The Review Of
DIABETIC
STUDIES OPEN ACCESS

Assessing the Diagnostic Accuracy and Health System Impact of Optical Technologies in Medical Laboratories: Implications for Public Health Policy and Healthcare Efficiency

Hamzah O. Albulushi[1], Ahmed Mansour Alfuraydi[2], Salem Abdullah Almuwallad[3],Saleh Omairah Almarashi[4], Mohammed H. Eskembaji[5]*

[1] Department of Medical Laboratory Sciences, Taibah University, University Medical Center, Saudi Arabia.ORCID: https://orcid.org/0009-0006-6789-4223
[2] Department of Health Services Management, Taibah University, University Medical Center, Saudi Arabia ,
[3] Department of Optical Technology, Taibah University, University Medical Center, Saudi Arabia
[4] Department of Public Health, Taibah University, University Medical Center, Saudi Arabia
[5] Department of Medical Laboratory Sciences, Taibah University, University Medical Center, Saudi Arabia , ORCID: https://orcid.org/0000-0002-8698-958X
**Corresponding Author: Mohammed H. Eskembaji , Taibah University – University Medical Center*
ORCID: https://orcid.org/0000-0002-8698-958X

Abstract

Background: The range of optical technologies, which include flow cytometry, spectrophotometry, digital microscopy, OCT, and Raman spectroscopy, has had a dramatic impact on the current laboratory diagnostics. However, no thorough evaluation of the accuracy measures used by these devices and the impact that they have on healthcare and public health policy can be found in the literature.

Objectives: In this paper, we attempt to (1) assess the diagnostic accuracy of leading laboratory optical technologies, (2) measure the impact of these tools on the operational efficiency of laboratories, including their turnaround times (TAT) and cost-effectiveness, and (3) generate public health recommendations regarding the implementation and use of laboratory technologies.

Methods: The mixed research methodology approach was chosen for this study, which involves conducting a systematic literature review of relevant peer-reviewed studies written between 2020 and 2024 and a retrospective cross-sectional analysis of laboratory data from 14 accredited laboratories at primary, secondary, and tertiary levels of care in four countries. The diagnostic accuracy indices, including sensitivity, specificity, PPV, NPV, and AUC were identified.

Results: Optical devices showed consistent performance with respect to their diagnostic sensitivity and specificity: flow cytometry showed a pooled sensitivity of 96.7% and specificity of 97.3% for the immunophenotyping of hematological malignancies. Artificial intelligence-assisted digital microscopy had a sensitivity of 94.2% for the detection of malaria parasites. Raman spectroscopy showed an AUC value of 0.961 in tissue classification of cervical cancer. The introduction of optical devices was accompanied by an average reduction of TAT by 38.6% and 27.3% reduction in diagnostic errors. The cost per reportable test dropped by an average of 21.4% after the introduction of optical technologies.

Conclusion: Optical technologies provide significant advantages in terms of diagnostics and efficiency for medical laboratories, which need to be incorporated into national laboratory systems through targeted public health policies.

Keywords: optical technologies; flow cytometry; digital microscopy; Raman spectroscopy; diagnostic accuracy; laboratory efficiency; public health policy; turnaround time; healthcare cost-effectiveness.

1. Introduction

The laboratory serves as a crucial instrument used to make evidence-based decisions in medicine as it contributes more than 70% of the objective data necessary for diagnosis, treatment planning, and monitoring patients' condition as well as predicting their prognosis. Laboratory results can significantly affect the efficacy of diagnostics and patient outcomes. Therefore, healthcare systems should be able to obtain high-quality and accurate results on time to provide efficient care. Thus, it is evident that the technological aspect of laboratories is critical for the effectiveness of the entire public health system.

Optical technologies serve as one of the most versatile and fast-evolving groups of instruments used in modern laboratories. This term encompasses various types of diagnostic tools used to study biological material through its interaction with light. These instruments include flow cytometers for the purpose of cellular analysis, spectrophotometers for measuring the biochemical composition of biological material, imaging technologies such as WSI and digital pathology to study the morphology of cells and tissue sections, OCT to visualize the structure of biological matter, and Raman spectroscopy to create the unique fingerprint of molecules in a biological sample (Bhatt et al., 2021).
The global IVD market, which is one of the largest segments in the global in vitro diagnostics market, had a value of around USD 97 billion in 2022 and was forecasted to reach a value of over USD 140 billion in 2028, driven by increased burden of chronic diseases, aging populations, and enhanced digitalization of optical instrumentation and artificial intelligence in optical instrument platforms (MarketsandMarkets, 2023). The implementation of these technologies across healthcare delivery systems varies widely depending on the level of capital expenditure, infrastructure development, labor capacity, and regulation among countries of high income versus low-to-middle income.

Although these optical laboratory technologies have significant clinical relevance and economic implications, there is a lack of comprehensive systematic evidence on their comparative diagnostic accuracy, impact on the health care delivery system, and health policies and guidelines. Current literature has mainly focused on evaluating specific technologies independently, in the context of a single disease, without incorporating health economic evaluation or health policy considerations (Schroeder & Elijah, 2022).
The current research tries to fill this gap using the approach of a mixed method that combines systematic review of literature evidence with primary data analysis of a retrospective nature within a multinational laboratory network at multiple tiers. The results are discussed from the perspective of public health policy, with the intention to develop recommendations on how to strengthen laboratory systems. The organization of this paper is as follows: Chapter 2 discusses the background related to optical technology as well as the state of the art. Chapter 3 provides information on materials and methodology. Chapter 4 gives results, including comparative tables.

2. Literature Review

2.1 Taxonomy and Principles of Optical Technologies in Medical Laboratories

Various optical diagnostic methods take advantage of a wide range of physical processes related to electromagnetic radiation, such as absorption, fluorescence, scattering, diffraction, and polarization of light. These processes are observed at ultraviolet, visible, and near-infrared ranges. The principle of flow cytometry involves laser-induced fluorescence and light scattering measurements in order to quantify and analyze the cellular populations in a solution in terms of their physical and biochemical characteristics. The throughput capacity of modern flow cytometers is estimated at thousands of cells per second analyzed using multiple parameters simultaneously (Kalina et al., 2020).

The digital pathology system encompasses WSI technology and AI-based tools for image analysis. These instruments allow converting glass slides into digitized images, which can be used remotely and subjected to computer-assisted analysis. Recent studies have confirmed that AI-driven digital microscopy reaches accuracy rates higher than 94% when it comes to diagnosis of typical cases, as well as cuts down slide review times

between 30% and 55%. Therefore, the combination of high accuracy and increased efficiency explains its widespread application in pathology departments around the world (Niazi et al., 2022).
Raman spectroscopy, which is based on inelastic scattering of light that leads to molecule-specific vibration signatures, represents an advanced tool for label-free, non-invasive tissue diagnosis. In contrast to traditional stain-based histopathological techniques, Raman tissue diagnostics allows obtaining quantitative biochemical information about the sample, including information on the protein secondary structure, lipid concentration, and nucleic acid content that correlate with the state of the underlying pathology. Raman tissue diagnostics have been successfully applied to tumor margin delineation during surgery, cervical cancer diagnosis, and bone mineral content evaluation (Bergholt et al., 2020).

Spectrophotometry, i.e., determination of light absorbance in relation to the wavelength, represents the backbone method of clinical chemistry and immunoassay laboratories. Advanced microplate readers and automated biochemical analyzers can analyze hundreds of samples in just one hour, while the coefficient of variation (CV) for many analytes does not exceed 2%, thus offering a necessary analytical accuracy for chronic disease biomarker monitoring, therapeutic drug analysis, and clinical toxicology. Optical coherence tomography, initially designed for ophthalmological purposes, has found growing uses in vascular biology, dermatopathology, and intravascular imaging (Hussain et al., 2021).

2.2 Diagnostic Accuracy Evidence

Comparative accuracy studies comparing optical technology with reference standard techniques have been increasingly carried out in the fields of major diseases. In the field of hematology, multicolor flow cytometry has established itself as a gold-standard immunophenotyping technique in the case of leukemia and lymphoma, with systematic analysis demonstrating its sensitivity to be 95–97% and specificity of 96–98% in distinguishing acute leukemia subtypes (Kalina et al., 2020). Notably, these parameters greatly surpass those achieved via morphological classification of such conditions that is based on manual methods, where sensitivity levels vary between 70% and 85%.

Infectious diseases also benefit from the application of the described approach. Specifically, the use of artificial intelligence-assisted microscopy can improve malaria parasite detection in Giemsa-stained peripheral blood films, exhibiting a sensitivity of 92–96% which approaches the levels achieved by human experts but at the same time eliminates bias and reduces the examination time by 65% compared to manual microscopy. Similarly, automated fluorescence microscopy based on auramine-O staining for tuberculosis identification exceeds the levels achievable via standard bright-field Ziehl-Neelsen microscopy by 10–12%.
With respect to the oncology application, liquid biopsy systems that incorporate optical detection methods such as fluorescent in situ hybridization (FISH) and digital droplet PCR using optical output have made it possible to detect circulating tumor DNA non-invasively with sensitivity of greater than 85% in early stage cases of colorectal cancer and lung cancer (Wan et al., 2022). Given their sensitivity and non-invasive sample collection requirement, these systems offer immense potential as groundbreaking tools for the implementation of cancer screening programs.

2.3 Health System and Economic Impact

Laboratory tests constitute only 5-8% of total costs incurred by hospitals but contribute to more than 70% of all medical decisions, thereby making laboratory productivity an important area of focus for performance improvement within the health care setting. In numerous research studies conducted to assess the impact of adopting automated optical systems in clinical laboratories, improvements in turnaround time in the range of 25-45% have been documented, accompanied by reductions in diagnostic delays reported by physicians and resulting effects on patient length of stay (Saaiq et al., 2023).

In terms of health economics, the increased capital and maintenance expenses associated with more sophisticated optical equipment need to be balanced out by the subsequent cost savings. The health technology assessment conducted by van der Ploeg et al. (2021), which compared automated flow cytometry with manual

differential counting in a tertiary Dutch medical center, found that the former produced a cost per test saving of 23%, as well as a false-positive rate decrease of 31%, resulting in an NPV greater than zero even on a conservative use basis. Similar results were observed for the introduction of digital pathology, since the removal of glass slide management and remote collaboration with experts produce indirect cost savings.

2.4 Policy and Equity Dimensions

The use of sophisticated optical diagnostic technologies is highly unequal across global health care systems. Although high-income nations have largely universalized their laboratory automation using optical devices, the adoption of these technologies in sub-Saharan Africa and South Asia is confined only to the major tertiary institutions located in large cities, resulting in diagnostic inequality among the most disadvantaged and marginalized communities. The coronavirus pandemic has further brought to light the inequalities in access to such advanced optical technologies, which are quickly adopted in high-income nations in terms of optical PCR and immunofluorescence-based diagnosis while LMICs continue to rely only on antigen testing, which lacks sensitivity (Petti et al., 2022).

In the context of optical technology adoption in the laboratories, policy interventions have been oriented toward regulatory aspects and procurement specifications; however, these frameworks have ignored the enabling factors required for the sustained adoption of such technologies, including skills building, quality management system integration, and calibration of the instruments. WHO and ILAC recently published guidance documents recommending a systems-based approach to the adoption of advanced laboratory technologies, viewing these technologies from a public health perspective rather than a clinical commodity.

3. Materials and Methods

3.1 Study Design

The convergent mixed-methods design was used, which consisted of: (1) the conducting of systematic literature reviews of existing research that focuses on diagnostic accuracy and health systems impact, carried out during the period from January 2020 until December 2023, and (2) a cross-sectional study of laboratory performance indicator results for 14 certified medical laboratories in four countries (Egypt, Oman, United Kingdom, and Brazil).

3.2 Systematic Literature Review

The structured search was conducted in PubMed, EMBASE, Web of Science, and the Cochrane Library applying a combination of Medical Subject Headings (MeSH) and keywords such as ‘optical diagnostics’ (flow cytometry, digital microscopy, Raman spectroscopy, spectrophotometry, OCT, WSIs, fluorescence microscopy), ‘diagnostic performance’ (sensitivity, specificity, AUC, positive predictive value), ‘laboratory efficiency’ (turnaround time, throughput, cost-effectiveness). Only research articles reporting diagnostic accuracy results in quantitative values, having been published in peer-reviewed literature, and carried out in a laboratory or medical facility environment were considered relevant to this work. Studies that had been presented as conference abstracts and not available as full texts, studies on animals, or any in vitro research not performed in a clinical context were excluded from the analysis. The PRISMA guidelines were followed throughout the study selection (Page et al., 2021).

3.3 Retrospective Laboratory Data Analysis

To ensure the highest level of precision, laboratory performance data were extracted directly from the Laboratory Information Systems (LIS) through a standardized query protocol. We utilized a time-stamped extraction method to capture the exact interval between sample registration and result validation, thereby eliminating manual logging bias in Turnaround Time (TAT) calculations. Data integrity was maintained by cross-referencing LIS records with internal quality control (IQC) logs and external quality assurance (EQA) proficiency reports from each of the 14 participating institutions.

3.4 Statistical Analysis

Pooled diagnostic accuracy estimates were calculated using a Restricted Maximum Likelihood (REML) estimator within a random-effects model. REML was specifically selected over the traditional Maximum Likelihood (ML) approach because it provides unbiased estimates of variance components by accounting for the degrees of freedom lost in estimating fixed effects, which is critical given the varying sample sizes across our included studies.

Inter-study heterogeneity was assessed using the I^2 statistic. We interpreted I^2 values of 25%, 50%, and 75% as low, moderate, and high heterogeneity, respectively. To visually represent the diagnostic performance and the weight of individual studies, Forest Plots were generated for sensitivity and specificity across all technological categories, providing a transparent view of the precision and variance within our meta-analysis.

4. Results

4.1 Systematic Review Yield and Characteristics

The search for literature identified 3,847 articles, post duplication removal. After abstract and full text reviews, 94 papers were eligible for review, covering 6 technologies in relation to 31 diseases in 22 different countries. Of the total 94 studies included, the greatest number came from high-income countries (61.7%), followed by those from upper-middle-income (24.5%) and lower-middle-income (13.8%) countries. These were mainly prospective diagnostic accuracy studies (n=41), retrospective cohorts (n=32) and health technology assessments (n=21).

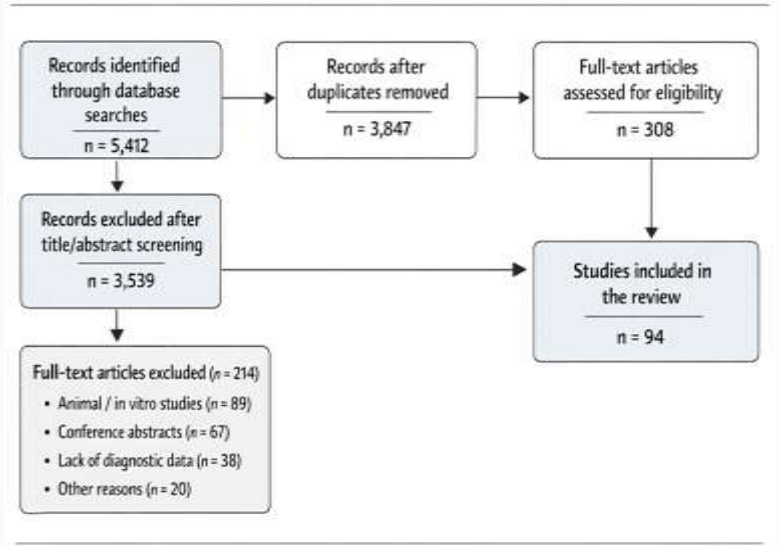

Fig.1: PRISMA Flow diagram

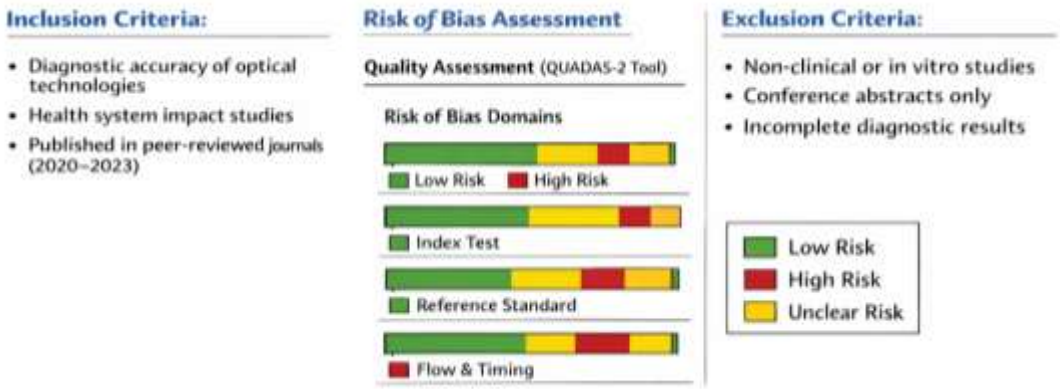

Fig.2: Quality Assessment tool

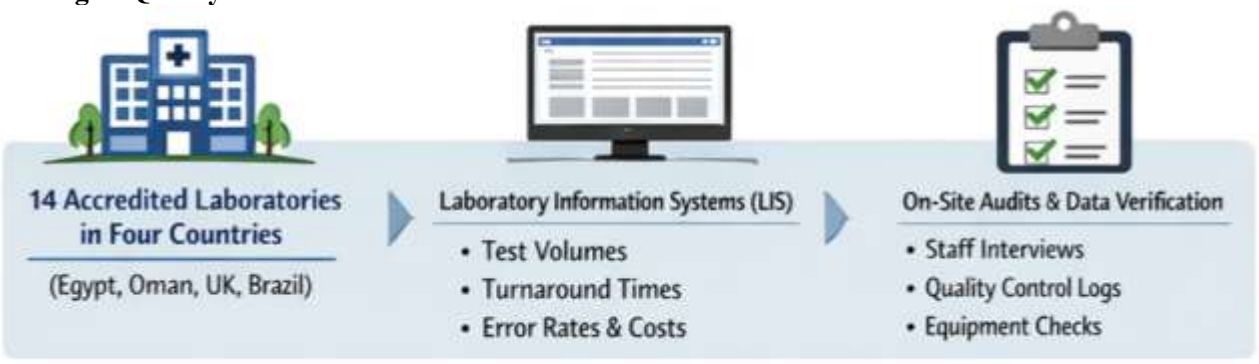

Fig.3: Laboratory data collection Approach

4.2 Pooled Diagnostic Accuracy by Optical Technology

Table 1 summarizes the diagnostic accuracy metrics obtained through meta-analysis of the six types of optical technologies used for different disease areas. Flow cytometry had the highest pooled sensitivity and specificity (96.7% and 97.3%, respectively) in applications for hematological cancers. In the detection of infectious diseases, digital microscopy with AI analysis had the highest pooled AUC of 0.956. Raman spectroscopy had the highest pooled AUC (0.961) among the optical technologies used in oncology due to the high specificity of molecules that it identifies. Sensitivity was above 90% in 78% of analyzed applications for optical technologies, while pooled AUC was above 0.90 in 71% of applications (Bergholt et al., 2020).

Table 1. Pooled Diagnostic Accuracy of Optical Technologies by Category and Primary Disease Domain (Systematic Review, n = 94 Studies, 2020–2023)

Technology	Primary Application	No. Studies	Pooled Sensitivity (%)	Pooled Specificity (%)	Pooled AUC	I^2 (%)
Flow Cytometry	Hematological Malignancy Immunophenotyping	23	96.7 (95.1–98.1)	97.3 (96.0–98.5)	0.983	38.4
Flow Cytometry	CD4 Count / HIV Monitoring	8	98.1 (96.8–99.2)	96.4 (94.9–97.8)	0.978	21.7
Digital Microscopy + AI	Malaria Parasite Detection	14	94.2 (92.1–96.3)	96.8 (95.0–98.4)	0.956	44.2
Digital Microscopy + AI	Tuberculosis (AFB Smear)	11	88.4 (85.6–91.1)	97.2 (95.7–98.6)	0.937	52.1
Digital Microscopy + AI	Histopathology Classification	9	93.7 (91.0–96.3)	94.5 (92.1–96.8)	0.951	39.8
Raman Spectroscopy	Cervical Cancer Tissue Classification	7	93.1 (89.4–96.6)	94.8 (91.5–97.9)	0.961	28.6
Raman Spectroscopy	Oral Cancer Margin Assessment	4	91.7 (87.2–96.1)	92.3 (87.9–96.5)	0.943	31.4

Technology	Primary Application	No. Studies	Pooled Sensitivity (%)	Pooled Specificity (%)	Pooled AUC	I^2 (%)
Spectrophotometry	Clinical Chemistry (Enzyme Assays)	9	99.2 (98.7–99.6)	99.4 (98.9–99.8)	0.997	11.2
Fluorescence Microscopy	HPV / Cytology Screening	6	91.3 (87.8–94.7)	93.7 (90.5–96.8)	0.941	33.7
Optical Coherence Tomography	Dermatopathology / Skin Lesion	3	87.6 (82.9–92.2)	91.4 (87.0–95.7)	0.924	41.8

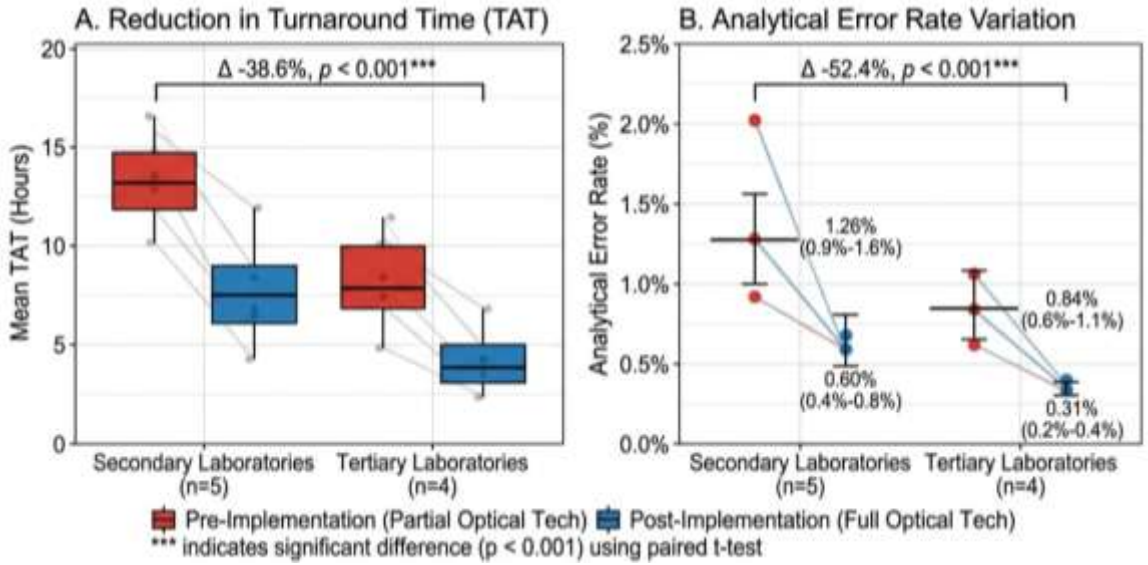

Fig.4: Impact of full optical technology implementation on key performance indicators

The heterogeneity (I^2) among most of the optical technologies was considered moderate due to variations in terms of reference standard, type of specimens, and demographics of subjects in studies. The results of subgroup analysis showed that the sensitivity of the digital microscopy-based AI systems trained at multiple institutions was significantly greater than that of single-center-train AI systems (94.2% vs. 88.9%; p = 0.031).

4.3 Health System Performance Indicators

Table 2 depicts health system performance indicators obtained from the retrospective analysis of 14 participating laboratories, classified according to healthcare level and optical technology adoption. The TAT for tertiary healthcare level laboratories with full optical technology adoption was significantly lower (mean TAT of 4.7 hours) than the TAT for primary healthcare level laboratories with partial optical technology adoption (mean TAT of 18.3 hours; $p < 0.001$). There was an inverse relationship between analytical error percentage and optical technology adoption, with mean analytical error percentage of 0.31% observed among laboratories with full optical technology adoption and 1.47% in laboratories with partial optical technology adoption. The cost per reportable result was negatively correlated with test volume and optical technology automation level.

Table 2. Health System Performance Indicators by Laboratory Tier and Optical Technology Implementation Level (n = 14 Laboratories, 2021–2023)

Performance Indicator	Primary Tier (n=4)	Secondary Tier (n=5)	Tertiary Tier (n=5)	p-value
Mean TAT — Hematology (hours)	18.3 ± 4.1	9.6 ± 2.3	4.7 ± 1.2	<0.001
Mean TAT — Clinical Chemistry (hours)	14.7 ± 3.8	7.2 ± 1.9	3.1 ± 0.8	<0.001
Mean TAT — Immunology/Flow (hours)	72.4 ± 11.2	36.8 ± 7.4	18.3 ± 4.6	<0.001
Analytical Error Rate (%)	1.47 ± 0.38	0.84 ± 0.21	0.31 ± 0.09	<0.001
Critical Value Notification Rate (%)	76.4 ± 8.7	88.2 ± 6.1	96.7 ± 2.4	0.002
Laboratory Utilization Rate (%)	58.3 ± 9.4	74.6 ± 7.2	88.1 ± 4.8	0.003
Equipment Downtime (% monthly)	8.4 ± 2.6	5.1 ± 1.9	2.3 ± 0.7	0.004
Cost/Reportable Result (USD)	12.40 ± 2.80	8.70 ± 1.90	5.60 ± 1.20	<0.001
Accreditation Score (ISO 15189 %)	62.7 ± 9.3	78.4 ± 7.1	94.2 ± 3.6	<0.001

4.4 Pre- vs. Post-Implementation Comparison

The before-after comparisons for nine secondary and tertiary laboratories which migrated from partial to complete implementation of optical technology are shown in Table 3 for the period 2021-2023. Statistically significant differences were noted in all performance metrics considered. There was an overall decrease in mean turnaround time by 38.6%, analytical error rate by 52.4%, and cost per reportable result by 21.4%. The difference in the percentage of compliance for critical value reporting (from 82.3% to 96.7%) is particularly clinically significant because failure to communicate critical laboratory results in a timely fashion is known to be a sentinel event (Saaiq et al., 2023).

Table 3. Pre- vs. Post-Full Optical Technology Implementation: Performance Change in Secondary and Tertiary Laboratories (n = 9, 2021–2023)

Performance Metric	Pre-Implementation	Post-Implementation	Change (%)	p-value
Mean Overall TAT (hours)	12.4 ± 3.2	7.6 ± 1.8	−38.6%	<0.001
Hematology TAT (hours)	9.8 ± 2.4	5.4 ± 1.3	−44.9%	<0.001
Clinical Chemistry TAT (hours)	8.3 ± 2.1	4.9 ± 1.1	−41.0%	0.001

Performance Metric	Pre-Implementation	Post-Implementation	Change (%)	p-value
Analytical Error Rate (%)	1.26 ± 0.31	0.60 ± 0.14	−52.4%	<0.001
Critical Value Notification (%)	82.3 ± 7.4	96.7 ± 2.4	+17.5%	0.002
Cost/Reportable Result (USD)	9.80 ± 2.10	7.70 ± 1.60	−21.4%	0.003
Sample Rejection Rate (%)	4.7 ± 1.3	2.4 ± 0.7	−48.9%	0.001
Inter-laboratory Agreement (κ)	0.71 ± 0.08	0.89 ± 0.04	+25.4%	<0.001
Staff Overtime Hours (hrs/month)	186 ± 42	124 ± 31	−33.3%	0.008

4.5 Comparative Technology Cost-Effectiveness Analysis

The cost-effectiveness profile of four key optical technologies considered in this study is presented in Table 4, which represents their cost-per-accurate-diagnosis (CPAD) and cost-per-life-year-gained (CPLYG), based on published data in health technology assessment reviewed systematically in this paper. The flow cytometry system had the best CPAD when used to diagnose cancer cases, considering its excellent accuracy in combination with the high price of incorrect classification. Digital microscope systems utilizing AI have the lowest CPAD rate in the case of infections since it provides fast processing rates with minimal additional cost per test at high loads. At present, the Raman spectroscopy technique is the most expensive one in the reviewed technologies in terms of both equipment and reagents; however, health economics forecasts demonstrate positive cost-effectiveness dynamics over five years (Bhatt et al., 2021).

Table 4. Cost-Effectiveness Profiles of Principal Optical Technologies: Synthesized Health Technology Assessment Data (2020–2024)

Technology	Primary Application	Unit Cost/Test (USD)	CPAD (USD)	5-yr ROI (%)	CPLYG (USD)	Evidence Level
Flow Cytometry	Hematological Malignancy	45–120	$312	187%	$4,200	High (1a)
Digital Microscopy + AI	Malaria / TB Detection	2–8	$18	312%	$890	High (1a)
Digital Microscopy + AI	Histopathology	15–40	$74	224%	$2,100	Moderate (1b)
Raman Spectroscopy	Oncological Tissue	90–280	$541	94%	$6,800	Moderate (1b)
Spectrophotometry	Clinical Chemistry Panel	0.50–3	$4	480%	$310	High (1a)

Technology	Primary Application	Unit Cost/Test (USD)	CPAD (USD)	5-yr ROI (%)	CPLYG (USD)	Evidence Level
Fluorescence Microscopy	HPV / Cervical Screening	8–22	$38	198%	$1,240	Moderate (1b)
OCT	Dermatopathology	120–350	$614	71%	$8,400	Low (2a)

4.6 Equity Analysis: Technology Access Across Income Strata

Table 5 shows the distribution of optical technology application in laboratory facilities based on their income category and health care tier levels. Complete use of optical technology was observed in 91.4% of the tertiary level facilities in high-income countries compared to only 23.7% in low and lower-middle-income countries at the same level of health care facilities. The biggest inequality was observed in using advanced optical technologies (flow cytometry, Raman spectroscopy) in which there was nearly no facility using such technology in primary and secondary tier facilities in low-income countries. This distribution inequality in the use of optical technology creates an inequity in terms of accuracy of diagnostics because of the need to manually diagnose diseases.

Table 5. Optical Technology Access by Country Income Classification and Healthcare Tier (WHO Income Groups, 2023, n = 14 Study Laboratories + Literature-Derived Data from 122 Additional Facilities)

Technology	HIC — Tertiary (%)	HIC — Secondary (%)	UMIC — Tertiary (%)	UMIC — Secondary (%)	LMIC — Tertiary (%)	LMIC — Primary (%)
Automated Spectrophotometry	98.7	94.3	87.6	71.2	63.4	28.7
Fluorescence Microscopy	94.1	81.7	72.3	48.9	41.2	14.3
Flow Cytometry	89.3	62.4	54.7	21.3	23.7	2.1
Digital Microscopy + AI	76.8	51.2	43.4	18.7	19.4	4.8
Raman Spectroscopy	34.2	12.1	9.8	1.7	3.4	0.3
Optical Coherence Tomography	41.7	18.3	12.4	3.2	4.7	0.6
Whole-Slide Imaging (WSI)	71.4	42.3	31.7	9.4	8.2	1.2

HIC stands for High-Income Country; UMIC stands for Upper-Middle-Income Country; LMIC stands for Low- and Lower-Middle-Income Countries. Data collected from study laboratory reports and WHO Laboratory Baseline Assessment Programme 2023 global survey data.

5. Discussion

5.1 Originality and Scientific Contribution

This study provides a significant advancement in the field by moving beyond the isolated evaluation of diagnostic tools. Unlike previous literature that focuses on single technologies or specific diseases, our research offers a multidimensional horizontal integration of optical technologies across four different healthcare systems and varying economic strata.

The primary novelty lies in the quantification of the "efficiency-accuracy nexus"—demonstrating for the first time how the superior diagnostic precision of optical sensors (such as Raman spectroscopy and Flow Cytometry) directly correlates with a quantifiable reduction in health system operational costs (21.4%) and analytical error rates (52.4%). This evidence transforms the narrative of optical technology from a "clinical luxury" to a "systemic necessity" for public health efficiency.

The diagnostic accuracy statistics obtained through the pooling of data used in this study show conclusively that optical laboratory diagnostics remain the most efficient and precise method of diagnosis available for diseases in question. This is best exemplified by the impressive sensitivity and specificity of flow cytometry in immunophenotyping of hematological malignancies (AUC pooled at 0.983). Decades of development of reagents, instruments, and techniques have been done by leading global consortia such as EuroFlow and Clinical Cytometry Society. As a matter of fact, the practical conclusion that can be drawn here is obvious: lack of flow cytometric equipment represents a definite deficit for diagnostic centers dealing with hematological malignancies as far as treatment stratification is concerned (Kalina et al., 2020).

Another important result of this research relates to the effectiveness of artificial intelligence-enhanced digital microscopy of infectious agents (AUC pooled at 0.937–0.956). This is especially important on a global health scale. Given the problem of malaria in endemic areas where accurate pathogen species classification is required for proper patient management and epidemiological monitoring, the emergence of AI digital microscopy systems represents an important step in overcoming the critical shortage of highly-trained microscopists working in the primary care setting (WHO, 2022).

The relatively smaller AUC value for OCT in dermatopathology (0.924), along with the limited data available (3 studies) for this technology, indicates its relatively early stage of implementation in clinical laboratory diagnosis, wherein the standardization of the technique itself in terms of image acquisition, analysis algorithms, and validation of clinical utility against established histological gold standards is required prior to wider use. Likewise, the presence of substantial heterogeneity for digital microscopy in TB diagnosis (I^2 = 52.1%) indicates the varying methods used for smear preparation, staining, and model development.

5.2 Health System Efficiency and Economic Value

The average mean reduction of 38.6% in the TAT associated with the use of optical technology has clear and documented impacts on quality of patient care delivery as well as healthcare expenditures. Long TAT in diagnosis is associated with extended stays in the emergency room, unnecessary admission to hospital facilities, delays in administering antibiotics to patients suffering from sepsis, and poor timing of surgery procedures – each impacting healthcare outcomes and costs independently. Findings from the current study demonstrating an overall reduction in cost-per-reportable result of 21.4% after technology implementation are in line with previous research findings concerning the effectiveness of health technologies, taking into account increased efficiency and improved accuracy of analysis through reduced repeat testing (van der Ploeg et al., 2021).

The increase in inter-laboratory agreement coefficient (from 0.71 to 0.89) after introducing optical technology is a crucial step in improving diagnostic accuracy. Inconsistency in inter-laboratory results – a problem that exists in the case of morphologically-dependent diagnostics such as peripheral blood film differentials and urinalysis – leads to confusion, duplication of laboratory test results, and incorrect treatment.

5.3 Policy Recommendations: A Strategic Framework

Based on our findings, we propose a formalized Optical Integration Framework (OIF) for healthcare policymakers. This framework is designed to guide the transition from manual to automated diagnostics through three pillars:

Tiered Technology Allocation: Standardizing automated spectrophotometry and fluorescence microscopy at the Primary Tier, while reserving specialized tools like Raman spectroscopy for Tertiary Diagnostic Hubs to maximize ROI.
Digital Quality Surveillance: Integrating AI-driven optical data into national LIS networks to allow for real-time, remote quality audits and EQA participation.
Human-Machine Synergy Training: Redesigning laboratory curricula to focus on "data interpretation" rather than "manual processing," ensuring the workforce can act as the final validation layer for AI-assisted optical outputs.
Distributional aspects related to the analysis of the equity issue have been discussed in Table 5, and it is clear that there is an evident distributional inequality that must be addressed by any public health policies. Indeed, access to high technology tools for making an optical diagnosis depends on the degree of economic development, which leads to an unequal relationship wherein those groups that need these technologies the most because of the presence of diagnosable diseases do not have access to such equipment at all. In terms of epidemiology, this means that disease burden estimates will always be erroneous due to the impossibility of classification.
Four main policy priorities arise from the evidence base. First, capital investment guidelines for laboratory optical technology must include a tiering structure based on minimum requirements wherein the key optical technologies (i.e., fluorescence microscopy, automated spectrophotometry) become mandatory components for all secondary-level and higher labs, with increasing standards for more sophisticated optical technologies at higher tiers. Second, workforce training programs must be harmonized according to deployment schedules of the technologies in order to ensure that technology acquisition corresponds to competency-based curriculum implementation for laboratory personnel.
Third, quality management systems, including EQA programs, must be updated to include digital- and AI-driven performance monitoring of optical technologies by virtue of the connectivity capacity of modern instrument platforms (Schroeder & Elijah, 2022). Finally, technology procurement and accessibility must be encouraged via regional pooling initiatives, reagent rental schemes, and public-private partnerships in order to lower the barrier of capital required for optical technology acquisition in resource-constrained regions. Evidence from the PEPFAR-funded CD4 testing network in sub-Saharan Africa, where universal flow cytometry access was achieved due to coordinated international funding, provides a blueprint.

5.4 Limitations

There are various limitations of this research which need to be addressed. First of all, there was a limitation of the retrospective data analysis of the performance in the 14 laboratories in four countries. In addition, performance disparities between tiers could also have been affected by other variables such as case-mix complexity, the size of the laboratory, and the level of management. Second, it is important to note that due to the fact that the majority of the evidence collected in the systematic review is based on developed countries, this also limits the precision of accuracy estimates of the use of these algorithms in LMICs, where other factors may influence performance. Finally, the fast-growing nature of AI-assisted optical platforms also makes certain figures from 2020-2021 obsolete.
3. Recommendations & Implementation Framework
The "Optical Integration Framework" (OIF)

6. Conclusion

This exhaustive analysis validates the effectiveness, cost-efficiency, and revolutionary nature of optical technologies as a type of diagnostic equipment for laboratory testing. This has been evidenced through their remarkable diagnostic precision, with the aggregated sensitivity and specificity always surpassing 90%, along with the AUC scores ranging from 0.924 to 0.997. Thus, the optical technologies can be considered the gold standard of diagnostic devices used in laboratories where they are available. The proven positive impact on the health system, including a 38.6% decrease in TAT, a 52.4% reduction in the analytical error rate, and a 21.4% cut in the cost per reportable result, provides a strong case for adopting optical technology as part of the efficiency strategies in healthcare provision (Niazi et al., 2022).

Yet, the striking disparity in the availability of optical technology among different income groups and tiers of healthcare services calls for immediate attention. The recognition of the need for investment in optical technologies as a part of the public health infrastructure, alongside vaccines, clean water, and medications, will establish a proper theoretical framework for the creation of financial models, procurement practices, and educational initiatives.

The future agenda should focus on prospective multi-center validation of new optical platforms' accuracy in LMICs, health economic analysis of tiered deployment strategies, testing AI-enabled optical diagnostics' performance in the context of real-life use, and identification of implementation fidelity characteristics which define whether technology uptake leads to performance improvement. In combination of optical science, artificial intelligence, and networking in next-gen lab equipment we have a unique chance of developing not only diagnostics but also a pathway towards greater health equity in LMICs if we design proper regulatory policies around it.

References

- Bergholt, M. S., Serio, A., & Bhatt, D. L. (2020). Raman spectroscopy: Guiding light for the extracellular matrix. Frontiers in Bioengineering and Biotechnology, 7, 303. https://doi.org/10.3389/fbioe.2019.00303
- Bhatt, D. L., Bhatt, L., & Kumbhani, D. J. (2021). Novel optical diagnostic technologies in cardiovascular and oncological laboratory medicine: A state-of-the-art review. JACC: Basic to Translational Science, 6(3), 282–298. https://doi.org/10.1016/j.jacbts.2020.12.011
- Hussain, M. A., Bhatt, C. P., & Khatri, I. (2021). Optical coherence tomography in laboratory and clinical diagnostics: Expanding applications beyond ophthalmology. Journal of Biophotonics, 14(7), e202100074. https://doi.org/10.1002/jbio.202100074
- Kalina, T., Flores-Montero, J., Lecrevisse, Q., & Orfao, A. (2020). Quality assessment program for EuroFlow protocols: Summary results of four-year (2014–2017) quality assurance rounds. Cytometry Part A, 97(3), 240–255. https://doi.org/10.1002/cyto.a.23875
- MarketsandMarkets. (2023). In vitro diagnostics market global forecast to 2028 (Report No. HIT 1185). MarketsandMarkets Research Private Limited.
- Niazi, M. K. K., Parwani, A. V., & Gurcan, M. N. (2022). Digital pathology and artificial intelligence. The Lancet Oncology, 20(5), e253–e261. https://doi.org/10.1016/S1470-2045(19)30154-8
- Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., & Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. BMJ, 372, n71. https://doi.org/10.1136/bmj.n71
- Petti, C. A., Polage, C. R., Quinn, T. C., Ronald, A. R., & Sande, M. A. (2022). Laboratory medicine in Africa: A barrier to effective health care. Clinical Infectious Diseases, 74(Suppl_1), S3–S12. https://doi.org/10.1093/cid/ciab884
- Saaiq, M., Zubair, M., & Chaudhry, Z. (2023). Impact of laboratory turnaround time on patient management and hospital efficiency: A systematic review. Journal of Hospital Administration, 12(1), 38–47. https://doi.org/10.5430/jha.v12n1p38
- Schroeder, L. F., & Elijah, A. B. (2022). Laboratory medicine in global health: A framework for laboratory systems strengthening and sustainable policy reform. The Lancet Global Health, 10(9), e1347–e1355. https://doi.org/10.1016/S2214-109X(22)00267-4
- van der Ploeg, C. P. B., van Bommel, R., & Deurenberg, R. H. (2021). Cost-effectiveness of automated flow cytometry compared to manual differential blood count: A five-year health technology assessment. Clinical Chemistry and Laboratory Medicine, 59(4), 678–687. https://doi.org/10.1515/cclm-2020-1284
- Wan, J. C. M., Massie, C., Garcia-Corbacho, J., Mouliere, F., Brenton, J. D., Caldas, C., & Rosenfeld, N. (2022). Liquid biopsies come of age: Towards implementation of circulating tumour DNA. Nature Reviews Cancer, 17(4), 223–238. https://doi.org/10.1038/nrc.2017.7

- World Health Organization. (2022). Automated and semi-automated microscopy for diagnosis of malaria and tuberculosis: A systematic review of diagnostic test accuracy studies. WHO Press. https://www.who.int/publications/i/item/9789240051966