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The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city

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Declaration

I Khadeejah Ajeelani AL-Ahreash confirm that the work contained in this thesis / dissertation, unless otherwise referenced is the researcher's own work, and has not been previously submitted to meet requirements of an award at this University or any other higher education or research institution, I furthermore, cede copyright of this thesis / dissertation in favour of University of Zawia.

Student name: Khadeejah Ajeelani AL-Ahreash...

Signature:

Date: 29 / 11/ 2025

Dedication

To the pure soul of my father, that beacon who illuminated my path, a teacher in his life, and in his passing, a memory that dwells in the heart and inspires determination.

To the souls of my sister " Khairiya" and my brother "Mohammed," who preceded us to the eternal abode, leaving in the heart an inexhaustible longing, and in the soul an unforgettable loyalty. May Allah bestow upon them His vast mercy and grant them Paradise.

To my mother, the inexhaustible wellspring of tenderness, the heart that embraced me in childhood and adulthood alike. May Allah bless her life and clothe her perpetually in health and wellness, for she is the unwavering support and the answered prayer.

To my husband "Osama," companion of the journey and partner in life, who stood by me in prosperity and adversity, a pillar in every step along the path of knowledge and learning. To him, my deepest appreciation and gratitude.

To my son "Mohammed," and to the blossoms of my life: "Areen" and "Aryam," my beloved twins, "Maysam" and "Hoor"—those who illuminate my existence with joy and bestow upon me a fragrance that gives life meaning and effort its fruit.

To my parents-in-law, who surrounded me with their care and prayers, becoming unto me as parents. To them, all my love and appreciation.

To my brothers and sisters, those who shared with me life's journey, serving as my support and strength, my companions along life's path.

To them all, I dedicate the fruit of my humble effort, beseeching Allah that this work may stand as testimony to my loyalty and evidence of my gratitude for their virtue. This achievement could not have been completed without their prayers, assistance, and patience.

And Allah is the grantor of success

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To all who supported and encouraged me in my academic journey, whether through kind words, sincere prayers, or practical assistance, I extend my sincerest thanks, for they have had a significant impact on completing this work.

And Allah is behind the purpose, and He guides the way

أثر تطبيق معيار (ISO 15189) على أداء المختبرات الطبية الخاصة في مدينة الزاوية

بواسطة: خديجة الجيلاني الأحرش

ملخص الدراسة باللغة العربية

هدفت هذه الدراسة إلى تقييم أثر تطبيق المواصفة القياسية الدولية (ISO 15189) على أداء المختبرات الطبية الخاصة في مدينة الزاوية، ليبيا، وذلك لسد فجوة بحثية هامة في سياق أنظمة الرعاية الصحية التي تواجه تحديات ما بعد النزاع ومحدودية الموارد. وتمثلت أهدافها الرئيسية في قياس التحسينات في الدقة التشخيصية والكفاءة التشغيلية، ودراسة تأثير المواصفة على تدريب الموظفين ومستوى انخراطهم، وفهم تصورات العاملين حول فوائد وتحديات تطبيقها، اعتمدت الدراسة المنهج الوصفي التحليلي، باستخدام استبانة مُحكّمة كأداة رئيسية لجمع البيانات، والتي وُزعت على عينة قصدية مكونة من 82 موظفًا من تسعة مختبرات خاصة. تم تحليل البيانات باستخدام حزمة SPSSالإحصائية، وشمل التحليل الإحصاءات الوصفية، ومعامل ارتباط بيرسون، وتحليل الانحدار الخطي البسيط، وتحليل التباين الأحادي. أظهرت النتائج وجود أثر إيجابي قوي بين تطبيق مواصفة ISO 15189 والأداء العام للمختبرات، حيث فسرت المواصفة ما يقارب 54% من التباين في الأداء. كما وُجدت أثر إيجابي مع عوامل الموارد البشرية، مع وجود تباين ملحوظ في مستوى التطبيق بين المختبرات المختلفة، بينما كان التحسن في زمن إنجاز الفحوصات متوسطًا. خلصت الدراسة إلى أن تطبيق المواصفة يعزز الجودة بشكل كبير، لكن للاستفادة الكاملة من إمكاناتها، توصي الدراسة بضرورة السعي للحصول على الاعتماد الرسمي، وتوفير برامج تدريب متخصصة حول المواصفة، والتركيز على تحسين إجراءات العمل لتقليل زمن تسليم النتائج، وتشجيع التعاون بين المختبرات لتبادل أفضل الممارسات.

The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city

By: Khadeejah Aljeelani AL-Ahrash

Abstract

This study aimed to evaluate the impact of implementing the International Standard ISO 15189 on the performance of private medical laboratories in Zawia, Libya, addressing a significant research gap within healthcare systems facing post-conflict challenges and resource constraints. Its primary objectives were to measure improvements in diagnostic accuracy and operational efficiency, examine the standard's effect on staff training and engagement, and understand personnel perceptions of its benefits and challenges. Adopting a descriptive-analytical approach, the study utilized a validated questionnaire as the main data collection instrument, distributed to a purposive sample of 82 employees from nine private laboratories. Data was analyzed using the SPSS statistical package, employing descriptive statistics, Pearson's correlation coefficient, simple linear regression, and one-way ANOVA. The results revealed a strong positive impact of ISO 15189 implementation on overall laboratory performance, with the standard explaining approximately 54% of the variance in performance. A positive correlation was also found with human resource factors. However, a significant variation in implementation levels was observed among different laboratories, and the improvement in test turnaround time was moderate. The study concluded that implementing the standard significantly enhances quality. To fully realize its potential, the study recommends that laboratories seek official accreditation, provide specialized training programs on the standard, focus on improving workflows to reduce result delivery times, and encourage collaboration among laboratories to share best practices.

Table of Contents

LIST of Tables

List of Shapes

List of Appendices

CHAPTER ONE: INTRODUCTION

1.0 Introduction

Medical laboratories generate critical diagnostic data upon which 70-80% of clinical decisions depend (Plebani & Sciacovelli, 2021), making accuracy and patient safety fundamental to modern healthcare, as laboratory errors lead to misdiagnosis, delayed treatment, and inappropriate therapy. ISO 15189, first published in 2003 by ISO in collaboration with IEC and revised in 2007, 2012, and 2022, emerged from the need to harmonize medical laboratory practices globally, drawing from ISO 9001 and ISO/IEC 17025 to create a comprehensive framework integrating technical competence requirements with quality management systems. The standard mandates rigorous protocols throughout the testing process—from sample collection to result reporting—requiring qualified personnel, validated equipment, and controlled environments, while simultaneously establishing systematic governance through defined policies, internal audits, management reviews, and corrective/preventive actions (CAPA) within a continuous improvement cycle. Empirical evidence demonstrates that ISO 15189-accredited laboratories exhibit enhanced diagnostic accuracy through standardized procedures and External Quality Assessment participation (Vanstapel et al., 2023), improved operational efficiency with faster turnaround times (Schneider et al., 2017; Huf et al., 2024), strengthened quality culture promoting accountability (Asemahagn, 2014), increased result reliability (Yang et al., 2016), improved risk management enhancing patient safety (Alali et al., 2024), and international recognition facilitating cross-border acceptance of results. However, Libya's healthcare system faces challenges from conflict, political instability, and resource constraints, with private medical laboratories in Zawia emerging as vital healthcare components while confronting variable regulatory oversight, competitive market pressures, workforce challenges, infrastructure limitations, and trust-building needs. While global benefits of ISO 15189 are well-documented, its specific impact within private laboratories in post-conflict developing economies, particularly North Africa, remains underexplored, as the Libyan context with its distinct challenges necessitates localized investigation to understand whether significant accreditation investment translates into measurable performance gains, reduced error rates, improved turnaround times for critical tests, enhanced staff retention, tangible patient outcomes, and competitive advantages.

This research therefore aims to rigorously explore the multifaceted impact of ISO 15189 implementation on the operational, technical, and clinical performance of private medical laboratories in Zawia city, providing concrete, context-specific evidence beyond broad generalizations.

1.1 Research Problem and Questions

Despite the well-documented benefits of ISO 15189 accreditation in enhancing laboratory quality and patient safety globally, a critical knowledge gap exists regarding its practical implementation and measurable impact within private medical laboratories operating in post-conflict, resource-constrained settings. In Zawia city, Libya, private laboratories face significant operational deficiencies including inconsistent adherence to standard operating procedures, inadequate internal quality control practices, compromised traceability systems, and insufficient staff competency assessment (Huf et al., 2024; Schneider et al., 2017). These deficiencies contribute to elevated error rates, delayed turnaround times, and diminished clinician confidence in laboratory results (Alali et al., 2024).

While ISO 15189 implementation could theoretically address these challenges, private laboratories in Zawia confront substantial barriers including: (1) significant financial investments in infrastructure, equipment, and training; (2) limited local expertise in quality management systems; (3) difficulties sustaining continuous improvement culture (Vanstapel et al., 2023; Yang et al., 2016); (4) competing market pressures prioritizing cost containment over quality investment; and (5) infrastructural limitations including power supply inconsistencies. Consequently, the fundamental research problem is the disconnect between ISO 15189's potential benefits and its tangible realization within Zawia's private laboratory sector, compounded by implementation barriers and insufficient empirical evidence demonstrating its specific efficacy in this unique socio-economic context.

Main Research Question: What is the impact of implementing ISO 15189 standards on the overall operational performance and quality outcomes of private medical laboratories in Zawia city?

Sub-Questions:

RQ1: To what extent does ISO 15189 implementation improve diagnostic accuracy and reduce error rates in private laboratories in Zawia city?

RQ2: How does ISO 15189 implementation affect operational efficiency metrics (turnaround times, resource utilization, workflow optimization) in private laboratories in Zawia city?

RQ3: What is the relationship between ISO 15189 implementation and human resource factors (staff training, competency levels, engagement, retention) in private laboratories in Zawia city?

RQ4: What are the perceived benefits and challenges of ISO 15189 accreditation from the perspective of laboratory personnel in Zawia city?

RQ5: How does ISO 15189 accreditation influence clinician confidence and patient trust in private laboratory services in Zawia city?

1.2 Research Significance:

The pursuit of implementing ISO 15189 within Zawia's private medical laboratories transcends mere procedural compliance; it represents a vital investment in the foundational quality and safety of healthcare delivery for the city's population. This study's significance is profound and multi-layered, addressing urgent local needs while contributing to broader healthcare improvement goals in a region striving for stability and development.

1. At its core, this research investigates a direct pathway to enhancing the quality management systems (QMS) that underpin reliable diagnostic services. Private laboratories in Zawia, as initial observations suggest, often operate with fragmented or underdeveloped QMS, leading to inconsistent practices and heightened vulnerability to errors across the testing pathway (pre-analytical, analytical, post-analytical). The implementation of ISO 15189 mandates a systematic, holistic approach – from stringent sample handling protocols and rigorous equipment validation to comprehensive staff competency assessments and robust internal/external quality control (Schneider et al., 2017). By empirically examining the impact of this standard, the study will provide concrete evidence on *how* structured QMS implementation translates into measurable improvements in diagnostic accuracy. This is not an abstract concern; enhanced accuracy directly correlates with reduced misdiagnosis, appropriate treatment selection, and ultimately, the safeguarding of patient lives and well-being (Alali et al., 2024). In a context where diagnostic error can have severe consequences due to resource limitations or delayed access to alternative testing, establishing a proven link between ISO 15189 and improved accuracy is paramount for patient safety in Zawia.

2. The significance of this study is profoundly amplified by its specific focus on Zawia's private laboratories. Generic studies on ISO 15189 benefits, often conducted in resource-rich or stable environments (Vanstapel et al., 2023; Yang et al., 2016), offer limited actionable insights for labs navigating Zawia's unique challenges: infrastructural constraints, fluctuating resources, competitive market pressures, and evolving regulatory oversight. This research is designed to illuminate the *local* reality. By delving into the specific challenges encountered during implementation – whether financial hurdles, expertise shortages, or difficulties in sustaining continuous improvement – the findings will generate invaluable, context-specific knowledge. This knowledge is essential for laboratory managers and owners in Zawia, providing them with realistic roadmaps, evidence-based justifications for investment, and strategies tailored to overcome the barriers prevalent in their operating environment. Understanding which aspects of the standard yield the most significant operational improvements (e.g., reducing turnaround times, minimizing reagent wastage) within Zawia's constraints will empower labs to prioritize effectively and optimize their path to accreditation, thereby enhancing their service delivery and resilience.

3. Beyond individual laboratories, this study holds significant weight for elevating the entire diagnostic sector in northwestern Libya. Currently, a lack of standardized performance data makes it difficult to objectively assess how Zawia's private labs compare to regional or international best practices. This research will generate crucial baseline data on key performance indicators (KPIs) – such as error rates, proficiency testing scores, turnaround times, and documentation completeness – specifically linked to ISO 15189 adoption. This serves a dual purpose:

- Laboratories can use these findings to benchmark their own performance against peers who have implemented the standard, fostered healthy competition and provided clear targets for improvement. Demonstrating alignment with internationally recognized metrics enhances credibility.

- The empirical evidence generated will be indispensable for healthcare authorities and policymakers. It provides a concrete foundation for developing or strengthening local regulations and accreditation frameworks aligned with ISO 15189. Furthermore, by quantifying improvements in reliability and safety, the study can significantly bolster patient and clinician trust in accredited laboratory services within Zawia. When clinicians have confidence in the results, it reduces unnecessary retesting, streamlines patient management, and improves overall healthcare efficiency (Huf et al., 2024).

Patients benefit directly from knowing their diagnostic results meet internationally recognized standards of quality.

Then, this research is not merely an academic exercise; it is a pragmatic investigation with the potential to catalyze tangible improvements in the quality and safety of healthcare for the citizens of Zawia. By rigorously assessing the impact of ISO 15189 within the specific context of the city's private laboratories, the study addresses a critical evidence gap. Its findings promise to empower laboratory professionals with actionable strategies, provide policymakers with robust data for informed decision-making, and ultimately, contribute to building a more reliable, trustworthy, and patient-centered diagnostic infrastructure in northwestern Libya. The significance lies in its potential to transform local practice and align Zawia's healthcare services with the global imperative of quality and safety.

1.3 Research Aim and objectives

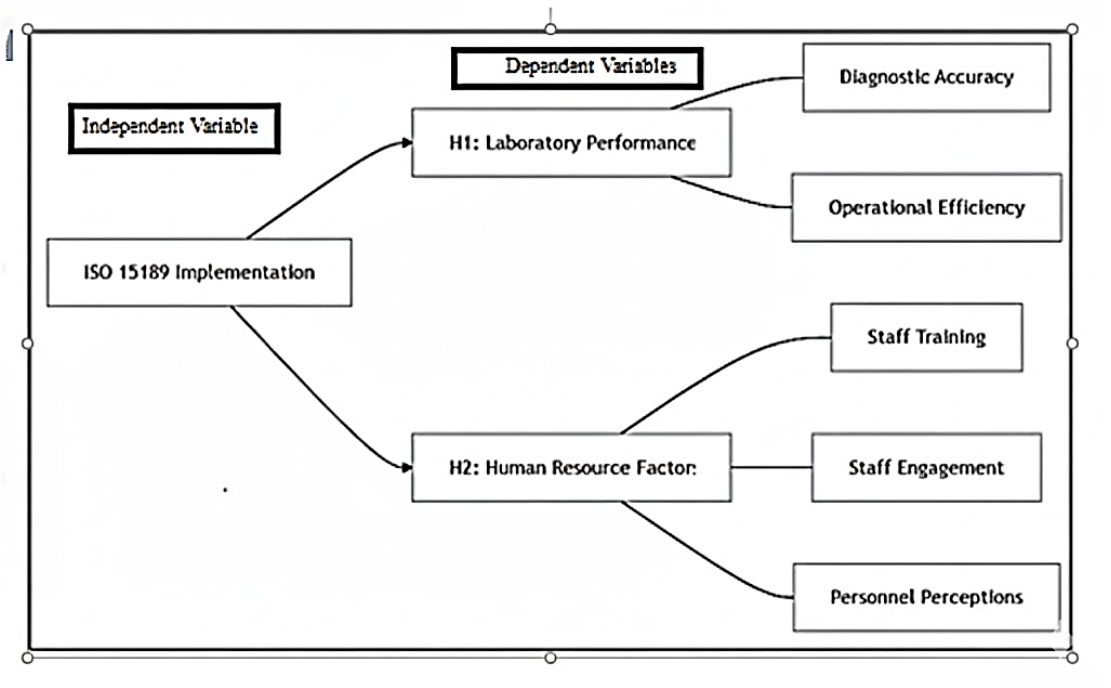
This study aims to explore the multifaceted impact of ISO 15189 implementation on private medical laboratories in Zawia city by examining improvements in diagnostic accuracy, operational efficiency, staff engagement, and personnel perceptions of accreditation benefits and challenges, the following objectives have been identified:

1- To Identify specific improvements in diagnostic accuracy and operational efficiency after ISO 15189 implementation

2- To Examine how ISO 15189 influences staff training and engagement levels

3- To Assess laboratory personnel perceptions regarding benefits and challenges of ISO 15189 accreditation

1.4 Conceptual Framework of the study:



Shape (1.1): Study model

Source: prepared by the researcher based on previous studies

1.5 Study Variables:

1- Independent Variable: Application of ISO 15189 standard in private laboratories in Zawia city.

2- Dependent Variables: Performance of private laboratories in Zawia city.

1.6 Study Hypotheses

1.6.1 Main Hypothesis:

H0: The application of ISO 15189 standards has no significant impact on overall operational performance and quality outcomes in private laboratories in Zawia city.

Ha: The application of ISO 15189 standards has a significant positive impact on overall operational performance and quality outcomes in private laboratories in Zawia city.

1.6.2 Null Hypotheses:

$H0_1$: There is no significant relationship between the implementation of ISO 15189 standards and laboratory performance in private laboratories in Zawia city.
$H0_2$: There is no significant relationship between ISO 15189 implementation and human resource factors in private laboratories in Zawia city.

1.6.3 Alternative Hypotheses:

HI_1: There is a significant relationship between the implementation of ISO 15189 standards and laboratory in performance private laboratories in Zawia city.

HI_2: There is a significant relationship between ISO 15189 implementation and human resource factors in private laboratories in Zawia city

1.7 Research methodology

The study employed a descriptive-analytical design to measure the level of ISO 15189 implementation and to analyze the impact of performance indicators and human resource factors in private laboratories in Zawia city.

1.7.1 Survey population and Employees Selection

The target population consisted of all employees working in private medical laboratories in Zawia. A purposive sampling approach was used to select a final sample of 82 respondents from nine different laboratories, including laboratory directors, physicians, technicians, and administrative staff to ensure a representative sample.

1.7.2 Data Collection

Data was collected using a structured questionnaire consisting of 50 items across five dimensions, rated on a five-point Likert scale. The questionnaire was developed based on ISO 15189 standards and relevant literature, and it was distributed in paper format after obtaining official approvals and informed consent from participants

1.7.3 Data Processing and Analysis

The collected data was analyzed using SPSS. The analysis included:

- **Descriptive Statistics:** Frequencies, percentages, means, and standard deviations to summarize demographic data and responses.

- **Inferential Statistics:** Pearson's correlation and simple linear regression were used to test associations, while one-way ANOVA was used to compare differences between laboratories, with a significance level set at $\alpha = 0.05$.

1.8 Scope of the Study

This study examines the impact of ISO 15189 standard implementation on the operational, technical, and quality performance of private medical laboratories in Zawia city, Libya, focusing on three primary dimensions: quality management systems (documentation practices, SOPs, IQC/EQA participation, CAPA implementation), laboratory performance indicators (diagnostic accuracy, error rates, turnaround times, traceability, resource utilization), and human resource development (staff training, competency assessment, engagement, retention). The research is geographically delimited to Zawia city, located 45 kilometers west of Tripoli with an estimated population of 290,000, serving as a representative urban center facing typical post-conflict challenges including infrastructure limitations and evolving regulatory environments. The institutional scope comprises private medical laboratories operational for minimum two years with daily testing volumes exceeding 50 samples, offering routine clinical chemistry, hematology, and immunology services, comparing facilities with ISO 15189 accreditation or active pursuit thereof against non-accredited laboratories, while explicitly excluding public hospital laboratories, specialized reference facilities, and international organization-operated laboratories. The study employs a cross-sectional design with retrospective elements conducted over 12 months, including six-month primary data collection period and 24-month retrospective performance analysis, utilizing mixed-methods approach integrating quantitative components (structured questionnaires, secondary performance data analysis) and qualitative components (semi-structured interviews, direct observational assessments). The research is delimited to private sector laboratories in Zawia city focusing on routine diagnostics and ISO 15189 specifically, with acknowledged limitations including potential self-selection bias, cross-sectional design constraints on causal inference, reliance on some self-reported data, possible recall bias, and generalizability constraints to similar contexts, yet providing robust, contextually relevant evidence addressing the research gap regarding ISO 15189 impact in resource-constrained, post-conflict settings with findings offering valuable insights for laboratory management, policymakers, and quality improvement stakeholders in comparable developing economy contexts.

1.9 Operational Definitions of Study Concepts

1.9.1 ISO 15189 Implementation

The systematic adoption of ISO 15189:2022 requirements within laboratory operations, measured by accreditation status (accredited, in preparation, non-accredited), documented quality management system components (SOPs, IQC, EQA, competency records, CAPA), and implementation duration. Laboratories with valid accreditation or documented implementation ≥12 months are classified as "ISO 15189-compliant."

1.9.2 Laboratory Performance

Measurable diagnostic testing outcomes across three dimensions: (a) Technical Performance (diagnostic accuracy, error rates per 1000 tests, IQC compliance, EQA scores), (b) Operational Efficiency (turnaround times, sample rejection rates, equipment downtime), and (c) Quality Management Effectiveness (documentation completeness, SOP adherence, corrective action timeliness). Assessed through composite scoring using 24-month retrospective data.

1.9.3 Human Resource Factors

Personnel-related elements measured through: (a) Staff Competency (qualifications, training hours, assessment scores), (b) Employee Engagement (satisfaction levels, quality objective understanding, error reporting willingness), and (c) Organizational Development (retention rates, professional development frequency, quality culture support). Data collected via questionnaires, records review, and interviews.

1.9.4 Private Medical Laboratory

A privately-owned, for-profit diagnostic facility in Zawia city providing routine chemistry, hematology, and immunology testing (≥50 daily samples), operating independently ≥2 years with qualified personnel and distinct pre-analytical, analytical, and post-analytical areas. Excludes hospital-based, NGO-operated, and specialized reference laboratories.

1.10 Structure of the Study

This research comprises four chapters examining ISO 15189 implementation impact on private laboratory performance in Zawia city.

Chapter One: General Framework introduces the research problem, objectives, questions, hypotheses, variables, scope, and conceptual framework, establishing the study's foundation and purpose.

Chapter Two: Theoretical Framework and Literature Review explores quality management theories, reviews global ISO 15189 implementation literature, and identifies knowledge gaps particularly in resource-constrained settings, positioning this research within existing scholarship.

Chapter Three: Methodology presents the mixed-methods design, study population, sampling procedures, data collection instruments, analytical techniques, and ethical considerations ensuring research rigor.

Chapter Four: Results, Discussion, and Recommendations reports findings, interprets results against theoretical frameworks and existing literature, and provides practical recommendations for laboratory managers, policymakers, and future researchers.

These chapters systematically address whether ISO 15189 genuinely improves laboratory performance in Zawia's context, identifying specific benefits, challenges, and implications for healthcare quality enhancement in developing regions.

CHAPTER TWO: LITERATURE REVIEW AND PREVIOUS.

2.0 Introduction

This chapter establishes a comprehensive theoretical and empirical foundation for examining the impact of quality standards on medical laboratory performance. It begins by systematically deconstructing the ISO 15189 standard, outlining its conceptual framework, core requirements, and historical development as the international benchmark for quality and competence. The discussion then broadens to explore the foundational principles of Quality Management (QM) and Performance Measurement, delineating the systems, indicators, and methodologies essential for operational excellence. Synthesizing evidence from a diverse range of previous studies, this review critically analyzes the documented benefits of accreditation in various global contexts, from high-resource to limited-resource settings. Crucially, this chapter contextualizes this global knowledge within the unique operational landscape of Libya, examining the specific systemic challenges and realities confronting its private medical laboratories. Ultimately, this literature review serves not only to build a robust scholarly groundwork but also to identify the precise gap in existing research that the present study on private laboratories in Zawia city aims to address.

2.1 ISO 15189 – Conceptual Framework and Fundamentals

In recent decades, the clinical laboratory sector has undergone a substantial transformation, driven by advancements in diagnostic technologies and the increasing reliance on laboratory test results for accurate diagnosis and informed clinical decisions. In this evolving context, ISO 15189:2012 — Medical laboratories – Requirements for quality and competence — emerges as a global benchmark designed to ensure the reliability and accuracy of laboratory services.

This standard not only emphasizes the quality management system of medical laboratories but also integrates specific technical requirements related to staff competencies, testing methods, and result validation. With its dual focus on both administrative and technical competence, ISO 15189 provides a comprehensive framework for medical laboratories striving to deliver high-quality, patient-centered services. This chapter aims to outline the conceptual foundation of the standard, discussing its definition, historical evolution, objectives and principles, administrative

and technical components, comparison with other standards, and the implementation process, with particular reference to private laboratories in Zawiya, Libya.

2.1.1 Definition and Scope of ISO 15189

ISO 15189 is an international standard that outlines the specific requirements for quality and competence in medical laboratories. It goes beyond administrative quality assurance by incorporating criteria for technical proficiency, such as personnel qualifications, validation of testing procedures, and the accuracy of test results (ISO, 2012). It ensures that laboratories are not merely test-processing units but healthcare entities that integrate into the broader clinical decision-making process.

Youssef (2022) highlighted that ISO 15189 treats laboratories as integral components of healthcare systems, focusing on the clinical relevance of results and emphasizing effective communication with physicians and patients. Similarly, Ismail (2015) noted that adopting this standard signifies a shift toward a systematic quality-oriented culture, transforming the laboratory into a structured institution governed by transparent policies and evidence-based practices.

2.1.2 Historical Development of the Standard

ISO 15189 was developed in response to the growing need for a specialized standard that would address the unique requirements of medical laboratories. Inspired by ISO 9001 (general quality management) and ISO/IEC 17025 (technical competence of testing laboratories), ISO 15189 was first published in 2003, marking a significant milestone in clinical laboratory quality assurance (ISO, 2012).

- The 2003 edition addressed the specificities of the medical laboratory context, especially the clinical implications of test results.
- The 2007 revision included refinements for improved clarity and harmonization with related standards.
- The 2012 version, currently the most widely used, expanded the emphasis on risk management, patient safety, continual improvement, and leadership accountability (ILAC, 2020).

Recent developments suggest that upcoming revisions may include enhanced digital integration, molecular diagnostics, and data-driven quality improvement (Youssef, 2022). These adjustments reflect a broader trend toward interoperability with electronic health systems and the growing complexity of modern laboratory operations.

2.1.3 Objectives and Core Principles of ISO 15189

ISO 15189 aims to elevate laboratory practices through a structured framework that ensures high-quality, patient-centered care. Its key objectives include:

- The ISO 15189 standard establishes a comprehensive regulatory framework designed to enhance laboratory operations through patient-centered quality assurance mechanisms that prioritize diagnostic precision and clinical reliability.
- This international standard fundamentally seeks to guarantee that analytical outcomes provide accurate representations of patient health status, thereby supporting evidence-based clinical decision-making processes (ISO, 2012).
- The framework emphasizes operational optimization by implementing systematic protocols that reduce procedural errors while accelerating service delivery through enhanced workflow management strategies (Mahmoud & Salama, 2014).
- The standard's implementation cultivates stakeholder trust by demonstrating institutional commitment to quality excellence, which subsequently strengthens professional relationships and public confidence in laboratory capabilities (Al-Sharawneh, 2013).
- ISO 15189 serves as a critical tool for regulatory alignment, enabling laboratories to meet stringent national and international healthcare compliance requirements while maintaining consistent quality standards (Ismail, 2015).
- accreditation under this framework facilitates global laboratory networking by establishing mutual recognition agreements that enable seamless result interpretation and acceptance across international healthcare systems, thereby supporting collaborative medical practice and research initiatives (ILAC, 2020).

These objectives rest on several foundational principles, including customer focus, leadership involvement, employee engagement, evidence-based decision-making, continuous improvement, and relationship management with suppliers (CLSI, 2020; ISO, 2012).

2.1.4 Key Requirements of ISO 15189 (Administrative and Technical)

The ISO 15189 standard establishes a dual-component framework encompassing both administrative and technical requirements that collectively define the operational excellence parameters for medical laboratory accreditation. This comprehensive

approach ensures systematic quality assurance across all dimensions of clinical testing environments, from organizational governance to technical execution.

Organizational Architecture and Leadership Framework: The establishment of robust organizational frameworks constitutes the primary administrative requirement under ISO 15189. This encompasses the delineation of hierarchical structures, definition of individual accountability parameters, and establishment of decision-making authority distribution throughout the laboratory organization (ISO, 2012). Effective governance mechanisms ensure operational continuity and provide clear pathways for responsibility assignment across all functional areas.

Quality Management System Development: Central to ISO 15189 compliance is the development and maintenance of comprehensive quality management systems. These systems necessitate systematic documentation of operational protocols, policy frameworks, and record-keeping procedures that collectively govern laboratory activities. The quality management approach requires integration of all laboratory processes within a unified framework that facilitates consistent performance monitoring and continuous improvement initiatives.

Service Agreement and Capacity Assessment: Laboratory capacity evaluation prior to test acceptance represents a critical administrative function that prevents overcommitment and ensures service delivery capabilities align with customer requirements. This process involves systematic assessment of technical competencies, resource availability, and turnaround time feasibilities before contractual obligations are established.

Stakeholder Engagement and Communication Systems: Systematic approaches to managing external relationships form an essential component of the administrative requirements. This includes establishing formal mechanisms for addressing stakeholder inquiries, processing complaints through structured protocols, and implementing feedback collection systems that inform continuous improvement efforts. Effective communication management ensures transparency and maintains professional relationships with referring physicians, patients, and regulatory bodies.

Systematic Improvement and Corrective Action Framework: The implementation of structured approaches to identifying, analyzing, and addressing system deficiencies represents a cornerstone of administrative excellence. These protocols require

systematic root cause analysis methodologies and the development of mitigation strategies that prevent recurrence of identified nonconformities. The corrective and preventive action framework ensures organizational learning and systematic improvement over time.

Internal Assessment and Management Oversight: Regular assessment of system effectiveness through internal auditing processes and management review activities ensures ongoing compliance and identifies opportunities for enhancement. These mechanisms provide systematic evaluation of all administrative and technical components, facilitating evidence-based decision-making and strategic planning initiatives.

Research conducted in challenging operational environments has identified significant implementation barriers, particularly regarding foundational administrative infrastructure development. Youssef (2022) documented substantial deficiencies in document control systems, stakeholder communication protocols, and leadership engagement levels within laboratories operating in conflict-affected regions, highlighting the critical importance of administrative foundation establishment prior to technical implementation efforts.

Technical Excellence Requirements: The technical specifications outlined in Section 5 of ISO 15189 address the operational integrity and scientific validity of laboratory testing processes. These requirements establish comprehensive standards for personnel competency, infrastructure adequacy, analytical reliability, and clinical relevance of laboratory services.

Human Resource Development and Competency Management: Professional development and continuous competency validation constitute fundamental technical requirements for diagnostic accuracy and reliability. The standard mandates systematic approaches to personnel qualification assessment, ongoing training program implementation, and performance evaluation mechanisms that ensure sustained technical proficiency across all laboratory functions.

Infrastructure and Environmental Control Systems: Adequate physical infrastructure encompasses spatial requirements, safety protocols, ventilation systems, and controlled environmental conditions necessary for optimal laboratory operations.

These specifications ensure that physical conditions support accurate analytical processes while maintaining personnel safety and sample integrity throughout all phases of testing.

Instrumentation and Reagent Management Protocols: Technical excellence requires systematic approaches to equipment validation, regular calibration procedures, and preventive maintenance programs. Additionally, reagent management protocols must ensure consistent quality and traceability of analytical materials, supporting reliable test performance and result reproducibility.

Pre-analytical Process Management: Comprehensive management of pre-examination procedures encompasses patient preparation guidelines, specimen collection protocols, transportation requirements, and storage conditions. These processes significantly impact analytical accuracy and require systematic standardization to minimize pre-analytical variability and ensure sample integrity.

Analytical Process Validation and Quality Control: The implementation of validated testing methodologies, combined with robust internal quality control systems and participation in external quality assessment programs, ensures analytical reliability and comparability. These technical requirements establish the scientific foundation for accurate diagnostic testing and result confidence.

Clinical Reporting and Result Communication: Technical requirements extend to the generation of timely, accurate, and clinically relevant reports that facilitate appropriate medical decision-making. This includes establishing protocols for result interpretation, critical value communication, and consultation services availability.

Professional Consultation Services: The provision of qualified professional consultation represents an essential technical component that bridges analytical expertise with clinical application. This requirement ensures that complex analytical results receive appropriate interpretation and that healthcare providers have access to specialized knowledge when needed (CLSI, 2020).

Implementation research has demonstrated that technical requirements frequently present greater challenges than administrative components, particularly in resource-constrained environments. Ismail (2015) identified significant barriers related to personnel qualification availability and advanced equipment accessibility in low-

resource settings, emphasizing the critical importance of strategic resource planning and capacity building initiatives for successful technical implementation.

2.1.5 ISO 15189 Compared to Other Quality Standards

The positioning of ISO 15189 within the broader landscape of international quality standards requires systematic examination of its distinctive characteristics relative to established quality management frameworks. This comparative analysis illuminates the specialized nature of medical laboratory accreditation requirements and demonstrates the evolution toward sector-specific quality assurance approaches.

Comparative Framework: ISO 15189 and ISO 9001: The fundamental distinction between ISO 15189 and ISO 9001 lies in their respective operational domains and specificity of application. While ISO 9001 establishes universal quality management principles applicable across diverse industrial sectors, ISO 15189 represents a specialized adaptation designed specifically for medical laboratory environments with particular emphasis on clinical outcomes and patient safety considerations (Al-Sharawneh, 2013).

Scope and Application Differentiation: The broader applicability of ISO 9001 across multiple industries contrasts significantly with the focused medical laboratory orientation of ISO 15189. This specialization enables ISO 15189 to address the unique challenges and requirements inherent in clinical testing environments, including regulatory compliance, patient safety protocols, and clinical decision-making support systems. The medical laboratory focus ensures that quality management systems align with healthcare delivery objectives rather than general commercial principles.

Technical Specification Depth: A critical differentiating factor between these standards involves the technical specificity incorporated within their respective frameworks. ISO 15189 encompasses comprehensive technical requirements that address analytical validation procedures, specimen traceability systems, and personnel competency standards specific to clinical laboratory operations (ISO, 2012). These technical specifications extend beyond the general quality management principles found in ISO 9001, providing detailed guidance for maintaining analytical accuracy and clinical relevance.

Professional Recognition and Credibility: The medical field recognizes ISO 15189 accreditation as definitive evidence of both quality management excellence and technical competency in clinical laboratory operations. This dual recognition

encompasses not only administrative efficiency but also scientific rigor and clinical relevance, establishing ISO 15189 as the premier accreditation standard for medical laboratory services (ILAC, 2020). The healthcare-specific recognition provides laboratories with enhanced credibility among medical professionals and regulatory authorities.

Analytical Comparison: ISO 15189 and ISO/IEC 17025

The relationship between ISO 15189 and ISO/IEC 17025 represents a more nuanced comparison, as both standards address testing laboratory environments while serving different sectoral applications and regulatory requirements.

Sectoral Application Boundaries: ISO/IEC 17025 encompasses a comprehensive range of testing and calibration laboratory types across various industries, from environmental monitoring to materials testing. In contrast, ISO 15189 maintains exclusive focus on medical laboratory operations, enabling specialized attention to healthcare-specific requirements and clinical applications (ISO, 2012). This focused approach allows for detailed consideration of medical laboratory challenges that may not be adequately addressed by broader testing laboratory standards.

Healthcare-Specific Integration: The clinical orientation of ISO 15189 incorporates healthcare delivery elements that extend beyond traditional laboratory testing parameters. These include pre-analytical patient preparation protocols, clinical interpretation services, and critical result communication systems that directly impact patient care outcomes (Youssef, 2022). Such healthcare-integrated approaches distinguish ISO 15189 from the more technically focused ISO/IEC 17025 framework.

Quality Assurance Methodologies: While both standards emphasize quality assurance principles, ISO 15189 mandates specific participation in external quality assessment programs and implementation of internal quality control measures tailored to clinical environments. These requirements reflect the critical nature of medical testing accuracy and the potential consequences of analytical errors in healthcare settings (CLSI, 2020). The clinical focus ensures that quality assurance measures align with patient safety objectives and medical decision-making requirements.

Strategic Positioning and Implementation Considerations: The comparative analysis reveals that while administrative quality management principles remain consistent across standards, the specialized requirements of ISO 15189 establish it as the optimal choice for clinical laboratories pursuing healthcare excellence. The integration of technical competency with quality management, combined with

healthcare-specific requirements, positions ISO 15189 as uniquely suited to address the complex operational environment of medical laboratories.

The evolution toward specialized quality standards reflects the recognition that sector-specific requirements necessitate tailored approaches to quality assurance. For medical laboratories, the comprehensive framework provided by ISO 15189 ensures alignment with both quality management best practices and clinical excellence objectives, supporting optimal patient care outcomes through reliable laboratory services.

2.1.6 Implementation and Accreditation Process

The transformation of medical laboratories toward ISO 15189 compliance requires systematic implementation approaches that integrate organizational change management with technical excellence development. This comprehensive process encompasses strategic planning, systematic execution, and continuous improvement mechanisms that collectively ensure sustainable accreditation achievement and maintenance:

1. **Leadership commitment**: Top management must allocate resources and demonstrate support.
2. **Staff training**: All personnel must be trained in both quality systems and technical aspects (Mahmoud & Salama, 2014).
3. **Gap analysis**: Identifying areas of non-conformity between current practices and ISO 15189 requirements.
4. **Documentation and system development**: Drafting SOPs, policies, and quality manuals aligned with the standard.
5. **System implementation**: Applying documented procedures, ensuring compliance in daily operations.
6. **Monitoring and internal audits**: Using performance indicators, internal audits, and management reviews to evaluate progress.
7. **Accreditation application**: Submission of documentation and readiness for evaluation by an accreditation body.
8. **On-site assessment**: Evaluation of technical performance and system effectiveness by external auditors.
9. **Corrective action and approval**: Addressing any non-conformities and achieving final accreditation.

10. **Surveillance and re-assessment**: Annual monitoring and full reassessment every 3–4 years (ILAC, 2020).

2.1.7 Challenges in the Libyan Context

The implementation of ISO 15189 standards within Libya's healthcare infrastructure faces considerable obstacles that reflect broader systemic challenges documented across similar regional contexts. Research conducted by Mahmoud and Salama (2014) alongside Youssef's (2022) comprehensive analysis reveals multiple interconnected barriers that significantly impede the successful adoption of international quality management systems in healthcare laboratories. These challenges are further corroborated by Al-Dhuwaib's (2024) examination of private health services in Libya, which highlights the persistent structural inadequacies affecting healthcare delivery.

1- Economic and Resource Constraints

The financial burden associated with ISO 15189 implementation represents a primary obstacle for many healthcare facilities. Laboratory administrators must navigate substantial costs encompassing professional consultancy services, comprehensive staff training programs, mandatory external assessment procedures, and essential equipment modernization initiatives (Mahmoud & Salama, 2014; Youssef, 2022). These financial demands often exceed the operational budgets of many institutions, particularly within resource-constrained environments where competing healthcare priorities require immediate attention. The challenge is compounded by limited access to international funding sources and the economic instability that has affected Libya's healthcare sector (Eddib & Eddib, 2023).

2- Workforce Development Challenges

A critical shortage of appropriately qualified laboratory personnel compounds implementation difficulties (Abdulwahed & Elmansorry, 2021). The absence of structured continuing education frameworks further exacerbates this challenge, as existing staff lack opportunities to develop the specialized competencies required for quality management system maintenance (Mahmoud & Salama, 2014). This human resource deficit creates a cyclical problem where insufficient expertise prevents effective standard implementation, while the absence of standardized systems limits professional development opportunities. The situation is particularly acute in Libya,

where the healthcare workforce has been significantly impacted by ongoing political and economic instability.

3- Infrastructural Limitations

Libya's healthcare laboratory infrastructure frequently exhibits significant deficiencies that directly impact quality standard compliance (Al-Mahdawi, 2017). Aging facility designs often fail to meet contemporary operational requirements, while inconsistent access to high-quality reagents and reliable maintenance services creates ongoing operational vulnerabilities (Badi & Ballem, 2018). These infrastructural inadequacies necessitate substantial capital investments before meaningful progress toward ISO 15189 compliance becomes feasible. Additional concerns regarding biosafety and biosecurity aspects in diagnostic clinical laboratories have been documented in Tripoli, further highlighting the infrastructural challenges (Magrahi *et al*., 2017).

4- Regulatory Framework Deficiencies

The absence of robust national regulatory frameworks creates an environment where quality mandate enforcement remains inconsistent (WHO, 2021). Limited governmental oversight mechanisms fail to provide the structural support necessary for widespread standard adoption, while unclear policy directives create uncertainty regarding compliance expectations and accountability measures. The existing Health Law in Libya (Law No. 106 of 1973 and its amendments in Law No. 93 of 1975) lacks specific provisions for laboratory quality management systems, creating a regulatory gap that hinders systematic implementation efforts.

5- Organizational Resistance Factors

Cultural and institutional resistance to comprehensive procedural documentation represents an additional implementation barrier (Mahmoud & Salama, 2014). Established operational practices often conflict with the systematic approach required by ISO 15189, creating internal opposition to change initiatives. This resistance manifests through reluctance to adopt documentation-intensive processes that may initially appear to reduce operational efficiency. The challenge is particularly pronounced in traditional healthcare settings where informal procedures have been the norm for extended periods.

6- Strategic Value Proposition

Despite these multifaceted challenges, the strategic advantages associated with ISO 15189 implementation justify the required investment commitment (Alali *et al.,* 2024). Enhanced diagnostic accuracy, improved institutional credibility, and international recognition provide compelling reasons for laboratories to pursue certification (Schneider *et al.,* 2017). These benefits position compliant facilities advantageously within an increasingly competitive healthcare marketplace where quality assurance directly influences patient outcomes and organizational sustainability (Plebani & Sciacovelli, 2017).

The evidence suggests that while implementation barriers are substantial, they are not insurmountable (Beyanga *et al.,* 2018). Successful standard adoption requires coordinated efforts addressing financial, human resource, infrastructural, and regulatory constraints simultaneously. Organizations that successfully navigate these challenges typically demonstrate improved operational performance and enhanced competitive positioning within both domestic and international healthcare markets (Yang *et al.*, 2016). The experience of other developing countries in implementing ISO 15189 provides valuable lessons for Libya's healthcare sector in overcoming these systemic challenges.

The ISO 15189:2012 represents a pivotal standard in the quest for quality and competence in medical laboratories. It integrates robust quality management with rigorous technical criteria, aligning laboratory operations with clinical priorities and patient needs. Unlike broader standards such as ISO 9001 or ISO/IEC 17025, ISO 15189 provides a uniquely clinical perspective on quality, making it the gold standard for medical laboratory accreditation. For private laboratories in Libya, adopting ISO 15189 is more than a technical exercise; it is a strategic move toward professional excellence, public trust, and international competitiveness. The conceptual and practical understanding presented in this chapter serves as a foundation for evaluating the tangible impacts of ISO 15189 implementation — which will be explored in subsequent sections of this study.

2.2 Quality Management in Medical Laboratories – Foundations, Systems, and Contextual Challenges

The modern medical laboratory functions as the cornerstone of clinical decision-making, with an estimated 60-70% of critical medical diagnoses and treatment plans contingent upon the accuracy and timeliness of laboratory data (Plebani, 2021). This immense responsibility necessitates a robust, systematic approach to quality that transcends mere technical proficiency. Quality Management (QM) in this context represents an integrated, organizational-wide philosophy dedicated to ensuring diagnostic reliability, safeguarding patient safety, and enhancing overall healthcare efficacy. As technological advancements accelerate and the complexity of diagnostic testing grows, the implementation of comprehensive QM systems aligned with international benchmarks has transitioned from a laudable ambition to an operational imperative.

This chapter provides a critical exploration of the foundational principles and practical applications of quality management within clinical laboratories. It deconstructs the concept of quality into its constituent dimensions, examines the overarching framework of Total Quality Management (TQM), and delves into the specific mechanisms of internal and external quality control. Further, it addresses the critical roles of equipment calibration, preventive maintenance, and proactive risk management strategies. The discussion culminates in an analysis of continuous improvement models and a frank assessment of the formidable challenges impeding the full realization of these quality systems, with a particular focus on the resource-constrained environment of Libya. The ultimate aim is to establish a theoretical and practical foundation for evaluating the impact of a formalized international standard, namely ISO 15189, on the performance of private laboratories in the city of Zawia.

2.2.1 The Multifaceted Concept of Quality in Medical Laboratories

In the specific milieu of medical laboratories, "quality" is a multidimensional construct defined as the consistent delivery of accurate, reliable, and timely results that meet the predefined needs of patients and clinicians, while simultaneously minimizing risks throughout the total testing process (Plebani, 2021). This definition moves beyond a narrow focus on the analytical phase to encompass the entire pathway, from patient preparation to result interpretation.

The quality paradigm in laboratory medicine can be understood through three interlocking dimensions:

- **Technical Quality:** This is the foundational layer, concerned with the scientific accuracy and precision of test results. It is achieved through rigorous verification and validation of methods, instrument performance checks, and the use of certified reference materials. Technical quality ensures that a measured analyte value truthfully reflects its concentration in the patient sample (Westgard & Westgard, 2020).
- **Procedural Quality:** This dimension focuses on the efficiency, standardization, and reliability of all operational processes. It spans the entire testing cycle—including pre-analytical phases (e.g., patient identification, sample collection, transportation), analytical phases (test performance), and post-analytical phases (result calculation, validation, reporting, and interpretation). Procedural quality aims to eliminate errors and reduce turnaround times through standardized operating procedures (SOPs) (CLSI, 2020).
- **Service Quality:** This aspect addresses the perceptions and satisfaction of the laboratory's clients, primarily the ordering physicians and the patients themselves. It encompasses factors such as the clarity of reports, the courtesy and expertise of staff, the accessibility of phlebotomy services, responsiveness to inquiries, and the overall efficiency of service delivery (Elghazli & Albadri, 2014). A laboratory may produce technically perfect results, but if reports are consistently delayed or difficult to interpret, its service quality is deemed poor.

2.2.2 Framework Total Quality Management (TQM): A Holistic Organizational

Total Quality Management is a comprehensive management strategy that seeks to embed a culture of quality throughout an entire organization. In a laboratory setting, TQM involves the continuous effort of all personnel to achieve sustained excellence and meet or exceed customer expectations. Its implementation is guided by several core principles:

- **Customer Focus:** The entire system is designed around fulfilling the requirements of patients and clinicians, recognizing that their needs are the ultimate rationale for the laboratory's existence.
- **Leadership Commitment:** Effective leadership is paramount. Management must actively establish a unified purpose, direct strategy, and foster an environment

where quality can flourish by providing necessary resources, training, and motivation (Al-Manzou & Dabar, 2024).

- **Engagement of People:** Empowering all levels of staff is crucial. This involves delegating responsibility, encouraging participation in problem-solving, and investing in continuous professional development. A trained and motivated workforce is the first line of defense against errors.
- **Process Approach:** Understanding and managing interrelated processes as a coherent system enhances efficiency and effectiveness. This involves mapping the total testing process and optimizing each step.
- **Evidence-Based Decision Making:** Decisions regarding quality improvements must be based on the analysis of data and information, derived from quality control, audits, and key performance indicators (KPIs).
- **Continuous Improvement (Kaizen):** This is a permanent objective of the organization, often operationalized through models like the Plan-Do-Check-Act (PDCA) cycle, which provides a framework for iterative improvement (Kharoubi et al., 2021).

The practical application of TQM in a medical laboratory manifest through the development and enforcement of standardized operating procedures (SOPs), routine internal audits to assess compliance, systematic data collection for performance metrics, and structured management reviews to steer quality policy.

2.2.3 The Pillars of Analytical Assurance: Internal and External Quality Control

To ensure the ongoing reliability of results, laboratories employ a two-tiered system of quality control: internal and external.

2.2.3.1 Internal Quality Control (IQC)

IQC constitutes the day-to-day monitoring of analytical precision and accuracy. It involves the routine analysis of stable control materials of known concentration alongside patient samples. The results from these controls are plotted on Levey-Jennings charts, and statistical rules (e.g., Westgard rules) are applied to identify shifts (indicating systematic error) and trends (indicating increasing random error) in the analytical process (Karaattuthazhathu et al., 2023). The sophistication of IQC has advanced with the adoption of Six Sigma metrics, which quantify process performance. A sigma value of ≥6 signifies a world-class process with minimal error rates, enabling

laboratories to design more efficient and effective QC protocols tailored to the performance of each assay (Westgard & Westgard, 2020).

2.2.3.2 External Quality Assessment (EQA) / Proficiency Testing (PT)

While IQC monitors internal consistency, EQA provides an objective assessment of a laboratory's accuracy by comparing its results with those of peer laboratories using the same methodologies and materials. In EQA schemes, samples of unknown value are sent to participating laboratories from an accredited provider; the lab analyzes them and returns the results for evaluation. EQA is critical for:

- Identifying unsuspected systematic biases inherent to a laboratory's instruments, reagents, or methods.
- Providing an objective benchmark for performance against a broader peer group.
- Fulfilling a mandatory requirement for accreditation to international standards like ISO 15189, which explicitly requires participation in clinically relevant EQA schemes where available (ISO, 2023; Jassam & Mussa, 2022).

The context in Libya, however, presents significant hurdles. As noted by Alrabai et al. (2022), there is a scarcity of locally organized EQA programs, and economic sanctions and logistical complexities often hinder the reliable importation of stable EQA materials, leaving many laboratories to operate in an analytical vacuum without this crucial external validation.

2.2.4 Foundational Infrastructure: Equipment Calibration and Preventive Maintenance

The generation of reliable data is intrinsically linked to the proper functioning of laboratory instrumentation. This reliance mandates a rigorous program of calibration and maintenance.

- **Calibration** is the set of operations that establish, under specified conditions, the relationship between values indicated by an instrument and the corresponding values realized by international measurement standards (e.g., from NIST). It ensures traceability to higher-order references. Calibration must be performed at regular intervals prescribed by the manufacturer or based on a risk assessment, and every action must be meticulously documented to ensure a verifiable audit trail (CLSI, 2020).

- **Preventive Maintenance (PM)** involves scheduled activities—such as cleaning, lubrication, parts replacement, and system checks—designed to prevent equipment failure and maintain optimal performance. A robust PM program is not merely a technicality; it is a strategic investment. Studies have shown that consistent preventive maintenance can reduce unplanned equipment downtime by up to 40%, directly preventing diagnostic delays, reducing costly emergency repairs, and safeguarding the integrity of results (Chowdhuri & Pal, 2022).

2.2.5 Proactive Vigilance: Risk Management in Laboratory Operations

Modern quality standards emphasize a proactive approach to identifying and mitigating potential failures before they occur. Risk management is the systematic application of policies and procedures to identify, analyze, evaluate, treat, and monitor risks. Common methodologies include:

- **Failure Mode and Effects Analysis (FMEA):** A structured, bottom-up approach that identifies potential failure modes for each step in a process, assesses their causes and effects, and prioritizes them for action based on their severity, occurrence, and detectability (Andrada et al., 2018).
- **Risk Mapping:** A tool for visualizing risks on a matrix based on their probability of occurrence and potential impact on patient safety or operations, allowing management to focus resources on high-probability, high-impact risks (Jayamani et al., 2022).

In laboratories, common high-risk areas include patient/sample misidentification, sample cross-contamination, improper sample storage, and critical equipment failure during urgent testing. The challenging Libyan environment, with its infrastructure instability, inherently elevates certain risks, such as the loss of sample integrity due to frequent power outages affecting refrigerators and freezers (Alrabai et al., 2022).

2.2.6 The Journey of Perpetual Enhancement: Continuous Quality Improvement (CQI)

Quality management is not a destination but a continuous journey. CQI is the ongoing, cyclical process of measuring outcomes, identifying areas for improvement, and implementing changes. Key tools for driving CQI include:

- **Key Performance Indicators (KPIs):** Quantifiable measures used to gauge performance over time. Critical KPIs for laboratories include turnaround time

(TAT), sample rejection rates, critical value reporting rates, and patient identification error rates.

- **Root Cause Analysis (RCA):** A structured method used to investigate serious adverse events or recurring errors to identify their underlying, systemic causes rather than simply addressing superficial symptoms.
- **Benchmarking:** The practice of comparing internal performance data with the best practice/es of other leading (reference) laboratories to identify gaps and set ambitious yet achievable goals (Chaudhry et al., 2023).

The efficacy of a CQI program is demonstrated in case studies. For instance, a laboratory in Saudi Arabia documented a 30% reduction in pre-analytical errors within one year of implementing a structured, KPI-driven CQI model, underscoring the tangible benefits of this systematic approach (Al-Manzou & Dabar, 2024).

2.2.7 Contextual Challenges to Implementation: The Libyan Perspective

The theoretical framework of quality management, while universally applicable, collides with stark realities in resource-constrained settings like Libya. The implementation of sophisticated QM systems in cities like Zawia faces a confluence of interconnected barriers:

- **Human Resource Constraints:** There is a critical shortage of personnel formally trained in the principles and practices of quality management. This skills gap makes the establishment, documentation, and maintenance of a quality system profoundly challenging (Alrabai et al., 2022).
- **Infrastructural Deficiencies:** Unreliable electricity grids lead to frequent power cuts, jeopardizing the continuous operation of sensitive analytical equipment and compromising the stability of samples and reagents that require refrigerated storage (Chowdhuri & Pal, 2022).
- **Economic and Logistical Barriers:** Economic sanctions and foreign exchange crises severely restrict the ability to procure essential reagents, quality control materials, calibration standards, and spare parts. This leads to stockouts, the use of expired materials, and the inability to participate in international EQA schemes.
- **Absence of a Supportive Regulatory Framework:** Unlike in many nations, there is often no mandatory national accreditation requirement for private laboratories in Libya. The lack of a strong regulatory driver and oversight body reduces the

incentive for laboratories to invest the significant resources required for implementing standards like ISO 15189 (Elghazli & Albadri, 2014).

The Quality management in medical laboratories is an indispensable, multi-disciplinary endeavor integral to patient safety and effective healthcare delivery. It encompasses a holistic system ranging from technical accuracy and standardized processes to customer-focused services, all underpinned by principles of continuous improvement. While international standards like ISO 15189 provide a robust blueprint for excellence, their successful implementation is heavily dependent on local context. For private laboratories in Zawia, Libya, the path to accreditation and improved performance is fraught with significant challenges related to human capital, infrastructure, economics, and regulation. A pragmatic, phased adoption strategy—prioritizing staff training, strengthening internal controls, leveraging available risk management tools, and advocating for supportive policy changes—represents the most viable approach to enhancing laboratory performance and, ultimately, patient care outcomes in the region.

2.3 Performance Measurement in Medical Laboratories – Foundations, Indicators, and Methodologies

In the contemporary healthcare landscape, medical laboratories are not merely ancillary support services but are recognized as fundamental drivers of clinical efficacy and patient outcomes. For private laboratories operating within competitive and often resource-constrained environments, such as those in Zawia, Libya, the systematic measurement of performance transcends simple operational oversight; it becomes a strategic imperative for ensuring clinical credibility, operational viability, and long-term sustainability. Performance in this context is a multifaceted construct that integrates the accuracy of diagnostic outputs, the efficiency of operational processes, the satisfaction of stakeholders, and the soundness of financial management. This chapter constructs a comprehensive conceptual framework for institutional performance within medical laboratories. It delineates a suite of Key Performance Indicators (KPIs) across technical, managerial, and financial domains, critically examines the methodologies for their measurement, and contextualizes the significant implementation challenges within the Libyan healthcare ecosystem. The analysis is anchored in contemporary academic literature and international best practices, providing a foundation for assessing the impact of standardized quality systems on laboratory efficacy.

2.3.1 The Conceptual Framework of Institutional Performance

Institutional performance for a medical laboratory is defined as its integrated capacity to achieve predefined strategic and operational objectives with maximal effectiveness and efficiency, while unwavering in its commitment to quality standards and patient safety (Tsai *et al*., 2019). This definition encapsulates both the outcomes (what is achieved) and the processes (how it is achieved). The World Health Organization (WHO, 2021) elaborates on this by outlining core dimensions of performance applicable to healthcare institutions, which can be directly adapted to the laboratory setting:

- **Effectiveness:** The degree to which stated objectives, primarily the production of accurate, reliable, and clinically actionable diagnostic information, are met.
- **Efficiency:** The optimal utilization of resources—including time, financial capital, human expertise, and materials—to produce the desired outputs without waste.
- **Equity:** The provision of consistent, high-quality services to all patient groups without discrimination or disparity in access or outcome.
- **Relevance:** The alignment of laboratory services with the evolving needs and expectations of its users, including patients, physicians, and the broader public health system.
- **Sustainability:** The ability to maintain performance levels and continuous improvement over the long term, balancing financial health with technical excellence (Azocar González *et al*., 2024).

A performance measurement system that effectively captures these dimensions provides a holistic view of the laboratory's health, guiding strategic decision-making and resource allocation.

2.3.2 A Taxonomy of Key Performance Indicators (KPIs) in Medical Laboratories

KPIs are quantifiable measures used to gauge performance over time for a specific strategic objective. They serve as navigational instruments, providing objective data to track progress, identify areas for improvement, and benchmark against standards. For medical laboratories, KPIs can be categorized into three interdependent domains.

2.3.2.1 Technical and Quality KPIs

These indicators are the bedrock of laboratory performance, directly reflecting the scientific integrity of the testing process.

- **Analytical Accuracy and Error Rates:** This is the most critical technical KPI. Errors are categorized by the phase of the total testing process in which they occur:

– Pre-analytical Errors: Occurring prior to testing (e.g., misidentification of patients, improper sample collection, inadequate sample volume, incorrect transport conditions). Literature consistently shows this phase accounts for 48–68% of all laboratory errors, making it the most fertile ground for improvement initiatives (Azocar González *et al.*, 2024).

– Analytical Errors: Occurring during the testing process itself (e.g., instrument malfunction, calibration drift, reagent instability, operator mistake) (Tasneem *et al.*, 2024).

– Post-analytical Errors*:* Occurring after testing is complete (e.g., data transposition mistakes, delayed reporting, failure to communicate critical results).

– The Repeat Analysis Rate, the percentage of tests requiring repetition, is a direct surrogate for quality. A rate exceeding 2% typically signals underlying process instability and warrants investigation (Plebani, 2010).

- **Turnaround Time (TAT):** TAT is a crucial indicator of both efficiency and service quality. It is typically segmented:

– Total TAT: Measured from the time of sample collection (or receipt in the lab) to the time the validated result is available to the clinician. ISO 15189 recommends that laboratories establish and monitor their TAT, with a common benchmark being 90% of routine tests reported within an agreed-upon time (ISO, 2012).

– STAT (Emergency) TAT: For critical results impacting immediate patient care, a stringent target of under 60 minutes is often adopted (Al-Kamim, 2020).

- **Quality Control Performance:** This includes:

– Internal Quality Control (IQC) Acceptance Rate: The percentage of QC runs that fall within predefined control limits.

– External Quality Assessment (EQA) Performance Score: The rate of acceptable results in proficiency testing schemes. Accreditation bodies like ISO 15189 require a demonstrated performance of ≥90% acceptable results across all EQA programs (ISO, 2023).

2.3.2.2 Managerial and Operational KPIs

These indicators assess the effectiveness of the laboratory's processes and its human resource management.

- **Stakeholder Satisfaction:** The laboratory's ultimate customer is the physician and the patient.
- Satisfaction Surveys: Structured surveys targeting physicians can assess perceptions of result accuracy, report clarity, TAT reliability, and the professionalism of interactions.
- Complaint Rate: Tracking the number of formal complaints per 100 tests performed. A well-performing lab aims for a complaint rate of <0.1% (Tsai *et al.*, 2019).
- **Process Efficiency:**
- Equipment Utilization Rate: The ratio of actual operational time to available time, with an optimal range of 70-85% to balance workload with necessary maintenance.
- Reagent and Sample Wastage Rate: Losses due to expiration, mishandling, or error. A wastage rate exceeding 5% of inventory value indicates poor inventory management or process flaws (Badi & Ballem, 2018).
- Absenteeism Rate: High rates can point to low morale, poor working conditions, or inadequate staffing, indirectly affecting all other performance areas.
- **Human Resource Development:**
- Process Bottleneck Analysis: Identifying stages where samples accumulate (e.g., centrification, data entry) helps target process re-engineering.
- Training Hours per Employee: Investment in continuous professional development is a leading indicator of a laboratory’s commitment to quality and innovation (Azocar González *et al.*, 2024).

2.3.2.3 Financial KPIs

For private laboratories, financial sustainability is a prerequisite for fulfilling their clinical mission.

- **Cost Management:**
- Cost per Test: A fundamental metric that aggregates the costs of reagents, consumables, labor, equipment depreciation, and overheads. Monitoring this helps in pricing strategies and identifying inefficiencies.

– Operating Expense to Revenue Ratio (Opex/Revenue): This measures operational efficiency. A ratio below 70% is generally considered healthy for a diagnostic service provider (Al-Kamim, 2020).

- **Profitability and Investment:**

– Gross Profit Margin: Indicates the financial return after accounting for the direct costs of performing tests.

– Return on Investment (ROI): Critical for justifying capital expenditures on new, high-throughput analyzers or laboratory information systems.

- **Financial Health:**

– Average Collection Period: The number of days it takes to receive payment for services rendered.

– Debt-to-Income Ratio and Unpaid Tests Rate: Particularly salient in contexts like Libya, where economic instability can lead to high rates of bad debt and challenges in revenue cycle management (Badi & Ballem, 2018).

2.3.3 Methodologies for Performance Measurement and Analysis

Selecting appropriate methodologies is key to transforming raw data into actionable intelligence.

- **Quantitative Methodologies:**

– Sigma Metrics: This powerful statistical tool quantifies process performance in terms of defects per million opportunities (DPMO). A Six Sigma process (3.4 DPMO) is considered world-class. For laboratories, calculating the sigma value for an assay provides an objective measure of its quality level; values below 3 Sigma indicate processes requiring urgent and fundamental improvement (Plebani, 2010).

– Pareto Analysis: This technique helps prioritize efforts by identifying the "vital few" sources of problems. For instance, a Pareto chart might reveal that 80% of pre-analytical errors are caused by just 20% of root causes (e.g., improper phlebotomy technique and mislabeling), allowing for targeted interventions (Oktay & Hanikoğlu, 2023).

- **Qualitative and Integrated Methodologies:**

– SERVQUAL Model: This framework assesses service quality from the customer's perspective across five dimensions: reliability, responsiveness, assurance, empathy,

and tangibles. Applying this model through surveys can uncover gaps between customer expectations and perceptions (Tsai et al., 2019).

- Dashboard Systems: Modern data visualization tools (e.g., Power BI, Tableau) allow laboratories to integrate data from various sources (LIMS, financial software) into real-time dashboards. These provide management with an at-a-glance view of all critical KPIs, enabling rapid response to emerging trends (Azocar González et al., 2024).

An effective performance management system requires that these KPIs are not viewed in isolation but as an interconnected web. For example, improving technical quality (reducing errors) directly enhances customer satisfaction, reduces the cost of repeat testing (improving financial KPIs), and improves operational efficiency.

2.3.4 Contextual Challenges to Performance Measurement in Libya

The implementation of a sophisticated performance measurement regime in Libyan laboratories, particularly in private facilities in Zawia, faces profound obstacles:

1. **Absence of National Standardization:** There is no unified national framework defining mandatory KPIs or providing benchmarking data against which laboratories can compare their performance. This leads to ad-hoc, inconsistent measurement practices (Badi & Ballem, 2018).
2. **Technological and Infrastructural Deficits:** The widespread lack of robust Laboratory Information Management Systems (LIMS) forces many laboratories to rely on manual data collection, which is inherently prone to error, inefficient, and incapable of supporting real-time analytics.
3. **Analytical Capacity Gap:** There is a significant shortage of personnel trained in biostatistics, data science, and quality management methodologies. This limits the ability to not only collect data but, more importantly, to correctly interpret it and derive meaningful insights for improvement.
4. **Macroeconomic Volatility:** Extreme currency fluctuations, import restrictions, and supply chain disruptions make consistent cost assessment and financial planning nearly impossible. The cost of reagents and equipment can vary wildly, distorting financial KPIs and challenging sustainability (Al-Kamim, 2020).

The Performance measurement is the central nervous system of a modern, high-functioning medical laboratory. It provides the evidence base for strategic planning, quality enhancement, and financial stewardship. For a private laboratory in Zawia,

embracing a structured framework of KPIs—spanning technical, managerial, and financial domains—is the first step toward achieving excellence and competitiveness. This necessitates the adoption of internationally recognized standards like ISO 15189, which provides a ready-made structure for such measurement. While the path forward is fraught with challenges related to standardization, technology, human capital, and macroeconomic stability, a committed, phased approach focused on building measurement capabilities offers the most viable strategy. By investing in digital infrastructure, building analytical capacity, and fostering a culture of data-driven decision-making, laboratories can significantly enhance their diagnostic accuracy, operational efficiency, and financial resilience, thereby securing their role as indispensable pillars of Libya's healthcare system.

2.4 The Impact of Quality Standards on Medical Laboratory Performance – Implementation Analysis and Outcomes

The role of the medical laboratory within the healthcare continuum is undergoing a profound paradigm shift. No longer perceived as a passive producer of numerical data, the modern laboratory is an active, indispensable partner in the diagnostic and therapeutic process. This elevated status brings with it an increased responsibility for unwavering accuracy, reliability, and efficiency. Central to meeting these demands is the structured adoption of internationally recognized Quality Management Systems (QMS). ISO 15189:2012, specifically tailored for medical laboratories, provides a comprehensive framework integrating both managerial and technical requirements. This chapter conducts a rigorous analysis of the causal mechanisms linking the implementation of ISO 15189 to measurable enhancements in laboratory performance. It synthesizes empirical evidence from diverse international settings, from high-income European nations to resource-limited African contexts, to build a compelling case for its adoption. Finally, it extrapolates these findings, critically examining the potential applicability, challenges, and strategic adaptations necessary for successful implementation within the unique operational environment of private laboratories in Zawia, Libya.

2.4.1 Theoretical Foundations: Linking Accreditation to Enhanced Performance

The connection between ISO 15189 accreditation and superior performance is not merely correlational; it is underpinned by robust organizational theory. The **Resource-Based View (RBV)** of the firm posits that sustained competitive advantage is derived from valuable, rare, inimitable, and non-substitutable (VRIN) internal resources and capabilities. From this perspective, the pursuit of ISO 15189 accreditation is a strategic investment that builds such capabilities:

- **Structured Processes as Intangible Assets:** The standard mandates the development of a hierarchical documentation system (quality manual, procedures, SOPs, records). This creates an invaluable institutional memory, ensuring consistency and reducing reliance on individual tacit knowledge, which is often lost through staff turnover.
- **Enhanced Human Capital:** The training and competency assessment requirements force an investment in staff development, creating a more skilled and engaged workforce capable of problem-solving and innovation.
- **Cultural Transformation:** The standard fosters a culture of quality, objectivity, and continuous improvement. This cultural shift becomes an inimitable resource, as it is socially complex and developed over time.
- **Reputational Capital:** Accreditation serves as a powerful signal to physicians, patients, and payers of a laboratory's commitment to excellence, building trust and loyalty in a competitive market.

Thus, ISO 15189 accreditation helps transform a laboratory from a simple service provider into a learning organization with a unique, hard-to-replicate capability for delivering consistent, high-quality diagnostics.

2.4.2 Empirical Evidence: Documented Performance Gains from Global Implementation

2.4.2.1 High-Resource Context: A Nationwide Study in Austria

A large-scale study analyzing over 52,000 immunohematology External Quality Assessment (EQA) results across Austria provided compelling quantitative evidence. The research demonstrated that laboratories accredited to either ISO 15189 or ISO 9001 achieved an overall error rate of 0.7%, which was half the rate of 1.4% observed in non-accredited laboratories—a statistically significant difference. Perhaps more

importantly, the longitudinal data showed that laboratories saw their error rates drop from 1.3% *before* certification to 0.7% *after* achieving it ($p = 0.0468$), establishing a clear causal link between implementation and quality improvement (Buchta *et al.*, 2018).

2.4.2.2 Resource-Limited Context: A Transformative Case Study from Tanzania

The experience of Bugando Medical Centre's clinical laboratory in Mwanza, Tanzania, is particularly instructive for the Libyan context. Operating with significant constraints, the laboratory underwent a structured ISO 15189 implementation process between 2012 and 2014, supported by external mentorship. The outcomes were dramatic and multifaceted:

- **EQA Performance:** Scores improved drastically: Parasitology from 45% to 100% acceptable, Biochemistry from 50% to 95%, and Microbiology from 48.1% to 100%.
- **Pre-analytical Quality:** Sample rejection rates plummeted from 7.2% to 1.2%.
- **Efficiency:** Turnaround Time (TAT) compliance reached 92% for tests within target time.
- **Safety and Satisfaction:** Blood culture contamination rates were reduced from 16% to 4%, and weekly customer complaints decreased from eight to two. This case powerfully demonstrates that the standard's benefits—enhanced reliability, consistency, and stakeholder trust—are achievable even in low-resource environments through committed implementation.

2.4.3 A Multidimensional Analysis of Expected Benefits

2.4.3.1 Enhancement of Technical and Analytical Quality

The standard's greatest impact is on the core product: the diagnostic result. Its requirements enforce rigor across the total testing process:

- **Pre-analytical Phase:** By standardizing procedures for patient identification, sample collection, handling, and transportation—the source of an estimated 70% of errors—the standard directly targets the largest source of inaccuracy. Anecdotal data from a private lab in Benghazi showed pre-analytical errors falling from 12% to 3% within eight months of implementing ISO-aligned protocols (Plebani, 2012; Azocar González *et al*., 2024).

- **Analytical Phase:** The mandatory use of Internal Quality Control (IQC) and participation in EQA schemes create a system of continuous verification. A Saudi laboratory reported a reduction in analytical error rates from 0.7% to 0.2% post-implementation.
- **Post-analytical Phase:** Requirements for clear reporting, critical value notification, and data management ensure that accurate results are effectively communicated and acted upon by clinicians.

2.4.3.2 Improvement in Administrative and Service Performance

ISO 15189 enhances the entire service experience. Documented workflows eliminate ambiguities and bottlenecks, leading to more reliable TAT, as seen in Egyptian labs that achieved 90% TAT compliance post-accreditation. Furthermore, requirements for clear communication (e.g., patient instructions, interpretative comments on reports) build trust. This is quantified in satisfaction surveys; for instance, an Irish histopathology lab recorded a rise in client satisfaction from 75% to 92% after certification, with staff also reporting higher confidence in their work (O'Connor *et al.*, 2022).

2.4.4 Proactive Risk Mitigation

The standard transitions laboratories from a reactive ("fire-fighting") mode to a proactive, preventive stance. The mandate to establish a risk management system, often utilizing tools like Failure Mode and Effects Analysis (FMEA), forces laboratories to identify and control potential failures before they occur. The practical impact is significant; a hospital in Sudan reported a 40% reduction in needlestick injuries and sample handling incidents after integrating risk management into its daily operations.

2.4.4.1 Operational Efficiency and Financial Sustainability

A common misconception is that quality is costly. In reality, a well-implemented QMS is a cost-saving strategy. Reducing errors directly decreases the financial waste of repeat tests on reagents and labor. A study from Jordan noted a 15% reduction in the cost per test following process improvements aligned with ISO 15189. Furthermore, stringent requirements for inventory control (Section 5.3) minimize wastage; one report highlighted a reduction in expired reagent waste from 8% to 2% annually—a critical saving in environments like Libya with import difficulties and currency volatility.

2.4.5 Synthesized Performance Outcomes: A Comparative Overview

Table (2.1): Illustrative Key Performance Indicator (KPI) Comparison Pre- and Post-ISO 15189 Implementation

KPI Indicator	Before Implementation/Accreditation	After Implementation/Accreditation	Context / Notes
Overall, Error Rate (EQA - Blood Immunology)	≈ 1.3% – 1.4%	≈ 0.7%	Austrian study on >52,000 EQA results: significant decrease after implementing ISO 9001/ISO 15189 quality systems (1.3% before vs 0.7% after). (Buchta *et al.*, 2018)
Sample Rejection Rate (Regional Laboratory, Tanzania)	≈ 7.2%	≈ 1.2%	Bugando experience after achieving ISO 15189 accreditation: significant improvement in pre/post-analytical indicators within QMS program toward accreditation (Beyanga *et al.*, 2018)
Turnaround Time (TAT) Compliance	—	Reduction in "Excessive TAT" by ~0.75 sigma	Aga Khan University Hospital - Nairobi: notable improvement observed in pre/post-analytical indicators during ISO 15189 accreditation journey (and reduction in administrative complaints) (Kibet *et al.*, 2014)
Customer/Clinical User Satisfaction	—	≈ 98% satisfaction post-implementation	TB laboratory in Kenya: after implementing QMS and achieving ISO 15189 accreditation, 98% customer satisfaction was recorded; baseline percentage not published (Musau *et al.*, 2015)
Cost per Test (Economic Analysis)	$1.80/test	$1.57/test (≈ –13%)	Quasi-experimental study - Khartoum: proven reduction in cost per unit study after implementing ISO 15189 accreditation activities; control group costs increased (1.97→2.08). (Hamza *et al.*, 2013)

Source: Prepared by the researcher from previous studies

2.4.6 Navigating Implementation Challenges and Barriers

Despite the clear advantages, the path to accreditation is fraught with obstacles, particularly for private laboratories in Libya.

- **Financial and Resource Constraints:** The initial investment for accreditation fees, consultancy, training, and documentation can be prohibitive, often ranging from USD 15,000 to 20,000 for a medium-sized lab. Ongoing costs for EQA, calibration, and control materials are exacerbated by Libya's import restrictions and currency fluctuations, with reports of costs inflated by up to 30% (Mahmoud & Salama, 2014).
- **Technical and Organizational Hurdles:** Developing the required documentation system is a massive undertaking that can take 6-12 months. A critical shortage of skilled quality managers—over 70% of Libyan labs may lack a full-time quality officer—severely impedes progress (Jassam & Mussa, 2022).
- **Cultural and Behavioral Resistance:** Staff often perceive new, documentation-heavy systems as bureaucratic burdens that slow them down. Overcoming this requires strong change management to shift the culture from one of informal experience to one of documented procedure and continuous improvement.
- **Contextual Libyan Challenges:** Chronic power instability threatens sample and reagent integrity and equipment functionality. The widespread lack of Laboratory Information Management Systems (LIMS) makes the automated data tracking and KPI monitoring required by the standard immensely difficult to achieve manually.

2.4.7 Critical Success Factors for Implementation in the Zawia Context

For a private laboratory in Zawia to overcome these barriers and realize the benefits, a strategic approach grounded in several critical success factors is essential:

1. **Unwavering Leadership Commitment:** The drive must come from the top. Ownership and management must champion the initiative, allocate necessary resources, and consistently communicate its importance.
2. **Phased and Adaptive Implementation:** Attempting full accreditation at once is a recipe for failure. A pragmatic approach starts with high-impact, achievable areas: mastering pre-analytical processes and internal quality control. This builds momentum, demonstrates early wins, and generates buy-in before tackling more complex areas like management review and full risk management.

3. **Investment in Competent Human Capital:** Allocating a defined portion of the budget (e.g., 5%) for continuous training is non-negotiable. This includes training for internal auditors and quality managers. Exploring collaborations with local universities to secure graduates in quality management or biotechnology could help address the expertise gap.
4. **Cultivation of a Quality Culture:** Leadership must foster an environment where errors are reported as opportunities for system improvement, not for blaming individuals. This psychological safety is the bedrock of a true continuous improvement culture.
5. **Leveraging External Support:** Seeking mentorship from already-accredited labs (nationally or internationally) and engaging with accreditation bodies early for guidance can provide invaluable direction and prevent wasted effort.

Empirical evidence from diverse global settings confirms that the implementation of ISO 15189 functions as a powerful catalyst for multidimensional performance enhancement in medical laboratories. It drives technical proficiency through measurable reductions in error rates, optimizes operational workflows to improve efficiency and reduce costs, and elevates service quality to build stakeholder trust and satisfaction. For a private laboratory in Zawia, the journey toward accreditation represents a strategic investment in building sustainable competitive advantage and clinical credibility. While the challenges—financial, technical, and cultural—are substantial, they are not insurmountable. Success hinges on a committed, pragmatic, and phased approach that is sensitively adapted to the local context. By building internal capabilities, fostering a culture of quality, and strategically managing the implementation process, laboratories in Zawia can harness the power of ISO 15189 to significantly improve their performance, ensure their long-term sustainability, and ultimately contribute to elevating the standard of healthcare in their community.

2.5 Private Medical Laboratories in Libya

The Libyan healthcare system has undergone profound transformation since the political upheaval of 2011, characterized by fluctuating public sector funding and infrastructure challenges. Within this volatile environment, the private healthcare sector has emerged not merely as a supplementary provider but as a critical pillar of national diagnostic capacity. Private medical laboratories, in particular, have filled a vital void, offering services that are often perceived as more reliable and accessible than their

public counterparts. This chapter provides a comprehensive analysis of the state of private clinical laboratories in Libya, with a specific focus on the city of Zawia. It examines their quantitative growth, operational realities, and the unique market characteristics that define their operation. Furthermore, the chapter delves into the multifaceted systemic challenges—structural, human, logistical, and regulatory—that these facilities confront. By synthesizing recent data and academic sources, this analysis aims to contextualize the operational landscape within which these laboratories strive to implement quality standards like ISO 15189, ultimately assessing their capacity for evolution and improvement in a complex socio-economic setting.

2.5.1 The Reality of Private Medical Laboratories in Libya: A Quantitative Overview

The proliferation of private medical laboratories across Libya is a direct response to gaps in public healthcare provision. According to the most recent figures from the Libyan Ministry of Health (2023), there are approximately 411 licensed private laboratories operating nationwide. The distribution of these facilities is heavily skewed, with an estimated 65% concentrated in the capital, Tripoli, reflecting the urban-centralized nature of economic activity and infrastructure. In contrast, the city of Zawia, located approximately 50 kilometers west of Tripoli, hosts around 17 of these facilities, representing roughly 4.1% of the national total (Libyan Ministry of Health, 2023).

Despite operating in a challenging environment, the sector has demonstrated notable resilience and growth. From 2020 to 2023, the private laboratory sector posted an annual growth rate of approximately 7.2%, indicative of sustained demand for private diagnostic services (Al-Dhuwaib, 2024). It is estimated that private facilities now conduct over half (52%) of all diagnostic testing nationally, underscoring their indispensable role in the national healthcare ecosystem (Abed *et al.*, 2022).

A deeper dive into their operational capabilities reveals a mixed picture of gradual modernization constrained by persistent obstacles:

- **Automation:** Approximately 68% of private laboratories employ at least semi-automated systems for routine tests in hematology and clinical chemistry, representing a significant technological advance over purely manual methods.
- **Quality Participation:** Engagement with External Quality Assessment (EQA) schemes is inconsistent; while 42% of labs report some level of participation, it is often irregular and hampered by import difficulties.

- **Accreditation Gap:** A mere 9% of laboratories hold ISO 15189 or any equivalent international accreditation, highlighting a significant gap in formalized quality management systems.
- **Supply Chain Vulnerability:** An overwhelming majority—85%—report chronic challenges in reliably importing essential reagents, calibrators, and quality control materials due to currency instability, banking restrictions, and fragmented supply chains (Abdulwahed & Elmansorry, 2021; Abdulrabai *et al*., 2022).

2.5.2 Sector-Wide Challenges: Impediments to Growth and Quality

The operational environment for private laboratories in Zawia and across Libya is fraught with interconnected challenges that stifle their potential for quality enhancement and sustainable growth.

2.5.2.1 Structural and Infrastructural Deficits

The most immediate challenge is the crippling state of public infrastructure. Zawia experiences daily electricity outages averaging 7.4 hours, which jeopardizes the operation of sensitive analytical instrumentation, compromises the integrity of temperature-sensitive reagents, and disrupts critical IT systems (Abdulwahed & Elmansorry, 2021). The near-total absence of reliable, high-speed internet networks further impedes the adoption of Laboratory Information Management Systems (LIMS), which are fundamental to modern quality management and efficiency. Financing for capital investment is another major hurdle. Prohibitive bank interest rates, averaging around 18%, make loans for upgrading equipment virtually unaffordable for most small to medium-sized laboratory owners (Al-Dhuwaib, 2024).

2.5.2.2 Human Resource Constraints

The sector is suffering from a severe brain drain. An estimated 35% of qualified laboratory technicians and pathologists emigrated between 2015 and 2023 in search of better professional opportunities and stability abroad (Abdulwahed & Elmansorry, 2021). This exodus has created a significant skills vacuum. Compounding this problem is a lack of continuous professional development; only 28% of laboratories offer certified annual training programs for their staff, resulting in widespread skill deficits, particularly in emerging diagnostic technologies and quality management principles.

2.5.2.3 Logistical and Supply Chain Barriers

Logistical inefficiencies pose a direct threat to operational continuity. The delivery of essential reagents from order to arrival typically takes between 45 to 90 days, a stark contrast to the 14-day average in neighboring Tunisia (Al-Dhuwaib, 2024). This protracted timeline forces laboratories to maintain large, costly inventories, tying up capital and increasing the risk of material expiration. Furthermore, transportation costs within Libya have soared by approximately 120% since 2020, driven by fuel shortages and security concerns, adding another layer of financial pressure onto laboratory operations.

2.5.3 The Regulatory and Legal Quagmire

The regulatory framework governing private medical laboratories in Libya is fragmented and inconsistently enforced. The primary legislation, Law 18/2022, governs the licensing of private medical facilities but notably lacks any mandate for international accreditation or adherence to specific quality standards beyond basic operational requirements (Libyan Official Gazette, 2022). Technical standards are often incomplete or outdated, and oversight is hampered by overlapping jurisdictions between the Ministry of Health, the National Center for Disease Control (NCDC), and local municipal authorities, creating confusion and bureaucratic delays (Al-Dhuwaib, 2024).

The enforcement of existing regulations is weak. A startling 61% of laboratories reported undergoing zero official inspections during the 2022-2023 period (Eddib & Hasan, 2023). This regulatory vacuum not only fails to incentivize quality improvement but also fosters an environment where malpractices can go unchecked. Disturbingly, 23% of laboratory managers reported encountering requests for bribes or experiencing extortion during the license renewal process, further eroding trust in the regulatory system and increasing the cost of doing business (Eddib & Hasan, 2023).

2.5.4 The Zawia Market Profile: Dynamics and Consumer Behavior

Zawia, with a population of approximately 351,000, represents a secondary urban market with its own distinct dynamics (World Health Organization, 2021). Its ten private laboratories are estimated to service about 45% of the city’s diagnostic needs, with the remainder relying on public facilities or traveling to Tripoli for specialized tests (Al-Dhuwaib, 2024).

The service landscape is predominantly geared toward general diagnostics: 70% of labs focus on routine chemistry, hematology, and basic immunology. About 20% offer microbiology and parasitology services, while a limited 10% provide more advanced testing, such as hormonal assays or genetic testing, indicating a market gap for specialized diagnostics (Abed *et al.*, 2022). Competition is primarily price-driven; a complete blood count (CBC) test costs about 25 LYD in Zawia, roughly 40% cheaper than in Tripoli, largely due to lower rents and operating costs (Al-Dhuwaib, 2024).

Understanding the preferences of physicians and patients is crucial. For physicians (who are the primary referrers), the top three selection criteria are: 1) perceived accuracy of results (92%), 2) turnaround speed (87%), and 3) the clarity and professionalism of reporting. For patients, cost-effectiveness is paramount, especially for older and low-income demographics. A significant 68% of patients expressed a preference for private over public laboratories, citing perceptions of better service quality, shorter waiting times, and greater reliability as key deciding factors (Al-Dhuwaib, 2024).

2.5.5 Emerging Strategies, Opportunities, and Policy Recommendations

In the face of these challenges, laboratory owners in Zawia are demonstrating remarkable ingenuity and resilience through local collaborative initiatives.

- **Collaborative Procurement:** A consortium of four laboratories in Zawia has begun collaborating on bulk reagent procurement, achieving economies of scale that have led to an estimated 20% reduction in material costs (Al-Dhuwaib, 2024).
- **Academic Partnerships:** A formal partnership with the medical faculty of Zawia University has been established to provide technical internships for medical and laboratory science students. This initiative helps mitigate staffing shortages while creating a pipeline for future talent.
- **Digital Innovation:** Three laboratories have recently launched digital services, including online appointment booking and mobile result delivery via SMS or secure apps, enhancing customer convenience and operational efficiency.

Significant market opportunities remain, particularly in the domain of specialized testing (e.g., molecular diagnostics, advanced immunology), which is virtually absent and represents a potential niche for premium services (Abed *et al*., 2022).

To foster a more conducive environment for growth and quality improvement, targeted policy interventions are essential:

1. **Regulatory Reform:** Unifying laboratory licensing and quality oversight under a single, empowered national authority would reduce bureaucratic confusion. New legislation should incorporate a phased pathway toward mandatory accreditation.
2. **Fiscal Incentives:** Implementing duty and tax exemptions for the importation of medical laboratory equipment, reagents, and quality control materials would significantly lower financial barriers and modernize the sector.
3. **Investment in Infrastructure:** Public-private partnerships aimed at improving reliable electricity supply and internet connectivity in commercial areas would yield substantial benefits for all businesses, including laboratories.

The Private medical laboratories in Zawia, and across Libya, have established themselves as indispensable components of the healthcare delivery system. They have grown in number and market share despite operating in an environment plagued by infrastructural decay, economic instability, regulatory fragmentation, and a debilitating brain drain. Their resilience is evidenced by adaptive strategies such as collaborative procurement and digital innovation. However, for these laboratories to evolve from basic service providers into accredited, quality-driven institutions capable of rivaling international standards, a more supportive ecosystem is required. This evolution depends on two parallel tracks: continued bottom-up initiative and innovation from laboratory owners themselves, and top-down legislative clarity and tangible fiscal support from governmental bodies. Only through this dual approach can the private laboratory sector in Zawia truly realize its potential as a cornerstone of high-quality, reliable healthcare for the local population.

2.6 Previous studies

The Previous studies constitute one of the fundamental pillars of scientific research, providing the theoretical and practical framework upon which understanding of the research topic is built and identifying the knowledge gaps that the researcher seeks to bridge. Within the context of this study examining "The Impact of Applying the Standard (ISO 15189) on Performance at Private Labs in Zawia City," the review of previous studies gains special significance due to the relatively recent emergence of quality management in medical laboratories and the evolution of international accreditation standards.

This chapter aims to provide a comprehensive and systematic review of the scientific literature and applied research that has addressed the topic of implementing international quality standards in medical laboratories, with particular focus on the ISO 15189 standard and its impact on various aspects of laboratory performance. The chapter also seeks to analyze international and regional experiences in implementing this standard, extract lessons learned from these experiences, and identify critical success factors for implementing quality standards in medical laboratories.

2.6.1 ISO 15189 Standard - Concept, Requirements, and Implementation

Study (Linko *et al*., 2024): "EN ISO 15189 revision: EFLM Committee Accreditation and ISO/CEN standards analysis," the research focused on the recent updates to the EN ISO 15189:2022 standard, which governs the quality and competence of medical laboratories. The study employed a qualitative methodology, utilizing document analysis to assess changes and implications of the revised standards. The target population consisted of laboratory professionals and accreditation bodies across Europe, with the sample comprising representatives from various accredited laboratories. Data collection tools included surveys and interviews with key stakeholders in laboratory medicine. For data analysis, thematic analysis was used to identify patterns and insights regarding the implementation of the new standard. The study concluded that the revision promotes greater clarity, aligns with ISO/IEC 17025:2017, and emphasizes patient safety and risk management in laboratory practices. Additionally, it recommended that laboratories focus on continuous education and adaptation to effectively meet the updated requirements. The importance of this study to the current research topic "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city" lies in its provision of a framework for understanding how adherence to the updated ISO standard can enhance the quality of laboratory services, ensuring that private labs can improve their operational efficiency and patient outcomes through standardized practices. This research highlights the need for private laboratories in Zawia to adopt similar comprehensive approaches in order to align with international best practices, thereby enhancing their credibility and service delivery. Furthermore, the findings underscore the potential benefits of implementing structured quality management systems based on the ISO 15189 standard, which can lead to improved patient safety and satisfaction in Zawia's healthcare environment.

Study (Brguljan *et al.*, 2024): "EFLM Working Group Accreditation and ISO/CEN standards on dealing with ISO 15189 demands for retention of documents and examination objects," the research focused on the significance of document retention in medical laboratories to ensure quality service. The study employed a qualitative methodology, utilizing a failure-mode-effects-analysis (FMEA) approach to assess risks associated with document retention practices. The study population comprised medical laboratories across various European countries represented by EFLM member societies. The sample consisted of responses from nine national societies, reflecting diverse practices in document retention. Data collection tools included structured questionnaires and risk assessment frameworks to evaluate current retention practices. For data analysis, both qualitative and quantitative methods were applied, including statistical analysis of the responses and thematic evaluation of qualitative feedback. The findings revealed significant variability in retention periods and highlighted the need for standardized retention schedules based on risk assessment. The study recommended that laboratories adopt a risk-based approach to define appropriate retention times, aligning with ISO 15189:2022 guidelines. This research is crucial for the current study, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," as it underscores the importance of establishing clear retention policies to enhance laboratory performance and compliance with international standards. By implementing these recommendations, private labs in Zawia can improve their operational efficiency and ensure the quality of their services, ultimately benefiting patient care and safety.

Study (Vanstapel *et al.*, 2023): "ISO 15189 is a sufficient instrument to guarantee high-quality manufacture of laboratory developed tests for in-house use conform requirements of the European In-Vitro-Diagnostics Regulation." The study addressed the compliance of laboratory-developed tests (LDTs) with the European In-Vitro Diagnostic Device Regulation (IVDR), emphasizing the role of ISO 15189 in ensuring quality and safety. It utilized a qualitative approach, focusing on case studies from various laboratories across Europe. The population of the study consisted of clinical laboratories that implement LDTs for specific medical needs, and the sample included representatives from different institutions involved in laboratory medicine. Data collection tools included document analysis and interviews with laboratory professionals. For data analysis, thematic analysis was employed to identify key themes related to ISO 15189 compliance and its impact on laboratory performance. The study

concluded that adherence to ISO 15189 significantly enhances the reliability and effectiveness of LDTs, thereby improving patient care and diagnostic accuracy. The authors recommended that laboratories continue to align their practices with ISO standards to facilitate compliance with IVDR requirements, while also advocating for clearer regulatory guidance to support LDTs in clinical settings. The importance of this study for the current topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its demonstration of how established quality standards can enhance laboratory performance and patient outcomes, providing a valuable framework for private labs seeking to improve their operational efficiency and compliance with international regulations.

Study (Jayamani *et al.*, 2022): "A Practical Tool for Risk Management in Clinical Laboratories". The study addressed the critical role of risk management within the Quality Management System (QMS) of medical laboratories. It employed a practical tool consisting of five cyclical steps: risk identification, quantification, prioritization, mitigation, and surveillance. The study population comprised various clinical laboratory processes, and the sample consisted of responses from laboratory supervisors using a comprehensive seventy-point risk identification questionnaire. The tools utilized included failure modes and effects analysis (FMEA) for risk quantification and a structured approach to quality assurance activities. For data analysis, the authors applied scoring systems to calculate risk priority numbers (RPN) based on severity, likelihood of occurrence, and detectability. The study concluded that effective risk management is essential for ensuring patient safety and enhancing laboratory performance. It recommended the implementation of regular quality assurance activities to monitor and mitigate emerging risks. The significance of the study for the current research topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its demonstration of how systematic risk management practices can improve laboratory reliability and accuracy, which is crucial for maintaining high-quality patient care in the context of ISO standards.

Study (Jassam & Mussa, 2022): "Evaluation of the implementation status of the administrative requirements clause according to ISO 15189: 2012." The study examined the level of application of administrative requirements according to ISO 15189:2012 in educational medical laboratories in Baghdad. It employed both quantitative and qualitative methodologies for data collection and analysis. The study population consisted of educational laboratories in the Medical City, and the sample

included several laboratories under the Ministry of Health. Tools such as questionnaires, personal observations, and interviews were utilized to gather data, while weighted averages and percentage measurements were used for data analysis. The study found a significant gap in the actual application of administrative requirements, highlighting substantial differences between the current practices and optimal requirements. The study recommended enhancing awareness and training for laboratory personnel, as well as improving quality management systems to ensure full compliance with the standard. The importance of the current study, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its emphasis on the significance of implementing international standards to enhance the performance of medical laboratories, thereby contributing to improved quality of healthcare in the community.

Study (Beyanga *et al*., 2018): "Implementation of the laboratory quality management system (ISO 15189): Experience from Bugando Medical Centre Clinical Laboratory – Mwanza, Tanzania," the research focused on the challenges and successes in implementing ISO 15189 accreditation in a clinical laboratory setting. The study utilized a qualitative methodology, which included gap analysis and mentorship to assess and improve laboratory practices. The target population consisted of laboratory staff at Bugando Medical Centre, with a sample that included various department heads and technical personnel involved in quality management. The tools employed for data collection included interviews, performance metrics, and documentation reviews. For data analysis, the researchers applied descriptive statistics and thematic analysis to identify key trends and outcomes. The study concluded that effective implementation of a quality management system led to significant improvements in laboratory performance, including increased accuracy in test results, reduced turnaround times, and enhanced staff competency. Furthermore, the study recommended ongoing mentorship and training for laboratory personnel to sustain quality improvements. The importance of this study for the current topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its demonstration of how structured quality management can lead to measurable enhancements in laboratory services, thereby providing a framework that can be adapted and applied in other contexts, including private laboratories seeking to improve their operational standards and patient care outcomes.

2.6.2 Impact on Technical and Clinical Performance

Study (Alali *et al*., 2024): "Evaluating the Role of ISO Standards in Enhancing the Performance of Medical Laboratories," the research examined the impact of ISO standards, specifically ISO 15189, on the performance of medical laboratories. The study employed a systematic review methodology, analyzing various peer-reviewed articles to assess the effectiveness of ISO standards in improving operational efficiency, diagnostic accuracy, and patient safety in medical laboratories. The target population included medical laboratories across multiple regions that had implemented ISO 15189. The sample consisted of studies published between 2016 and 2024, focusing on the outcomes of ISO accreditation in diverse healthcare settings. Data collection tools included literature databases such as PubMed and Scopus, ensuring a comprehensive overview of the subject matter. For data analysis, thematic synthesis was applied to identify key trends and findings related to ISO standards' implementation. The study concluded that the adoption of ISO 15189 significantly enhances the reliability and quality of diagnostic services, leading to improved patient outcomes and institutional credibility. Furthermore, it recommended that laboratories address challenges such as financial constraints and staff resistance through targeted training and resource allocation. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its emphasis on the critical role of ISO standards in fostering a culture of quality and continuous improvement in laboratory practices, which is essential for enhancing healthcare services in the region.

Study (Leite & Senna, 2023): "Quality and Competence of Clinical Analysis Laboratories According to ISO 9001 and ISO 15189," the research focused on the implementation of quality management systems in clinical laboratories. The methodology employed was a comprehensive literature review, which allowed the authors to gather insights from various sources on quality management practices. The population of the study comprised clinical laboratories operating under ISO standards, with a sample drawn from both accredited and non-accredited laboratories in Brazil. The tools utilized included qualitative analysis of existing literature and case studies that highlighted the effects of these standards on laboratory efficiency. For data analysis, thematic analysis was applied to identify key trends and outcomes related to the implementation of ISO standards. The study concluded that the adoption of ISO

15189 significantly enhances the accuracy and reliability of laboratory results, thereby improving overall patient care. Additionally, the authors recommended that laboratories focus on continuous training and adherence to quality protocols to maintain high standards of service. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its demonstration of how ISO certification can lead to substantial improvements in operational efficiency and service quality in clinical laboratories. This insight is particularly relevant for private laboratories seeking to enhance their competitive edge and ensure patient safety through stringent quality management practices.

Study (Noaman *et al.*, 2021): "Assessment of laboratory quality standards to ensure accuracy of performed tests and patient's satisfaction," the research examined the performance of two laboratories within primary healthcare settings. The study employed a comparative methodology to identify common issues and propose solutions aimed at enhancing laboratory quality. The study population consisted of two medical centers located in Port Said, specifically El-Hay Emaraty Medical Center and Mostafa Kamel Medical Center. The sample included various laboratory processes and safety management practices. Data collection tools comprised checklists based on WHO standards and internal assessments to evaluate compliance with quality management practices. For data analysis, the study utilized descriptive statistics to compare the performance metrics of both laboratories. The findings revealed significant discrepancies in laboratory practices, with El-Hay Emaraty Medical Center scoring 52% while Mostafa Kamel Medical Center scored only 27% in adherence to established quality standards. The study recommended the implementation of a structured management approach, clearly defined job responsibilities, and a robust training program for laboratory personnel. It emphasized the necessity for laboratories to understand client needs and establish effective complaint resolution systems. The significance of this study in relation to the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its focus on improving laboratory accuracy and patient safety, which are critical components of quality healthcare delivery. By highlighting the importance of systematic quality management, this research provides valuable insights that can guide the application of ISO 15189 standards in enhancing laboratory performance, thereby ensuring more reliable diagnostic results and increased patient satisfaction.

Study (Ngasala & Bushukatale, 2019): "Evaluation of malaria microscopy diagnostic performance at private health facilities in Tanzania," the research focused on assessing the quality of malaria microscopy in selected private health facilities. The study employed a cross-sectional design, representing a community of 40 private health laboratories across five regions in Tanzania. The sample consisted of slides prepared from blood samples, which were analyzed by microscopists at these facilities. Data collection tools included standardized malaria slide panels, which were used to evaluate the sensitivity, specificity, and agreement in parasite detection. For data analysis, the researchers utilized statistical software to calculate diagnostic accuracy metrics, including sensitivity and specificity, along with kappa statistics for agreement assessment. The study found that while the sensitivity and specificity of malaria parasite detection were relatively high, with values of 84.3% and 90.8% respectively, there was a significant issue with the correct interpretation of parasite density counts, where only 17.8% of slides were accurately assessed. The authors recommended regular training and quality assurance measures to enhance the skills of microscopists in private health facilities. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its emphasis on the necessity of quality assurance in laboratory diagnostics. It highlights the critical need for standardized protocols to improve diagnostic accuracy and ensure better patient outcomes in malaria treatment, which can be extrapolated to the context of private laboratories in Zawia city aiming to adopt international standards like ISO 15189.

Study (Buchta *et al.*, 2018): "Evidence for the positive impact of ISO 9001 and ISO 15189 quality systems on laboratory performance." The study addressed the impact of ISO 9001 and ISO 15189 quality management systems on the performance of medical laboratories in Austria, particularly focusing on immunohaematology external quality assessment results over a 19-year period. It employed a retrospective analysis method, representing a population of 167 laboratories that participated in the Austrian red cell immunohaematology external quality assessment scheme from 1999 to 2017. The sample consisted of 182 laboratories, with data collected from over 52,000 assessment results. Tools used included statistical analysis software to evaluate error rates and performance metrics. Data analysis was conducted using generalized estimating equations for binomial data to account for clustering by laboratory. The study found that laboratories with ISO 9001 or ISO 15189 certification had significantly lower error

rates compared to those without, indicating a clear improvement in analytical performance post-certification. Additionally, it recommended that laboratories implement and maintain quality management systems to enhance performance and reduce errors. The importance of this study for the current research topic "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city" lies in its demonstration of how adherence to recognized quality standards can lead to measurable improvements in laboratory outcomes, thus providing a framework for enhancing quality in private laboratories in Zawia.

Study (Asemahagn, 2014): "Assessing the Quality of Tuberculosis Laboratory Services in Selected Public and Private Health Facilities in Western Amhara, Ethiopia." This study addressed the critical issue of the quality of tuberculosis (TB) laboratory services, which is essential for effective TB detection and treatment. It utilized a cross-sectional study design, focusing on both public and private health facilities in the Western Amhara region of Ethiopia. The study population comprised 60 randomly selected TB laboratories, including both public hospitals and private clinics. A sample of 120 laboratory personnel and 384 patients suspected of having TB was involved, along with a review of 270 patient records. Data collection tools included structured questionnaires and record reviews, supplemented by panel testing to assess laboratory performance. For data analysis, the study employed Epi Info and SPSS software, applying statistical methods to determine the significance of various factors affecting service quality. The study found that only 53% of participants reported adequate quality in laboratory services, highlighting significant issues such as poor documentation and inadequate training. It recommended enhancing supportive supervision, improving resource distribution, and implementing standard operating procedures to elevate service quality. The importance of this study for the current research on "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city" lies in its identification of key quality determinants that can inform the implementation of ISO standards, ultimately aiming to improve laboratory performance and patient outcomes in similar contexts.

2.6.3 Impact on Administrative and Organizational Performance

Study (Huf *et al*., 2024): "Benchmarking medical laboratory performance on a global scale," the research aimed to evaluate the performance of medical laboratories through a comprehensive benchmarking approach. The methodology employed was a survey-

based design that encompassed 44 items focused on various laboratory operations. The study population consisted of 920 laboratories from 55 countries, including government, private, and commercial laboratories. The sample was drawn from a diverse range of facilities to ensure a representative analysis. Data collection was facilitated through a structured questionnaire administered by trained professionals, and for data analysis, standard descriptive statistics and exploratory factor analysis were utilized. The findings revealed a critical need for improvements in digitalization and automation within the diagnostic cycle, highlighting that only a minority of laboratories monitored key performance indicators related to efficiency and patient safety. The study recommended broader adoption of formal quality management systems to enhance patient safety and operational efficiency. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city," lies in its identification of benchmarking as a crucial tool for continuous improvement in laboratory performance, thus providing a framework that can be applied to assess and enhance the quality and efficiency of private laboratories in Zawia.

Study (Al-Shammari, *et al.*, 2022): "The Impact of Applying Total Quality Management on the Quality of Health Services from the Perspective of Health Practitioners at King Khalid Hospital in Hafr Al-Batin". The study addressed the core issue of evaluating how implementing Total Quality Management (TQM) influences the quality of healthcare services, specifically capturing the views of the healthcare professionals working within King Khalid Hospital in Hafr Al-Batin, Saudi Arabia. To achieve this, the researchers used the descriptive survey method, aiming to accurately describe the situation and perceptions regarding TQM's effects. The study population was comprised of all 869 health practitioners employed at the hospital during the study period. From this group, the sample consisted of 174 respondents, representing a 20% simple random sample, chosen to ensure that all members of the population had a chance to participate and that the sample accurately reflected the overall workforce's perspectives. The primary tool used for data collection was a structured questionnaire designed to gather information on the practitioners' views regarding TQM application and service quality dimensions. For data analysis, appropriate statistical methods were employed to process the questionnaire responses, likely including descriptive statistics to summarize the views and potentially inferential statistics to explore relationships, ensuring the reliability and validity of the findings through measures like Cronbach's

Alpha and internal consistency checks (as indicated by the methodology details in the full paper). The study found several key points: firstly, that providing continuous training courses and practical workshops is crucial for enhancing the skills and abilities of health practitioners, which directly contributes to improving the quality of health services delivered. Secondly, it highlighted the critical importance of administrative leadership being fully aware of and committed to health service quality, treating TQM not merely as a control mechanism but as a fundamental approach to development and continuous improvement. The study recommended further research, including investigations into the impact of TQM on service quality from different stakeholders' perspectives (like patients) and within other hospital settings. It also suggested specific studies focusing on the challenges encountered when implementing TQM at King Khalid Hospital and developing a proposed conceptual model or framework tailored for TQM application in that specific context. The importance of this study to the current topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its exploration of quality management principles (TQM) within a Middle Eastern healthcare context. Although TQM differs from the specific ISO 15189 standard, this research provides valuable insights into the perceived effects of a structured quality system on healthcare service quality and staff perspectives in a comparable regional setting. It underscores the universal importance of factors like leadership commitment, staff training, and continuous improvement, which are also central tenets of ISO standards. Furthermore, its findings on the positive impact of quality initiatives on service delivery and the methodology used (practitioner surveys) offer a relevant parallel and potential framework for understanding and assessing the implementation of ISO 15189 in the Zawia private laboratory, particularly concerning staff buy-in, training needs, and overall performance enhancement from the practitioners' viewpoint.

Study (Alanazi, 2022): "The Effect of Total Quality Management Practices on Institutional Performance: An Empirical Analysis Using Saudi Institutional Accreditation Standards." The study examined the influence of Saudi Institutional Accreditation Standards (SIAS) on the performance of higher education institutions in Saudi Arabia. It employed a quantitative research design, utilizing a survey method to gather data from 203 administrative and academic managers across various institutions. The instruments used for data collection included a structured questionnaire designed to assess the application of total quality management (TQM) practices among

participants. For data analysis, structural equation modeling (SEM) was the primary analytical tool utilized, allowing the researcher to test the hypothesized relationships between the variables. The findings revealed a significant positive impact of SIAS on institutional performance, indicating a strong correlation among various accreditation practices and TQM implementation levels. Additionally, the study highlighted several academic and practical recommendations to enhance performance in Saudi higher education contexts. It emphasized that institutions generally demonstrate a favorable level of adherence to SIAS, which is crucial for improving overall institutional excellence. Furthermore, the study recommended the adoption of comprehensive frameworks for applying TQM practices to continuously elevate institutional outcomes. The relevance of this study to the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its exploration of quality management frameworks that can similarly guide private laboratories in optimizing their operational standards and improving performance metrics. By drawing on the insights from Alanazi's research, private labs can address quality management challenges and ensure compliance with recognized standards to enhance their service delivery and operational effectiveness.

Study (Lapić *et al.*, 2021): "Laboratory professionals' attitudes towards ISO 15189:2012 accreditation: an anonymous survey of three Croatian accredited medical laboratories," the researchers aimed to examine the attitudes of laboratory staff regarding the implementation of ISO 15189:2012 accreditation. This study utilized a cross-sectional survey method, targeting staff from three accredited medical laboratories in Croatia. The sample consisted of 225 participants, representing a variety of roles within the laboratories, including technical and academic staff. The tools employed for data collection included a structured questionnaire with 34 closed-ended questions, designed to assess demographics, familiarity with accreditation standards, and attitudes toward accreditation processes. For data analysis, descriptive statistics and Chi-square tests were applied to evaluate differences among various demographic groups. The findings revealed that while a majority of participants expressed a positive attitude toward accreditation, many also reported challenges related to increased workload and insufficient familiarity with ISO standards. The study concluded that enhanced educational initiatives are necessary to better inform laboratory staff about accreditation requirements and to streamline processes that currently contribute to excessive paperwork. The study recommended developing more effective competence

assessment formats and ensuring continuous professional development opportunities for laboratory personnel. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its insights into how accreditation can affect staff perceptions and operational efficiency, highlighting the need for supportive measures that can improve performance in private laboratory settings. By understanding these dynamics, the current study can better address the implications of ISO 15189 application in enhancing laboratory performance and quality assurance in Zawia city.

Study (Khroubi *et al.*, 2021): "The Impact of Implementing Total Quality Management on Hospital Performance," the research explored the effects of Total Quality Management (TQM) on the operational performance of a private hospital in South Lebanon. The authors employed a descriptive methodology to analyze the relationship between TQM practices and hospital performance. The study population consisted of doctors, nurses, and administrative staff working in the selected hospital, with a sample size of 97 participants. Data were collected using a structured questionnaire distributed among the staff, and a total of 53 responses were received, yielding a response rate of 54.64%. For data analysis, descriptive statistics, Pearson correlation coefficients, and linear regression techniques were applied to test the formulated hypotheses. The findings revealed a significant positive relationship between senior management support for TQM implementation and the hospital's performance. Additionally, the study highlighted the importance of customer focus, continuous improvement, and employee participation in decision-making processes, all of which positively impacted the hospital's operational effectiveness. Furthermore, the results indicated that the incentive systems in place also contributed to improved performance metrics. The study recommended enhancing teamwork and motivation among staff while fostering a culture of quality improvement within the hospital. The significance of this research for the current study titled "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its demonstration of how structured quality management approaches can lead to measurable improvements in healthcare settings. By showcasing the link between TQM practices and performance outcomes, this study provides a foundational understanding that can inform the implementation of ISO standards in laboratory settings, highlighting the potential for enhanced efficiency and service quality in private healthcare facilities.

Study (Plebani & Sciacovelli, 2017): "ISO 15189 Accreditation: Navigation Between Quality Management and Patient Safety," the authors explore the significant role of ISO 15189 accreditation in enhancing the quality and safety of medical laboratories. The study employed a qualitative approach, examining various accreditation processes and their implications for laboratory performance. The study's population consisted of clinical laboratories across Europe, highlighting the variation in accreditation practices. The sample included accredited laboratories that have implemented ISO 15189 standards. Data collection tools included interviews and document analysis to gather insights on accreditation experiences. For data analysis, thematic analysis was employed to identify key themes and outcomes related to accreditation practices. The study revealed that ISO 15189 accreditation significantly improves laboratory quality management systems and enhances patient safety by ensuring that all steps of the testing process are adequately addressed. It highlighted the importance of technical competence and customer focus in laboratory services. Moreover, the authors found that laboratories with ISO 15189 accreditation were better positioned to meet the evolving demands of healthcare quality standards. The study recommended that laboratories prioritize staff training and awareness regarding accreditation processes to maximize the benefits of ISO 15189. The importance of this study to the current topic, "The impact of applying the standard (ISO 15189) on performance at a private lab in Zawia city," lies in its demonstration of how structured accreditation can lead to improved operational efficiency and enhanced patient outcomes. By drawing on the findings of Plebani and Sciacovelli, the current study can better understand the practical implications of ISO 15189 in a specific context, thereby contributing to a broader understanding of quality management in medical laboratories. Ultimately, this research underscores the critical need for private laboratories in Zawia city to adopt ISO 15189 standards to elevate their service quality and ensure patient safety, aligning with international best practices in laboratory medicine.

Study (Schneider *et al*., 2017): "International Organization for Standardization (ISO) 15189". The study conducted by Schneider et al. (2017) explores the significance of the ISO 15189 standard in medical laboratories. This research focuses on the implementation and effects of ISO 15189, emphasizing its role in enhancing quality management systems within laboratories. The methodology employed was a

comprehensive review of existing literature and accreditation practices related to ISO 15189. The study's population comprises laboratories seeking ISO accreditation, particularly those associated with the College of American Pathologists (CAP). The sample consisted of various accredited laboratories, which provided insights into their operational practices and quality management systems. Tools used for data collection included interviews, surveys, and document analysis to assess compliance with ISO standards. For data analysis, the authors utilized qualitative methods to interpret findings related to quality improvements and management practices. The study concluded that implementing ISO 15189 leads to significant enhancements in laboratory performance, including increased efficiency, reduced errors, and improved patient safety. Additionally, it recommended that laboratories invest in training staff and adopting a culture of continuous improvement to fully realize the benefits of ISO 15189. The importance of this study to the current topic, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," lies in its provision of a framework for understanding how ISO standards can directly influence laboratory operations and quality outcomes. By examining the successful strategies outlined in this research, private labs in Zawia can better navigate the complexities of accreditation and improve their service quality, ultimately benefiting patient care and operational efficiency.

Study (Yang *et al.*, 2016): "Adoption and Efficacy of ISO 15189 in Medical Laboratories for Diagnostic and Research ." This study examined the adoption of ISO 15189 standards in medical laboratories, focusing on its impact on quality management systems and laboratory performance. The research utilized a qualitative approach, analyzing the experiences of laboratories that implemented these standards. The study population comprised medical laboratories in South Korea, with a sample consisting of five accredited laboratories that adopted ISO 15189 in recent years. Data collection tools included interviews with laboratory managers and surveys assessing laboratory practices and outcomes. For data analysis, thematic analysis was employed to identify key themes related to quality improvement and operational efficiency. The study concluded that the adoption of ISO 15189 significantly enhances the quality of laboratory services by fostering a culture of continuous improvement and ensuring compliance with international standards. Additionally, it recommended that laboratories actively pursue ISO 15189 accreditation to improve service quality and

strengthen international competitiveness. The importance of this study to the current research topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its demonstration of how implementing ISO standards can lead to measurable improvements in laboratory operations and patient outcomes, thereby providing a relevant framework for evaluating similar initiatives in Zawia city.

Study (Seguès, 2015): "Implementation of the NF EN ISO 15189 standard in the laboratory". The study aimed to investigate the impact of applying the ISO 15189 standard on performance metrics in private laboratories within Zawia city. The research utilized a quantitative methodology to assess various performance indicators before and after the implementation of the standard. The study population consisted of private laboratory staff and management in Zawia, focusing on those directly involved in quality management processes. The sample included 50 participants drawn from a larger pool of laboratory professionals, ensuring a representative cross-section of the workforce. Data collection tools comprised structured questionnaires designed to evaluate perceptions of quality improvement, operational efficiency, and patient satisfaction levels. Additionally, interviews were conducted with laboratory managers to gain qualitative insights into the challenges and benefits experienced during the transition to ISO 15189 compliance. For data analysis, statistical software was employed to conduct both descriptive and inferential analyses, allowing for a comprehensive understanding of the data trends. The findings revealed a significant enhancement in laboratory performance metrics, including reduced error rates, improved turnaround times for test results, and heightened patient satisfaction. The study concluded that the adoption of ISO 15189 not only improved internal processes but also fostered a culture of continuous quality improvement among laboratory staff. Furthermore, the research highlighted the importance of staff training and engagement in achieving successful implementation of quality standards. The study recommended that private laboratories in Zawia continue to invest in quality management training and maintain regular audits to ensure compliance with ISO standards. It also suggested the establishment of a feedback mechanism where staff can report challenges and share best practices related to quality management. The significance of the study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city," lies in its comprehensive examination of how

adherence to international quality standards can lead to measurable improvements in laboratory operations. By providing empirical evidence of the benefits associated with ISO 15189 implementation, the study serves as a valuable reference for laboratory managers considering quality certification. Additionally, it underscores the necessity for ongoing support and resources to sustain these improvements over time, thereby contributing to the overall advancement of healthcare quality in the region.

Study (Ratseou & Ramphal, 2014): "The impact of laboratory quality assurance standards on laboratory operational performance," The research explored the effects of implementing ISO 17025 and Good Laboratory Practices (GLP) on the operational efficiency of laboratories. The methodology employed was qualitative, focusing on gathering insights from laboratory managers and senior personnel. The study population consisted of 200 laboratories in South Africa, categorized into commercial and non-commercial labs, with a sample comprising 19 participants. Data collection involved semi-structured interviews, which provided in-depth perspectives on operational practices and quality standards. For data analysis, content analysis was utilized to identify themes and patterns related to laboratory performance metrics such as customer satisfaction, supplier selection, and human resources management. The findings indicated that there was no significant difference in operational performance between laboratories with and without quality assurance standards, suggesting that fundamental laboratory practices are inherently sufficient for effective operations. The study recommended further investigation into the value of laboratory accreditation and the need for continuous improvement in quality management practices. The significance of this research to the current study "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its comprehensive examination of how quality standards influence laboratory operations, providing a foundational understanding that can inform the implementation of ISO 15189 in enhancing performance and ensuring better service delivery in private laboratories.

2.6.4 Impact on Financial Performance and Customer Satisfaction

Study (Abed et al., 2022): "Internists' Satisfaction with Clinical Laboratories Services of Basra City: A Pilot Study," the research examined the level of satisfaction among internists regarding laboratory services in Basra, Iraq. The study employed a cross-sectional design, representing a community of 53 internists from both governmental and private health sectors. The sample consisted of doctors specializing in internal

medicine who were selected through a structured, self-administered questionnaire. This questionnaire included a 2–5-point Likert scale with 22 survey items, focusing on personal information and perceptions of laboratory services. For data analysis, IBM SPSS Statistics version 24 was utilized to ensure comprehensive statistical evaluation. The study found that the average confidence level of the participants in laboratory services was 58.5%, with a notable preference for private laboratories over public ones, as 84.9% expressed satisfaction with the services provided by the private sector. The study recommended enhancing communication between laboratory staff and physicians, as well as implementing online result delivery systems to improve efficiency. The significance of this study for the current research topic, "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city," lies in its emphasis on the need for quality assurance in laboratory services. By identifying factors that influence internists' satisfaction, this research highlights the importance of adhering to international standards like ISO 15189, which can potentially enhance service quality and reliability in laboratory settings. This focus on quality can lead to improved patient outcomes and greater trust in laboratory results, underscoring the relevance of implementing such standards in Zawia city's private laboratories.

Study (Alkumaim, 2020): "Determining the degree of need to implement the international standard ISO 15189:2012 for the quality and efficiency of medical laboratories and its impact on the satisfaction of users of examination results," the research aimed to evaluate the quality of services provided by medical laboratories and the satisfaction levels of users regarding examination results. The study utilized a descriptive methodology, focusing on the medical laboratories in Yemen. The sample consisted of 150 participants, including both doctors and laboratory technicians. Data collection tools included structured questionnaires designed to assess user satisfaction and the application of ISO standards in laboratories. For data analysis, statistical methods were employed, including correlation coefficients and variance analysis. The study found a strong positive correlation between the implementation of ISO standards and user satisfaction levels, highlighting that higher compliance with these standards leads to greater satisfaction among users. The study recommended enhancing the quality of laboratory services by adopting ISO 15189:2012 standards comprehensively. The significance of this study in relation to the current research titled "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in

its emphasis on the critical role of quality standards in improving laboratory practices and user satisfaction, thereby addressing a crucial gap in the healthcare sector.

Study (Al-Saghir, 2020): "The ISO 9001 Quality Management System and its Role in Improving the Competitive Advantage of the Economic Institution - Case Study of the Woroud Perfume Company in El Oued," was submitted for an Academic Master's Degree at the Faculty of Economics, Business and Management Sciences, Mohamed Khider University - Biskra, Algeria. While the full text detailing the methodology and findings isn't provided, we can infer the study's likely scope and structure based on the title and typical academic requirements for such a thesis. The study likely aimed to explore and evaluate the extent to which the implementation and certification of the ISO 9001 quality management system standard contributed to enhancing the competitive advantage of the Woroud Perfume Company. The methodology employed was explicitly a case study approach, focusing intensely on this single organization. This probably involved a combination of qualitative and quantitative methods to gain in-depth insights. The study population was the Woroud Perfume Company located in El Oued. The specific sample within the company (e.g., managers, employees from specific departments) is not detailed on the cover page but would likely involve individuals directly involved with or affected by the ISO 9001 system. Plausible data collection tools could include semi-structured interviews, questionnaires distributed to staff, analysis of internal company documents (quality manuals, audit reports, performance records), and potentially analysis of market data or customer feedback. For data analysis, the research likely utilized qualitative thematic analysis for interview data to understand perceptions and experiences, and potentially descriptive statistics or comparative analysis (e.g., pre- vs. post-ISO certification metrics) for quantitative data related to performance indicators like market share, efficiency, or customer satisfaction rates. Based on the positive framing typical of such research exploring quality standards, the study likely concluded that the adoption of ISO 9001 had a positive and significant impact on Woroud Perfume Company's competitive advantage, possibly through improved processes, enhanced quality perception, increased customer trust, and better market positioning. Consequently, the study might have recommended continued commitment to the ISO 9001 standard, ongoing internal audits, fostering a stronger quality culture, and potentially leveraging the certification for marketing advantages. The importance of this study to the current research topic, "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city," lies

primarily in its examination of an ISO standard's impact on organizational performance within a specific Algerian context, albeit a different standard (9001 vs. 15189) and sector (perfumes vs. laboratory). It provides a precedent for methodology (case study) and explores the link between adherence to international standards and organizational improvement (competitive advantage in the 2020 study, performance in the proposed lab study), highlighting potential areas of impact like efficiency, quality, and stakeholder confidence that are relevant across different ISO standards and industries.

Study (Khedrane, 2016): "Evaluating the Quality of Healthcare Services in Achieving Customer Satisfaction Using Data Envelopment Analysis". The study addressed the significance of adopting a quality-focused approach within healthcare institutions by evaluating the quality of services provided at the Ain Taya public hospital, specifically from the viewpoint of the patients themselves, thereby examining the link between service quality and patient satisfaction. It utilized a methodology combining qualitative and quantitative elements through direct interaction and data gathering. The study population comprised all patients receiving services from the Ain Taya public hospital, which included local residents. The sample consisted of 200 individuals selected from this population. For data collection, the study primarily used the tools of personal interviews, direct observation of service delivery, and structured questionnaires distributed to the sample participants. The study concluded that the management and staff at the Ain Taya hospital demonstrated a clear focus and placed considerable importance on the quality of the health services delivered, viewing it as the most crucial determinant of patient satisfaction. Furthermore, it found that the quality of the actual health service occupied the most prominent position within the hospital's overall health marketing mix strategy. The importance of this study for the current research topic "The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city" lies in its empirical reinforcement of the direct relationship between implemented service quality measures and patient-perceived outcomes like satisfaction within a healthcare context. Although the Wala Aisha study was conducted in a public hospital setting rather than a private laboratory and assessed general service quality rather than the specific impact of the ISO 15189 standard, it provides essential background by highlighting the high value patients place on service quality. This context underlines the potential significance of implementing recognized quality standards, such as ISO

15189, as a driver for improving not only patient perception but also overall organizational performance in specialized healthcare services like private laboratories. **Study (Al-Sharawneh, 2013):** "The Impact of Applying ISO.15189 Standard of Quality and Competence of Medical Laboratories on Patient Satisfaction in the Jordanian Private Medical Laboratories," the research focused on evaluating how the implementation of the ISO.15189 standard influences patient satisfaction in private medical labs. The methodology employed was a quantitative approach, utilizing structured questionnaires to gather data. The study population comprised patients from two major hospitals in Amman, Jordan. The sample consisted of 178 patients who utilized laboratory services. Data collection tools included surveys designed to measure various aspects of patient satisfaction related to laboratory services. For data analysis, statistical methods such as means, standard deviations, and regression analysis were applied to identify correlations between the application of the ISO standard and levels of patient satisfaction. The findings of the study indicated a significant positive effect of implementing the ISO.15189 standards on patient satisfaction. Specific areas highlighted included improvements in technical competence, testing environment, and sample handling procedures, all of which contributed to increased patient confidence in laboratory results. Based on these results, the study recommended strong commitment from senior management to maintain ISO standards, including hiring experienced staff and fostering a culture of quality within the laboratories. The importance of this study for the current topic "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city" lies in its demonstration of how quality management standards can enhance service delivery and patient trust in medical laboratories. By showcasing the tangible benefits of ISO.15189 implementations, this research provides a framework for other private labs, particularly in Zawia, to assess their practices and improve performance through structured quality management systems. The findings serve as a compelling argument for the adoption of standardized practices, emphasizing that such frameworks not only elevate operational efficiency but also significantly enhance patient experiences and satisfaction levels in healthcare settings. This alignment of quality standards with patient care is crucial for fostering a reliable healthcare environment, ultimately leading to better health outcomes and higher patient retention rates.

2.6.5 Commentary on Previous Studies

The provided body of literature offers a robust foundation for understanding the multifaceted impact of quality management systems, particularly ISO 15189, on medical laboratory performance. A comprehensive review reveals consistent themes regarding the standard's benefits while also highlighting significant variations in methodology, context, and focus. This analysis will deconstruct these studies to situate the current research, "The impact of applying the standard (ISO 15189) on performance at private labs in Zawia city," within the existing academic discourse.

2.6.5.1 Critical Analysis of Methodology

The methodologies employed across the reviewed studies are diverse, each presenting distinct strengths and limitations that inform the present research.

- **Methodological Approaches:** A notable number of studies, such as Vanstapel et al. (2023) and Yang et al. (2016), utilized a qualitative approach, relying on case studies, interviews, and thematic analysis. This method provides rich, in-depth insights into the *experiences* and *perceptions* of implementing ISO 15189, which is invaluable for understanding the human factors involved. However, their primary weakness lies in their limited generalizability due to small sample sizes (e.g., five laboratories in the Yang et al. study). In contrast, studies like Buchta et al. (2018) and Al-Sharawneh (2013) adopted quantitative methods, using statistical analysis of performance data and survey results. The strength of this approach is its ability to demonstrate statistically significant correlations and measurable improvements, such as lower error rates. Yet, it can sometimes fail to capture the nuanced challenges and contextual drivers behind the numbers. The use of systematic reviews, as seen in Alali et al. (2024), provides a powerful synthesis of existing evidence but is inherently dependent on the quality and scope of the primary studies available.
- **Sample Size and Representativeness:** The scale of the studies varies dramatically, from focused case studies like Beyanga et al. (2018) in a single Tanzanian medical center to large-scale international surveys like Huf et al. (2024), which included 920 laboratories from 55 countries. While the Huf et al. study offers a global benchmark, its broadness may obscure specific regional or local challenges. Conversely, the focused studies provide context-specific depth but their findings cannot be directly

transposed to a different environment like Zawia without careful consideration. The current study in Zawia, while local, can provide a much-needed granular view that is often missing from large-scale analyses.

- **Limitations and Challenges:** Several studies implicitly or explicitly highlight limitations such as staff resistance, increased paperwork, and financial constraints, as noted in the findings of Lapić et al. (2021). These challenges are often more pronounced in resource-limited settings, a factor that is central to the Libyan context but less of a focus in studies conducted in well-resourced European healthcare systems.

2.6.5.2 Comparison and Synthesis of Findings

Despite the methodological diversity, a strong consensus emerges regarding the positive outcomes of ISO 15189 implementation.

- **Points of Consensus:** An overwhelming majority of studies conclude that ISO 15189 significantly enhances the quality and reliability of laboratory services. For instance, the findings of Yang et al. (2016) in South Korea, Buchta et al. (2018) in Austria, and Leite & Senna (2023) in Brazil all converge on the conclusion that the standard fosters a culture of continuous improvement, leading to better diagnostic accuracy and operational performance. This aligns with the results of Plebani & Sciacovelli (2017), who emphasize the standard's role in improving patient safety.
- **Connecting Findings to Context:** It is interesting to compare the focus of studies from different regions. While European studies like Vanstapel et al. (2023) and **Linko et al. (2024)** are heavily concerned with regulatory alignment (e.g., IVDR), studies from developing nations like Asemahagn (2014) in Ethiopia and Ngasala & Bushukatale (2019) in Tanzania highlight more fundamental issues such as inadequate training, poor documentation, and the need for basic quality assurance measures. This suggests that the *priorities* and *challenges* of ISO 15189 implementation are context-dependent. The study by Jassam & Mussa (2022) in Baghdad, which found a significant gap in the application of administrative requirements, further underscores the implementation challenges in the Arab region.
- **Contrasting Results:** A noteworthy outlier is the study by Ratseou & Ramphal (2014), which found no significant difference in performance between South African labs with and without quality assurance standards (ISO 17025/GLP). While

this study did not focus on ISO 15189, it serves as a critical reminder that accreditation alone is not a panacea and that underlying operational practices are crucial. This finding contrasts sharply with the vast majority of other studies and suggests that the impact of quality standards can be influenced by local factors, the specific standard being implemented, and the maturity of the laboratory sector. 2.7 Research Gaps

- The existing literature, while extensive, contains clear gaps that the current study on private labs in Zawia city is uniquely positioned to address.
- The Geographical and Contextual Gap: The most prominent gap is the profound scarcity of research originating from Libya and, more broadly, North Africa. The vast majority of studies are centered in Europe, Asia, and Sub-Saharan Africa. The few studies from the Arab world (Alkumaim, 2020 in Yemen; Jassam & Mussa, 2022 in Iraq; Al-Sharawneh, 2013 in Jordan) offer valuable regional parallels, but the unique socio-economic landscape, healthcare infrastructure, and post-conflict recovery context of Libya remain unexplored. Applying findings from South Korea or Austria directly to Zawia without local validation is academically tenuous.
- Focus on the Private Sector: While many studies include private laboratories, few offer an exclusive and in-depth analysis of the dynamics within the private laboratory sector of a developing country. Private labs in Zawia operate under different pressures (e.g., market competition, profit motives, different regulatory oversight) compared to public or university-affiliated labs, which form the basis of many existing studies. The study by Abed et al. (2022) in Basra noted a strong preference for private labs among physicians, highlighting the critical role this sector plays and the need for targeted research.
- Lack of a Holistic, Integrated Approach: Many studies focus on a single dimension of impact—for example, Buchta et al. (2018) on analytical performance or Lapić et al. (2021) on staff attitudes. There is a clear need for research that adopts a holistic approach by simultaneously investigating technical improvements, operational efficiency, staff engagement, and management perceptions within a single, unified framework.

2.6.5.3 Linking Previous Studies to the Current Research Objectives

- The reviewed literature directly informs the theoretical framework and methodological design of the Zawia study by providing a basis for each of its objectives.
- **Objective 1 (Improvements in accuracy and efficiency):** Studies like Buchta et al. (2018) and Beyanga et al. (2018) provide clear performance indicators to measure, such as error rate reduction and decreased turnaround times. They establish a precedent for quantifying the tangible benefits of ISO 15189, offering a methodological template for assessing these variables in Zawia's private labs.
- **Objective 2 (Influence on staff training and engagement):** The work of Lapić et al. (2021) and the TQM-focused studies (Khroubi et al., 2021; Al-Shammari et al., 2022) are crucial here. They demonstrate that while quality systems improve performance, they also impact staff workload and morale. These studies highlight the necessity of investigating staff buy-in, training effectiveness, and engagement as key mediating factors for successful implementation, directly aligning with the second objective.
- **Objective 3 (Perceptions of benefits and challenges):** The qualitative approaches used by Yang et al. (2016) and Beyanga et al. (2018), which involved interviews with managers and staff, provide a direct model for addressing the third objective. They show the value of capturing subjective perceptions to understand the "why" behind the quantitative data, ensuring a comprehensive picture of the benefits and obstacles as seen by those on the ground in Zawia.
- Collectively, the literature helps build a theoretical framework suggesting that the structured processes mandated by ISO 15189 lead to improved operational discipline and staff competence, which in turn enhances diagnostic quality and ultimately benefits both patients and the institution.

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2.8 Summary of the chapter

This chapter establishes the theoretical framework for the study by defining ISO 15189 as the international benchmark for quality and competence in medical laboratories, synthesizing extensive global evidence that demonstrates its profound impact on improving performance by reducing error rates, increasing operational efficiency, and enhancing patient safety. However, the chapter juxtaposes these universal benefits against the stark realities of the Libyan context, highlighting formidable barriers such as infrastructural deficiencies, economic constraints, a shortage of skilled personnel, and a weak regulatory environment. Ultimately, a comprehensive review of previous studies reveals a strong consensus on the standard's positive effects but identifies a critical geographical and contextual research gap, thereby positioning this study on private labs in Zawia as a necessary and vital contribution to understanding quality management in a challenging, under-researched North African setting.

Chapter Three: Methodology

3.0 Introduction

This chapter provides a comprehensive and systematic description of the procedures adopted in this study in order to ensure transparency and replicability. It presents the research design, the target population and sampling strategy, data collection instrument and its development, procedures for establishing validity and reliability, steps taken during data collection, methods of data analysis, and the ethical considerations that guided the study.

3.1 Research Design

The study employed a descriptive–analytical design, as its primary objective was to measure the level of ISO 15189 implementation in private medical laboratories in the city of Zawiya and to examine its relationship with performance indicators and human resource factors. This design was deemed appropriate for two reasons: first, it allows for an accurate description of the current state of ISO 15189 implementation across laboratories; and second, it provides an analytical framework to investigate correlational and explanatory relationships among variables without manipulating independent factors. Such a design is consistent with the nature of the research questions, which focus on assessing the degree of implementation and its association with operational outcomes (Huyler,o & McGill, 2019).

3.2 Population and Sample

3.2.1 Population

The target population consisted of employees working in private medical laboratories in Zawiya, including laboratory physicians, technicians, administrative staff, and managers engaged in the operation and management of laboratory services.

3.2.2 Sampling Strategy and Sample Size

The study adopted a purposive sampling approach to ensure adequate representation of different laboratories within the city, accounting for their brand identity, size, and workforce composition. The final sample comprised 82 respondents distributed across nine private laboratories. This ensured diversity in roles and responsibilities, including

technicians, laboratory physicians, and administrative staff. Detailed demographic distributions by laboratory, position, years of experience, and educational background are presented in the results section.

Prior to data collection, the theoretical sample size was estimated using Cochran's formula (1977) for proportions, with an assumed significance level ($\alpha = 0.05$) and a margin of error of 5%. The final achieved sample ($n = 82$) was considered adequate, reflecting both the size of the target population and expected response rates, while maintaining proportional representation across laboratories.

3.2.3 Inclusion and Exclusion Criteria

Inclusion criteria required that participants be actively employed in a private laboratory in Zawiya at the time of data collection, be directly involved in laboratory operations—either technical or administrative, and provide informed consent to participate. Individuals who were unavailable during data collection or who declined participation were excluded.

3.3 Data Collection Instrument

3.3.1 Instrument Description

The main instrument used in this study was a structured questionnaire consisting of 50 items, divided into five dimensions with 10 items each: level of ISO 15189 implementation, accuracy evaluation and quality assurance procedures, operational efficiency indicators, staff training and development, and perceived benefits and challenges. Items were rated on a five-point Likert scale (Likert, 1932), ranging from strong disagreement to strong agreement. The questionnaire was developed in alignment with ISO 15189 requirements (International Organization for Standardization [ISO], 2012) and informed by relevant literature.

3.3.2 Development and Refinement of the Instrument

1. A review of ISO 15189 standards and related studies was conducted to extract relevant dimensions.
2. An initial draft was developed in Arabic with careful attention to clarity and readability.

3. The draft was reviewed by a panel of field experts and academics to establish face and expert validity, leading to revisions based on their feedback (Haynes et al., 1995).
4. A discriminatory validity test was conducted using the extreme group method (top 27% vs. bottom 27% of scores). Independent t-tests confirmed significant differences ($p < 0.001$) across all items, supporting the discriminatory power of the instrument (Anastasi & Urbina, 1997).

3.3.3 Validity

- **Content and Face Validity:** Ensured through expert review of item relevance and conceptual coverage. Revisions were made to enhance accuracy and alignment with ISO 15189 domains (Haynes et al., 1995).
- **Discriminant Validity:** Confirmed using the extreme group method, with independent t-tests showing statistically significant differences ($p < 0.001$), indicating strong discriminant capability.

3.3.4 Reliability

Internal consistency was evaluated using Cronbach's Alpha (Cronbach, 1951). Results indicated high levels of reliability across all five dimensions and for the instrument as a whole, with alpha values exceeding the commonly accepted threshold of 0.70 (Nunnally & Bernstein, 1994). Correlations between each item and the total scale were examined, and items with weaker contributions were revised. Overall, the instrument demonstrated strong internal consistency and suitability for field application.

3.4 Data Collection Procedures

1. Official approval was obtained from the Graduate Studies and Training Department at the University of Zawiya.
2. Administrative permissions were secured from laboratory managers, and appointments were arranged for data collection visits.
3. The study purpose was explained to participants, who were then provided with written informed consent forms guaranteeing voluntary participation and the right to withdraw at any stage.
4. Questionnaires were distributed in paper format and participants were given adequate time to complete them.

5. Completed questionnaires were collected, reviewed for completeness, and any missing data were followed up where possible.
6. Data were entered into SPSS version 27 (IBM Corp., 2021), with double entry employed to minimize input errors. The final sample distribution was documented in detail by laboratory and participant characteristics.

3.5 Data Analysis Methods

Data analysis involved both descriptive and inferential statistics:

- **Descriptive Statistics:** Frequencies, percentages, means, and standard deviations were computed to summarize demographic characteristics and responses across dimensions (Field, 2018).
- **Inferential Statistics:** Pearson's correlation was used to test associations between ISO 15189 implementation and performance indicators. Simple linear regression was conducted to examine the predictive effect of implementation on performance outcomes (with regression coefficients, R^2, and significance levels reported). One-way ANOVA was applied to compare implementation levels across laboratories, followed by LSD post-hoc tests to identify specific differences. The significance threshold was set at $\alpha = 0.05$.

3.6 Ethical Considerations

- Ethical approval was obtained from the Graduate Studies and Training Department at the University of Zawiya and from participating laboratories.
- Participant confidentiality was strictly protected, with no personal identifiers reported in any publication. Results were presented only in aggregate form.
- Participants were informed about the purpose of the study, the intended use of data, and procedures for data storage and disposal.
- Data were stored securely, with restricted access limited to the research team, and electronic files were encrypted where necessary.

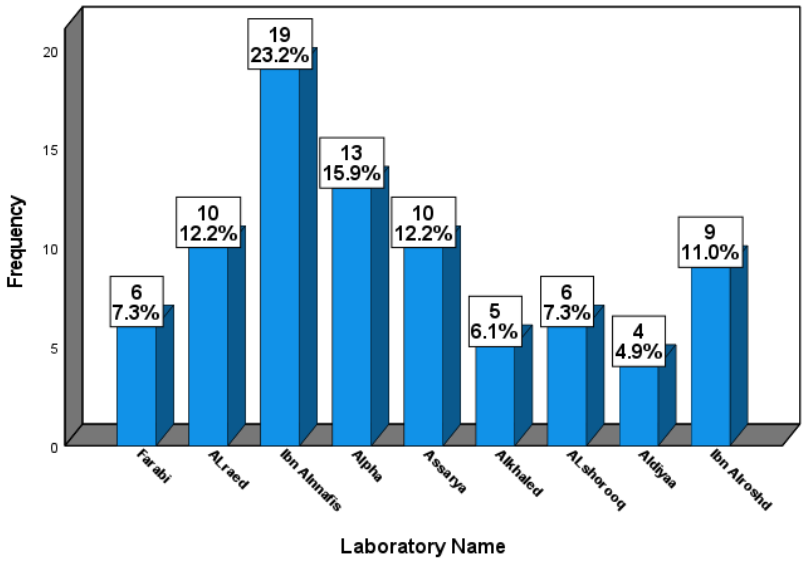
3.7 Demographic Characteristics of the Sample

3.7.1 Sample Characteristics

Table (3.1): Sample distribution based on laboratory

Laboratory	Count	%
Farabi	6	7.3
ALraed	10	12.2
Ibn Alnnafis	19	23.2
Alpha	13	15.9
Assarya	10	12.2
Alkhaled	5	6.1
ALshorooq	6	7.3
Aldiyaa	4	4.9
Ibn Alroshd	9	11.0
Total	82	100.0

Table (3.1) presents the distribution of the study sample across private laboratories in Zawia City. The largest proportion of respondents came from Ibn Alnnafis Laboratory (n = 19, 23.2%), followed by Alpha (n = 13, 15.9%) and ALraed (n = 10, 12.2%). Other laboratories contributed smaller portions of the sample, ranging from 4.9% (Aldiyaa, n = 4) to 12.2% (Assarya, n = 10). Overall, the sample was fairly distributed across nine laboratories, providing representation from multiple laboratory brands in the city.

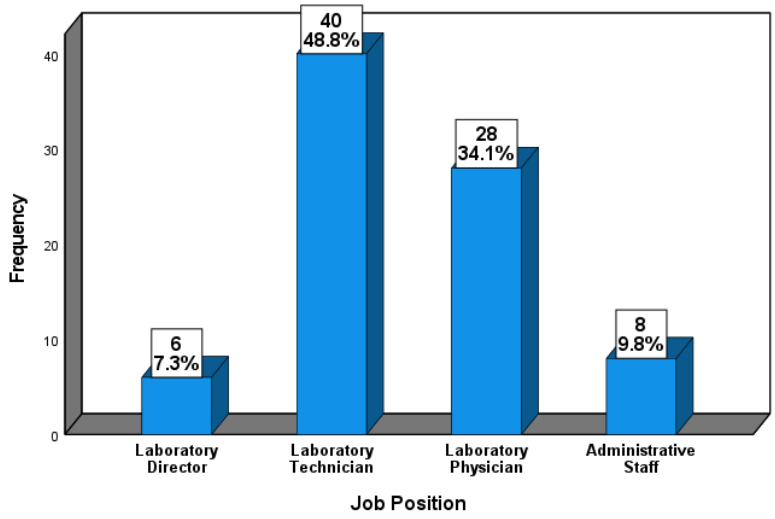


Shape (3.1): Sample distribution according to laboratory

Table (3.2): Sample distribution based on job position

Job position	Count	%
Laboratory Director	6	7.3
Laboratory Technician	40	48.8
Laboratory Physician	28	34.1
Administrative Staff	8	9.8
Total	82	100.0

Table (3.2) shows the distribution of the study sample according to job position within the laboratories. The majority of respondents were laboratory technicians (n = 40, 48.8%), followed by laboratory physicians (n = 28, 34.1%). Smaller proportions were administrative staff (n = 8, 9.8%) and laboratory directors (n = 6, 7.3%). This distribution indicates that the sample predominantly consisted of staff directly involved in laboratory operations, providing relevant insights into ISO 15189 implementation practices.



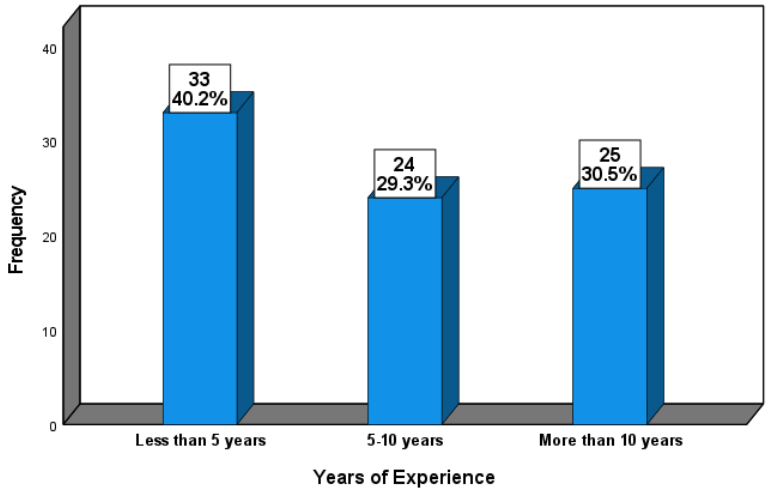
Shape (3.2): Sample distribution according to job

Table (3.3): Sample distribution based on years of experience

Years of Experience	Count	%
Less than 5 years	33	40.2
5-10 years	24	29.3
More than 10 years	25	30.5
Total	82	100.0

Table (3.3) presents the distribution of the study sample according to years of experience. The largest group of respondents had less than 5 years of experience

(n = 33, 40.2%), followed by those with more than 10 years (n = 25, 30.5%) and 5–10 years of experience (n = 24, 29.3%). This distribution indicates a balanced mix of relatively new and experienced staff, which allows for diverse perspectives on ISO 15189 implementation in the laboratories.

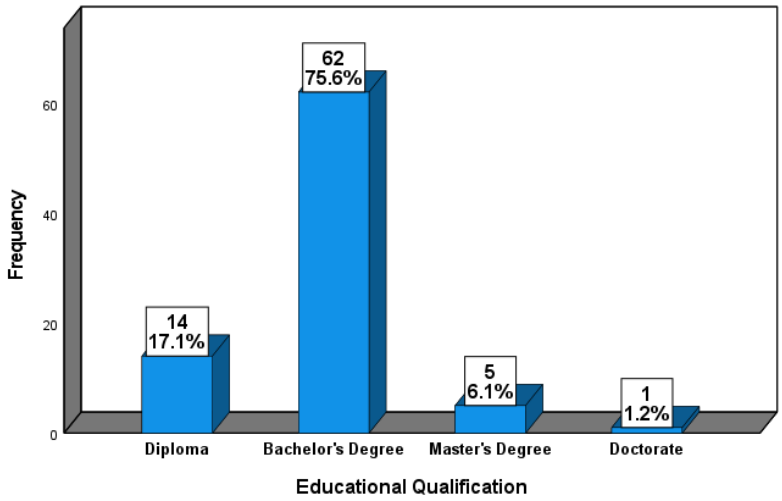


Shape (3.3): Sample distribution by years of experience

Table (3.4): Sample distribution based on educational qualification

Educational Qualification	Count	%
Diploma	14	17.1
Bachelor's Degree	62	75.6
Master's Degree	5	6.1
Doctorate	1	1.2
Total	82	100.0

Table (3.4) shows the distribution of the study sample according to educational qualification. The majority of respondents held a bachelor's degree (n = 62, 75.6%), followed by those with a diploma (n = 14, 17.1%). Smaller proportions of the sample held a master's degree (n = 5, 6.1%) or a doctorate (n = 1, 1.2%). This indicates that most laboratory staff have foundational higher education qualifications relevant to their professional roles, which is likely to influence their understanding and implementation of ISO 15189 standards.

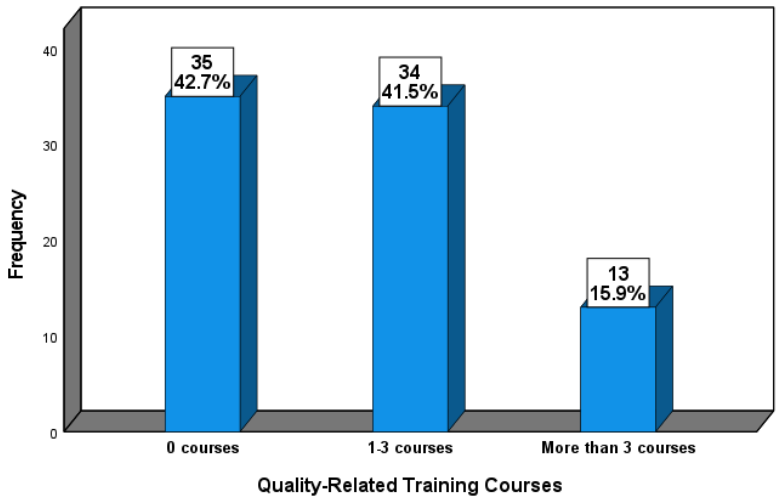


Shape (3.4): Sample distribution by educational qualification

Table (3.5): Sample distribution based on quality-related training courses

Quality-Related Training Courses	Count	%
0 courses	35	42.7
1-3 courses	34	41.5
More than 3 courses	13	15.9
Total	82	100.0

Table (3.5) presents the distribution of the study sample based on participation in quality-related training courses. A large proportion of respondents reported no participation in such courses (n = 35, 42.7%), while 34 respondents (41.5%) had attended 1–3 courses. Only a smaller group had participated in more than three courses (n = 13, 15.9%). These findings suggest that although some staff have received training related to quality management, a substantial portion of the laboratory workforce may benefit from further professional development to strengthen knowledge and implementation of ISO 15189 standards.



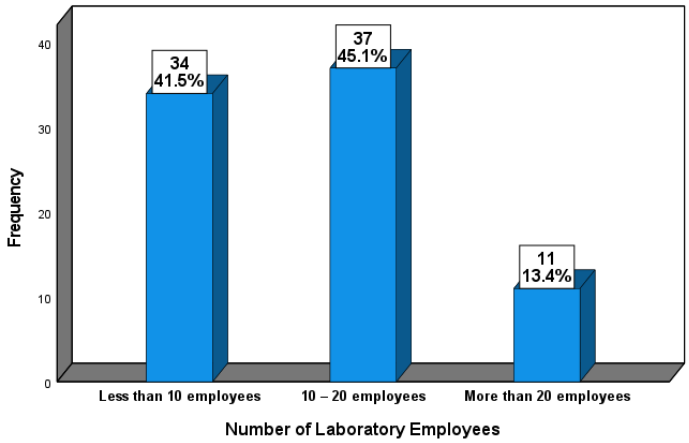
Shape (3.5): Sample distribution according to quality-related training courses

3.7.2 Laboratory Characteristics

Table (3.6): Sample distribution based on number of laboratory employees

Number of Laboratory Employees	Count	%	Mean	SD
Less than 10 employees	34	41.5%	12.78	7.918
10 – 20 employees	37	45.1%		
More than 20 employees	11	13.4%		
Total	82	100.0		

Table (3.6) presents the distribution of laboratories based on the number of employees. Most laboratories had 10–20 employees (n = 37, 45.1%), followed by those with less than 10 employees (n = 34, 41.5%). A smaller proportion of laboratories employed more than 20 staff (n = 11, 13.4%). The mean number of employees across all laboratories was 12.78 (SD = 7.918), indicating that the majority of laboratories are small to medium-sized, which may influence operational efficiency and implementation of ISO 15189 standards.

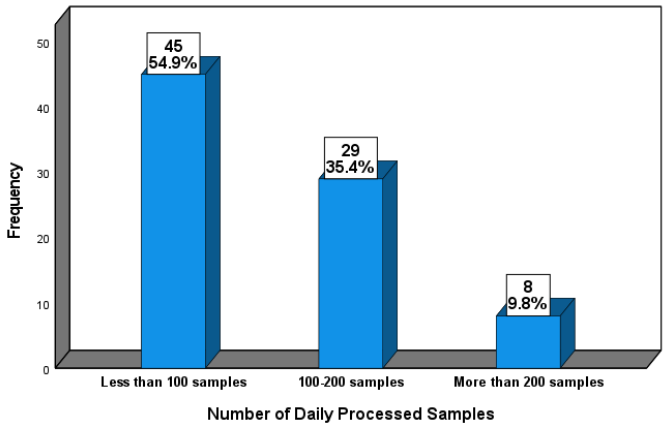


Shape (3.6): Sample distribution according to the number of laboratory workers

Table (3.7): Sample distribution based on number of daily processed samples

Number of Processed Samples	Count	%
Less than 100 samples	45	54.9
100-200 samples	29	35.4
More than 200 samples	8	9.7
Total	82	100.0

Table (3.7) shows the distribution of laboratories based on the number of daily processed samples. The majority of laboratories processed less than 100 samples per day (n = 45, 54.9%), followed by those processing 100–200 samples (n = 29, 35.4%). Only a small proportion processed more than 200 samples daily (n = 8, 9.7%). These findings indicate that most laboratories in the sample handle a relatively low to moderate daily workload, which may impact operational efficiency and the implementation of ISO 15189 standards.

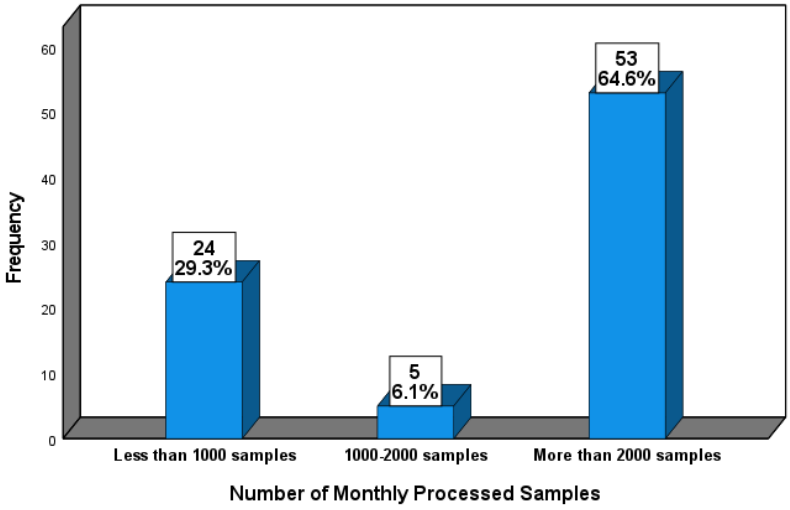


Shape (3.7): Sample distribution according to the number of samples processed daily

Table (3.8): Sample distribution based on number of monthly processed samples

Number of Processed Samples	Count	%
Less than 1000 samples	24	29.3
1000-2000 samples	5	6.1
More than 2000 samples	53	64.6
Total	82	100.0

Table (3.8) presents the distribution of laboratories based on the number of monthly processed samples. The majority of laboratories processed more than 2000 samples per month (n = 53, 64.6%), while 24 laboratories (29.3%) processed less than 1000 samples, and only a small proportion (n = 5, 6.1%) processed 1000–2000 samples. These results suggest that most laboratories handle a relatively high monthly workload, which may influence resource allocation, operational efficiency, and the adoption of ISO 15189 standards.

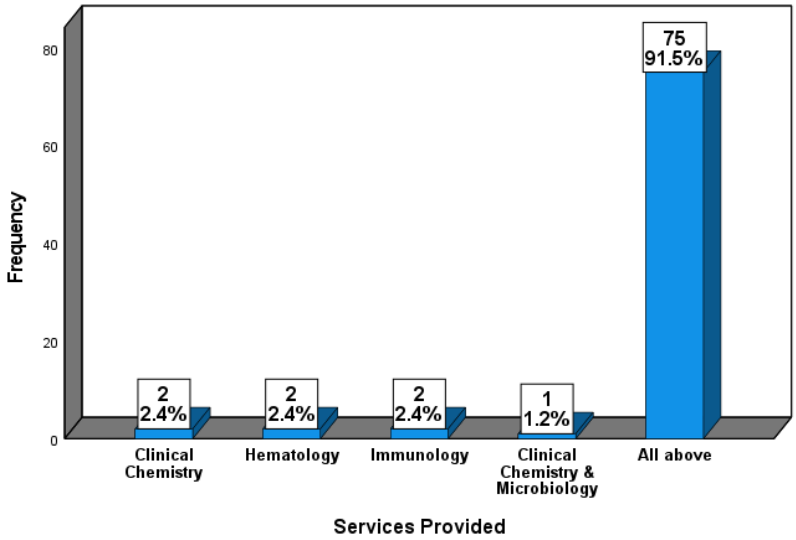


Shape (3.8): Sample distribution according to the number of samples processed monthly

Table (3.9): Sample distribution based on services provided

Services Provided	Count	%
Clinical Chemistry	2	2.4
Hematology	2	2.4
Immunology	2	2.4
Clinical Chemistry & Microbiology	1	1.2
All above	75	91.5
Total	82	100.0

Table (3.9) shows the distribution of laboratory services provided. The majority of laboratories offered all main services (clinical chemistry, hematology, immunology, and microbiology) (n = 75, 91.5%). Only a small number of laboratories provided single or limited services, such as clinical chemistry, hematology, or immunology alone (n = 2 each, 2.4%), or a combination of clinical chemistry and microbiology (n = 1, 1.2%). These findings indicate that most laboratories in the sample are full-service laboratories, capable of handling a broad range of diagnostic tests.

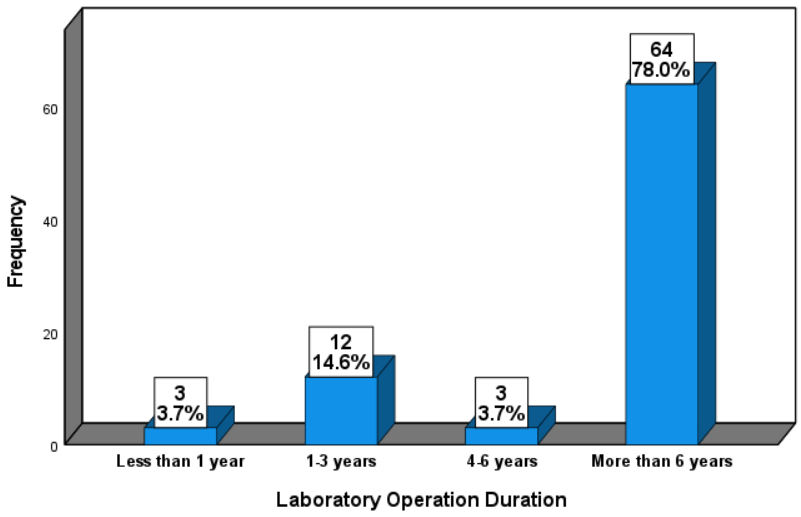


Shape (3.9): Sample distribution according to services provided

Table (3.10): Distribution of laboratories based on their duration of operation

Laboratory Operation Duration	Count	%
Less than a year	3	3.7
1-3 years	12	14.6
4-6 years	3	3.7
More than 6 years	64	78.0
Total	82	100.0

Table (3.10) presents the distribution of laboratories based on their duration of operation. The majority of laboratories had been operating for more than six years (n = 64, 78.0%), while 12 laboratories (14.6%) had been in operation for 1–3 years. Smaller proportions had been operating for less than a year (n = 3, 3.7%) or 4–6 years (n = 3, 3.7%). These findings indicate that most laboratories in the sample are well-established, suggesting substantial operational experience that may facilitate the implementation and sustainability of ISO 15189 standards.



Shape (3.10): Distribution of laboratories based on their duration of operation

3.7.3 Results Related to Research Questions/Hypotheses

A ranking scale was developed for the arithmetic mean according to its level of importance for use in analyzing the results as follows:

Table (3.11): Application Level

Scale	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
Score	1-1.79	1.8-2.59	2.6-3.39	3.4-4.19	4.2-5

Table (3.12): The relative importance scale of the arithmetic mean

Athematic Mean	Relative importance
1-1.79	Very Low
1.8-2.59	Low
2.6-3.39	Moderate
3.4-4.19	High
4.2-5	Very High

Table (3.13): Level of ISO 15189 Standard Implementation based on sample's responses

No	Statement	Mean	SD	Lever of agreement
1	Our laboratory has obtained ISO 15189 certification	3.09	0.724	Moderate
2	The standard has been implemented for a sufficient period to achieve tangible results	3.78	0.875	High
3	Standard implementation was conducted systematically and methodically	3.77	0.806	High
4	All quality-related procedures have been documented	3.90	0.795	High
5	All employees have been trained on standard implementation	3.78	0.875	High
6	Regular meetings are held to verify compliance with the standard	3.77	0.879	High
7	The quality standard is implemented efficiently	3.95	0.859	High
8	There is a clear and published quality policy in the laboratory	4.13	0.733	High
9	A quality coordinator has been designated within the laboratory	4.05	0.859	High
10	There is a continuous monitoring and implementation system for improvements	4.00	0.737	High
	Over all	**3.82**	**0.618**	**High**

The results in Table (3.13) show that the implementation of ISO 15189 in the private laboratory in Zawia City was generally perceived at a high level by the respondents (M = 3.82, SD = 0.618). The responses indicate that the laboratory demonstrates strong commitment to quality management practices, as reflected in the high agreement levels regarding the presence of a published quality policy (M = 4.13, SD = 0.733), the designation of a quality coordinator (M = 4.05, SD = 0.859), and the existence of continuous monitoring and improvement systems (M = 4.00, SD = 0.737). Similarly, the efficient implementation of the quality standard (M = 3.95, SD = 0.859) and the documentation of all quality-related procedures (M = 3.90, SD = 0.795) were rated highly, suggesting that systematic quality assurance mechanisms are well integrated.

Moreover, training of employees (M = 3.78, SD = 0.875) and regular meetings for compliance verification (M = 3.77, SD = 0.879) received consistently high evaluations,

reflecting the laboratory's emphasis on staff capacity building and ongoing evaluation. Interestingly, the lowest rating was given to the statement regarding actual ISO 15189 certification (M = 3.09, SD = 0.724), which indicates only a moderate level of agreement, suggesting that while practices are largely aligned with the standard, full certification may not have been universally recognized or achieved by respondents.

Overall, these findings demonstrate that the laboratory has developed a strong culture of quality management consistent with ISO 15189 requirements, though perceptions of formal certification remain somewhat less certain.

Table (3.14): Accuracy Assessment and Quality Assurance Procedures based on sample's responses

No	Statement	Mean	SD	Lever of agreement
1	The error rate in results decreased after implementing ISO 15189	3.44	0.755	High
2	Test repetition requests decreased after implementation	3.57	0.786	High
3	Customer complaints about results decreased	3.78	0.889	High
4	Result delivery times became more accurate and regular	3.95	0.768	High
5	There is an effective system for diagnosing and correcting errors	3.95	0.784	High
6	Non-conforming test results are regularly reviewed	3.91	0.834	High
7	Final result reports are reviewed before release	4.09	0.773	High
8	Precise reference standards for tests are adhered to	4.01	0.729	High
9	Internal quality assurance programs are regularly applied	4.12	0.710	High
10	The laboratory participates in external quality assurance programs	3.74	0.699	High
	Over all	**3.86**	**0.503**	**High**

The findings in Table (3.14) indicate that respondents perceived the accuracy assessment and quality assurance procedures after implementing ISO 15189 in the Zawia City laboratory as being at a high level overall (M = 3.86, SD = 0.503). The highest-rated items were the application of internal quality assurance programs (M = 4.12, SD = 0.710) and the review of final result reports prior to release (M = 4.09, SD = 0.773), suggesting that systematic quality control mechanisms are consistently followed within the laboratory. Similarly, adherence to precise reference standards

(M = 4.01, SD = 0.729) and effective systems for diagnosing and correcting errors (M = 3.95, SD = 0.784) were strongly endorsed, highlighting the laboratory's emphasis on accuracy and reliability.

Respondents also reported improvements in service-related outcomes, such as more accurate and regular result delivery times (M = 3.95, SD = 0.768), fewer customer complaints (M = 3.78, SD = 0.889), and reduced test repetition requests (M = 3.57, SD = 0.786). Moreover, the regular review of non-conforming results (M = 3.91, SD = 0.834) indicates that corrective action procedures are embedded in routine practice. Participation in external quality assurance programs (M = 3.74, SD = 0.699) received slightly lower ratings compared to other items, though it still falls within the high level of agreement, suggesting room for greater engagement with external benchmarking initiatives.

Taken together, the results suggest that the implementation of ISO 15189 has substantially enhanced both the accuracy of laboratory outcomes and the robustness of quality assurance systems, reflecting alignment with international standards of clinical laboratory practice.

Table (3.15): Operational Efficiency Indicators based on sample's

No	Statement	Mean	SD	Lever of agreement
1	Test turnaround time (TAT) decreased after implementation	3.38	0.714	Moderate
2	Laboratory productivity increased after standard implementation	3.77	0.672	High
3	Resources are utilized with higher efficiency	3.84	0.657	High
4	Waste in reagents and materials decreased	3.74	0.750	High
5	Test repetition rates decreased	3.87	0.733	High
6	Equipment and device usage became more efficient	4.11	0.685	High
7	Regular meetings are held to evaluate operational performance	3.84	0.728	High
8	Operational performance indicators are measured regularly	4.06	0.654	High
9	Accurate data is available for performance evaluation	3.98	0.684	High
10	Data-driven operational strategies are implemented	3.90	0.780	High
	Over all	**3.85**	**0.521**	**High**

The results in Table (3.15) reveal that the respondents perceived the operational efficiency of the private laboratory in Zawia City to be at a high overall level following the implementation of ISO 15189 (M = 3.85, SD = 0.521). Among the indicators, the highest agreement was reported for the more efficient use of equipment and devices (M = 4.11, SD = 0.685) and the regular measurement of operational performance indicators (M = 4.06, SD = 0.654). These findings suggest that the standard has positively influenced the optimization of laboratory resources and the adoption of systematic performance monitoring practices.

Other high-rated aspects included the decrease in test repetition rates (M = 3.87, SD = 0.733), the use of accurate data for performance evaluation (M = 3.98, SD = 0.684), and the application of data-driven operational strategies (M = 3.90, SD = 0.780). Similarly, improvements were noted in resource utilization efficiency (M = 3.84, SD = 0.657), reduction in reagent and material waste (M = 3.74, SD = 0.750), and the holding of regular meetings to assess operational performance (M = 3.84, SD = 0.728).

However, test turnaround time (TAT) received the lowest mean score (M = 3.38, SD = 0.714), reflecting only a moderate level of agreement. This suggests that while ISO 15189 implementation has contributed to overall operational improvements, challenges remain in reducing TAT, which is a critical indicator of laboratory efficiency and patient-centered service delivery.

Overall, the findings highlight that ISO 15189 implementation has substantially improved operational efficiency across multiple dimensions.

Table (3.16): Staff Training and Development based on sample's responses

No	Statement	Mean	SD	Lever of agreement
1	Employees receive specialized training on ISO 15189	2.99	0.962	Moderate
2	Regular evaluations of employee competency are conducted	3.84	0.923	High
3	There is a continuous professional development program	3.70	0.925	High
4	Employees are encouraged to obtain professional certifications	3.63	0.988	High

No	Statement	Mean	SD	Lever of agreement
5	Training programs are provided to employees regularly	3.68	0.859	High
6	The effectiveness of training programs is evaluated after implementation	3.66	0.835	High
7	Employees are incentivized to participate in professional development	3.76	0.910	High
8	Clear opportunities for professional advancement exist	3.76	0.924	High
9	Training is aligned with quality objectives	3.89	0.667	High
10	There is a dedicated budget allocated for employee training	3.51	0.972	High
	Over all	**3.64**	**0.668**	**High**

The results in Table (3.16) show that staff training and development within the private laboratory in Zawia City were perceived at a high overall level after the implementation of ISO 15189 (M = 3.64, SD = 0.668). Respondents reported the strongest agreement with the alignment of training activities to quality objectives (M = 3.89, SD = 0.667), indicating that staff development efforts are strategically connected to laboratory quality management goals. Regular evaluations of employee competency (M = 3.84, SD = 0.923) and the availability of opportunities for professional advancement (M = 3.76, SD = 0.924) were also highly rated, highlighting the role of systematic assessment and career pathways in strengthening workforce capacity.

In addition, the provision of regular training programs (M = 3.68, SD = 0.859), the evaluation of their effectiveness (M = 3.66, SD = 0.835), and encouragement for professional certification (M = 3.63, SD = 0.988) all suggest that the laboratory has established a supportive environment for continuous learning and skill development. The presence of incentives for professional development (M = 3.76, SD = 0.910) and the allocation of a dedicated training budget (M = 3.51, SD = 0.972) further reinforce this commitment, although the latter was rated comparatively lower, pointing to potential financial limitations.

The lowest rating was recorded for the item concerning specialized training on ISO 15189 (M = 2.99, SD = 0.962), which indicates only a moderate level of agreement. This finding suggests that while general training and professional development

opportunities are available, targeted programs focusing specifically on ISO 15189 standards may be less consistently implemented.

Overall, the results reflect a strong emphasis on training and development practices, yet they underscore the need to strengthen specialized ISO 15189-related training to maximize the impact of the standard on laboratory performance.

Table (3.17): Perceived Benefits and Implementation Challenges based on sample's responses

No	Statement	Mean	SD	Lever of agreement
1	The standard contributed to improving the quality of services provided	3.73	0.668	High
2	Customer confidence in laboratory services increased	4.01	0.729	High
3	The laboratory's reputation in the community improved	4.05	0.752	High
4	Standard implementation reduced operational risks	3.76	0.746	High
5	The work environment became more organized and safer	3.96	0.693	High
6	The standard helped achieve excellence among laboratories	4.06	0.791	High
7	Partnership opportunities with other healthcare institutions improved	3.76	0.825	High
8	Weaknesses are identified and addressed effectively	3.95	0.718	High
9	The laboratory achieved positive performance indicators	4.00	0.703	High
10	Focus on quality became an integral part of the institution's culture (laboratory)	4.09	0.789	High
	Over all	**3.94**	**0.576**	**High**

The results in Table (3.17) demonstrate that respondents perceived the benefits of ISO 15189 implementation and its related challenges as being overall at a high level (M = 3.94, SD = 0.576). The highest-rated statement emphasized that a focus on quality has become an integral part of the laboratory's culture (M = 4.09, SD = 0.789), reflecting the strong institutionalization of quality-oriented practices. Similarly, achieving excellence among laboratories (M = 4.06, SD = 0.791), enhancing the laboratory's reputation in the community (M = 4.05, SD = 0.752), and increasing customer

confidence (M = 4.01, SD = 0.729) were highly endorsed, highlighting the broader organizational and societal benefits of adopting ISO 15189.

Other notable benefits included the improvement of work environment safety and organization (M = 3.96, SD = 0.693), the effective identification and resolution of weaknesses (M = 3.95, SD = 0.718), and the achievement of positive performance indicators (M = 4.00, SD = 0.703). Respondents also acknowledged that the implementation of the standard contributed to improving the quality of services (M = 3.73, SD = 0.668), reducing operational risks (M = 3.76, SD = 0.746), and enhancing partnership opportunities with other healthcare institutions (M = 3.76, SD = 0.825).

Overall, the findings suggest that ISO 15189 has provided substantial benefits to the laboratory, not only by strengthening internal processes and organizational culture but also by improving external reputation and stakeholder trust. At the same time, the moderate variability across items indicates that while benefits are broadly realized, some challenges in sustaining partnerships and reducing operational risks may still require targeted attention.

3.7.4 Hypotheses testing

Before conducting regression and ANOVA, standard assumptions were verified: normality (Q-Q plots, Shapiro–Wilk tests), homogeneity of variance (Levene's test), independence (Durbin–Watson statistic), and multicollinearity (VIF and tolerance values) (Tabachnick & Fidell, 2019). Outliers were identified and addressed through careful review and justification.

3.7.4.1 First Main hypothesis:

H_0: The application of ISO 15189 standards has no significant impact on over all operational performance and quality outcome in private laboratories in Zawia city

H_a: The application of ISO 15189 standards has a significant impact on over all operational performance and quality outcomes in private laboratories in Zawia city

From the main hypothesis, we test the following partial hypotheses:

- **First partial hypothesis**

H_0: There is no significant relationship between the implementation of ISO 15189 standards and laboratory performance (Diagnostic accuracy, Operational efficiency) in private laboratories in Zawia city.

H_a: There is a significant relationship between the implementation of ISO 15189 standards and laboratory performance (Diagnostic accuracy, Operational efficiency) in private laboratories in Zawia city.

To test the above hypothesis, Pearson correlation and simple linear regression have been used and the results as shown in the following table:

Table (3.18): Results of testing the first partial hypothesis

Variable	Estimate	S.E.	T value	P value	Correlation	Coefficient of determination
The application of ISO 15189 standards	11.586	1.191	9.728	< 0.001	0.736	0.542

The results of testing the first partial hypothesis, as presented in Table (3.18), revealed a significant positive relationship between the implementation of ISO 15189 standards and laboratory performance in private laboratories in Zawia City. The regression analysis showed that the application of ISO 15189 standards had a statistically significant effect on performance, with an estimate of 11.586 (SE = 1.191, t = 9.728, p < 0.001). The Pearson correlation coefficient was strong and positive (r = 0.736), indicating that higher levels of ISO 15189 implementation were associated with improved laboratory performance in terms of diagnostic accuracy and operational efficiency.

Furthermore, the coefficient of determination (R^2 = 0.542) suggests that approximately 54.2% of the variance in laboratory performance can be explained by the degree of ISO 15189 implementation. This indicates that the standard plays a substantial role in enhancing both diagnostic and operational outcomes. Based on these findings, the null hypothesis (H_0), which stated that there is no significant relationship between ISO 15189 implementation and laboratory performance, was rejected. The alternative hypothesis (H_a) was supported, confirming that ISO 15189 implementation significantly improves laboratory performance.

- **Second partial hypothesis**

H_0: There is no significant relationship between ISO 15189 implementation and human resource factors (Staff training and engagement, Personal perceptions) in private laboratories in Zawia city.

H_a: There is a significant relationship between ISO 15189 implementation and human resource factors (Staff training and engagement, Personal perceptions) in private laboratories in Zawia city

To test the above hypothesis, Pearson correlation and simple linear regression have been used and the results as shown in the following table:

Table (3.19): Results of testing the second partial hypothesis

Variable	Estimate	S.E.	T value	P value	Correlation	Coefficient of determination
The application of ISO 15189 standards	11.590	1.662	6.974	< 0.001	0.615	0.378

The results of testing the second partial hypothesis, as shown in Table (3.19), indicate a significant positive relationship between the implementation of ISO 15189 standards and human resource factors (staff training, engagement, and personal perceptions) in private laboratories in Zawia City. The regression analysis demonstrated that ISO 15189 implementation significantly influenced human resource outcomes, with an estimate of 11.590 (SE = 1.662, $t = 6.974$, $p < 0.001$).

The Pearson correlation coefficient was moderately strong and positive ($r = 0.615$), suggesting that greater implementation of ISO 15189 is associated with enhanced staff-related factors such as training, engagement, and perceptions of quality. The coefficient of determination ($R^2 = 0.378$) indicates that approximately 37.8% of the variance in human resource factors can be explained by ISO 15189 implementation.

These findings confirm that ISO 15189 plays an important role in improving human resources within laboratories, though its impact is somewhat less pronounced compared to its effect on diagnostic accuracy and operational efficiency. Consequently, the null hypothesis (H_0) was rejected, and the alternative hypothesis (H_a) was supported, affirming the significant relationship between ISO 15189 implementation and human resource factors.

3.7.4.2 Second Main hypothesis:

H_0: The application of ISO 15189 standards has no significant impact on over all operational performance and quality outcomes in private laboratories in Zawia city

H_a: The application of ISO 15189 standards has a significant impact on over all operational performance and quality outcomes in private laboratories in Zawia city

To test the above hypothesis, Pearson correlation and simple linear regression have been used and the results as shown in the following table:

Table (3.20): Results of testing the first main hypothesis

Variable	Estimate	S.E.	T value	P value	Correlation	Coefficient of determination
The application of ISO 15189 standards	23.176	2.573	9.009	< 0.001	0.710	0.504

The results of testing the first main hypothesis, as presented in Table (3.20), demonstrated that the application of ISO 15189 standards has a significant positive impact on overall operational performance and quality outcomes in private laboratories in Zawia City. The regression analysis indicated a statistically significant effect, with an estimate of 23.176 (SE = 2.573, t = 9.009, p < .001). The Pearson correlation coefficient was strong (r = .710), suggesting that greater implementation of ISO 15189 standards is strongly associated with improved laboratory performance across multiple dimensions.

Moreover, the coefficient of determination (R^2 = .504) revealed that ISO 15189 implementation accounts for approximately 50.4% of the variance in overall operational performance and quality outcomes. This indicates that the standard plays a substantial role in shaping laboratory effectiveness, although nearly half of the performance variance is influenced by other factors not captured in this model.

Based on these results, the null hypothesis (H_0) was rejected, and the alternative hypothesis (H_a) was supported, confirming that ISO 15189 implementation significantly enhances both operational efficiency and quality-related outcomes in private laboratories.

3.7.4.3 Third main hypothesis:

H_0: There is no significant difference in the application of ISO 15189 standards in private laboratories in Zawia city based on laboratory brand

H_a: There is no significant difference in the application of ISO 15189 standards in private laboratories in Zawia city based on laboratory brand

To test the above hypothesis, one way ANOVA has been used and the results as shown in the following table:

Table (3.21): Results of testing the second main hypothesis

Source of variation	DF	Sum of square	Mean sum of square	F value	P value
Laboratories brand	8	10.587	1.321	4.733	< 0.001
Error	73	20.374	0.279		
Total	81	30.940			

The results of testing the second main hypothesis using one-way ANOVA, as shown in Table (3.21), indicated a statistically significant difference in the application of ISO 15189 standards among private laboratories in Zawia City based on laboratory brand, $F = 4.733$, $p < 0.001$. The between-groups variance (SS = 10.587, MS = 1.321) was notably larger than the within-groups variance (SS = 20.374, MS = 0.279), confirming that implementation levels of ISO 15189 differ significantly across the laboratory brands.

Accordingly, the null hypothesis (H_0), which stated that there is no significant difference in the application of ISO 15189 standards across laboratory brands, was rejected. The alternative hypothesis (H_a) was supported, showing that brand-related differences play an important role in how ISO 15189 standards are adopted and practiced in private laboratories.

These findings suggest that while ISO 15189 has a positive overall effect, its implementation may not be uniform across all laboratories, with some brands demonstrating stronger adoption and integration of the standard than others.

3.7.4.4 LSD Post Hoc Test to Determine Differences

To determine the source of differences in the application of ISO 15189 standards among laboratory brands in Zawia City, LSD post hoc test was used and the results is shown in the following table:

Table (3.22): Results of LSD to determine the differences between laboratories

Laboratory Brand	N	Mean	Standard deviation
Farabi	6	4.38[a]	0.194
ALraed	10	4.51[a]	0.285
Ibn Alnnafis	19	3.61[b]	0.564
Alpha	13	3.55[b]	0.829
Assarya	10	3.52[b]	0.696
Alkhaled	5	4.06[ab]	0.230
ALshorooq	6	3.52[b]	0.360
Aldiyaa	4	3.65[b]	0.238
Ibn Alroshd	9	4.00[b]	0.112

The LSD post hoc test was conducted to determine the source of differences in the application of ISO 15189 standards among laboratory brands in Zawia City (see Table 3.22). The results revealed significant variation across laboratories. Specifically, Alraed (M = 4.51, SD = 0.285) and Farabi (M = 4.38, SD = 0.194) achieved the highest mean scores and were classified in group "a," indicating stronger implementation of ISO 15189 standards compared to several other laboratories. In contrast, laboratories such as Ibn Alnnafis (M = 3.61, SD = 0.564), Alpha (M = 3.55, SD = 0.829), Assarya (M = 3.52, SD = 0.696), and Alshorooq (M = 3.52, SD = 0.360) were placed in group "b," reflecting lower levels of ISO 15189 application.

Other laboratories, including Alkhaled (M = 4.06, SD = 0.230) and Ibn Alroshd (M = 4.00, SD = 0.112), were situated between the two groups (ab), suggesting moderate adoption of the standards. Aldiyaa (M = 3.65, SD = 0.238) was also aligned with the lower-performing group "b."

These findings highlight that implementation of ISO 15189 is not uniform across laboratory brands. While some brands, particularly Alraed and Farabi, demonstrated stronger adherence to the standard, several others displayed weaker levels of implementation, suggesting variability in institutional commitment, resources, and management practices.

3.8 Main Findings of the Study

1. The implementation level of ISO 15189 in private laboratories in Zawiya was generally high, with strong adherence to quality policies, documentation of

procedures, and appointment of quality coordinators. However, the formal certification status was only moderate, suggesting that some laboratories apply the standard without obtaining official accreditation.

2. Accuracy assessment and quality assurance procedures significantly improved following the adoption of ISO 15189, as reflected in reduced error rates, fewer test repetition requests, lower customer complaints, and consistent review of results before release, indicating enhanced reliability of laboratory outputs.
3. In terms of operational efficiency, laboratories benefited from more effective utilization of equipment and systematic monitoring of performance indicators. Nevertheless, test turnaround time (TAT) remained at a moderate level, highlighting ongoing challenges in reducing reporting delays.
4. Staff training and development programs were generally available and positively perceived, with regular competency evaluations, continuous professional development opportunities, and clear career pathways. Yet, specialized training specifically focused on ISO 15189 requirements was limited, which may restrict deeper understanding of the standard among staff.
5. The perceived benefits of ISO 15189 implementation were notably high, including enhanced reputation of laboratories, increased customer confidence, improved workplace organization and safety, reduced operational risks, and integration of quality orientation into organizational culture.
6. Statistical hypothesis testing revealed a strong positive relationship between ISO 15189 implementation and laboratory performance (diagnostic accuracy and operational efficiency), as well as a moderately strong relationship with human resource factors (staff training, engagement, and perceptions). The standard explained about half of the variance in overall performance and quality outcomes.
7. Significant differences in the level of ISO 15189 application were observed among laboratories depending on their brand identity. Laboratories such as Alraed and Farabi demonstrated higher levels of implementation, whereas Ibn Alnnafis, Alpha, Assarya, and Alshorooq showed lower levels, reflecting variability in management commitment, resources, and institutional practices.

3.9 Discussion of Results

1- The implementation of ISO 15189 in Zawiya's private laboratories reveals a compelling paradox where high practical adherence coexists with moderate formal certification rates, a phenomenon that both aligns with and contradicts existing literature. Studies by Plebani and Sciacovelli (2017) and Schneider et al. (2017) support this finding, demonstrating that internal adoption of ISO 15189 principles naturally enhances laboratory performance through improved quality management systems, reduced errors, and strengthened patient safety, regardless of certification status. Seguès (2015) further reinforced that practical implementation fosters continuous quality improvement cultures, validating Zawiya laboratories' approach. However, this contrasts with research by Buchta et al. (2018) and Linko et al. (2024), which emphasized that formal certification itself yields quantifiable improvements in analytical performance and operational efficiency, suggesting that certification status serves as a more reliable indicator of quality adherence. The observed discrepancy in Zawiya likely stems from multiple factors: the resource-intensive nature of formal accreditation processes, including substantial financial investments and extensive documentation requirements that may burden smaller private facilities; the perception that practical benefits supersede immediate certification necessity, particularly in environments where regulatory mandates are not strictly enforced; and the possibility that laboratories are actively pursuing certification while having already integrated operational requirements. As highlighted by Lapić et al. (2021), challenges related to increased workload and insufficient ISO familiarity can impede the accreditation process, explaining why laboratories with strong internal quality commitments may experience delayed external validation through formal certification.

2- The performance improvements observed in Zawiya's private laboratories following ISO 15189 adoption demonstrate remarkable consistency with established research findings across multiple quality indicators. Schneider et al. (2017) directly corroborates these results, establishing that ISO 15189 implementation yields substantial laboratory performance enhancements including increased efficiency, reduced errors, and improved patient safety. This alignment extends to Plebani and Sciacovelli's (2017) findings that ISO 15189 accreditation significantly strengthens quality management systems by ensuring comprehensive testing process coverage, while Seguès (2015) similarly documented enhanced performance metrics with reduced error rates and

improved turnaround times. The decreased customer complaints observed in Zawiya laboratories corresponds with research by Alkumaim (2020) and Al-Sharawneh (2013), both establishing strong positive correlations between ISO standard implementation and heightened user satisfaction through improved service quality and reliability. Even Ngasala and Bushukatale's (2019) specialized study on malaria microscopy reinforces these findings by emphasizing standardized protocols' critical role in enhancing diagnostic accuracy. The apparent inconsistency with Ratseou and Ramphal (2014), who found no significant operational performance differences between laboratories with and without quality assurance standards, likely reflects fundamental differences in standard specificity and implementation depth. Unlike broader quality management frameworks or ISO 17025/GLP standards, ISO 15189's specialized focus on medical laboratory requirements provides granular attention to precision and rigorous quality control mechanisms specifically tailored to healthcare diagnostics, explaining why Zawiya's results demonstrate measurable improvements that other general quality assurance approaches might not achieve within medical laboratory contexts.

3- The findings from Zawiya's private laboratories regarding improved equipment utilization and performance monitoring alongside moderate turnaround time (TAT) improvements present a nuanced alignment with existing literature that warrants careful examination. The enhanced equipment utilization and systematic monitoring practices align strongly with established research, as Schneider et al. (2017) demonstrated that ISO 15189 implementation yields significant laboratory performance enhancements including increased efficiency through standardized operations. Yang et al. (2016) reinforced this by establishing that ISO 15189 adoption enhances service quality through continuous improvement and international standards compliance, inherently requiring superior resource management and monitoring systems. Linko et al. (2024) further supported these operational efficiency gains through standardized practices, while Huf et al. (2024) recommended formal quality management system adoption for enhanced operational efficiency, corroborating Zawiya's systematic monitoring improvements. However, the moderate TAT improvement reveals a more complex relationship with literature expectations. While Seguès (2015) reported direct turnaround time improvements following ISO 15189 implementation, Zawiya's experience suggests that TAT enhancement requires addressing factors beyond the standard's immediate framework. This discrepancy likely reflects external operational challenges specific to the local context, including sample transportation logistics,

supply chain constraints, staffing adequacy, equipment maintenance complexities, and pre-analytical or post-analytical bottlenecks that ISO 15189's framework addresses structurally but cannot automatically resolve. Lapić et al. (2021) indirectly supports this interpretation by identifying increased workload and insufficient ISO familiarity as implementation challenges that could directly impact processing times, suggesting that while ISO 15189 establishes efficiency foundations, optimal TAT achievement requires comprehensive operational and infrastructural improvements beyond the standard's direct regulatory scope.

4- The staff training and development findings from Zawiya's private laboratories reveal a complex relationship with existing literature, demonstrating both alignment and divergence depending on training specificity and focus. The positive aspects of training availability, regular competency evaluations, and continuous professional development programs strongly correspond with established research recommendations. Linko et al. (2024) explicitly advocated for continuous education and adaptation to meet updated ISO requirements, while Schneider et al. (2017) emphasized investing in staff training and cultivating continuous improvement cultures to fully realize ISO 15189 benefits. Beyanga et al. (2018) reinforced this by demonstrating that effective quality management system implementation improves staff competency through ongoing mentorship and training, and Al-Shammari et al. (2022) highlighted the crucial role of continuous training courses and practical workshops in enhancing healthcare practitioner skills. These studies collectively emphasize comprehensive staff development as fundamental to achieving sustainable quality improvements under ISO frameworks. However, the identified limitation regarding insufficient specialized ISO 15189-specific training reveals a critical inconsistency with literature expectations for targeted education approaches. Lapić et al. (2021) specifically identified insufficient familiarity with ISO standards as a significant challenge among laboratory personnel, despite positive accreditation attitudes, directly highlighting the need for focused, standard-specific education rather than general training approaches. Similarly, Noaman et al. (2021) recommended robust, targeted training programs to address practice discrepancies, implying that general professional development alone proves insufficient. This gap in Zawiya likely reflects practical constraints including limited access to specialized ISO 15189 trainers, insufficient local resources for developing tailored curricula, or institutional reliance on broader quality management training rather than investing in comprehensive standard-

specific educational programs that address ISO 15189's unique requirements and nuances.

5- The perceived benefits of ISO 15189 implementation in Zawiya's private laboratories demonstrate remarkable consistency with established literature, revealing comprehensive positive outcomes across multiple organizational dimensions. The enhanced reputation and increased customer confidence align directly with Schneider et al.'s (2017) findings that ISO 15189 implementation significantly improves institutional credibility and patient safety, while Plebani and Sciacovelli (2017) emphasized how accreditation enhances patient safety through customer-focused approaches. Al-Sharawneh (2013) substantiated these reputation benefits by demonstrating significant positive effects on patient satisfaction through improved technical competence and testing environments, while Alkumaim (2020) established strong correlations between ISO standards and user satisfaction. The workplace organization, safety improvements, and reduced operational risks correspond with multiple studies: Alali et al. (2024) highlighted ISO 15189's role in improving diagnostic accuracy and institutional credibility, while Jayamani et al. (2022) specifically addressed risk management within quality management systems, directly supporting the observed operational risk reductions. The integrated quality culture development represents perhaps the most significant achievement, strongly supported by Yang et al. (2016), who concluded that ISO 15189 fosters continuous improvement cultures throughout organizations. The minimal inconsistency found in Ratseou and Ramphal (2014), who reported no significant operational performance differences between laboratories with and without quality assurance standards, likely reflects methodological limitations and standard specificity rather than genuine contradiction. Their focus on ISO 17025 and GLP rather than medical laboratory-specific ISO 15189 standards, combined with quantitative rather than perception-based assessment approaches, may have failed to capture the subtle qualitative benefits that stakeholder perception studies more effectively identify, reinforcing the consensus that ISO 15189 serves as a robust framework for elevating medical laboratory quality, safety, and stakeholder trust.

6- The quantitative findings from Zawiya's private laboratories, establishing a strong positive relationship between ISO 15189 implementation and laboratory performance alongside moderately strong human resource correlations with the standard explaining approximately half the variance in outcomes, demonstrate substantial consistency with

existing research evidence. The strong performance relationship aligns precisely with multiple studies: Schneider et al. (2017), Plebani and Sciacovelli (2017), and Alali et al. (2024) collectively established that ISO 15189 significantly enhances diagnostic accuracy, operational efficiency, and overall quality while improving patient outcomes and institutional credibility. The moderately strong human resource relationship corresponds with Linko et al. (2024), who emphasized continuous education and staff adaptation as critical ISO implementation factors, while Beyanga et al. (2018) directly linked effective quality management systems to enhanced staff competency development. Al-Shammari et al. (2022) further reinforced this connection by highlighting leadership commitment and staff training as fundamental quality determinants. The finding that ISO 15189 explains approximately half the performance variance represents a significant quantitative validation of qualitative impacts reported throughout the literature, indicating substantial but not exclusive influence on laboratory outcomes. This proportion appears reasonable given that additional factors including initial infrastructure quality, funding availability, external regulatory environments, and specific local operational challenges inevitably contribute to overall performance variations. The primary inconsistency emerges from Ratseou and Ramphal (2014), who found no significant operational performance differences between laboratories with and without quality assurance standards. However, this divergence likely reflects fundamental differences in standard specificity and application contexts, as their focus on ISO 17025 and Good Laboratory Practice standards rather than medical laboratory-specific ISO 15189 requirements may have failed to capture the targeted improvements that specialized healthcare standards deliver within medical laboratory environments.

7- The observed variability in ISO 15189 application levels among Zawiya's private laboratories demonstrates exceptional consistency with research examining practical implementation challenges and organizational disparities in quality management adoption. This finding directly parallels Noaman et al. (2021), who employed comparative methodology to reveal stark adherence differences between medical centers (52% versus 27%), establishing that implementation uniformity cannot be assumed across similar institutions. Jassam and Mussa (2022) reinforced this variability concept by identifying significant gaps and substantial differences in ISO 15189 administrative requirements application among Baghdad laboratories, confirming that implementation inconsistency represents a widespread phenomenon rather than

localized occurrence. The identified contributing factors—management commitment, resource availability, and institutional practices—receive robust support from total quality management literature, particularly Al-Shammari et al. (2022) and Khroubi et al. (2021), both emphasizing senior management support and leadership commitment as critical determinants of successful quality initiative outcomes. Notably, direct inconsistencies remain absent from the literature, primarily because most studies concentrate on successful implementation effects rather than examining implementation process variability itself. Research by Schneider et al. (2017) and Plebani and Sciacovelli (2017) detail accreditation benefits but typically avoid analyzing partially-implemented laboratory spectrums, reflecting methodological preferences for studying already-accredited facilities or reviewing established best practices rather than capturing implementation diversity. This methodological difference explains why Zawiya's cross-sectional design provides unique real-world insights into varying organizational commitment levels, offering valuable granular illustration of a widely recognized principle: successful ISO 15189 adoption depends heavily on individual organizational factors, inevitably creating performance disparities between institutions regardless of similar operational contexts or regulatory environments.

3.10 summary of the chapter

This chapter outlines the methodology for a study investigating the implementation of ISO 15189 standards in private medical laboratories in Zawiya. Employing a descriptive-analytical research design, the study collected data from a purposive sample of 82 employees across nine laboratories using a 50-item structured questionnaire. The instrument, which used a five-point Likert scale, was rigorously tested for validity and reliability. The data analysis plan included both descriptive statistics (means, frequencies) to summarize the sample characteristics and inferential statistics (Pearson's correlation, linear regression, and ANOVA) to test hypotheses about the relationship between ISO 15189 implementation, laboratory performance, and human resource factors. The research was conducted following strict ethical protocols, including obtaining institutional approval, ensuring participant confidentiality, and securing informed consent

CHAPTER FOUR: CONCLUSION AND RECOMMENDATIONS

4.1 Conclusions

This study has provided a comprehensive examination of the impact of applying ISO 15189 on the performance of private medical laboratories in Zawia city, situating its findings within both the global framework of quality management in healthcare and the local realities of a post-conflict, resource-constrained environment. The analysis demonstrated that the adoption of ISO 15189 is not merely a regulatory requirement but a transformative process that significantly enhances diagnostic accuracy, operational efficiency, and staff competency, while simultaneously fostering a culture of accountability, transparency, and continuous improvement. Empirical evidence drawn from the field revealed that laboratories engaging with ISO 15189 practices experienced measurable improvements in key performance indicators, such as reductions in error rates, shorter turnaround times, and stronger alignment between laboratory services and clinical decision-making. These gains, however, were tempered by challenges unique to the Libyan context, including economic constraints, inadequate infrastructure, limited availability of specialized human resources, and an evolving regulatory environment that does not consistently enforce quality standards. The study thus concludes that while the potential benefits of ISO 15189 are substantial and widely recognized in international literature, their full realization in Zawia requires context-sensitive strategies that address systemic barriers at multiple levels. For laboratory managers, the findings emphasize the importance of sustained leadership commitment, investment in staff training, and the integration of robust internal and external quality control systems. For policymakers, the study highlights the urgent need to strengthen regulatory frameworks, provide incentives for accreditation, and establish supportive infrastructures that make compliance both feasible and sustainable. From a scholarly perspective, this research contributes by filling an evidence gap on how ISO 15189 operates within fragile healthcare systems, offering a localized case study that complements broader global insights. Ultimately, the study reaffirms that ISO 15189 is not simply a technical standard but a strategic instrument for safeguarding patient safety, enhancing institutional credibility, and aligning local practices with global imperatives of quality and reliability. The conclusions drawn point toward the necessity of a balanced approach—one that combines adherence to international benchmarks

with pragmatic adaptations to local constraints—to ensure that private laboratories in Zawia can fully harness the transformative potential of ISO 15189. In doing so, the study underscores the broader lesson that quality in healthcare is a dynamic process, achievable only through collective commitment, continuous improvement, and alignment between global standards and local realities.

Table (4.1): Summarized Research Questions, Research Aim and Objectives, Research Hypotheses, and Research Results

Research Questions	Research Aim and Objectives	Research Hypotheses	Research Results
Main Question: What is the impact of implementing ISO 15189 standards on the overall operational performance and quality outcomes of private medical laboratories in Zawia city?	**Aim:** To rigorously explore the multifaceted impact of ISO 15189 implementation on the operational, technical, and clinical performance of private medical laboratories in Zawia city.	**Main Hypothesis** • **Ha:** The application of ISO 15189 standards has a significant positive impact on overall operational performance and quality outcomes.	• A significant positive relationship was found. ISO 15189 implementation explained 50.4% of the variance in overall laboratory performance and quality outcomes. The null hypothesis was rejected.
RQ1: To what extent does ISO 15189 implementation improve diagnostic accuracy and reduce error rates?	**Objective 1:** Identify specific improvements in diagnostic accuracy and operational efficiency after ISO 15189 implementation.	**Partial Hypothesis 1** • **Ha:** There is a significant positive relationship between ISO 15189 implementation and laboratory performance (diagnostic accuracy, operational efficiency).	• Accuracy assessment and quality assurance procedures were perceived to be at a high level. Significant improvements were noted in reduced error rates, fewer test repetitions, and lower customer complaints. • ISO 15189 implementation explained 54.2% of the variance in laboratory performance (accuracy and efficiency).
RQ2: How does ISO 15189 implementation affect operational efficiency metrics (turnaround	(Covered under Objective 1)	(Covered under Partial Hypothesis 1)	• Operational efficiency was perceived to be at a high level, with the most significant improvements in equipment utilization and systematic performance monitoring.

Research Questions	Research Aim and Objectives	Research Hypotheses	Research Results
times, resource utilization, workflow optimization)?			• Improvement in test turnaround time (TAT) was only moderate, indicating remaining challenges in this area.
RQ3: What is the relationship between ISO 15189 implementation and human resource factors (staff training, competency levels, engagement, retention)?	**Objective 2:** Examine how ISO 15189 influences staff training and engagement levels.	**Partial Hypothesis 2:** • **Ha:** There is a significant relationship between ISO 15189 implementation and human resource factors.	• A moderately strong positive relationship was found. ISO 15189 implementation explained 37.8% of the variance in human resource factors. • While general training programs were available, specialized training on ISO 15189 was perceived as only moderately implemented.
RQ4: What are the perceived benefits and challenges of ISO 15189 accreditation from the perspective of laboratory personnel?	**Objective 3:** Assess laboratory personnel perceptions regarding benefits and challenges of ISO 15189 accreditation.	(Qualitatively Assessed)	• The perceived benefits of implementation were high. Key benefits included an enhanced laboratory reputation, increased customer confidence, a more organized and safer work environment, and the integration of a quality-focused culture.
RQ5: How does ISO 15189 accreditation influence clinician	(Qualitatively Assessed through Perceptions)	**Hypothesis 3 (Differences between labs):**	• "Customer confidence in laboratory services increased" was a highly rated benefit, directly answering this question.

Research Questions	Research Aim and Objectives	Research Hypotheses	Research Results
confidence and patient trust in private laboratory services?		• **Ha:** There is a significant difference in the application of ISO 15189 standards based on laboratory brand.	• A statistically significant difference was found in the level of ISO 15189 implementation among different laboratory brands. Laboratories like Alraed & Farabi showed higher levels of implementation than others.

4.2 Recommendations and Suggestions

4.2.1 Recommendations

1. Laboratories demonstrating moderate or suboptimal performance ratings should prioritize obtaining official ISO 15189 accreditation to ensure standardized recognition and enhance staff confidence in quality management systems.
2. Establish comprehensive training initiatives specifically designed for ISO 15189 requirements to guarantee that all personnel achieve full competency in standard-specific procedures and quality management protocols.
3. Focus on reducing diagnostic test completion periods through systematic workflow enhancement and strategic resource allocation to improve operational efficiency and patient satisfaction.
4. Facilitate the dissemination of successful strategies and best practices from exemplary laboratories, particularly Alraed and Farabi, to underperforming facilities to minimize performance variability across the sector.
5. Sustain emphasis on ongoing enhancement initiatives, systematic quality monitoring, and evidence-based decision-making processes to preserve and advance laboratory performance standards.

4.2.2 Suggestions

1. Promote active engagement in external quality assurance schemes and establish strategic partnerships to benchmark performance against international standards while fostering continuous professional development opportunities.
2. Develop collaborative networks among local laboratories to facilitate knowledge exchange, technical expertise sharing, and collective problem-solving approaches to common operational challenges.
3. Design comprehensive quality management frameworks incorporating clearly defined performance indicators and systematic review mechanisms to ensure sustained compliance with international standards.
4. Invest in advanced technological solutions and automated systems to improve diagnostic accuracy, reduce human error, and accelerate testing processes while maintaining quality standards.

5. Create sophisticated training curricula for technical and administrative personnel to address emerging trends in laboratory medicine and ensure optimal implementation of evolving quality standards and regulatory requirements.

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Appendices

Appendix (1): The questionnaire in its initial form

Questionnaire: Impact of ISO 15189 Standard on Performance of Private Laboratories in Zawiya City

Dear Participant,

Greetings and appreciation.

I would like to inform you that this is a field study titled "**The impact of applying the standard (ISO 15189) on performance at private lab in Zawia city**", conducted as part of the requirements for obtaining a Master's degree in Health Administration. I kindly request your cooperation by carefully reading this questionnaire and providing accurate and honest responses with complete objectivity. Please note that the data and information collected through this questionnaire will not be used for any purpose other than scientific research, and all information will be handled with complete confidentiality.

This questionnaire aims to measure the extent of the impact of implementing ISO 15189 standard on improving the overall performance of private laboratories in Zawiya City, analyzing the degree of compliance with the standard, and its reflections on diagnostic quality, operational efficiency, staff training level, perceived benefits, and challenges associated with implementation.

Please read each statement carefully and indicate your level of agreement by placing a checkmark (✓) in front of the appropriate choice.

Researcher: Khadeejah Ajeelani AL-Ahreash

Part One: Demographic Data and Laboratory Characteristics

First: Personal Information about the Participant

1. **Job Position:**

Laboratory Manager ☐ Laboratory Technician ☐

Laboratory Physician ☐ Administrator ☐

2. **Years of Experience in Laboratory Field:** _____ years
3. **Educational Qualification:**

Diploma ☐ Bachelor's ☐ Master's ☐ PhD ☐

Specialization: _____

4. **Training Courses Related to Quality:**

No courses ☐ 1-3 courses ☐ More than 3 courses ☐

Second: Laboratory Characteristics

1. **Number of Staff in Laboratory:** _____
2. **Number of Samples Processed:**

Daily: _____ Monthly: _____

3. **Services Provided** (multiple selections allowed):

Clinical Chemistry ☐ Hematology ☐ Immunology ☐

Microbiology ☐

4. **Laboratory Operating Duration:**

Less than 1 year ☐ 1-3 years ☐ 4-6 years ☐

More than 6 years ☐

Part Two: Survey Dimensions

Dimension 1: Level of ISO 15189 Standard Implementation

This dimension focuses on the extent of laboratory commitment to ISO 15189 standard for laboratory quality and accreditation. It includes questions about planning and implementation phases, such as documentation, training, and compliance procedures, in addition to the existence of a quality management system, documentation, and corrective actions. The aim of this dimension is to measure the depth of standard integration in the laboratory's daily operations.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Our laboratory obtained ISO 15189 certification					
2. The standard has been implemented for sufficient time to achieve tangible results					
3. Standard implementation phases were carried out systematically and methodically					
4. All quality-related procedures have been documented					
5. All staff have been trained on standard application					
6. Periodic meetings are held to verify compliance with the standard					
7. Quality documents are managed efficiently					
8. There is a clear and declared quality policy in the laboratory					
9. A quality officer has been designated within the laboratory					
10. There is a continuous monitoring and implementation system for improvements					

Dimension 2: Diagnostic Accuracy and Quality Assurance Procedures

This dimension addresses the extent of ISO 15189 standard impact on the accuracy of test results, reducing error rates, customer response, and improving external and internal quality assurance procedures. It also includes questions about equipment calibration and periodic maintenance. The goal is to identify improvements that have occurred in test accuracy and quality.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Result error rates decreased after ISO 15189 implementation					
2. Test repetitions decreased after implementation					
3. Customer complaints about results became less frequent					
4. Result delivery times became more accurate and regular					
5. There is an effective system for tracking and analyzing errors					
6. Inconsistent test results are regularly reviewed					
7. Final result reports are reviewed before issuance					
8. Precise reference standards for tests are adhered to					
9. Internal quality assurance programs are regularly applied					
10. The laboratory participates in external quality programs					

Dimension 3: Operational Efficiency Indicators

This dimension aims to evaluate the impact of ISO 15189 standard implementation on laboratory operational efficiency. It also covers financial performance indicators such as completion time, resource utilization, productivity, and helps determine the extent of the standard's contribution to improving work volume, overall satisfaction, and the laboratory's practical and financial performance.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Test completion time (TAT) was reduced after implementation					
2. Laboratory productivity increased after standard implementation					
3. Resources are utilized with higher efficiency					
4. Waste in reagents and materials was reduced					
5. Unnecessary test repetition rates decreased					
6. Equipment and device usage became more efficient					
7. Regular meetings are held to review operational performance					
8. Operational performance indicators are measured regularly					
9. Accurate data is available for performance analysis					
10. Data-based operational strategies are implemented					

Dimension 4: Staff Training and Development

This dimension addresses the extent of laboratory interest in training and continuous professional development of its staff in light of ISO 15189 requirements, as well as their understanding of quality importance and their effective participation in improvement processes. The goal of this dimension is to determine the relationship between staff empowerment and achieving sustainable quality.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Staff received specialized training on ISO 15189					
2. Periodic assessments of staff competency are conducted					
3. There is a continuous professional development program					
4. Staff are encouraged to obtain professional certifications					
5. All job categories participate in training programs					
6. Training program effectiveness is evaluated after implementation					
7. Staff are motivated to participate in professional development					
8. Clear opportunities for professional advancement exist					
9. Training is aligned with quality objectives					
10. There is a dedicated budget for staff training					

Dimension 5: Perceived Benefits and Implementation Challenges

This dimension reviews the benefits achieved as a result of implementing ISO 15189 standard, such as improving service quality, increasing trust, and reducing risks. It also monitors the challenges faced by the laboratory during implementation, such as costs and lack of expertise. The dimension also includes evaluating the support required to ensure continuity of implementation and improvement.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. The standard contributed to improving the quality of services provided					
2. Customer confidence in laboratory services increased					
3. The laboratory's reputation in the medical community improved					
4. Standard applications reduced operational risks					
5. The work environment became more organized and safer					
6. The standard helped distinguish the laboratory from competitors					
7. Partnership opportunities with other healthcare institutions improved					
8. Weaknesses were identified and addressed effectively					
9. The laboratory achieved positive performance indicators					
10. Focus on quality became an integral part of institutional culture					

Thank you for your cooperation

Researcher: Khadeejah Ajeelani AL-Ahreash

Appendix (2): The questionnaire in its final form

Survey: Impact of ISO 15189 Standard on Laboratory Performance in Private Laboratories in Zaatari City

Dear Participant,

Greetings and highest regards,

I would like to inform you that this is a field study titled **"The Impact of ISO 15189 Standard on Laboratory Performance in Private Laboratories in Zawia City"**, conducted to fulfill the requirements for a Master's degree in Health Administration.

I kindly request your cooperation in completing this survey with accurate and honest responses, maintaining complete objectivity. Please note that the data and information collected will be used solely for scientific research purposes, and all information will be treated with complete confidentiality. This survey aims to measure the extent of ISO 15189 standard implementation's impact on improving the overall performance of private medical laboratories in Zaatari city, including its effects on diagnostic quality, operational efficiency, staff training levels, employee satisfaction, and the challenges associated with implementation. Please read each statement carefully and indicate your level of agreement by placing a checkmark (✓) in front of your chosen response.

Part One: Demographic Data and Laboratory Characteristics

A. Personal Information About the Participant

1. Job Position:

[ ] Laboratory Director [ ] Laboratory Technician [ ] Laboratory Physician

[ ] Administrative Staff

2. Years of Experience in the Laboratory Field:

[ ] Less than 5 years [ ] 5-10 years [ ] More than 10 years

3. Educational Qualification:

[ ] Diploma [ ] Bachelor's Degree [ ] Master's Degree

[ ] Doctorate **Specialization: _____**

4. Quality-Related Training Courses:

[ ] 0 courses [ ] 1-3 courses [ ] More than 3 courses

B. Laboratory Characteristics

1. Number of Laboratory Employees: _____

2. Number of Processed Samples:

Daily: _____ Monthly: _____

3. Services Provided (multiple selections allowed):

[ ] Clinical Chemistry [ ] Hematology [ ] Immunology

[ ] Microbiology [ ] Other: _____

4. Laboratory Operation Duration:

[ ] Less than 1 year [ ] 1-3 years [ ] 4-6 years [ ] More than 6 years

Part Two: Survey Sections

Section One: Level of ISO 15189 Standard Implementation

This section focuses on the extent of the laboratory's commitment to ISO 15189 standard for quality and accreditation of medical laboratories. It includes questions about planning and implementation phases, such as documentation, training, review processes, in addition to the existence of a quality management system, documentation, and corrective procedures. The purpose of this section is to measure the depth of standard integration into the laboratory's daily operations.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Our laboratory has obtained ISO 15189 certification					
2. The standard has been implemented for a sufficient period to achieve tangible results					
3. Standard implementation was conducted systematically and methodically					
4. All quality-related procedures have been documented					
5. All employees have been trained on standard implementation					
6. Regular meetings are held to verify compliance with the standard					
7. The quality standard is implemented efficiently					

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
8. There is a clear and published quality policy in the laboratory					
9. A quality coordinator has been designated within the laboratory					
10. There is a continuous monitoring and implementation system for improvements					

Section Two: Accuracy Assessment and Quality Assurance Procedures

This section addresses the extent of ISO 15189 standard implementation's impact on the accuracy of test results, reducing error rates, responding to customer observations, and improving quality assurance procedures. It also includes questions about internal and external quality assurance programs, equipment calibration and periodic maintenance. The aim is to identify improvements that have occurred in test accuracy and quality.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. The error rate in results decreased after implementing ISO 15189					
2. Test repetition requests decreased after implementation					
3. Customer complaints about results decreased					
4. Result delivery times became more accurate and regular					
5. There is an effective system for diagnosing and correcting errors					
6. Non-conforming test results are regularly reviewed					
7. Final result reports are reviewed before release					
8. Precise reference standards for tests are adhered to					

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
9. Internal quality assurance programs are regularly applied					
10. The laboratory participates in external quality assurance programs					

Section Three: Operational Efficiency Indicators

This section aims to evaluate the impact of ISO 15189 standard implementation on the laboratory's operational efficiency. It also covers financial performance indicators such as turnaround time, resource utilization, and productivity. This section helps determine the extent of the standard's contribution to improving practical and financial performance, work volume growth, and overall satisfaction of the laboratory.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Test turnaround time (TAT) decreased after implementation					
2. Laboratory productivity increased after standard implementation					
3. Resources are utilized with higher efficiency					
4. Waste in reagents and materials decreased					
5. Test repetition rates decreased					
6. Equipment and device usage became more efficient					
7. Regular meetings are held to evaluate operational performance					
8. Operational performance indicators are measured regularly					
9. Accurate data is available for performance evaluation					
10. Data-driven operational strategies are implemented					

Section Four: Staff Training and Development

This section addresses the laboratory's interest in training its staff and their continuous professional development in light of ISO 15189 requirements. It also measures employee satisfaction, understanding of quality importance, and their active participation in improvement processes. The purpose of this section is to determine the relationship between staff empowerment and achieving sustainable quality.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Employees receive specialized training on ISO 15189					
2. Regular evaluations of employee competency are conducted					
3. There is a continuous professional development program					
4. Employees are encouraged to obtain professional certifications					
5. Training programs are provided to employees regularly					
6. The effectiveness of training programs is evaluated after implementation					
7. Employees are incentivized to participate in professional development					
8. Clear opportunities for professional advancement exist					
9. Training is aligned with quality objectives					
10. There is a dedicated budget allocated for employee training					

Section Five: Perceived Benefits and Implementation Challenges

This section reviews the benefits achieved as a result of implementing ISO 15189 standard, such as improving service quality, increasing trust, and reducing risks. It also monitors the challenges faced by the laboratory during implementation, such as costs

and lack of expertise. To ensure comprehensive evaluation, this section also includes assessment of the support required for continuous implementation and improvement.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. The standard contributed to improving the quality of services provided					
2. Customer confidence in laboratory services increased					
3. The laboratory's reputation in the community improved					
4. Standard implementation reduced operational risks					
5. The work environment became more organized and safer					
6. The standard helped achieve excellence among laboratories					
7. Partnership opportunities with other healthcare institutions improved					
8. Weaknesses are identified and addressed effectively					
9. The laboratory achieved positive performance indicators					
10. Focus on quality became an integral part of the institution's culture (laboratory)					

Thank you for your cooperation

Researcher: Khadija Al-Jaylani Al-Amrish

Appendix (3): List of arbitrators

Name	degree	university
Osama Diya	Associate Professor	University of Zawiya
Nasser Al-Shaibani	Assistant Professor	University of Zawiya
Khaled Al-Basheer Al-Harari	Associate Professor	Sabratha University
Abdul Salam Mohammed Ashour	Associate Professor	University of Zawiya
Naima Ahmed Shaheeda	Associate Professor	University of Zawiya

Appendix (4): Official Documents

Ministry Of Higher Education
And Scientific Research
University Of Zawia
General Administration

وزارة التعليم العالي
والبحث العلمي
جامعة الزاوية
الإدارة العامة

الرقم الإشاري: ....1/.5.54/.ع.ج.د.م.

التاريخ: / / 2022م الموافق: / / 14هـ

السيد المحترم /مدير ادارة الخدمات الصحية بمدينة الزاوية

تحية طيبة ...

في الوقت الذي نحييكم فيه على الجهود التي تبذلونها لخدمة العملية التعليمية وبناء على الطلب المقدم من الطالبة /خديجة الجيلاني الاحرش احدى الطلبة المسجلين بالدراسات العليا بكلية الاقتصاد بقسم الادارة الصحية وهي بمرحلة إعداد الرسالة.

عليـــــه ....

نأمل .... مساعدة الطالب المعني لإجراء دراسة ميدانية والحصول على البيانات والمعلومات الخاصة ببحثه .

د.حمزة الهادي كشلاف
مدير إدارة الدراسات العليا بالجامعة

ص ب 16418 الزاوية هاتف: 00218.23.7626384 فاكس: 00218.23.7626882 الموقع الإلكتروني: www.zu.edu.ly
البريد الإلكتروني: info@zu.edu.ly

Ministry Of Higher Education
And Scientific Research
University Of Zawia
General Administration

وزارة التعليم العالي
والبحث العلمي
جامعة الزاوية
الإدارة العامة

التاريخ: / / 20م الموافق: / / 14هـ الرقم الإشاري: .....

تعريف طالب دراسات عليا

فيدكم. إدارة الدراسات العليا والتدريب جامعة الزاوية أن الطالبة / خديجة الجيلاني الاحرش

هي أحد طلبة الدراسات العليا (الماجستير) كلية الاقتصاد / قسم الإدارة الصحية

لفصل الربيع 2024 /2025م وسجلت تحت رقم قيد (5253039010)

أعطي هذا العريف لاستعماله في الأغراض المسموح بها قانوناً

م/ نوري خليل البوم

مدير مكتب التسجيل والقبول

صورة/الملف الصادر

الدوري+ العام

8/2025م

ص ب 16418 الزاوية هاتف: 00218.23.7626384 فاكس: 00218.23.7626882 الموقع الإلكتروني: www.zu.edu.ly
البريد الإلكتروني: info@zu.edu.ly

Appendix (5): Laboratories targeted by the study

المختبرات الطبية

ت	اسم المختبر	صاحب الترخيص	مقرالمختبر
1	مختبر ابن النفيس	م.على الهادي ارحومه	شرق مجمع العيادات الزاوية
2	مختبر ملاك الرحمة	رشا محمود سليمان	مقابل مستشفى الزاوية
3	مختبر الشروق	محمد اسامة الشكشوكى	مقابل مستشفى الزاوية
4	مختبر الضياء للتحاليل الطبية	سميرة محمد الحراري	الزاوية الجديدة
5	مختبر تحاليل فتحى البشير الحامى	فتحى البشير الجامي	بجوار كلية التربية
6	مختبر أساريا للتحاليل الطبية	مروة ابراهيم السباتى	
7	مختبر الفرابى المتطور للتحاليل الطبية	خالد عمران جدور	الزاوية
8	مختبر الرائد للتحاليل الطبية	اميرة ابوعجيلة طلوبه	شارع القرضابية
9	مختبر ألفا للتحاليل الطبيبة	مبروكة عياد خليل	شارع الولاني
10	مختبر الخالد	مروة الكبير	تفرع من شارع عمر المختار

(اعداد مكتب الخدمات الطبية (قسم القطاع الخاص)