuri *et al*.,2016), Finding in this study 88.2% of the laboratory personnel interviewed stated that they participated in EQC and those who did not participate mentioned lack of management support and high cost of the panels. Management of hospitals should be educated in the importance of participating in the external quality assessment programs despite their high cost and the providers of the same should be encouraged to look for cost effective ways bearing in mind their great importance in error detention and error prevention.

This study did not investigate matters on sample rejection but of course an abnormal sample that does not meet the standard requirements should be rejected and should not be used for analysis and in so doing you avoid laboratory errors. A current study indicated that, the top three reasons for sample refusal were inadequate amount (23.3%) followed by coagulated sample (21.9%) and non-labelled miss-labelled specimen at 19.2%. The finding on mislabelling confirms the findings in this study. Haemolysis was not investigated also in this study with the assumption that all haemolysis samples should be rejected, it could be interesting in the future to look at haemolysis as a pre analytical error because in yet one more study done in Ethiopia presented the greatest recurrent reason of sample refusal was haemolysis at (33.3%) and there are discussions that are ongoing on how best to manage laboratory errors especially pre-analytical errors associated with the most common being the haemolysis of blood sample, the related prices, the great variety in how haemolysis is controlled throughout healthcare surroundings, countries and continents, and snowballing patient cross-border movement, regulation and quality development processes targeted at fighting this imperative to pre-analytical difficulty are obviously justified (Simundic *et al.*, 2020).

The next second most common pre-analytical error according to this study was a sample with correction of the wrong sample at (17.1%) the inconsistency may be the consequence of an absence of proper clinician alignment and sample gathering orientation of the patient during sample collection according to (Addi *et al.*,2021;Ambachew *et al.*, 2018). This study had limitations because the patients and the healthcare workers were not followed to give their take on these findings by the

laboratory personnel. However, it is good to note that despite the limitations in this study the confirmation of what other previous studies have evidenced was clear that laboratory errors happened more in the pre-and post-analytical phase of total examination process. These errors can be stopped by providing consistent trainings that can consist of all stakeholders to upsurge their pledge for quality enhancement, applying laboratory information systems (LIS) that can reduce the physical works in the laboratories, recurrent managements by local laboratories, and better-quality guarantee system will warranty decrease in mistakes in laboratory (Tadesse *et al*., 2018).

In fact, a process that was started for continuous improvement in some laboratories in Ghana and Burkina Faso clinical trials centres showed that the methodological errors reduced by 35%, when there was introduction of quality improvement however the study suggested that more improvement is always necessary (Ibrahim *et al*., 2012). This study also strongly agrees that despite the efforts that have been put in place more improvement is equally necessary to reduce the occurrences of laboratory errors.

5.1.7 Healthcare workers' views on the quality of laboratory results

This study almost all healthcare workers frequently requested laboratory tests in the County, citing the importance of the results for confirmation of their diagnosis this finding was in agreement with another study that stated that the laboratory is the greatest significant determining factor in the procedure of diagnosis of disease (Bate *et al*., 2006). It is because almost all healthcare workers used laboratory results to

diagnose their patients. Moreover, various studies investigating the importance of diagnostic sciences were highly rated because of their importance, and other health professionals highly rated medical laboratory sciences (Lippi & Plebani, 2020; Derbie and Mekonnen, 2017). Furthermore, in agreement with a study done in Mozambique that claimed the facilities lacking laboratories amplified the probability of expensive referrals, stays, and even loss of lives (Tadeu and Geelhoed, 2018).

A study in Malawi recommended that, to improve the usage of laboratory test findings in patient management were to reinforce the stock chain, decrease turn-around times, advance the test set of choices and increase the laboratory organization. In the study Ninety-one (91%) percent of healthcare workers expressed the need of laboratories to upgrade their infrastructure. The study further indicated a 91% use of laboratory results for patient management (Moyo *et al*., 2015). Previous studies show that, as physicians rise utilization of the laboratory results, opportunities will carry on rising in terms stretched out test menus, smaller turn-around times, noble quality and analysis of results (Van, 2022).

The findings of this study found that almost all the healthcare workers interviewed in the focused group discussions had received wrong results one time or another. This was in agreement with the feedback received from the laboratory personnel themselves in this study, whereby 75% of the laboratory participants had done errors in the course of their work in the laboratory and 68% described seeing other laboratory employees doing errors. The mistakes done ranged in all the phases, where mislabelling was the most error committed in the pre-analytical phase, which is in

total agreement with the findings that approximately 93% of laboratory errors take place in the course of the pre-analytical testing phase (Jagannatha *et al*., 2019). Others included the incorrect measuring the sample in the analytical phase and sending results to the wrong location in the analytical phase, which was also the concern of the healthcare workers interviewed.

In Nigeria, Sokoto, in a study performed by Kaonje *et al*., 2017 revealed that nearly all the healthcare workers in tertiary health Centres had obtained wrong results; however, this did not stop the healthcare workers from relying on the laboratory results. Preferably, quick and accurate diagnostic testing should be accessible at the initial consultation to enable healthcare workers to make the right diagnosis and to evade the waste of resources and amplified ill health related with improper first diagnosis, clinical misdiagnosis, insufficient health care infrastructure, and laboratory competency and diagnostic accuracy (Petti *et al*., 2016) this is not the case in this study because one of the major concerns of the healthcare workers especially in the public facilities was shortage and unavailability of test reagents, though in some areas availability was not an issue. This finding agreed with two separate studies done in Rwanda and west Ethiopia where by lack of availability of reagents was a concern to healthcare workers (Rusanganwa *et al*., 2020; Ejeta *et al*., 2015).

Still, yet in another study found out that some common tests are not in routine use in Ghana’s Northern Region for the reason that they are deliberated too costly or have not been sufficiently assessed in real-life state of affairs siting availability of diagnostic testing in severely inadequate matched to the WHO's essential diagnostic

list (EDL) (Ward *et al*., 2021). In this study the unavailability of test reagents was more pronounced in rural facilities in public level 3 and level 2 settings. The solution to this could probably establishment of payment rates by the facilities that would be able to ensure these tests are available in so as to realize the Universal Health Coverage aim of the maintainable development goals.

This study did not associate the level of satisfaction in the various levels of health facilities, it could be interesting in the future to compare because a study conducted on the patients' contentment and quality of clinical diagnostic laboratory services delivery at public health facilities in northeast Ethiopia gives a differing opinion whereby the patients were extra probable to be contented in health centers (75.2%) than in major well established hospitals (68.6%) (AOR=1.9, 95%CI: 1.0-3.6, p=0.036) (Abebe *et al*., 2022). It is good to note that level of satisfaction of health professionals and change of perception keep on changing depending on the specific area of study also for example in a study done to evaluate the view and their fulfilment of health professionals regarding malaria quality diagnostic services in Northern Ethiopia was different from other studies done on general laboratory service (Bogale *et al*., 2020).This means that it is possible that if this same study was repeated with the same study subjects only but asking on a specific area of diagnostic service you would expect a different response, because general services would be satisfying but a test like H. pylori diagnosis would receive a different response.

Healthcare workers in this study felt that the laboratory services are generally quality which was contrary to a study done in Congo to evaluate the quality of clinical

laboratory services (Alain *et al*., 2021) which showed that only 45.2% of the customers using laboratory services were happy with the laboratory services siting the concern of correctness of tests' results, accessibility of requested tests, and laboratory turnaround time which should be the three top main concern for quality enhancement in our case here in Kenya.

Healthcare workers felt that the conduct and attitude of laboratory employees were above average; this revelation is comparable to the study that was done in west part of Ethiopia (Ejeta *et al*., 2015). Most cooperated with them; however, those working in public facilities felt that a few laboratory personnel were not serious about their work, especially during emergencies and urgent test requests. These findings agree with a study done in Egypt for the evaluation and enhancement of turnaround times (TAT) as well as client gratification as a vital ingredient for laboratory quality management that evidenced that the maximum satisfaction rating was the need of staff courtesy. In contrast, the bottommost scores were for laboratory management receptiveness, outpatient TAT, and life-threatening value warning. Quality or dependability of examinations was refereed by healthcare workers as the most significant influence (32.3%), then next was routine test TAT (18.5%) (Abebe *et al*., 2023).

A great number of healthcare workers felt that the most of the laboratory personnel were competent to perform their duties similar with Rwandan study (Rusanganwa *et al*.,2020) however they felt that the medical field is growing and they should be conversant with the new guidelines and continue with medical education and familiarize themselves with the basic normal to avoid serious errors that could be fatal

for the patients which is with agreement with the sentiments of Dede et al., 2005 and those of Benyanga *et al*., 2018 and Manickam, and Ankanagari, 2015 that there is need to in cooperate current trends in the laboratory curriculum in order for the graduates to accommodate changes in the laboratory science practice (Kemzi *et al*., 2022, Temri *et al*., 2014) because consistent teaching for entirely all the staff creates cognizance and attentiveness to implement quality in laboratory process in fact (Rusanganwa *et al*., 2020) alluded to luck of training a major contributor to the decline of laboratory services in Rwanda despite the recommendation from Uganda that continuous mentorship and training and also regional supportive supervision as was the objective of this study are necessary for continual enhancement of the quality of laboratory services especially in the sub Saharan African countries (Taremwa *et al*., 2017). The quality control and assurance efforts should be concentrated both to the low level facilities and the high level facilities because studies have shown that the low income facilities perform the most bulk of laboratory diagnosis and the quality assurance programmes concentrate more on the higher levels of the laboratories (Amakel *et al*., 2015), though this study did not assess the testing volumes of laboratory tests done at every level of the laboratories.

However, according to Kamau (2013), application and enhancements in laboratory services cannot be taken into consideration alone. Using proof-based decision-making in both medical practice and public health will need an alteration in attitude to one that prices laboratory information. In conclusion, improving laboratory infrastructure only will not be helpful except related or bigger care is assumed to the larger healthcare system. The reasons explaining this reduction were lacking coordination to

guarantee constant quality improvement, absence of mentorship, and consistent exterior evaluation of the laboratory to pinpoint and address shortcomings.

Regarding the level of satisfaction, most healthcare workers in this study were satisfied with the laboratory results, which are in contrast with the finding from Rwanda, whereby merely 36% of healthcare workers were contented with laboratory services in referral hospitals. Seventy (70%) percent were gratified with the dependability of test findings, suggesting that most healthcare workers generally found laboratory results reliable, as in the case in this study, also similar to another study in the USA and Ethiopia where there was a great level of healthcare workers satisfaction and fidelity with clinical laboratory whereby the generally, the greater number (72.8%) of healthcare workers were satisfied found out that also upper fraction of physicians were contented in established hospitals more than in primary health centres (56.0% vs. 76.8%, $p = 0.003$) services (Abebe et al., 2023). A study directed towards in public health hospitals in Ethiopia similarly evidenced that majority of physicians were displeased with the current test list of options (67.3%) and want for a standby specimen referral system (62.0%) (Hailu *et al*.,2020). Another study from the Jordan pointed out that a greater percentage of tests existing in institutions had an important positive relationship with healthcare workers' average happiness score (Suleiman *et al.,* 2020).

Emphasized frequently is that Test turnaround times are insistent parts that cause of displeasure and show for openings for future improvement. (Rusanganwa *et al*., 2020; Abebe *et al*., 2023; Shahangian and Snyder, 2009) whereas the level of

satisfaction in Ethiopia from the average utmost satisfaction tally of healthcare workers [range 1-5] was 3.46 [SD 0.49], meaning it was moderate (Abebe *et al*., 2023).

Most Healthcare workers in this study indicated that they did not have time to discuss the results with the laboratory personnel, stating a long que, especially in public facilities. However, this could be a disadvantage because, according to (Rusanganwa *et al*., 2020), in a study done in Rwanda, real communication amongst laboratories and healthcare workers would upsurge physicians' contentment and probably increase the quality of health care. Laboratory workers involvement in clinical consultations and ward rounds with physicians may address majority of the healthcare workers' apprehensions.

Frequent customer satisfaction surveys are equally important because the issues that are raised by the Clients are useful for improving laboratory services and therefore contributing to the health and are necessary for continual quality improvement (Etukudoh and Obeta, 2021; Mosadeghrad *et al*.,2017).

5.2 Conclusions

1. The study revealed several key insights into the quality of diagnostic haematological testing and laboratory personnel competency in Kiambu County. Firstly, the diagnostic haematological control results demonstrated reliability across different laboratories. However when you closely look the haematological profiles the results show a significant difference from those from the control.

However generally this result reflects positively on laboratory practices and personnel adherence to procedures.

2. The two immunological control tests exhibited also good precision, despite the fact that only three laboratories were doing CD4 cell count. This area warrants further investigation to better understand and address the reasons why these tests are not available.
3. The study found out that the laboratory staff generally displayed good training and skills and were satisfied with their work, despite feelings of being overworked and underpaid, which could impact service quality. In relation to compliance to World Health Organisation guidelines the study found that most laboratory adhered despite, the absence of an accident or incident record book that was noted in several facilities
4. Healthcare workers remained highly satisfied with the reliability and validity of laboratory tests, recognizing their critical role in patient management. This underscores the importance of continued efforts to provide high-quality laboratory services and address any challenges impacting service delivery however worth noting is laboratory errors, particularly pre-analytical ones, were common but did not significantly affect healthcare workers' perception of laboratory service quality.

5.3 Recommendations

1. It is crucial to ensure availability of external quality control programs in the, laboratories. This can be achieved through development of affordable panels of tests and also establishment of EQC program that can be funded by the government especially for non-funded tests and programs and increased funding to

the laboratories to ensure that laboratories have the necessary resources to perform required tests consistently.

2. Laboratories should implement comprehensive quality assurance measures, including the establishment of incident record books. This will help in tracking and addressing errors, ensuring adherence to safety protocols, and continuously improving laboratory practices.
3. While most laboratory personnel were well-trained, ongoing professional development should be supported to address emerging challenges and maintain high standards. Additionally, addressing issues of overwork and underpayment is essential to ensure staff satisfaction and retention, which directly impacts service quality. Reinforce the importance of following safety guidelines by conducting regular audits and training sessions. Ensuring that all safety protocols are consistently followed will help maintain a safe working environment and enhance the overall quality of laboratory services.
4. Laboratories should continue to engage with healthcare workers to ensure that their needs are met and to receive feedback on service quality. This collaboration will help in maintaining high standards of diagnostic accuracy and patient management.

5.3.1 Recommendation for Further Research

Further research should be conducted compare the results by evaluating the different types of equipment and also multiple panels of tests to be performed per equipment at any given time.

REFERENCES

Aarestrup, F. M., & Koopmans, M. G. (2016). Sharing data for global infectious disease surveillance and outbreak detection. Trends in microbiology, 24(4), 241-245.

Abebe, D. D., Temesgen, M. M., & Abozin, A. T. (2022). Healthcare workers' perceived quality of laboratory services provided at public hospitals and primary health centres in northeast Ethiopia.

Abebe, D. D., Temesgen, M. M., & Abozin, A. T. (2023). Healthcare workers' satisfaction with laboratory services and associated factors at public health facilities in Northeast Ethiopia. BMC Health Services Research, 23(1), 1-9.

Adan, A., Alizada, G., Kiraz, Y., Baran, Y., & Nalbant, A. (2017). Flow cytometry: basic principles and applications. Critical reviews in biotechnology, 37(2), 163-176.

Addi, Z., Wondimagegn, T., & Tachebele, B. (2021). Types and frequency of pre-analytical errors at University of Gondar hospital laboratory.

Adewoyin, A., Ogbenna, A., & Harteveld, C. (2019). Laboratory quality systems in clinical laboratory practice in Lagos, Nigeria (West Africa): Associated problems and prospects.

Ahmed, I., Reshi, Q. M., & Fazio, F. (2020). The influence of the endogenous and exogenous factors on hematological parameters in different fish species: a review. *Aquaculture international*, *28*, 869-899.

Ahmed, S. (2019). Integrating DMAIC approach of Lean Six Sigma and theory of constraints toward quality improvement in healthcare. Reviews on environmental health, 34(4), 427-434.

Alain, C. B., Rostin, M. M. M., Joël, K. N. N., Hypolite, N. M. M., Donatien, K. N., Koffi, T. A., ... & Hippolyte, S. N. (2021). Evaluation of the quality of clinical laboratory services in the University Hospital of Kinshasa, Democratic Republic of the Congo. Journal of Economics and International Business Management, 9(1), 44-50.

Alghamdi, R. S., Alharbi, T. S., & Alsubaie, W. R. (2021). Quality Standards of Histopathology Laboratory and Work Facilities in a Developed Country. Archives of Pharmacy Practice, 12(1), 90-97.

Alharbi, M. S. S., Alharbi, A. A. F., Alotaibi, R. J., Alyami, M. S. A., Kindasa, T. M. A., Maglia, A. I. A., ... & Al-Masabi, M. A. A. (2023). Exploring the Role Of Medical Laboratories In Modern Healthcare: A Comprehensive Overview. Journal of Namibian Studies: History Politics Culture, 36, 1893-1904.

Allou, K., Vial, J. P., Béné, M. C., & Lacombe, F. (2015). The routine leukocyte differential flow cytometry Hemato F low™ method: A new flagging system for automatic validation. Cytometry Part B: Clinical Cytometry, 88(6), 375-384.

Ambachew, S., Adane, K., Worede, A., Melak, T., Asmelash, D., Damtie, S., ... & Biadgo, B. (2018). Errors in the total testing process in the clinical chemistry laboratory at the University of Gondar Hospital, Northwest Ethiopia. Ethiopian journal of health sciences, 28(2), 235-244.

Amin, M. E. K., Nørgaard, L. S., Cavaco, A. M., Witry, M. J., Hillman, L., Cernasev, A., & Desselle, S. P. (2020). Establishing trustworthiness and authenticity in qualitative pharmacy research. Research in social and administrative pharmacy, 16(10), 1472-1482.

Amukele, T. K., Schroeder, L. F., Jackson, J. B., & Elbireer, A. (2015). Most clinical laboratory testing in kampala occurs in high-volume, high-quality laboratories or low-volume, low-quality laboratories: a tale of two cities. American journal of clinical pathology, 143(1), 50-56.

Anido, G. (1975). Quality Control: Preparation of Quality Control Materials in Clinical Chemistry and Haematology. Pg numbers missing careful preparation). The Clinical Biochemist Reviews, 35(3), 143.

Archetti, C., Montanelli, A., Finazzi, D., Caimi, L., & Garrafa, E. (2017). Clinical laboratory automation: a case study. Journal of public health research, 6(1), jphr-2017.

Asmelash, D., Worede, A., & Teshome, M. (2020). Extra-analytical clinical laboratory errors in Africa: a systematic review and meta-analysis. Ejifcc, 31(3), 208.

Ast, V., Costina, V., Eichner, R., Bode, A., Aida, S., Gerhards, C., ... & Haselmann, V. (2021). Assessing the quality of serological testing in the COVID-19 pandemic: results of a European external quality assessment (EQA) scheme for anti-SARS-CoV-2 antibody detection. Journal of clinical microbiology, 59(9), 10-1128.

Attal-Juncqua, A., Standley, C. J., Tordjmann, A., Burci, G. L., & Katz, R. (2019).Legislative assessments as a tool for strengthening health security capacity: the example of Guinea post-2014 Ebola outbreak.

Aziz, N., Detels, R., Quint, J. J., Gjertson, D., Ryner, T., & Butch, A. W. (2019). Biological variation of immunological blood biomarkers in healthy individuals and quality goals for biomarker tests. BMC immunology, 20(1), 1-11.

Aziz, N., Fahey, J. L., Detels, R., & Butch, A. W. (2003). Analytical performance of a highly sensitive C-reactive protein-based immunoassay and the effects of laboratory variables on levels of protein in blood. *Clinical and Vaccine Immunology*, *10*(4), 652-657.

Badrick, T., Jones, G., Miller, W. G., Panteghini, M., Quintenz, A., Sandberg, S., & Spannagl, M. (2022). Differences between educational and regulatory external quality assurance/proficiency testing schemes. Clinical Chemistry, 68(10), 1238-1244.

Bahati, F., English, M., Sayed, S., Horton, S., Odhiambo, O. A., Samatar, A. A., & McKnight, J. (2021). Information asymmetry in the Kenyan medical laboratory sector. Global Health Action, 14(1), 1964172.

Bakan, E., & Bakan, N. (2021). Prevention of extra-analytical phase errors by non-analytical automation in clinical laboratory. Turkish Journal of Biochemistry, 46(3), 235-243.

Bakan, E., & Umudum, F. Z. (2021). Automation of extra-analytical phase for clinical laboratory. Turkish Journal of Biochemistry, 46(2), 115-128.

Ball Jr, R. T., John Jr, J. F., & Schmidt, M. G. (2024). Pandemic Planning: Roles of Clinical and Public Health Laboratories. Clinical Laboratory Management, 727-743.

Bates, D. W., & Singh, H. (2018). Two decades since to err is human: an assessment of progress and emerging priorities in patient safety. Health Affairs, 37(11), 1736-1743.

Bates, I., & Maitland, K. (2006). Are laboratory services coming of age in sub-Saharan Africa?. CID: 42:1

Berry, L. L., Letchuman, S., Ramani, N., & Barach, P. (2021, November). The high stakes of outsourcing in health care. In Mayo Clinic Proceedings (Vol. 96, No. 11, pp. 2879-2890). Elsevier.

Beyanga, M., Gerwing-Adima, L., Jackson, K., Majaliwa, B., Shimba, H., Ezekiel, S., ... & Kasang, C. (2018). Implementation of the laboratory quality management system (ISO 15189): experience from Bugando Medical Centre Clinical Laboratory–Mwanza, Tanzania. African Journal of Laboratory Medicine, 7(1), 1-6.

Biadgo, B., Zakir, A., Malede, T., Getachew, E., & Girma, M. (2019). Assessment of Quality of Medical Laboratory Services Provision and Associated Factors in Public Health Facilities at Gondar Town, Amhara Regional State, Northwest Ethiopia. Clinical laboratory, 65(6).

Bianchi, F., Clemens, S., Arif, Z., Sacks, E., Cohn, J., & EGPAF POC EID Study Team. (2020). Acceptability of routine point-of-care early infant diagnosis in eight African countries: findings from a qualitative assessment of clinical and laboratory personnel. JAIDS Journal of Acquired Immune Deficiency Syndromes, 84, S41-S48.

Birt, L., Scott, S., Cavers, D., Campbell, C., & Walter, F. (2016). Member checking: a tool to enhance trustworthiness or merely a nod to validation?. Qualitative health research, 26(13), 1802-1811.

Bogale, A. L., Ali, J. H., Tsegaye, A., & Hassen, F.(2020) Health Professionals Perception and Satisfaction on Quality of Laboratory Malaria Diagnostic Service; the Case Awi Zone, North Ethiopia. Am J Med Public Health. 2020; 1 (2), 1010.

Bowolaksono, A., Lestari, F., Satyawardhani, S. A., Kadir, A., Maharani, C. F., & Paramitasari, D. (2021). Analysis of bio-risk management system implementation in indonesian higher education laboratory. International Journal of Environmental Research and Public Health, 18(10), 5076.

Breyer, J. Z., Giacomazzi, J., Kuhmmer, R., Lima, K. M., Hammes, L. S., Ribeiro, R. A., ... & Wendland, E. M. (2019). Hospital quality indicators: a systematic review. International Journal of Health Care Quality Assurance, 32(2), 474-487.

Briggs, C. (2009). Quality counts: new parameters in blood cell counting. *International journal of laboratory hematology*, *31*(3), 277-297.

Briggs, C., Guthrie, D., Hyde, K., Mackie, I., Parker, N., Popek, M., ... & Stephens, C. (2008). Guidelines for point-of-care testing: haematology. *British journal of haematology*, *142*(6), 904-915.

Britannica, T. Editors of Encyclopaedia (2021). Immunologic blood test. Encyclopedia Britannica. Https://www.britannica.com/science/immunologic-blood-test

Brown, J. V. E., Meader, N., Wright, K., Cleminson, J., & McGuire, W. (2020). Assessment of C-reactive protein diagnostic test accuracy for late-onset infection in newborn infants: a systematic review and meta-analysis. *JAMA pediatrics*, *174*(3), 260-268.

Brugnara, C. (2015). Automated Hematology Analyzers: State of the Art, An Issue of Clinics in Laboratory Medicine.

Buch, M. H., Mallat, Z., Dweck, M. R., Tarkin, J. M., O'Regan, D. P., Ferreira, V., ... & Plein, S. (2024). Current understanding and management of cardiovascular involvement in rheumatic immune-mediated inflammatory diseases. *Nature Reviews Rheumatology*, *20*(10), 614-634.

Cadamuro, J., Gaksch, M., Mrazek, C., Haschke-Becher, E., & Plebani, M. (2018). How do we use the data from pre-analytical quality indicators and how should we. J Lab Precis Med, 3(6), 40-40.

Carter, J. Y. (2017). External quality assessment in resource–limited countries. Biochemia medica, 27(1), 97-109.

Cha, Y. J., & Cho, H. I. (2002). External quality assurance in diagnostic immunology: a twenty-year experience in Korea. The Southeast Asian Journal of Tropical Medicine and Public Health, 33, 104-111.

Chopra, P., Bhardwaj, S., & Arora, A. (2021). Comparison of basophil count by Beckman Coulter UniCel DxH 800, Sysmex XN-1000, and manual microscopy in cases of suspected chronic myeloid leukemia. Iraqi Journal of Hematology-Volume, 10(2).

Church, D. L., & Naugler, C. (2019). Benefits and risks of standardization, harmonization and conformity to opinion in clinical laboratories. Critical Reviews in Clinical Laboratory Sciences, 56(5), 287-306.

CLSI/NCCLS. A Quality Management System Model for Health Care; Approved Guideline—Second Edition. CLSI/NCCLS document HS1-A2. Wayne, PA: NCCLS; 2004.

Cornish, N. E., Anderson, N. L., Arambula, D. G., Arduino, M. J., Bryan, A., Burton, N. C., ... & Campbell, S. (2021). Clinical laboratory biosafety gaps: lessons learned from past outbreaks reveal a path to a safer future. Clinical microbiology reviews, 34(3), 10-1128.

Coucke, W., & Soumali, M. R. (2020). A critical view at the ISO 13528 and IUPAC's harmonized protocol approach for proficiency testing for homogeneity assessment for quantitative variables. Analyst, 145(23), 7630-7635.

Curtin, A. G., Anderson, V., Brockhus, F., & Cohen, D. R. (2020). Novel team-based approach to quality improvement effectively engages staff and reduces adverse events in healthcare settings. BMJ Open Quality, 9(2), e000741.

Davies, J., Abimiku, A. L., Alobo, M., Mullan, Z., Nugent, R., Schneidman, M., ... & Onyebujoh, P. (2017). Sustainable clinical laboratory capacity for health in Africa. The Lancet Global Health, 5(3), e248-e249.

Desalegn, D. M., Abay, S., & Taye, B. (2016). The availability and functional status of focused antenatal care laboratory services at public health facilities in Addis Ababa, Ethiopia. BMC research notes, 9(1), 1-8.

Dhorda, M., Ba, E. H., Kevin Baird, J., Barnwell, J., Bell, D., Carter, J. Y., ... & Research Malaria Microscopy Working Group. (2020). Towards harmonization of microscopy methods for malaria clinical research studies. Malaria Journal, 19, 1-14.

Di Fazio, N., Scopetti, M., Delogu, G., La Russa, R., Foti, F., Grassi, V. M., ... & Fineschi, V. (2023, May). Analysis of Medico-Legal Complaint Data: A Retrospective Study of Three Large Italian University Hospitals. In Healthcare (Vol. 11, No. 10, p. 1406). MDPI.

Dickerson, J. A., Fletcher, A. H., Procop, G., Keren, D. F., Singh, I. R., Garcia, J. J., ... & Astion, M. L. (2017). Transforming laboratory utilization review into laboratory stewardship: guidelines by the PLUGS National Committee for Laboratory Stewardship. The Journal of Applied Laboratory Medicine, 2(2), 259-268.

Dignos, P. N., Khan, A., Gardiner-Davis, M., Papadopoulos, A., Nowrouzi-Kia, B., Sivanthan, M., & Gohar, B. (2023, October). Hidden and Understaffed: Exploring Canadian Medical Laboratory Technologists' Pandemic Stressors and Lessons Learned. In Healthcare (Vol. 11, No. 20, p. 2736). MDPI.

Dixit, S., Jha, T., Gupta, R., Shah, D., Dayal, N., & Kotru, M. (2022). Practical Approach to the Interpretation of Complete Blood Count Reports and Histograms. Indian pediatrics, 59(6), 485–491.

Dolan, E., Kosasi, S., & Sari, S. N. (2022). Implementation of Competence-Based Human Resources Management in the Digital Era. Startupreneur Business Digital (SABDA Journal), 1(2), 167-175.

Duan, M., Kang, F., Zhao, H., Wang, W., Du, Y., He, F., ... & Wang, Z. (2019). Analysis and evaluation of the external quality assessment results of quality indicators in laboratory medicine all over China from 2015 to 2018. Clinical Chemistry and Laboratory Medicine (CCLM), 57(6), 812-821.

Ducrest, S., Meier, F., Tschopp, C., Pavlovic, R., & Dahinden, C. A. (2005). Flowcytometric analysis of basophil counts in human blood and inaccuracy of hematology analyzers. Allergy, 60(11), 1446-1450.

Dugad, V., Deshmukh, S., Anand Bhosale, D. P. S. C., Prasad Bhanap, D. R. S., & Rajan Bindu, D. P. A. (2022). Pre-Analytical And Post-Analytical Errors In The Clinical Laboratory: A Systematic Review. Journal of Pharmaceutical Negative Results, 8540-8550.

DURGUT, Y. (2021). Inter-laboratory Comparisons and Their Roles in Accreditation. Avrupa Bilim ve Teknoloji Dergisi, (28), 402-406.

Ejeta, E., Tadele, G., Desalegn, M., Abere, S., & Elias, K. (2015). Health care provider's satisfaction with the clinical laboratory service of nekemte referral hospital, Western Ethiopia. International Journal of Medicine and Medical Sciences, 7(5), 91-97.

El-Osta, N. M. (2024). The Current Effects of Automation on The Clinical Laboratory Workforce Among Sectors: A Case Study in Libya from 2020-2021. مجلة البحوث الأكاديمية, 28, 101-90.

Etukudoh, N. S., & Obeta, U. M. (2021). Patients'(clients) satisfaction with medical laboratory services contributes to health and quality improvement. In Healthcare Access. IntechOpen.

Fazal, M. (2021). C-reactive protein a promising biomarker of COVID-19 severity. Korean Journal of Clinical Laboratory Science, 53(3), 201-207.

Fazio, F. (2019). Fish haematology analysis as an important tool of aquaculture: a review. Aquaculture, 500, 237-242.

Federal Regulation(2010).Haematology and pathology manual,864;4020 Sliverspring Hamsphire:US Food and drugs Administation.

Feinberg, B., & Wooton, I. (2020). The effect of price on purchase decision with service quality as an intervening variable (case study on American medical health and shop store). Medalion journal: medical research, Nursing, Health and Midwife Participation, 1(3), 114-120.

Fenta, D. A., & Ali, M. M. (2020). Factors affecting quality of laboratory result during ordering, handling, and testing of the patient's specimen at hawassa University College of medicine and health science comprehensive specialized hospital. Journal of Multidisciplinary Healthcare, 809-821.

Feriel, J., Depasse, F., & Geneviève, F. (2020). How I investigate basophilia in daily practice. International journal of laboratory hematology, 42(3), 237-245.

Fonjungo, P. N., Kebede, Y., Arneson, W., Tefera, D., Yimer, K., Kinde, S., ... & Kenyon, T. (2013). Preservice laboratory education strengthening enhances sustainable laboratory workforce in Ethiopia. Human Resources for Health, 11, 1-7.

Gagneux, S. (2018). Ecology and evolution of Mycobacterium tuberculosis. Nature Reviews Microbiology, 16(4), 202.

Gandra, S., Merchant, A. T., & Laxminarayan, R. (2016). A role for private sector laboratories in public health surveillance of antimicrobial resistance.

Gawor, A., Kurek, E., Ruszczyńska, A., & Bulska, E. (2021). Key issues related to the accreditation of academic laboratories. Accreditation and Quality Assurance, 26(6), 285-291.

Gebregzabher, E. H., Tesfaye, F., Cheneke, W., Negesso, A. E., & Kedida, G. (2023). Continuing professional development (CPD) training needs assessment for medical laboratory professionals in Ethiopia. Human Resources for Health, 21(1), 1-9.

Getahun, M. S., Yemanebrhane, N., Desalegn, D. M., Kitila, K. T., Dinku, T. T., Wondimagegnehu, D. D., ... & Tura, G. B. (2019). Medical laboratory accreditation in a resource-limited district health centre laboratory, Addis Ababa, Ethiopia. African journal of laboratory medicine, 8(1), 1-5.

Ghys, T., Malfait, R., & Van den Bossche, J. (2009). Performance evaluation of the Sysmex XS-1000i automated haematology analyser. International journal of laboratory hematology, 31(5), 560-566.

Giavarina, D., & Lippi, G. (2017). Blood venous sample collection: Recommendations overview and a checklist to improve quality. Clinical biochemistry, 50(10-11), 568-573.

Girma, M., Deress, T., & Adane, K. (2020). Laboratory Quality Management System and Quality Indicators Implementation Status as Perceived by Laboratory Professionals in Preparation for the Accreditation Process from Selected Government Hospitals of Ethiopia. Clinical laboratory, 66(4), 10.7754/Clin.Lab.2019.190718.

Gonzalez, M. E. (2019). Improving customer satisfaction of a healthcare facility: reading the customers' needs. Benchmarking: An International Journal, 26(3), 854-870.

Gonzalez-Ortiz, C., Emrick, A., Tabak, Y. P., Vankeepuram, L., Kurtz, S., Sellers, D., ... & Levent, F. (2020). Impact on microbiology laboratory turnaround times following process improvements and total laboratory automation. medRxiv, 2020-10.

Gopolang, F., Zulu-Mwamba, F., Nsama, D., Kruuner, A., Nsofwa, D., Kasvosve, I., Gomo, R., Motlhabane, T., Chohan, B., Soge, O., Osterhage, D., Campbell, N., Noble, M., Downer, A., Flandin, J. F., Nartker, A., Koehn, C., Nonde, L. K., Shibemba, A., Ndongmo, C. B., … Perrone, L. A. (2021). Improving laboratory quality and capacity through leadership and management training: Lessons from Zambia 2016-2018. African journal of laboratory medicine, 10(1), 1225.

Greaves, R. F., Bernardini, S., Ferrari, M., Fortina, P., Gouget, B., Gruson, D., ... & Kricka, L. J. (2019). Key questions about the future of laboratory medicine in the next decade of the 21st century: a report from the IFCC-Emerging Technologies Division. Clinica Chimica Acta, 495, 570-589.

Green, S. F. (2013). The cost of poor blood specimen quality and errors in preanalytical processes. Clinical biochemistry, 46(13-14), 1175-1179.

Gregson, S., Moorhouse, L., Dadirai, T., Sheppard, H., Mayini, J., Beckmann, N., ... & Nyamukapa, C. (2021). Comprehensive investigation of sources of misclassification errors in routine HIV testing in Zimbabwe. Journal of the International AIDS Society, 24(4), e25700.

Grzelak, L., Temmam, S., Planchais, C., Demeret, C., Tondeur, L., Huon, C., ... & van Der Werf, S. (2020). A comparison of four serological assays for detecting anti–SARS-CoV-2 antibodies in human serum samples from different populations. Science translational medicine, 12(559), eabc3103.

Gulati, G., Uppal, G., & Gong, J. (2022). Unreliable automated complete blood count results: causes, recognition, and resolution. Annals of Laboratory Medicine, 42(5), 515.

Hailu, H. A., Desale, A., Yalew, A., Asrat, H., Kebede, S., Dejene, D., ... & Abate, E. (2020). Patients' satisfaction with clinical laboratory services in public hospitals in Ethiopia. BMC health services research, 20(1), 1-9.

Hannoodee, S., & Nasuruddin, D. N. (2020). Acute inflammatory response.

Harrison, M. (2015). Abnormal laboratory results: Erythrocyte sedimentation rate and C-reactive protein. Australian prescriber, 38(3), 93.

Haselmann, V., Ahmad-Nejad, P., Geilenkeuser, W. J., Duda, A., Gabor, M., Eichner, R., ... & Neumaier, M. (2018). Results of the first external quality assessment scheme (EQA) for isolation and analysis of circulating tumour DNA (ctDNA). Clinical Chemistry and Laboratory Medicine (CCLM), 56(2), 220-228.

Haselmann, V., Özçürümez, M., Klawonn, F., Ast, V., Gerhards, C., Eichner, R., Costina, V., Dobler, G., Geilenkeuser, W., Wölfel, R. & Neumaier, M. (2020). Results of the first pilot external quality assessment (EQA) scheme for anti-SARS-CoV2-antibody testing. Clinical Chemistry and Laboratory Medicine (CCLM), 58(12), 2121-2130.

Herwald, H., & Egesten, A. (2021). C-reactive protein: more than a biomarker. Journal of innate immunity, 13(5), 257-258.

Howanitz, P. J., Valenstein, P. N., & Fine, G. (2000). Employee competence and performance-based assessment: a College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. Archives of pathology & laboratory medicine, 124(2), 195-202.

Ibrahim, A. (2020). Quality assurance in continuous assessment: A strategy for improving standard in higher education. Dynamics of educational planning, policy and management, 178-188.

Ibrahim, F., Dosoo, D., Kronmann, K. C., Ouedraogo, I., Anyorigiya, T., Abdul, H., ... & Koram, K. (2012). Good clinical laboratory practices improved proficiency testing performance at clinical trials centers in Ghana and Burkina Faso. PLoS One, 7(6), e39098.

Inayat, W., & Jahanzeb Khan, M. (2021). A study of job satisfaction and its effect on the performance of employees working in private sector organizations, Peshawar. Education Research International, 2021, 1-9.

Ishaque, S., Asrhad, A., Haider, M. A., & Fatima, F. (2021). Biosafety and biosecurity of lab and hospital acquired infections. Biological and Clinical Sciences Research Journal, 2021(1).

Ishengoma, D. R. S., Rwegoshora, R. T., Mdira, K. Y., Kamugisha, M. L., Anga, E. O., Bygbjerg, I. C., ... & Magesa, S. M. (2009). Health laboratories in the Tanga region of Tanzania: the quality of diagnostic services for malaria and other communicable diseases. Annals of Tropical Medicine & Parasitology, 103(5), 441-453.

ISO 15189 International standard: Medical laboratories — Requirements for quality and competence. ISO 15189:2012 (E); Geneva, Switzerland.

Jagannatha, D. S. B., Chandrakar, D. S., & Durg, C. (2019). Study of Pre-Analytical Errors in a Clinical Biochemistry Laboratory: The Hidden Flaws in Total Testing. Galore International Journal of Health Sciences and Research, 4(1).

Kalinga, A. K., Mgata, S., Kavishe, R. A., Mahikwano, L., Temu, L., Mswanya, C., ... & Ishengoma, D. S. (2020). Implementation of external quality assessment of microscopy for improved parasite detection and confirmatory diagnosis of malaria in Tanzanian Military health facilities. BMC Research Notes, 13(1), 1-7.

Kamau,E. (2013). Navigating laboratory services quality in challenging environments: A perspective for implementation in small, low-income countries and post –contact settings. Afri. J.Lab. Medicine 2:48.

Kaoje, A. U., Mohammed, U., Mohammed, Y., Ibrahim, U., Alhassan, S., Obi, A., ... & Mohammed Ango, U. (2017). Quality of medical laboratory services in a tertiary health institution in Sokoto, Nigeria. International Journal of Medical Laboratory, 4(4), 246-259.

Karasahin, O., Tasar, P. T., Timur, O., Yıldırım, F., Binici, D. N., & Sahin, S. (2018). The value of C-reactive protein in infection diagnosis and prognosis in elderly patients. Aging Clinical and Experimental Research, 30, 555-562.

Karijo, E. K., Otieno, G. O., & Mogere, S. (2021). Determinants of data use for decision making in health facilities in Kitui County, Kenya. Management, 3(1).

Karthiyayini, N., & Rajendran, C. (2017). Critical factors and performance indicators: accreditation of testing-and calibration-laboratories. Benchmarking: An International Journal, 24(7), 1814-1833.

Kasvosve, I., Ledikwe, J. H., Phumaphi, O., Mpofu, M., Nyangah, R., Motswaledi, M. S., ... & Semo, B. W. (2014). Continuing professional development training needs of medical laboratory personnel in Botswana. Human resources for health, 12, 1-8.

Kavak, D. G., Öksüz, A. S., Cengiz, C., Kayral, I. H., & Şenel, F. Ç. (2020). The importance of quality and accreditation in health care services in the process ofstruggle against COVID-19. Turkish journal of medical sciences, 50(8), 1760-1770.

Kebede, Y., Fonjungo, P. N., Tibesso, G., Shrivastava, R., Nkengasong, J. N., Kenyon, T., ... & Ayana, G. (2016). Improved specimen-referral system and increased access to quality laboratory services in Ethiopia: the role of the public-private partnership. The Journal of infectious diseases, 213(suppl_2), S59-S64.

Kemzi Elechi-Amadi, G., Iweriso George, B., Orukwowu, U., & M Manuel, A. (2022). Perception and Acceptance of Nursing Profession among Secondary School Students in Port Harcourt, Nigeria. AJMPCP.

Khadambi-Morokane, H., Bhowan, K., & Ayuk, S. (2021). An overview of medical diagnostic laboratories in South Africa that meet the international standard of accreditation: ISO 15189. The Journal of Medical Laboratory Science and Technology of South Africa, 3(1), 27-34.

Khalil, R. H., & Al-Humadi, N. (2020). Types of acute phase reactants and their importance in vaccination. Biomedical reports, 12(4), 143-152.

Khanmiri, H. H., Yazdanfar, F., Mobed, A., Rezamohammadi, F., Rahmani, M., & Haghgouei, T. (2023). Biosensors; noninvasive method in detection of C-reactive protein (CRP). *Biomedical Microdevices*, *25*(3), 27.

Kierkegaard, P., McLister, A., & Buckle, P. (2021). Rapid point-of-care testing for COVID-19: quality of supportive information for lateral flow serology assays. BMJ open, 11(3), e047163.

Kim, K., Lee, S. G., Kim, T. H., & Lee, S. G. (2022). Economic evaluation of total laboratory automation in the clinical laboratory of a tertiary care hospital. Annals of laboratory medicine, 42(1), 89.

Kimathi, L. (2017). Challenges of the devolved health sector in Kenya: teething problems or systemic contradictions?. Africa development, 42(1), 55-77.

Kimengech, K. K., Waithaka, S. K., Onyuka, J., & Kigondu, C. S. (2017). Determination of errors that compromise the quality of laboratory service in a tertiary hospital. Asian Journal of Medical Sciences, 8(1), 64-70.

Kingangi, L. (2018). Mapping and tracking the complexity of financial flows through non-state non-profit (faith-based) health providers in Kenya (Master's thesis, University of Cape Town).

Kiwanuka, S. N., Namuhani, N., Akulume, M., Kalyesubula, S., Bazeyo, W., & Kisakye, A. N. (2020). Uganda's laboratory human resource in the era of global health initiatives: experiences, constraints and opportunities—an assessment of 100 facilities. Human Resources for Health, 18, 1-10.

Konieczka, P., & Namiesnik, J. (2018). Quality assurance and quality control in the analytical chemical laboratory: a practical approach. CRC Press.

Kploanyi, E. E., Kenu, J., Atsu, B. K., Opare, D. A., Asiedu-Bekoe, F., Schroeder, L. F., ... & Kenu, E. (2023). An assessment of the laboratory network in Ghana: A national-level ATLAS survey (2019–2020). African Journal of Laboratory Medicine, 12(1), 1844.

Kruk, M. E., Gage, A. D., Arsenault, C., Jordan, K., Leslie, H. H., Roder-DeWan, S., ... & Pate, M. (2018). High-quality health systems in the Sustainable Development Goals era: time for a revolution. The Lancet global health, 6(11), e1196-e1252.

Kumar, S., Chhabra, G., Sehrawat, K. S., & Singh, M. (2024). Developing a competency assessment framework for medical laboratory technologists in primary healthcare settings in India. Plos one, 19(4), e0294939.

Land, K. J., Boeras, D. I., Chen, X. S., Ramsay, A. R., & Peeling, R. W. (2019). REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nature microbiology, 4(1), 46-54

Lapić, I., Padoan, A., Bozzato, D., & Plebani, M. (2020). Erythrocyte sedimentation rate and C-reactive protein in acute inflammation: meta-analysis of diagnostic accuracy studies. *American journal of clinical pathology*, *153*(1), 14-29.

Layne, D. M., Nemeth, L. S., Mueller, M., & Martin, M. (2019, February). Negative behaviors among healthcare professionals: relationship with patient safety culture. In Healthcare (Vol. 7, No. 1, p. 23). MDPI.

Legido Quigley, H., Montgomery, C. M., Khan, P., Atun, R., Fakoya, A., Getahun, H., & Grant, A. D. (2013). Integrating tuberculosis and HIV services in low and middle income countries: a systematic review. Tropical medicine & international health, 18(2), 199-211.

Lehmann, J., Muture, B., Matu, M., & Schneidman, M. (2018). Performance evaluation of public health laboratories in Kenya. World Bank.

Lippi, G., & Da Rin, G. (2019). Advantages and limitations of total laboratory automation: a personal overview. Clinical Chemistry and Laboratory Medicine (CCLM), 57(6), 802-811.

Lippi, G., & Favaloro, E. J. (2013). Causes of errors in medical laboratories. Quality in Laboratory Hemostasis and Thrombosis, 22-31.

Lippi, G., & Plebani, M. (2020). The critical role of laboratory medicine during coronavirus disease 2019 (COVID-19) and other viral outbreaks. Clinical Chemistry and Laboratory Medicine (CCLM), 58(7), 1063-1069.

MacLeod, M. K., Clambey, E. T., Kappler, J. W., & Marrack, P. (2009, April). CD4 memory T cells: what are they and what can they do?. In *Seminars in immunology* (Vol. 21, No. 2, pp. 53-61). Academic Press.

Madhuri, D. S., Swathi, A., & Nagamani, K. (2016). Impact of quality indicators on the performance of clinical serology laboratory. Journal of Evolution 0f Medical And Dental Sciences-Jemds, 5(85), 6300-6303.

Maina, J., Ouma, P. O., Macharia, P. M., Alegana, V. A., Mitto, B., Fall, I. S., ... & Okiro, E. A. (2019). A spatial database of health facilities managed by the public health sector in sub Saharan Africa. Scientific data, 6(1), 134.

Makanjuola, R. O., & Taylor-Robinson, A. W. (2020). Improving accuracy of malaria diagnosis in underserved rural and remote endemic areas of sub-Saharan Africa: a call to develop multiplexing rapid diagnostic tests. Scientifica, 2020.

Makokha, E. P., Ondondo, R. O., Kimani, D. K., Gachuki, T., Basiye, F., Njeru, M., Junghae, M., Downer, M., Umuro, M., Mburu, M., & Mwangi, J. (2022). Enhancing accreditation outcomes for medical laboratories on the Strengthening Laboratory Management Toward Accreditation programme in Kenya via a rapid results initiative. African journal of laboratory medicine, 11(1), 1614.

Małecka, M., & Ciepiela, O. (2020). A comparison of Sysmex-XN 2000 and Yumizen H2500 automated hematology analyzers. Practical Laboratory Medicine, 22, e00186.

Manickam, T. S., & Ankanagari, S. (2015). Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation. Journal of Medical Laboratory and Diagnosis, 6(5), 27-35.

Manual, Q. P. (2021). National Laboratory Quality Policy Manual for South Sudan.

Markby, J., Gygax, M., Savoy, C., Giebens, Y., Janjanin, S., Machoka, F., ... & Vetter, B. N. (2023). Assessment of laboratory capacity in conflict-affected low-resource settings using two World Health Organization laboratory assessment tools. Clinical Chemistry and Laboratory Medicine (CCLM), 61(6), 1015-1024.

Markey, K., Douglas-Bardsley, A., Asokanathan, C., Fry, N. K., Barkoff, A. M., Bacci, S., ... & He, Q. (2019). Improvement in serological diagnosis of pertussis by external quality assessment. Journal of Medical Microbiology, 68(5), 741-747.

Mazziotta, D. (2009). Accreditation of clinical laboratories in the Latin-American region. *Clinical biochemistry*, *42*(4-5), 309.

McBride, J. A., & Striker, R. (2017). Imbalance in the game of T cells: What can the CD4/CD8 T-cell ratio tell us about HIV and health?. *PLoS pathogens*, *13*(11), e1006624.

Mckinnon, K. M. (2018). Flow cytometry: an overview. Current protocols in immunology, 120(1), 5-1.

Mesfin, E. A., Taye, B., Belay, G., Ashenafi, A., & Girma, V. (2017). Factors affecting quality of laboratory services in public and private health facilities in Addis Ababa, Ethiopia. EJIFCC, 28(3), 205.

Mesganaw, B., Fenta, A., Hibstu, Z., Belew, H., Misganaw, K., & Belayneh, M. (2023). Medical Laboratories Quality Management and Challenges in Ethiopia: A Systematic Review. Pathology and Laboratory Medicine International, 13-26.

Metter, D. M., Colgan, T. J., Leung, S. T., Timmons, C. F., & Park, J. Y. (2019). Trends in the US and Canadian pathologist workforces from 2007 to 2017. JAMA network open, 2(5), e194337-e194337.

Miggelbrink, A. M., Jackson, J. D., Lorrey, S. J., Srinivasan, E. S., Waibl-Polania, J., Wilkinson, D. S., & Fecci, P. E. (2021). CD4 T-cell exhaustion: does it exist and what are its roles in cancer?. *Clinical Cancer Research*, *27*(21), 5742-5752.

Milinković, N., Ignjatović, S., Šumarac, Z., & Majkić-Singh, N. (2018). Uncertainty of measurement in laboratory medicine. Journal of medical biochemistry, 37(3), 279.

Miller, W. G., & Nichols, J. H. (2020). Quality control. In Contemporary Practice in Clinical Chemistry (pp. 77-95). Academic Press.

Ministry of Health, African Medical and Research Foundation (1996). Essential Laboratory Program Pilot Study. A Feasibility Study for Primary Health Care Laboratories in Kenya 1992-1994 Ministry of Health, Nairobi.

Ministry of Ministry of Health/The Kenya Medical Laboratory Technicians and Technologists Board (MOH/KMLTTB) (2024). Medical laboratory Classification Manual MOH/ KMLTTB/LAD/001 -12th April 2024

Ministry of Health. Uganda National Health Laboratory Policy Kampala, Republic of Uganda

Mosadeghrad, A. M., & Woldemichael, A. (2017). Application of quality management in promoting patient safety and preventing medical errors. In Impact of medical errors and malpractice on health economics, quality, and patient safety (pp. 91-112). IGI Global.

Moyo, K., Porter, C., Kabue, M., Chilima, B., Zungu, L., Mwenda, R., & Sarr, A. (2015). Use of laboratory test results in patient management by healthcare workers in Malawi. African journal of laboratory medicine, 4(1), 1-8.

Müller, R., Mellors, I., Johannessen, B., Aarsand, A. K., Kiefer, P., Hardy, J., ... & Scott, C. S. (2006). European multi-center evaluation of the Abbott Cell-Dyn sapphire hematology analyzer. Laboratory Hematology: Official Publication of the International Society for Laboratory Hematology, 12(1), 15-31.

Mushi, M. F., Alex, V. G., Seugendo, M., Silago, V., & Mshana, S. E. (2019). C-reactive protein and urinary tract infection due to Gram-negative bacteria in a pediatric population at a tertiary hospital, Mwanza, Tanzania. African Health Sciences, 19(4), 3217-3224.

Muzyka, B. C., Christie, J., & Collins, B. (2021). Laboratory Medicine and Diagnostic Pathology. Burket's Oral Medicine, 1037-1058.

Nadif, R., Febrissy, M., Andrianjafimasy, M. V., Le Moual, N., Gormand, F., Just, J., ... & Nadif, M. (2020). Endotypes identified by cluster analysis in asthmatics and non-asthmatics and their clinical characteristics at follow-up: the case-control EGEA study. *BMJ open respiratory research*, *7*(1), e000632.

Nagemi, C., & Mwesigwa, C. (2020). Donor power and prioritization in development assistance for health policies: the case of Uganda. Journal of Developing Economies, 2(1), 54-74.

Nayupe, S. F., Mbulaje, P., Munharo, S., Patel, P., & Lucero-Prisno, D. E. (2023). Medical laboratory practice in Malawi-Current status. African Journal of Laboratory Medicine, 12(1), 1-4.

Ndlovu, N., Mataka, A., Lombard, C., Erasmus, R. T., & Zemlin, A. E. (2024). Survey and situation analysis of personal, employer-related, and environmental factors affecting participation in continuous professional development (CPD) programs of laboratory professionals in Africa. American Journal of Clinical Pathology, 161(4), 360-368.

Nega, D., Abebe, A., Abera, A., Gidey, B., G/Tsadik, A., & Tasew, G. (2020). Comprehensive competency assessment of malaria microscopists and laboratory diagnostic service capacity in districts stratified for malaria elimination in Ethiopia. PLoS One, 15(6), e0235151.

Nehring, S. M., Goyal, A., & Patel, B. C. (2017). C reactive protein.

Njoroge, W. G. (2014). Assessment of the Quality of Medical Laboratory Service Provision in Kenya (Doctoral dissertation, phd dissertation. Nairobi: Faculty of Health Sciences, Kenyatta University).

Nkengasong, J. N., Mbopi-Keou, F. X., Peeling, R. W., Yao, K., Zeh, C. E., Schneidman, M., & Hader, S. (2018). Laboratory medicine in Africa since 2008: then, now, and the future. The Lancet Infectious Diseases, 18(11), e362-e367.

Nkengasong, J. N., Yao, K., & Onyebujoh, P. (2018). Laboratory medicine in low-income and middle-income countries: progress and challenges. The lancet, 391(10133), 1873-1875.

Nyoike, J. (2020). Effects of training and development on employee performance: a case of Government Chemist Laboratory, Kenya (Doctoral dissertation, University of Nairobi).

Nyongesa, M. Onyango, R &Ombaka, J. (2013). Evaluation of the Level of Quality Health Care Accorded to Patients in Selected Public and Private Hospitals in Kiambu and Nairobi Counties in Kenya

Odhiambo, C. O., van der Puije, B., Maina, M., Mekonen, T., Diallo, S., Datema, T., Loembe, M. M., Kebede, Y., Ndlovu, N., & Ondoa, P. (2023). Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa. Tropical medicine & international health: TM & IH, 28(2), 126–135.

Okezue, M. A., Adeyeye, M. C., Byrn, S. J., Abiola, V. O., & Clase, K. L. (2020). Impact of ISO/IEC 17025 laboratory accreditation in sub-Saharan Africa: a case study. BMC health services research, 20, 1-9.

Olver, P., Bohn, M. & Adeli, K. (2023). Central role of laboratory medicine in public health and patient care. Clinical Chemistry and Laboratory Medicine (CCLM), 61(4), 666-673.

Ombewa, J. A. (2018). Total Quality Management in Iso 15189 Accredited Medical Laboratories in Kenya (Doctoral dissertation, university of nairobi).

Ondoa, P., Ndlovu, N., Keita, M. S., Massinga-Loembe, M., Kebede, Y., Odhiambo, C., ... & Nkengasong, J. (2020). Preparing national tiered laboratory systems and networks to advance diagnostics in Africa and meet the continent's health agenda: Insights into priority areas for improvement. African Journal of Laboratory Medicine, 9(2).

Ondoa, P., van der Broek, A., Jansen, C., de Bruijn, H., & Schultsz, C. (2017). National laboratory policies and plans in sub-Saharan African countries: gaps and opportunities. African journal of laboratory medicine, 6(1), 1-20.

Ong, S. K., Donovan, G. T., Ndefru, N., Song, S., Leang, C., Sek, S., ... & Perrone, L. A. (2020). Strengthening the clinical laboratory workforce in Cambodia: a case study of a mixed-method in-service training program to improve laboratory quality management system oversight. Human Resources for Health, 18, 1-9.

Pal, M., Tsegaye, M., Girzaw, F., Bedada, H., Godishala, V., & Kandi, V. (2017). An overview on biological weapons and bioterrorism. American Journal of Biomedical Research, 5(2), 24-34.

Perich, C., Ricós, C., Marqués, F., Minchinela, J., Salas, A., Martínez-Bru, C., ... & Fernández-Calle, P. (2020). Spanish Society of Laboratory Medicine external quality assurance programmes: evolution of the analytical performance of clinical laboratories over 30 years and comparison with other programmes. Advances in Laboratory Medicine/Avances en Medicina de Laboratorio, 1(2), 20200019.

Petti, C. A., Polage, C. R., Quinn, T. C., Ronald, A. R., & Sande, M. A. (2016). Laboratory medicine in Africa: a barrier to effective health care. Clinical Infectious Diseases, 42(3), 377-382.

Plebani, M. (2023). Why C-reactive protein is one of the most requested tests in clinical laboratories?. *Clinical Chemistry and Laboratory Medicine (CCLM)*, *61*(9), 1540-1545.

Plebani, M., & Sciacovelli, L. (2017). ISO 15189 accreditation: navigation between quality management and patient safety. Journal of medical biochemistry, 36(3), 225.

Plebani, M., Padoan, A., Negrini, D., Carpinteri, B., & Sciacovelli, L. (2020). Diagnostic performances and thresholds: The key to harmonization in serological SARS-CoV-2 assays?. Clinica chimica acta, 509, 1-7.

Price, C.P. (2005). Benchmarking in Laboratory Medicine: Are We Measuring the Right Outcomes? Benchmarking: An International Journal 12: 5, pp 449 – 466, Emerald Group Publishing Limited.

RA, M. (2017). Henry's clinical diagnosis and management by laboratory methods: First South Asia Edition_e-Book. Elsevier India, 1(23), 606.

Ragav, N. H., Sinduja, P., & Priyadharshini, R. (2021). Automated blood analysers and their testing principles: a comparative study. *J. Pharm. Res. Int*, *33*, 294-301.

Rahman, M. (2014). Quality Assurance (QA) in Laboratory Testing. Anwer Khan Modern Medical College Journal, 2(2), 3-5.

Rambiritch, V., Vermeulen, M., Bell, H., Knox, P., Nedelcu, E., Al-Riyami, A. Z., ... & Education Subcommittee of the AABB Global Transfusion Forum. (2021). Transfusion medicine and blood banking education and training for blood establishment laboratory staff: A review of selected countries in Africa. Transfusion, 61(6), 1955-1965.

Rastogi, S., Nair, S. C., Murugan, P., Sukumar, A. S., Mammen, J. J., & Mullai, S. (2022). Overall equipment effectiveness, efficiency and slide review analysis of high-end hematology analyzers. Practical Laboratory Medicine, 30, e00275.

Reyes, A. C. (2020). Enhancing Clinical Laboratory Professional Retention Through Employee Perspectives: A Qualitative Study (Doctoral dissertation, Northcentral University).

Rupprecht, C. D., Fujiyoshi, L., McGreevy, S. R., & Tayasu, I. (2020). Trust me? Consumer trust in expert information on food product labels. Food and Chemical Toxicology, 137, 111170.

Rusanganwa, V., Gahutu, J. B., Evander, M., & Hurtig, A. K. (2019). Clinical referral laboratory personnel's perception of challenges and strategies for sustaining the laboratory quality management system: a qualitative study in Rwanda. American Journal of Clinical Pathology, 152(6), 725-734.

Rusanganwa, V., Gahutu, J. B., Hurtig, A. K., & Evander, M. (2020). Physicians' satisfaction with clinical referral laboratories in Rwanda. Global Health Action, 13(1), 1834965.

Rusanganwa, Vincent Gahutu, Jean Bosco Hurtig, Anna-Karin Evanderm Magnus (2020) Physicians' satisfaction with clinical referral laboratories in Rwanda In: Global Health Action, ISSN 1654-9716, E-ISSN 1654-9880, Vol. 13, no 1, article id 1834965Article in journal (Refereed) Published

Saad Albichr, I., Sottiaux, J. Y., Hotton, J., De Laveleye, M., Dupret, P., & Detry, G. (2020). Cross-evaluation of five slidemakers and three automated image analysis systems: the pitfalls of automation?. International Journal of Laboratory Hematology, 42(5), 573-580.

Sabati, H., Mohsenzadeh, A., & Khelghati, N. (2019). Control of clinical laboratory errors by FMEA model. Contemporary Topics in Patient Safety-Volume 1.

Saharia, G. K., & Mangaraj, M. EFFECT OF BLOOD COLLECTION TUBES ON ESTIMATION OF SODIUM, POTASSIUM, CALCIUM AND LITHIUM: OUR EXPERIENCE.

Saleh, M., Naik, G., Mwirigi, A., Shaikh, A. J., Sayani, S., Ghesani, M., ... & Talib, Z. (2019). Bridging the gap in training and clinical practice in Sub-Saharan Africa. Current Breast Cancer Reports, 11, 158-169.

Samuel, M., Irene, M., & Kenny, K. (2020). Readiness of Primary Health Care Diagnostic Laboratory Services to Support UHC Programme in Kenya: A Case Study of Three Counties. Journal of Health and Environmental Research, 6(4), 128-142.

Sayed, S., Cherniak, W., Lawler, M., Tan, S. Y., El Sadr, W., Wolf, N., ... & Fleming, K. A. (2018). Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. The Lancet, 391(10133), 1939-1952.

Schakelaar, M. Y., Kemperman, H., Schoneveld, A. H., Hoefer, I. E., & Tiel Groenestege, W. M. (2023). Analysis of C-reactive protein from finger stick dried blood spot to predict high risk of cardiovascular disease. *Scientific Reports*, *13*(1), 2515.

Schneidman, M., Dacombe, R. J., & Carter, J. (2014). Laboratory professionals in Africa: the backbone of quality diagnostics.

Schroeder, L. F., & Amukele, T. (2014). Medical laboratories in sub-Saharan Africa that meet international quality standards. American journal of clinical pathology, 141(6), 791-795.

Schwartz, D. M., Kanno, Y., Villarino, A., Ward, M., Gadina, M., & O'Shea, J. J. (2017). JAK inhibition as a therapeutic strategy for immune and inflammatory diseases. *Nature reviews Drug discovery*, *16*(12), 843-862.

Selvi, M. T., & Ankanagari, S. (2019). Evaluation of Implementing Quality Management System and Accreditation Standards in Medical Laboratory for Quality of Services. Medical Laboratory Journal, 13(1).

Sexton, C., Russell, A. M., Nwaohiri, A., Kotey, A., & Galloway, E. (2020). Strengthening HIV/TB laboratory quality management systems and services in the Kingdom of Eswatini under the President's Emergency Plan for AIDS Relief: evaluation report.

Shah, T. J., Sadaria, R., & Vasava, S. (2021). Pre-Analytical Errors in Clinical Diagnostic Laboratory: A Crucial Step to Look for Accuracy and Reliability. Indian Journal of Forensic Medicine & Toxicology, 15(1).

Shahangian, S. And Snyder, S.R.(2009).Laboratory Medicine Quality Indicators American Journal of Clinical Pathology, 131, 418-431

Sharaki, O., Abouzeid, A., Hossam, N., & Elsherif, Y. (2014). Self-assessment of pre, intra and post analytical errors of urine analysis in Clinical Chemistry Laboratory of Alexandria Main University Hospital. Saudi Journal for Health Sciences, 3(2), 96-102.

Sharma, S., Schlusser, K. E., De La Torre, P., Tambussi, G., Draenert, R., Pinto, A. N., ... & INSIGHT START Study Group. (2019). The benefit of immediate compared to deferred ART on CD4+ Cell count recovery in early HIV infection. AIDS (London, England), 33(8), 1335.

Shokouhyar, S., Shokoohyar, S., & Safari, S. (2020). Research on the influence of after-sales service quality factors on customer satisfaction. Journal of Retailing and Consumer Services, 56, 102139.

Shrivastava, R., Gadde, R., & Nkengasong, J. N. (2016). Importance of public-private partnerships: strengthening laboratory medicine systems and clinical practice in Africa. The Journal of infectious diseases, 213(suppl_2), S35-S40.

Shrivastava, R., Poxon, R., Rottinghaus, E., Essop, L., Sanon, V., Chipeta, Z., ... & Nkengasong, J. N. (2021). Leveraging gains from African Center for Integrated Laboratory Training to combat HIV epidemic in sub-Saharan Africa. BMC Health Services Research, 21, 1-15.

Shumbej, T., Menu, S., Gebru, T., Girum, T., Bekele, F., Solomon, A., ... & Jemal, A. (2020). Essential in-vitro laboratory diagnostic services provision in accordance with the WHO standards in Guragae zone primary health care unit level, South Ethiopia. Tropical diseases, travel medicine and vaccines, 6(1), 1-7.

Simmonds, F. M., Cohn, J. E., Mafaune, H. W., Nyamundaya, T. H., Mahomva, A., & Chadambuka, A. (2020). Task shifting for point-of-care early infant diagnosis: a comparison of the quality of testing between nurses and laboratory personnel in Zimbabwe. Human Resources for Health, 18, 1-7.

Simundic, A. M., Baird, G., Cadamuro, J., Costelloe, S. J., & Lippi, G. (2020). Managing hemolyzed samples in clinical laboratories. Critical reviews in clinical laboratory sciences, 57(1), 1-21.

SLMTA. Strengthening laboratory management towards accreditation

SLMTA.org. Laboratories that have achieved accreditation

Srimarut, T., & Mekhum, W. (2020). The Influence of Workload and Co-Worker Attitude on Job Satisfaction among Employees of Pharmaceutical Industry in Bangkok, Thailand: The Mediating Role of Training. Systematic Reviews in Pharmacy, 11(2).

Stavelin, A., & Sandberg, S. (2023). Analytical performance specifications and quality assurance of point-of-care testing in primary healthcare. Critical Reviews in Clinical Laboratory Sciences, 1-14.

Studzinski, N. G., & Pasteur, L. (2020). Comprehensive pandemic risk management: A systems approach. Visiting International Research Fellow Policy Institute, King’s College, London.

Suleiman, A., Bsisu, I., Guzu, H., Santarisi, A., Alsatari, M., Abbad, A., ... & Almustafa, M. (2020). Preparedness of frontline doctors in Jordan healthcare facilities to COVID-19 outbreak. International journal of environmental research and public health, 17(9), 3181.

Tadesse, H., Desta, K., Kinde, S., Hassen, F., & Gize, A. (2018). Errors in the hematology laboratory at St. Paul’s hospital millennium medical college, Addis Ababa, Ethiopia. BMC research notes, 11(1), 1-5.

Tadeu, B. T. M., & Geelhoed, D. (2016). "This thing of testing our blood is really very important": a qualitative study of primary care laboratory services in Tete Province, Mozambique. International journal for equity in health, 15(1), 1-11.

Tanasiichuk, I., Karaman, O., & Natrus, L. (2023). Key success factors for the implementation of quality management systems in developing countries. African Journal of Laboratory Medicine, 12(1), 2058.

Taremwa, I. M., Ampaire, L., Iramiot, J., Muhwezi, O., Matte, A., Itabangi, H., ... & Boum II, Y. (2017). Assessment of three medical and research laboratories using WHO AFRO_SLIPTA Quality Standards in Southwestern Uganda: a long way to go. Pan African Medical Journal, 28(1), 137-137.

Tessema, Z. T., Worku, M. G., Tesema, G. A., Alamneh, T. S., Teshale, A. B., Yeshaw, Y., ... & Liyew, A. M. (2022). Determinants of accessing healthcare in Sub-Saharan Africa: a mixed-effect analysis of recent Demographic and Health Surveys from 36 countries. BMJ open, 12(1), e054397.

Thachil, J., & Bates, I. (2017). Approach to the diagnosis and classification of blood cell disorders. Dacie and Lewis Practical Haematology, 497.

To, M., Raizman, J. E., Goudreau, B. L., Higgins, T., Brun, M., & Tsui, A. K. Y. (2021). Centralization of multisite reagent lot-to-lot validation for Ortho Clinical Vitros chemistry instruments. Clinical biochemistry, 97, 62–66.

Tola, E. K., Dabi, Y. T., & Dano, G. T. (2022). Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia. Pathology and Laboratory Medicine International, 1-6.

Tripathi, S. C., Deshmukh, V., Patil, A., & Tripathy, J. P. (2020). COVID 19 diagnostic multiplicity and its role in community surveillance and control. Infez Med, 28, 18-28.

Van Hoof, V., Bench, S., Soto, A. B., Luppa, P. P., Malpass, A., Schilling, U. M., ... & Tintu, A. N. (2022). Failure Mode and Effects Analysis (FMEA) at the preanalytical phase for POCT blood gas analysis: proposal for a shared proactive risk analysis model. Clinical Chemistry and Laboratory Medicine (CCLM), 60(8), 1186-1201.

Van Spronsen, A. D. (2022). The Role of Medical Laboratory Professionals in Laboratory Stewardship.

Wain, J., Diep, T. S., Bay, P. V. B., Walsh, A. L., Vinh, H., Duong, N. M., ... & Day, N. P. (2008). Specimens and culture media for the laboratory diagnosis of typhoid fever. The Journal of Infection in Developing Countries, 2(06), 469-474.

Walper, S. A., Lasarte Aragonés, G., Sapsford, K. E., Brown III, C. W., Rowland, C. E., Breger, J. C., & Medintz, I. L. (2018). Detecting biothreat agents: From current diagnostics to developing sensor technologies. ACS sensors, 3(10), 1894-2024.

Walz, S. E., & Darcy, T. P. (2013). Patient safety & post-analytical error. Clinics in laboratory medicine, 33(1), 183-194.

Wanja, E., Achilla, R., Obare, P., Adeny, R., Moseti, C., Otieno, V., ... & Buff, A. M. (2017). Evaluation of a laboratory quality assurance pilot programme for malaria diagnostics in low-transmission areas of Kenya, 2013. Malaria Journal, 16(1), 1-13.

Wanjau, K. N., Muiruri, B. W., & Ayodo, E. (2012). Factors affecting provision of service quality in the public health sector: A case of Kenyatta national hospital.

Ward, C. L., Guo, M. Z., Amukele, T. K., Abdul-Karim, A., & Schroeder, L. F. (2021). Availability and prices of WHO essential diagnostics in laboratories in West Africa: a landscape survey of diagnostic testing in Northern Ghana. The journal of applied laboratory medicine, 6(1), 51-62.

Waring, J., Lindvall, C., & Umeton, R. (2020). Automated machine learning: Review of the state-of-the-art and opportunities for healthcare. Artificial intelligence in medicine, 104, 101822.

Wesolowski, P., & Roseff, S. D. (2024). Clinical Laboratory Management: Basic Principles and Practices. Clinical Laboratory Management, 1-24.

Westgard J.O (2008).Basic method of validation (3rd ed).Maddison WI:Westgad QC .

WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region (SLIPTA). World Health Organization-Regional Office for Africa (WHO-AFRO); 2015. 1–68 p.

WHO/CDC/CLSI . Overview of External Quality Assessment (EQA):module 10, content sheet 10-1. Geneva: WHO; 2016.

WHO/CDC/CLSI. Malaria Microscopy quality assurance manual; Version 2.; ISBN 978 92 4 154939 4. 2016. 113–124.

Willmington, C., Belardi, P., Murante, A. M., & Vainieri, M. (2022). The contribution of benchmarking to quality improvement in healthcare. A systematic literature review. BMC health services research, 22(1), 139.

Wilson, M. L., Fleming, K. A., Kuti, M. A., Looi, L. M., Lago, N., & Ru, K. (2018). Access to pathology and laboratory medicine services: a crucial gap. The Lancet, 391(10133), 1927-1938.

World Health Organization Regional Office for Africa. Strengthening laboratory management towards accreditation

World Health Organization. (2016). Malaria microscopy quality assurance manual-version 2. World Health Organization.

World Health Organization. (2016). Malaria microscopy quality assurance manual-version World Health Organization.

World Health Organization. (2017). Data quality review: module 1: framework and metrics.

World Health Organization. (2020). Guide for the stepwise laboratory quality improvement process towards accreditation (SLIPTA) in the WHO African Region—Revision 2.

World Health Organization. (2022). Towards a global guidance framework for the responsible use of life sciences: summary report of consultations on the principles, gaps and challenges of biorisk management, May 2022 (No. WHO/SCI/RFH/2022.01). World Health Organization.

Wu, J., Zhang, P., Zhang, L., Meng, W., Li, J., Tong, C., ... & Li, S. (2020). Rapid and accurate identification of COVID-19 infection through machine learning based on clinical available blood test results. MedRxiv, 2020-04.

Xiang, D., Yue, J., Lan, Y., Sha, C., Ren, S., Li, Y., ... & Wang, C. (2015). Evaluation of mindray bc-5000 hematology analyzer: a new miniature 5-part wbc differential instrument. *International journal of laboratory hematology*, *37*(5), 597-605.

Xu, W., Zhang, Y., Wang, H., Zhu, Z., Mao, N., Mulders, M. N., & Rota, P. A. (2017). Global and national laboratory networks support high quality surveillance for measles and rubella. International health, 9(3), 184-189.

Yadav, K., Kant, S., Ramaswamy, G., Ahamed, F., Jacob, O. M., Vyas, H., ... & Haldar, P. (2020). Validation of point of care hemoglobin estimation among pregnant women using digital Hemoglobinometers (HemoCue 301 and HemoCue 201+) as compared with Auto-Analyzer. Indian Journal of Hematology and Blood Transfusion, 36, 342-348.

Yibalih, N. K., Wolday, D., Kinde, S., & Weldearegay, G. M. (2019). External Quality Assessment on CD4+ T-Cell Count Using In-House Proficiency Testing Panels for CD4 Count Laboratories in Addis Ababa, Ethiopia. Ethiopian journal of health sciences, 29(3).

Yitbarek, T., Nega, D., Tasew, G., Taye, B., & Desta, K. (2016). Performance evaluation of malaria microscopists at defense health facilities in Addis Ababa and its surrounding areas, Ethiopia. PLoS One, 11(11), e0166170.

Yoshimura, K. (2017). Current status of HIV/AIDS in the ART era. Journal of Infection and Chemotherapy, 23(1), 12-16.

Younes, N., Al-Sadeq, D. W., Al-Jighefee, H., Younes, S., Al-Jamal, O., Daas, H. I., ... & Nasrallah, G. K. (2020). Challenges in laboratory diagnosis of the novel coronavirus SARS-cov-2. Viruses, 12(6), 582.

Yuan, X., Huang, W., Ye, B., Chen, C., Huang, R., Wu, F., Wei, Q., Zhang, W., & Hu, J. (2020). Changes of hematological and immunological parameters in COVID-19 patients. International journal of hematology, 112(4), 553–559.

Zandecki, M., Genevieve, F., Gerard, J., & Godon, A. (2007). Spurious counts and spurious results on haematology analysers: a review. Part II: white blood cells, red blood cells, haemoglobin, red cell indices and reticulocytes. International journal of laboratory hematology, 29(1), 21-41.

Zima, T. (2017). Accreditation of medical Laboratories–system, process, benefits for labs. Journal of medical biochemistry, 36(3), 231.

Zohoun, A., Agbodandé, T. B., Kpadé, A., Goga, R. O., Gainsi, R., Balè, P., ... & Milgotina, E. (2021). From benchmarking to best practices: Lessons from the laboratory quality improvement programme at the military teaching hospital in Cotonou, Benin. African Journal of Laboratory Medicine, 10(1), 1.

APPENDICES

Appendix I: Informed consent form

My name is Lilly Alice Murugi Njue. I am a Ph.D. student from Kenyatta University. I am conducting a study titled "Assessment of the quality of selected Immunological and Immunohematological tests in clinical Laboratories in Kiambu County, Kenya."

The information will be used to determine the accuracy of selected diagnostic results generated from clinical laboratories, Laboratory personnel's preparedness towards quality service delivery, and also clinician's opinion on the quality of diagnostic results generated by them.

Community consideration in line with covid-19 protocols

During data collection, you will be provided with face masks to protect you from Covid-19 infection.

Hand-washing facilities will be provided at specific data collection points to ensure you wash your hands and keep safe from COVID-19.

Hand-rubbing sanitizers will be available at all data collection stations to protect you and the community from COVID-19 infections, and social distance will be maintained.

Data will be collected in well-ventilated venues to protect you from COVID-19 infections.

Charts to indicate proper handwashing, proper mask-wearing, and availability of the COVID-19 vaccines at health facilities will be available at different locations.

Procedures to be followed

Participation in this study will require that you record honest information you are asked in the questionnaire provided.

Voluntarism

You have the right to refuse participation in this study. Please remember that participation in this study is voluntary. You may ask questions related to the study at any time.

You may refuse to respond to any questions and stop an interview at any time. You may also stop being in the study at any time without any consequences.

Discomforts and Risks

There will be no questions you will be asked on intimate subjects. However, if you are uncomfortable with a question, you may refuse to answer these questions if you so choose. You may also stop the interview at any time. The interview may take approximately half an hour of your time.

Benefits

If you participate in this study, you will help us learn how to improve the quality of laboratory tests and minimize laboratory errors.

Rewards

There are no rewards or any payment to you if you participate.

Confidentiality

Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping at Kenyatta University. Everything will be kept private and only shared with the study team.

Contact Information

If you have questions about the study, call the Dr. Margaret Muturi-07227585523 or Dr. Stanley Kinge-0722362719 or Dr. Nelson Menza-0725011570 or me-0723072738

However, if you have questions about your rights as a study participant, You may contact the Kenyatta University Ethical Review Committee Secretariat at chairman.kuerc@ku.ac.ke,

Participant's statement

The above information regarding my participation in the study is clear to me. The study has been explained to me, and I have been given a chance to ask questions, and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that records will be kept private and that I can leave the study anytime. I understand the information given will not affect my current employment at the institution.

Name of Participant: _____

Signature_____Date_____

Investigators statement

I, the undersigned, have explained to the volunteer in a language s/he understands the procedures to be followed in the study and the risks and benefits involved.

Name of Interviewer _____

Signature_____

Date_____

Appendix II: Introductory Letter

Dear Sir/Madam,

I am conducting a study to assess the quality of laboratory results generated from clinical laboratories in Kiambu County.

Your laboratory falls in the category I would like to assess. I would be grateful if you would give of your time and knowledge. Those who do not wish to participate in the survey are free to say so. This is an academic exercise, and the information obtained will remain confidential.

Thank you

Lilly Alice Murugi

PhD student

Medical laboratory science department

Kenyatta University

Participant Signature……..…….

Researcher Signature……..

Appendix III: Labels

EQC NAME

Exercise code number.

Identifier of the exercise material.

The volume of the material contained in the vial.

The material is infectious and handle with care.

Appendix IV: Data Report Form

1. Test method name.

2. Name of your facility.

3. Operator.

4. Test date.

5. Note: Kindly use the testing method you normally use.

6. Test Results obtained:

Appendix V: Questionnaire for Laboratory Personnel

INSTRUCTIONS

My name is Lilly Alice Murugi, a PhD student at Kenyatta University at the school of Medicine

This questionnaire is meant to gather information on professional skill and competency towards quality service delivery in clinical laboratories in Kiambu County

Following established research standards, all information gathered through this questionnaire will remain confidential and solely used for research.

Participants interested in the overall findings of the research will provide their email for appropriate communication. There are no risks attributed to participation in this study. Participation, however, is very beneficial to the improvement of the country's quality of health care. Those who voluntary consent to participate in this study will take about 30 minutes to complete the questionnaire.

For confidentiality, participants will not be required to write their names or any other identifying information.

Carefully read through the questionnaire and use a tick (√) to identify the response corresponding to your answer.

Date: _____ Time: _____

Interviewer: _____

Institution code: _____Respondents code: _____

SECTION A: Bio data

A1 Gender Male ( ) Female ( ) Transgender ( )

A2 Age_____

A3 Marital status: Single ( ) Married ( ) Separated ( ) Divorced ( )

A4 Education level: Diploma ( ) Higher diploma ( ) Degree ( )

Masters and above ( )

SECTION B: Laboratory characteristics

B1 Working experience 0 – 5 years ( ) 6-10years ( ) 10 years and above ( )

B2 Type of laboratory: Private ( ) Public ( )

B3 Biosafety level of the laboratory: Level 1 ( ) Level 2 ( ) Level 3 ( ) Level 4 ( ) Level 5 ( )

SECTION C: Continued Education

C1 Do you have a plan to pursue further education? Yes ( ) No ( )

C2 Are you currently enrolled in an educational program? Yes ( ) No ( )

C3 Have you participated in in-service training on quality management?

Yes ( ) No ( )

C4 If yes, how many times in the last two years? Once ( ) Twice ( )

Many times ( )

C5 What category does the in-service training you participated in fall under? Conference ( ) Seminar ( ) Workshop ( ) School environment ( )

C6 What was the approximate duration of the training? 1-7 days ( ) 1-3weeks ( ) 1-6months ( ) 1-3years ( )

C7 Which title accurately describes your current job position? Lab head

Supervisor ( ) Quality assurance officer ( ) Ordinary staff ( )

What laboratory discipline do you work in? Clinical Chemistry Hematology ( ) Parasitology ( ) BTS ( ) Immunology/Serology ( )

SECTION D: Job satisfaction

D1 Approximately how many employees work in this laboratory? 1-5 ( ) 6-10 ( ) more than 10 ( )

D2 Would you say that employees generally feel overworked? Yes ( ) No ( ) Sometimes ( )

D3 In your view, is it critical to hire more staff in this laboratory? Yes ( ) No ( )

D4 Are you happy with the job that you do? Yes ( ) No ( )

If No specify_____

D5 Is the salary that you receive commensurate to the work at your level? Yes ( ) No ( )

If No please explain why_____

D6 In your experience, how many lab requests do you receive in a day on average?
1-10 ( ) 10-20 ( ) More than 20 ( )

D7 From these requests, how many tests can you complete before the end of the day? All ( ) Some ( ) None ( )

SECTION E: Laboratory Infrastructure

Scale 1= not at all, 2. Poorly done 3- fairly done 4. Well done 5. Excellently done

	1	2	3	4	5
In terms of working space adequacy, how well done is the laboratory working space					
How well are the laboratory equipment maintained and calibrated?					
How well and timely are supplies to run tests provided?					
Is new equipment necessary for quality service provided when needed?					
How often are broken down equipment replaced					
To what extent does the lab administrators facilitate the performance of internal quality control?					

SECTION F: Laboratory Errors

F1 In the process of running requested tests, have errors occurred in the laboratory?

Yes ( ) No ( )

If yes, specify what type of error;…….

Preanalytical phase	TICK	Analytical phase	TICK	Post analytical phase	TIC K
Collecting the wrong sample		Failure to follow established guideline		Exchanging patient information	
Mislabelling the sample		Reporting tests findings when quality control materials are out of range		Handwritten report that is illegible	
Stored sample incorrectly before testing		Incorrect measuring/ dilution of the sample		Sending report to the wrong location	
Sample handling		Using expired or improperly stored reagents		Complete loss of report	
Improper storage of reagents				Not sending the report to the patient	

F2 Have you ever observed or heard other laboratory employees report on an error that occurred in the laboratory? Yes ( ) No ( )

If yes specify……...

Preanalytical phase	TICK	Analytical phase	TICK	Post analytical phase	TICK
Collecting the wrong sample		Failure to follow established guideline		Exchanging patient information	
Mislabelling the sample		Reporting tests findings when quality control materials are out of range		Handwritten report that is illegible	
Stored sample incorrectly before testing		Incorrect measuring/ dilution of the sample		Sending report to the wrong location	
Handling tests samples under conditions that will damage it		Using expired or improperly stored reagents		Complete loss of report	
Improper storage of reagents				Not sending the report to the patient	
Unfilled laboratory request form					

F3. Have you ever rejected a lab specimen? Yes ( ) No ( )

If yes what was the reason? _____

F4. Do you request further tests if your initial test produce abnormal results?

No ( ) sometimes ( ) always ( )

F5. While performing a microscopy examination, do you always seek a second opinion on the results from a colleague? No ( ) Sometimes ( ) Always ( )

F6 Do you participate in external quality control regularly? Yes ( ) No ( )

If no, why……

F7 On a scale of 1-5, what would you say are the causes of laboratory errors.

Scale 1= not at all, 2. Sometimes 3- fairly true 4. Often times 5. Always

Causes	1	2	3	4	5
Lack of Knowledge and skill					
Poor staff motivation					
Using non calibrated equipment					
Poor equipment quality					
High workload					
Poor Condition of the specimen					
Lack of management support					
Controls used to run the tests					
Transcription and reporting of results					
Lack of External quality assessment					

Thank you so much for your time!

COMPETENCY CHECKLIST

The laboratory in charge/manager will complete this section Kindly Score on a scale of 1-5

Score 1= Very poor, 2- Poor 3- Good 4- Very good 5-Excellent

	1	2	3	4	5
How would you rate the overall/general performance of this employee?					
Do the employee perform the tests and report results according to the specified laboratory's procedure?					
Has the employee received regular in-service training and education necessary for the tests they are performing?					
How does the employee address technical problems and ensure curative actions are implemented when a test system fails?					
Does the employee ensure that an adequate Quality Control (QC) program is in effect for the laboratory's testing performance?					
Does the employee have Good verbal skills?					
Does the employee demonstrate attention to Good Laboratory Practices?					

Administrative information

Questionnaire number……..

Start time ……. End time……

Date……

Appendix VI: Healthcare workers focused Group discussion

Date (dd/mm/yyyy)……..…

Institution Code……..…

Start time …….. End time……

Members present

Name	Area of speciality	Highest qualification	Job experience

General questions on FGDs

s/no	Focus theme	Probe/Question	Comment
1	Frequency of laboratory tests request	1. Do you request for laboratory tests for your patients? Tell me more on some of the reasons you request for the laboratory tests…. 2. Why do you request for laboratory results? In your own opinion why do you request? 3. Are laboratory results helpful in-patient diagnosis, treatment and management? When do you find them more useful? 4. Does laboratory diagnosis regularly tally with clinical diagnosis? Always? Sometimes? Never useful? 5. Do laboratory results inform patient management changes? Always? Sometimes? Never useful?	
2.	Trust of healthcare workers in the laboratory results	1. Do the laboratory personnel discuss the results with you? Sometimes? When? Reasons for not discussing? 2. Have you ever received wrong results from the laboratory? how many times? How often? 3. According to you which areas are usually misdiagnosed? Do they include the equipment generated or the serology? 4. Number of wrong or misleading results obtained in the last twelve months. Are they few? Or alaming? Tell me more… 5. Action taken on wrong result received? Do you discuss the issue with the laboratory personeal? 6. Do you find the laboratory results reliable? In your opinion which is the most reliable?	

		7. Do you seek a second opinion from another laboratory when not sure of the results? Always? Sometimes? Never useful?	
3	Healthcare workers' opinion on the Competency of laboratory personnel	1. What is your Perception on the quality of results from each laboratory section? Do you find them quality? What does quality mean to you? 2. What is your level of satisfaction with results from the various sections? Always satisfying? Sometimes? Never useful? 3. What is your take on the Competency of the laboratory staff in diagnosis? Are they competent?	
4	Healthcare workers' views on the Validity of the laboratory tests	1. How adequate is the information on laboratory form? Is there any other information you would like added? 2. Are you satisfied with the results generated in the laboratory? Always? Sometimes? Never useful?	
5.	Healthcare workers' opinion on the attitude of laboratory personnel	1. How is the general conduct or behavior of laboratory employees in relation to service? in your own opinion? 2. What is the duration of time that elapses between collecting tests samples and issuing tests results? Is it due to the delay of the laboratory staff?	

Appendix VII: Laboratory Observation checklist

Observation checklist

Date (dd/mm/yyyy)……..…

Institution Code……..…

Start time …….. End time……

	Compliance
General outlook of the laboratory Main working room with Enough Spacing Smooth floor non slippery Ventilation Lockable cupboards Two sinks with running tap water Mains power of 12-volt Batteries recharged or solar system Electrical power points	

Security and safety Metal bars on windows vents Secure lockable door	
Accessory rooms Waiting bay Wash room Store	
Essential facilities Running water or aspirator bottle, Container with tap rainwater collection Flush toilets Latrines Separate toilet facilities for patients and staff	
Presence of displayed SOPs Display of equipment calibration worksheet	

Laboratory safety practice (waste disposal) Fire extinguisher/buckets Laboratory coats Gloves First aid kit Accidents record book	
Credibility and courtesy Clean and neat premise Clean and neat personnel Politeness Respect Friendliness Cleanness and neatness of laboratory	

Appendix VIII: Ethical approval

KENYATTA UNIVERSITY
CENTRE FOR RESEARCH ETHICS AND SAFETY

Fax: 8711242/8711575
Email: chairman.kuerc@ku.ac.ke
Nairobi, 00100

P. O. Box 43844,

Website: www.ku.ac.ke
Our Ref: KU/ERC/APPROVAL/VOL.1

Tel: 8710901/12

Date: 11th /03/2022

Lily Alice Murugi
P.O BOX 43844-00100
Nairobi.

Dear Ms. Murugi,

APPLICATION NUMBER: PKU/2445/I1577 - ASSESSMENT OF THE QUALITY OF SELECTED IMMUNO HAEMOTOLOGICAL TESTS IN CLINICAL LABORATORIES IN KIAMBU.

This is to inform you that ***KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE*** has reviewed and approved your above research proposal. Your application approval number is **PKU/2445/I1577.** The approval period is ***11th /03/2022 to 11th /03/2023***

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE***
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE*** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE*** within 72 hours

Appendix IX: Graduate School Approval

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: kubps@yahoo.com
dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 810901 Ext. 57530

Internal Memo

FROM: Dean, Graduate School

DATE: 29th October, 2021

TO: Ms. Lilly A.M. Njue
C/o Department of Medical Laboratory Science
Kenyatta University

REF: P97/20977/20

SUBJECT: APPROVAL OF RESEARCH PROPOSAL

This is to inform you that the Graduate School Board at its meeting 27th October, 2021 approved your Ph.D. Research Proposal entitled **"Assessment of the Quality of Selected Immunological and Immunohaematological Tests in Clinical Laboratories in Kiambu County, Kenya".**

You may now proceed with your Data collection, subject to clearance with the Director, National Commission for Science & Technology.

As you embark on your data collection, please note that you will be required to submit to Graduate School completed supervision Tracking and Progress Report Forms. The Forms are available at the University's Website under Graduate School webpage downloads.

By copy of this letter, the Registrar (Academic) is hereby requested to grant you substantive registration for your Ph.D. studies.

Thank you.

KENYATTA UNIVERSITY
29 OCT 2021
GRADUATE SCHOOL
43844-00100 NAIROBI

REUBEN MURIUKI
FOR: DEAN, GRADUATE SCHOOL

c.c. Chairman, Department of Medical Laboratory Sciences
Registrar (Academic) Att; Mr. Richard Chweya

Supervisors:

1. Dr. Margaret Muturi
   C/o Department of Medical Laboratory Sciences
   Kenyatta University
2. Dr. Stanley Waithaka
   C/o Dept. of Medical Laboratory Science
   Kenyatta University
3. Dr. Nelson Menza
   C/o Department of Medical Laboratory Sciences
   Kenyatta University

RM/cao

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 8710901 Ext. 57530

OUR REF:P97/20977/20

Date:29th October, 2021

The Director General,
National Commission for Science, Technology & Innovation,
P.O. Box 30623-00100,
NAIROBI

Dear Sir/Madam,

RE: RESEARCH AUTHORIZATION FOR MS. LILLY A. NJUE REG. NO. P97/20977/20

I write to introduce Ms. **Njue** who is a Postgraduate Student of this University. She is registered for Ph.D. Degree programme in the **Department of Medical Laboratory Science in the School of Medicine.**

Ms. **Njue** intends to conduct research for Ph.D. Thesis entitled, **"Assessment of the Quality of Selected Immunological and Immunohaematological Tests in Clinical Laboratories in Kiambu County, Kenya".**

Any assistance given will be highly appreciated.

Yours faithfully,

PROF. ELISHIBA KIMANI
DEAN, GRADUATE SCHOOL

EO/cao

KENYATTA UNIVERSITY
OFFICE OF DEAN
29 OCT 2021
GRADUATE SCHOOL
P.O. BOX 43844-00100 NAIROBI

Appendix X: NACOSTI Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 501722

Date of Issue: 18/March/2022

RESEARCH LICENSE

This is to Certify that Ms.. Lilly murugi Alice of Kenyatta University, has been licensed to conduct research in Kiambu on the topic: ASSESSMENT OF THE QUALITY OF SELECTED IMMUNOLOGICAL AND IMMUNO HAEMATOLOGICAL TESTS IN CLINICAL LABORATORIES IN KIAMBU COUNTY for the period ending : 18/March/2023.

License No: NACOSTI/P/22/16371

501722

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix XI: NPHLS APPROVAL

MINISTRY OF HEALTH

Telephone: Nairobi 254-020-2725601/4
Telegrams: "BACTERIA"
Email:headnphl@nphl.go.ke
When replying please quote:

NATIONAL PUBLIC HEALTH
LABORATORY SERVICES
P.O BOX 20750-00200
NAIROBI, KENYA

31/05/2022

Ms. Lilly Alice Murugi Njue
P.O.BOX 5050-0200
THIKA

REF: APPROVAL RESEARCH APPLICATION AT NATIONAL PUBLIC HEALTH LABORATORY

Reference is made to your application on the above subject.

This is to notify you that the NPHL research committee reviewed your research application on the topic entitled "**Assessment of the quality of selected Immunological and Immunohaematological tests in clinical Laboratories in Kiambu County, Kenya".**

We are happy to inform you that the committee approved the application and you will be attached at the National Virology Reference Laboratory for your research.

You are adviced to liase with the Laboratory manager **Mr. Abdi Roba** for further directions.

He can be reached on the following contacts; Email- **robaabdi@yahoo.com**, Phone number- **+254713269010**.

Rosebella Kiplagat
Chair- NPHL Research Committee

Copy to: Manager, National Virology Reference Laboratory

Appendix XII: Approval from Kiambu County

COUNTY GOVERNMENT OF KIAMBU
DEPARTMENT OF HEALTH SERVICES
GATUNDU LEVEL 5 HOSPITAL

Telegram:"MEDICAL"Gatundu
Telephone:0786916894
When replying please quote
Email Adress

GATUNDU LEVEL 5 HOSPITAL
P.O. BOX 84 - 01030
GATUNDU
gatundul4h@gmail.com

Ref: GTD/GEN/37/VOL1/361

14TH OCTOBER 2022

MS. LILLY MURUGI ALICE
KENYATA UNIVERSITY

RE: AUTHORITY TO COLLECT DATA

Your application to conduct research on *"Assessment of The Quality of Selected Immunological and Immune Hematological Tests in Clinical Laboratories in Kiambu County"* in this institution has been granted.

During the entire period of your research, you will be reporting to the Medical Laboratory In charge, who will be the key Hospital Co-ordinator during the data collection. He will support you access any information that may be relevant for the successful undertaking of the research.

Finally, you are expected to adhere to all the regulations relating to confidentiality of patient information, ethics in research as well as all norms regarding conduct in a Public Health Institution.

Wishing you a successful research.

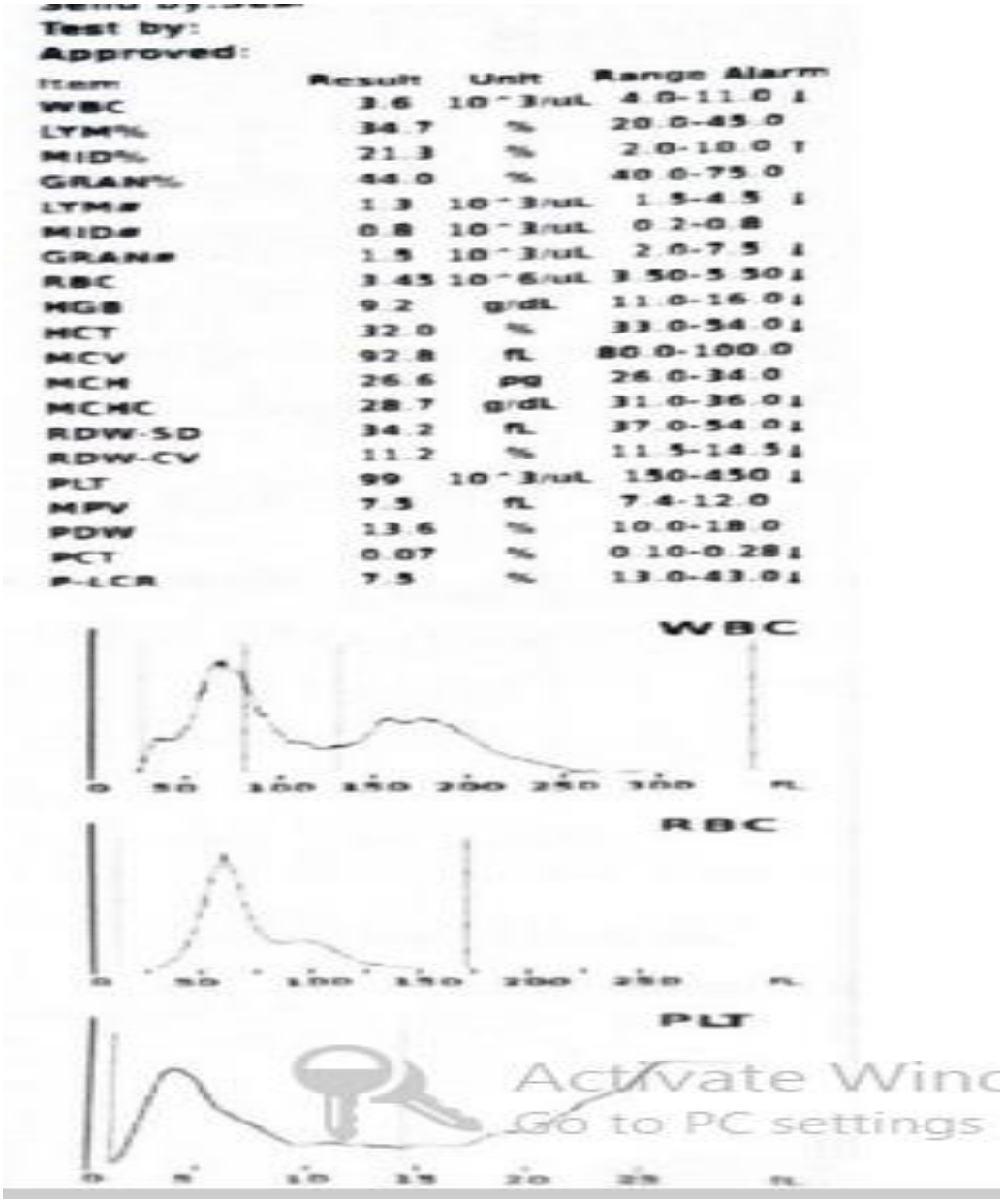
THE MEDICAL SUPERINTENDENT
14 OCT 2022
GATUNDU LEVEL 5 HOSPITAL

DR. JESSE NGUGI
MEDICAL SUPERINTENDENT
GATUNDU LEVEL 5 HOSPITAL

Appendix XIII: Photo of QC sample preparation

Appendix XIV: Laboratory personnel filling the request form in a private facility in Ruiru (used with permission)

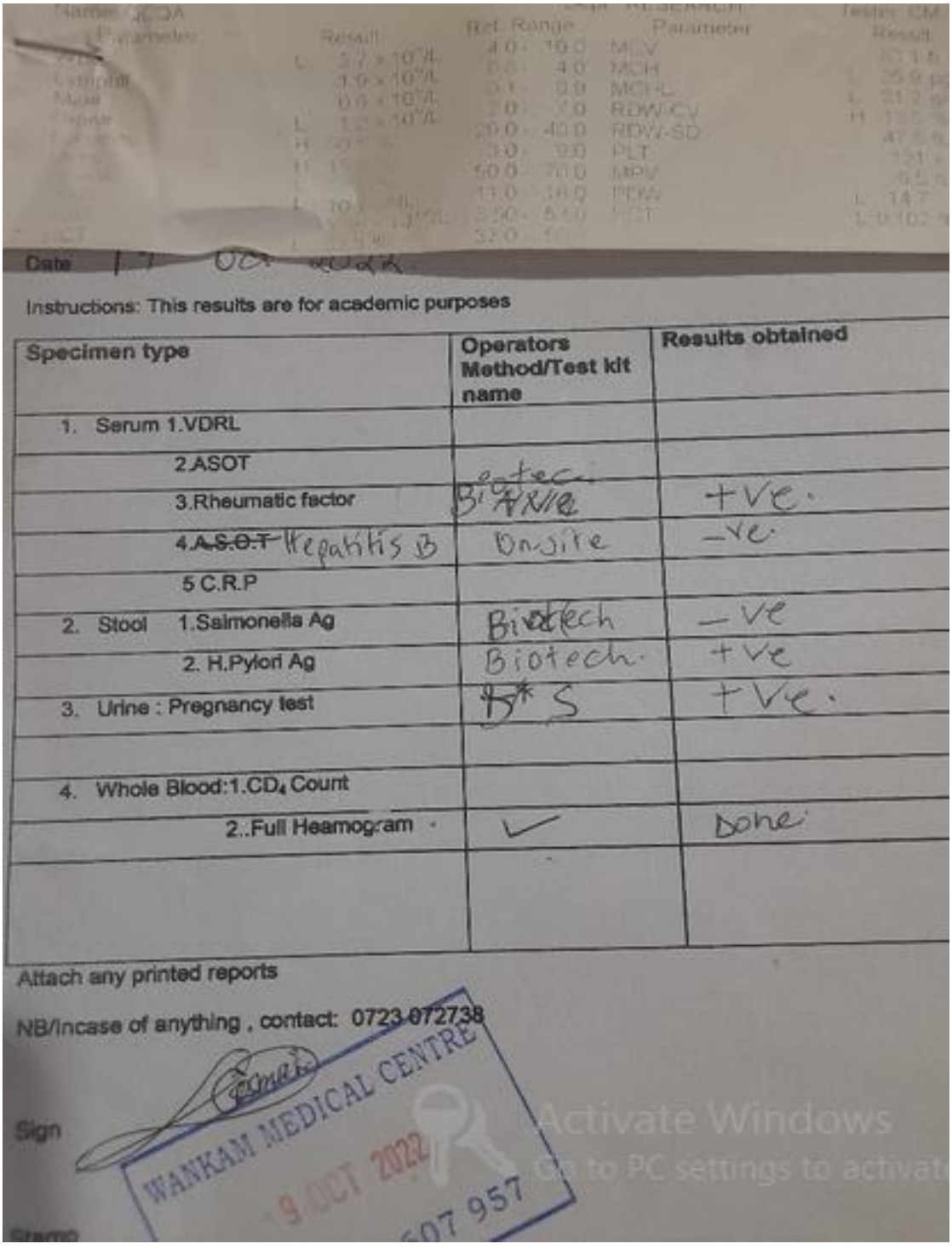
Appendix XV: Sample of immune-haematological results from the laboratories.



Test by:
Approved:

Item	Result	Unit	Range	Alarm
WBC	3.6	10^3/uL	4.0-11.0	↓
LYM%	34.7	%	20.0-45.0	
MID%	21.3	%	2.0-10.0	↑
GRAN%	44.0	%	40.0-75.0	
LYM#	1.3	10^3/uL	1.5-4.5	↓
MID#	0.8	10^3/uL	0.2-0.8	
GRAN#	1.5	10^3/uL	2.0-7.5	↓
RBC	3.45	10^6/uL	3.50-5.50	↓
HGB	9.2	g/dL	11.0-16.0	↓
HCT	32.0	%	33.0-54.0	↓
MCV	92.8	fL	80.0-100.0	
MCH	26.6	pg	26.0-34.0	
MCHC	28.7	g/dL	31.0-36.0	↓
RDW-SD	34.2	fL	37.0-54.0	↓
RDW-CV	11.2	%	11.5-14.5	↓
PLT	99	10^3/uL	150-450	↓
MPV	7.5	fL	7.4-12.0	
PDW	13.6	%	10.0-18.0	
PCT	0.07	%	0.10-0.28	↓
P-LCR	7.5	%	13.0-43.0	↓

Appendix XVI: Sample of immunological results from one of the facilities



Date 17 OCT 2022

Instructions: This results are for academic purposes

Specimen type	Operators Method/Test kit name	Results obtained
1. Serum 1.VDRL		
2.ASOT		
3.Rheumatic factor	Biotec.	+ve.
4.~~A.S.O.T~~ Hepatitis B	Onsite	-ve.
5 C.R.P		
2. Stool 1.Salmonella Ag	Biotech	-ve
2. H.Pylori Ag	Biotech.	+ve
3. Urine : Pregnancy test	B*S	+ve.
4. Whole Blood:1.CD_4 Count		
2..Full Heamogram	✓	Done

Attach any printed reports

NB/Incase of anything , contact: 0723 072738

Sign

WANKAM MEDICAL CENTRE
9 OCT 2022
607 957