UDC: 616-074:614.2
DOI: 10.62151/2786-9288.4.1-2.2026.03

Giuseppe Lippi
Section of Clinical Biochemistry, University of Verona, Verona, Italy

LABORATORY MEDICINE AT A CROSSROADS: VALUE, PRIVATIZATION, AND THE FUTURE OF DIAGNOSTIC STEWARDSHIP

Summary

Laboratory medicine plays a unique position within healthcare systems. Although it accounts for only a small fraction of expenditure, in vitro diagnostic testing plays a central role in screening, diagnosis, therapeutic decision-making, and disease monitoring. Increasing financial pressure on healthcare systems worldwide has stimulated discussions about outsourcing, privatization, and consolidation of laboratory services as strategies to improve efficiency. At the same time, the shift toward value-based healthcare requires healthcare disciplines to demonstrate measurable clinical and economic impact. This opinion paper presents personal reflections on the economic paradox of laboratory medicine, discusses the implications of privatization and outsourcing of diagnostic services, and highlights the growing strategic importance of laboratory diagnostics in the era of precision medicine. Ultimately, improving value-based healthcare in laboratory medicine does not mean indiscriminate cost reduction. Rather, it requires systematic measurement of outcomes, transparent demonstration of clinical value, and governance models that preserve accessibility and quality. Laboratory medicine must remain a cornerstone of sustainable and equitable healthcare systems.

Key words: *laboratory medicine, quality, value, cost.*

INTRODUCTION. Modern healthcare systems are facing unprecedented challenges. Rising healthcare expenditures, aging populations, technological innovation, and increasing patient expectations are placing enormous pressure on healthcare systems worldwide [1]. These pressures are compounded by natural disasters, pandemics, and armed conflicts, which can disrupt supply chains, overwhelm hospital capacity, and impede access to essential services, including diagnostic testing [2]. In these scenarios, the resilience and adaptability of laboratory medicine become especially critical, as timely and accurate diagnoses are essential for both acute response and long-term public health management [3]. Governments and healthcare administrators are therefore seeking strategies to improve efficiency while maintaining or improving the quality of care. Within this context, diagnostic services, especially laboratory medicine, have increasingly become a focal point of health policy discussions (Figure 1).

Assessing the contribution of laboratory medicine to clinical decision-making

Laboratory medicine represents an essential component of contemporary clinical practice. From screening and prevention to diagnosis, treatment monitoring, and prognostic assessment, laboratory data are deeply embedded in nearly every clinical pathway [4]. Despite its central role, however, laboratory medicine often remains less visible within healthcare systems, yet its results influence a large proportion of medical decisions.

Laboratory medicine is uniquely vulnerable to these pressures, because it serves as the backbone of almost all clinical decision-making. Historically, it has been estimated that 60–70% of clinical decisions are informed by laboratory results, including admission, discharge, therapy selection, and monitoring [5]. This figure is attributed to an article by Rodney Forsman published in 1996, which highlighted the paradox that although the laboratory accounts for only a small proportion of healthcare expenditure, its results influence the majority of critical clinical decisions. Laboratory

medicine is, in essence, a high-leverage component of healthcare, capable of shaping interventions that are far more expensive than the tests themselves [6].

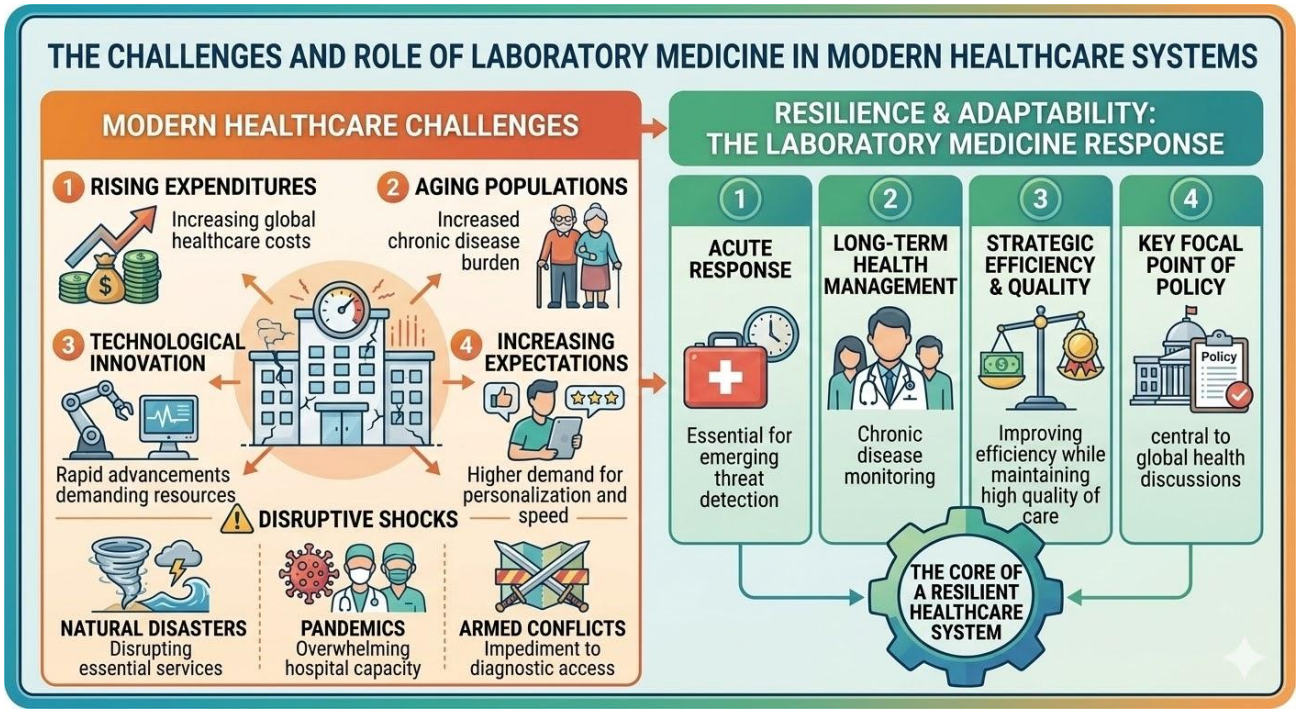

Figure 1. The challenges and role of laboratory medicine in modern healthcare systems.

However, as Mike Hallworth critically noted in 2011, the empirical support for the precise "70% claim" is limited [7]. He emphasized that while the intuitive importance of laboratory testing is undeniable, the scientific evidence for specific numerical claims remains weak. Hallworth's critique serves as a reminder that, as scientists, we must distinguish between anecdotal impressions and evidence-based quantification of laboratory influence. This caution is particularly important in modern policy discussions, where misperceptions about laboratory costs and impacts can influence decisions on outsourcing, consolidation, or privatization.

Recent conceptual work has helped to clarify the breadth of laboratory medicine's contribution to healthcare. For instance, Lord and colleagues recently proposed a framework mapping laboratory tests across the entire continuum of care, including predisposition and risk assessment, screening, early detection, diagnosis, staging, treatment guidance, prognostication, treatment monitoring, and disease surveillance [8]. Viewed in this way, laboratory testing underpins virtually every stage of the clinical pathway, from preventive health measures to complex therapeutic monitoring.

A provocative illustration of this dependency can be drawn from artificial intelligence (AI) simulations. If an AI system such as ChatGPT is asked to estimate the proportion of human diseases that could be managed without any laboratory testing, the calculation is striking: only about 0.16% of all recognized diseases could be managed entirely without laboratory input, while the remaining 99.84% require some form of laboratory investigation to support diagnosis, monitoring, or therapeutic decision-making. While this estimate is perhaps exaggerated, it still underscores a crucial point: modern medicine is essentially inseparable from laboratory diagnostics. With an estimated 30,000 to 40,000 recognized diseases, only a very small fraction can be managed without laboratory data, emphasizing the near-universal role of diagnostics in patient care (Figure 2).

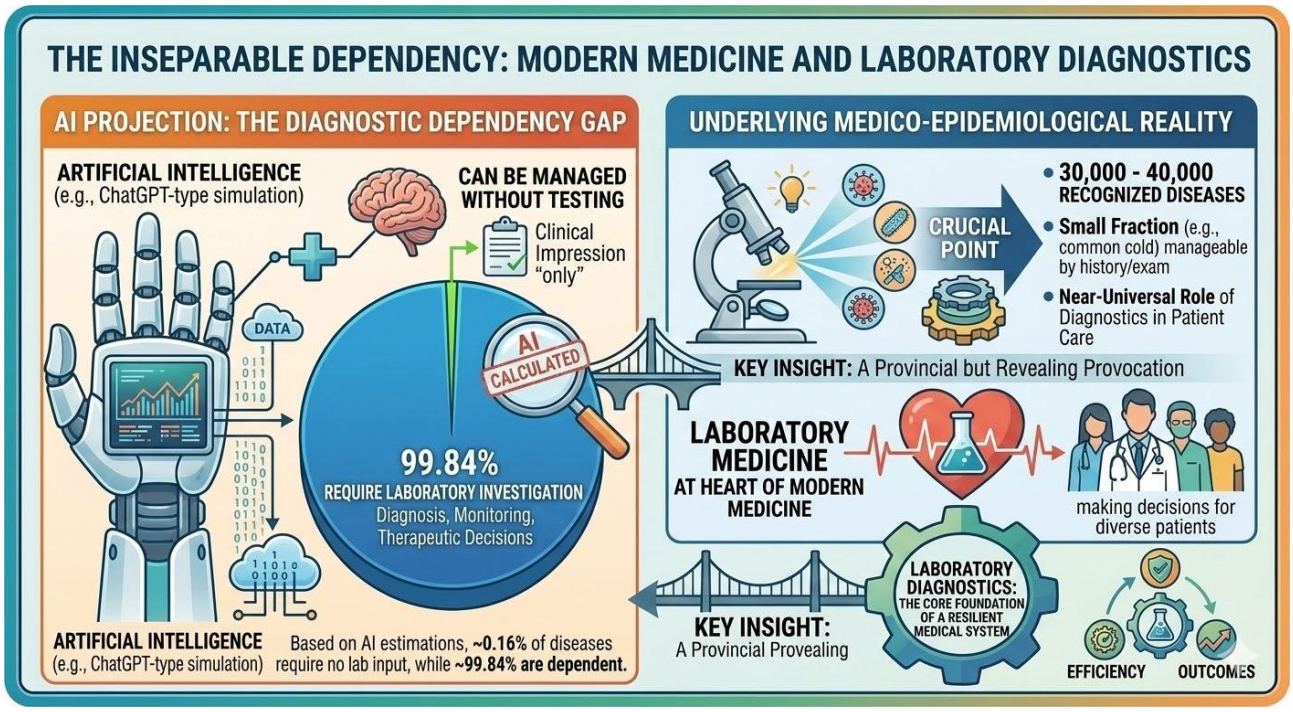

Figure 2. Assessing the contribution of laboratory medicine to clinical decision-making

These two anecdotes remind us that laboratory medicine has always been about transforming biological observations into actionable clinical information; only today, we do it quantitatively, standardized, and at an industrial scale. The reliance on laboratory medicine becomes even more apparent when considering time-critical conditions. The diagnosis of an acute myocardial infarction relies on high-sensitivity cardiac troponin testing, which detects subtle myocardial injury that would be missed by an electrocardiogram alone [11]. The adage "time is muscle" reflects the clinical imperative for rapid testing: delayed laboratory results are associated with worse outcomes and higher mortality. Similarly, in sepsis, procalcitonin measurement enables rapid distinction between bacterial and non-bacterial inflammatory states, guiding timely antibiotic therapy and reducing unnecessary antimicrobial exposure [12]. These examples highlight that laboratory medicine is not merely supportive but often decisive in clinical decision-making.

Historical and contemporary data illustrate that laboratory medicine provides high value at a low cost. When we compare laboratory margins with other industrial sectors, public clinical laboratories generate value that can exceed twice their operational costs. For example, hospital-level data from the University Hospital of Verona demonstrate that the local laboratory services accounted for only 1.1% of total hospital costs in 2025 (8.720 out of 778.415 million €), but generated nearly 2.8% of the hospital's total production value (19.660 out of 695.415 million €), representing approximately 2.25-fold efficiency relative to direct costs. Interestingly, when these figures are compared with profit margins reported in other major industrial sectors, based on recent Forbes data [13], a striking contrast emerges. Banking and financial services typically report average net profit margins of 25–31%, pharmaceuticals and biotechnology 15–22%, and highly profitable sectors such as software and cloud services 20–36%. By comparison, public clinical laboratories can realistically achieve profit margins up to 10 times higher than those observed in many other industries (Figure 3).

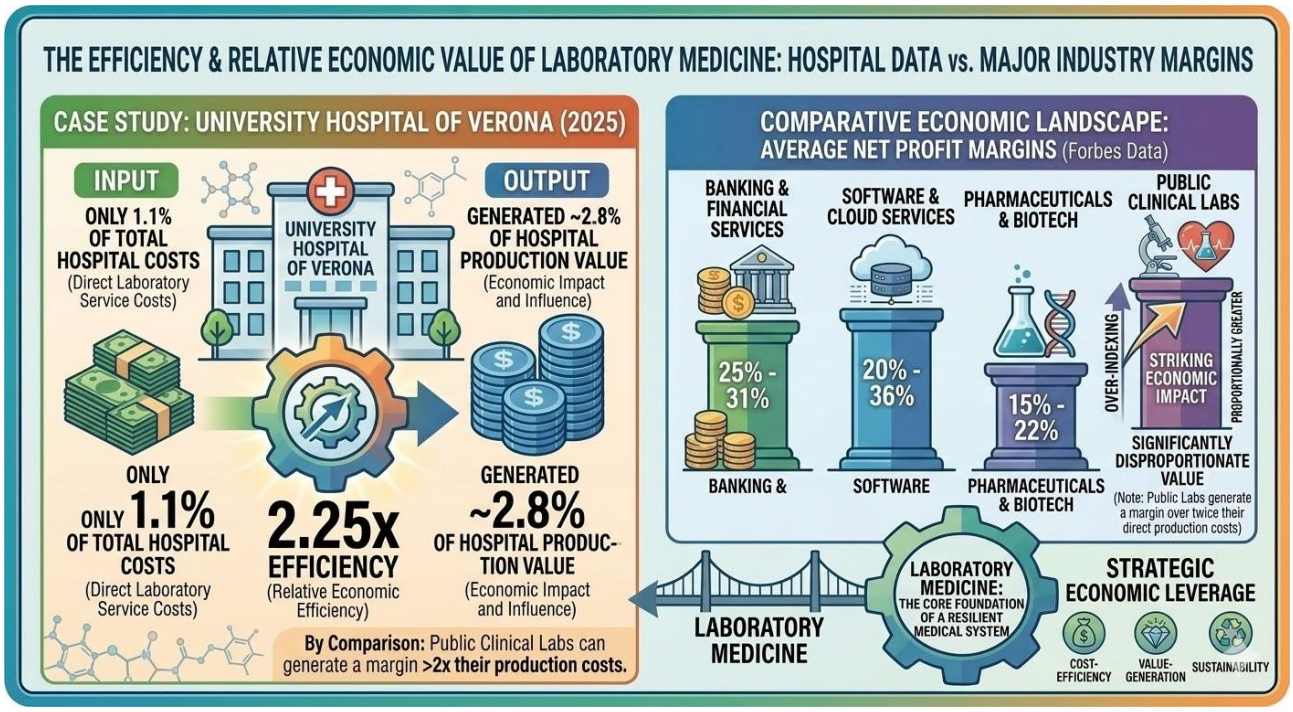

Figure 3. The economic value of laboratory medicine in modern healthcare

In other words, the economic efficiency of laboratory medicine is extraordinary, far exceeding that of many industries traditionally considered highly profitable. Which naturally leads to a rather obvious question: why would anyone want to kill the goose that lays the golden eggs? (Figure 4).

Figure 4. Laboratory medicine: the goose that lays the golden eggs in the modern healthcare industry.

The paradox of underappreciation: laboratory medicine in policy decisions

Despite its critical role, laboratory medicine remains underappreciated in policy discussions. Part of the explanation lies in the visibility of laboratory production: test volumes, reagent costs, and

automation make laboratories highly transparent, while their behind-the-scenes role in clinical decision-making is less obvious [14]. Furthermore, the high level of standardization and automation can create the perception that unlimited economies of scale are achievable [15], which may fuel policy interest in outsourcing.

Paradoxically, despite this major influence on patient management, we have already seen that laboratory medicine accounts for a relatively small proportion of healthcare budgets. Additional data from recent scientific literature show that, in most countries, diagnostic testing accounts for approximately 1–3% of total healthcare expenditure [16], yet it influences the use of a much larger proportion of healthcare resources through downstream clinical decisions. Moreover, many physicians tend to overestimate their share. In a representative survey, Rohr and colleagues found that the large majority of cardiologists and oncologists believed that in vitro diagnostic testing accounted for 10–20% of total healthcare expenditure, far above the actual figure [16]. This misperception partly explains why laboratories are often the first target when cost containment is discussed.

This imbalance also creates a unique economic paradox. On the one hand, laboratory medicine has enormous leverage over patient care and healthcare spending. On the other hand, it is frequently perceived primarily as a cost center rather than as a driver of value. Consequently, laboratory services often become targets of cost-containment strategies, including consolidation, outsourcing, and privatization [17].

At the same time, the global shift toward value-based healthcare has created a new framework for evaluating healthcare services. Rather than focusing solely on cost reduction, value-based healthcare emphasizes the relationship between outcomes achieved and resources invested. In this model, laboratory medicine has the potential to become a key enabler of improved healthcare value, provided its clinical and economic contributions can be systematically demonstrated [18-20].

Against this background, laboratory medicine currently stands at an important crossroads. The discipline must respond to economic pressures and organizational reforms while simultaneously strengthening its clinical integration and demonstrating its measurable impact on patient outcomes. This central role highlights the importance of considering laboratory medicine not merely as a cost item but as an investment in healthcare quality and efficiency. Appropriate diagnostic testing can reduce unnecessary procedures, shorten hospital stays, and enable earlier therapeutic interventions. Conversely, inadequate or delayed laboratory testing can lead to diagnostic errors, inappropriate treatments, and increased healthcare costs [20].

Estimating the true cost of laboratory testing

This data raises a natural question: if laboratories account for only about 1% of total healthcare spending, how much can we realistically allocate to them without compromising quality or access? In addition to local frameworks, the World Health Organization (WHO) has developed the “Laboratory Test Costing Tool” (LTCT) [21], which is freely available to laboratories seeking to accurately estimate the full cost of their diagnostic services. The tool is designed to capture a comprehensive range of cost drivers, including reagent prices, testing frequency, equipment acquisition and depreciation, maintenance, personnel salaries, facility overheads, and quality management activities. It is organized into six main sections: General Information, Reagents and Consumables, Equipment, Personnel, Facility, and Quality Management. The General Information section allows users to specify details such as the test name, intended use, sample type, method, whether a commercial or in-house kit is used, testing schedule, laboratory working hours, and batch sizes. The Reagents and Consumables section captures costs per unit, usage per patient sample, and quality controls for each batch. The Equipment section accounts for acquisition price, expected lifespan, and maintenance costs, while the Personnel section records staff categories, roles, and annual salaries. The Facility section includes overhead costs such as rent, utilities, and building maintenance, while the Quality Management section covers costs associated with accreditation, certification, and

ongoing quality assurance. When all relevant data are entered correctly, the tool provides a detailed estimate of the actual cost per test, encompassing both direct and indirect expenses. By systematically accounting for all cost components, the LTCT enables laboratories and administrators to make informed decisions about resource allocation, ensuring that funding aligns with the true value and operational requirements of diagnostic services.

Value-based healthcare and the role of laboratory medicine

The economic value of laboratory medicine, therefore, extends far beyond the direct cost of individual tests. The true value lies in the clinical decisions that laboratory information enables. However, this value is often difficult to quantify. Traditional laboratory metrics, such as test volumes, turnaround times, and analytical performance, do not fully capture the broader clinical and economic impact of diagnostic information [22]. As a result, laboratory medicine has historically struggled to demonstrate its value within health policy discussions. Recognizing this challenge, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has established initiatives to study the impact of laboratory diagnostics on patient outcomes [23]. Such efforts seek to provide stronger evidence linking laboratory testing to measurable improvements in healthcare quality and efficiency.

The concept of value-based healthcare has gained increasing attention over the past decade as healthcare systems seek to balance rising costs with the need to improve patient outcomes. In its simplest form, value-based healthcare can be defined as the health outcomes achieved per unit of cost [24]. Within this framework, healthcare services are evaluated not only on cost but also on their ability to improve patient outcomes. This shift represents a fundamental departure from traditional cost-containment approaches that focus primarily on reducing expenditures. Laboratory medicine is uniquely positioned to contribute to this modern conception of value-based healthcare as it represents a relatively inexpensive intervention that can substantially influence patient management [25].

Many authors have suggested that laboratory medicine could serve as a model for implementing value-based healthcare, precisely because of its ability to influence multiple stages of the clinical pathway [26]. However, achieving this potential requires a shift in the way laboratory services are evaluated. Laboratory medicine must increasingly focus on outcome-based metrics, including diagnostic accuracy, clinical utility, patient outcomes, and cost-effectiveness [27]. These metrics require close collaboration between laboratory professionals, clinicians, and healthcare administrators. Diagnostic stewardship programs represent one promising approach to improving value in laboratory medicine. Such programs aim to optimize test utilization, ensuring that the right test is ordered for the right patient at the right time. By reducing inappropriate testing while promoting evidence-based diagnostic strategies, diagnostic stewardship can improve both clinical outcomes and healthcare efficiency.

Outsourcing of laboratory services

As healthcare systems face increasing financial pressure, policymakers have explored various strategies to improve efficiency within diagnostic services. Among these strategies, outsourcing has attracted significant attention [28].

In theory, outsourcing certain laboratory functions to specialized providers may offer advantages, including economies of scale, access to advanced technologies, and potential cost savings. Large centralized laboratories may be able to perform high volumes of tests more efficiently than smaller hospital-based laboratories. However, the potential benefits of outsourcing must be carefully balanced against potential risks. Excessive consolidation or privatization of laboratory services may lead to unintended consequences, including reduced accessibility, longer turnaround times, and decreased integration between laboratory professionals and clinical teams, ultimately compromising the proximity with the patients [29].

Laboratory medicine is not merely a technical service; it is an integral component of clinical decision-making. Close interaction between clinicians and laboratory specialists is often essential for

appropriate test selection, result interpretation, and integration of diagnostic information into patient care. Excessive centralization may weaken these interactions, potentially reducing the clinical value of laboratory services. Moreover, transportation logistics associated with centralized testing may delay result delivery, which can be critical in time-sensitive clinical situations.

Recent policy debates in several countries illustrate the complexity of these issues. For example, proposals for centralizing or privatizing laboratory services have sometimes generated controversy among healthcare professionals and policymakers. Critics argue that such reforms may prioritize economic considerations over clinical integration and patient access. These concerns highlight the importance of evaluating laboratory reforms not only in terms of short-term financial savings but also in terms of their broader impact on healthcare quality, accessibility, and patient outcomes.

Privatization and access to diagnostic services

The potential implications of full privatization of laboratory diagnostics extend beyond organizational efficiency. Privatization may fundamentally alter the relationship between healthcare systems and patients by transforming diagnostic services from public health infrastructure into market commodities [30].

In healthcare systems where access to services depends heavily on private insurance or out-of-pocket payments, this transformation may create barriers to timely diagnosis and treatment. Diagnostic testing may become less accessible to vulnerable populations, potentially exacerbating health inequalities [31]. One striking example can be observed in healthcare systems with limited universal coverage. In the United States, for example, patients without adequate health insurance may face extremely high costs for medical care, including diagnostic services. In acute conditions such as myocardial infarction, the combined costs of diagnostic testing, emergency care, and hospitalization may exceed tens of thousands of dollars [32]. Such financial burdens can lead to what has been termed financial toxicity, a concept originally developed in oncology to describe the economic distress experienced by patients facing high medical costs. Financial toxicity may influence patient behavior, leading some individuals to delay seeking medical care even when experiencing serious symptoms [33].

These observations raise important ethical questions about the organization of diagnostic services. Access to essential diagnostic testing should ideally be determined by clinical need rather than by the patient's financial resources. Then, recent history provides cautionary examples of what can go wrong when promises of private technological innovations are not scientifically validated. The Theranos saga is perhaps the most dramatic illustration of the potential risks associated with aggressive privatization and overhyped diagnostic innovation [34]. Theranos, founded in 2003, promised to revolutionize laboratory medicine with technology that could perform hundreds of blood tests using only a few drops of blood. The company raised billions in investment, and its CEO became a household name. However, investigations revealed that the technology was largely unproven, test results were unreliable, and standard validation procedures were ignored. Operational shortcuts, secrecy, and lack of peer-reviewed evidence ultimately led to the company's collapse [35]. Thus, the Theranos case provides several key lessons for laboratory medicine (Table 1) [36]. First, technologies must undergo rigorous scientific validation, supported by peer-reviewed evidence, before clinical implementation. Second, operational transparency is essential to maintain quality, trust, and regulatory compliance. Third, economic models must be sustainable to protect both patient safety and service viability. Finally, robust regulation and oversight are critical to prevent unsafe or ineffective technologies from entering clinical practice.

These lessons underscore that outsourcing or private partnerships in laboratory medicine must be approached cautiously. While collaboration with private entities may bring access to specialized expertise, economies of scale, or innovative technologies, these opportunities must be balanced against the risks to quality, reliability, and patient safety. An open discussion of such strategies should

take place in both the scientific literature and public forums, so that the benefits and potential harms are understood [37].

Table 1

Ensuring Safe, Transparent, and Effective Diagnostic Innovation

Key Principle	Summary
Scientific validation	Technologies must undergo rigorous analytical testing and peer-reviewed evaluation before clinical use.
Operational transparency	Open processes are essential to maintain quality control, public trust, and regulatory compliance.
Sustainable economic models	Growth and expansion must be financially and operationally viable to protect patient safety.
Regulation and oversight	Independent oversight is required to prevent unsafe or ineffective technologies from reaching clinical practice.

The future of laboratory medicine in precision healthcare

Looking toward the future, the importance of laboratory medicine is expected to increase even further as healthcare enters the era of precision medicine [38]. Advances in genomics, proteomics, metabolomics, and molecular diagnostics are rapidly expanding the range of clinical decisions that rely on laboratory data. In oncology, for example, molecular diagnostics now play a central role in identifying actionable genetic mutations that guide targeted therapies [39]. Similarly, immunotherapy monitoring requires sophisticated laboratory tests capable of evaluating immune responses and predicting treatment outcomes [40]. These recent developments illustrate how laboratory medicine increasingly serves as the interface between biomedical research and clinical practice. As new diagnostic technologies emerge, laboratory professionals will play a critical role in translating scientific discoveries into clinically useful tools. At the same time, the increasing complexity of diagnostic technologies underscores the importance of maintaining strong expertise within laboratory medicine. Interpretation of advanced molecular tests often requires specialized knowledge that extends beyond simple analytical measurement. Consequently, preserving the clinical integration of laboratory professionals within healthcare systems will remain essential to ensure that diagnostic innovations translate into improved patient outcomes [41].

Conclusion

As healthcare systems face increasing complexity, rising costs, and unprecedented challenges, the role of laboratory medicine has never been more central [42], yet its true impact is often underestimated in policy and budget discussions. Despite accounting for only about 1% of healthcare expenditure, laboratory results influence nearly every diagnostic and therapeutic decision, making them among the most efficient and high-leverage investments in patient care. To sustain and enhance this role, it is essential that laboratories demonstrate value systematically. This includes evaluating clinical impact, measuring outcomes, documenting economic efficiency, and ensuring transparency in operations. By making the value of laboratory medicine visible to clinicians, administrators, and policymakers, we can strengthen its position as a strategic partner rather than a perceived cost center.

At the same time, caution is warranted when considering approaches such as aggressive outsourcing, excessive consolidation, or full privatization. Experiences such as the attempted laboratory privatization in some countries and the cautionary tale of Theranos illustrate that efficiency and innovation must always be balanced against quality, access, and public accountability.

Operational shortcuts, lack of scientific validation, or opaque business models can compromise patient safety and erode trust.

Looking ahead, the importance of laboratory diagnostics will only grow. From innovative biomarkers to immunotherapy monitoring, the ability to measure what truly matters will be essential to translating scientific innovation into meaningful patient outcomes. Improving value-based healthcare in laboratory medicine is therefore not about indiscriminate cost-cutting, but about systematically measuring impact, ensuring transparency and accountability, and maintaining laboratory medicine at the heart of a sustainable, equitable, and patient-centered healthcare system (Figure 5).

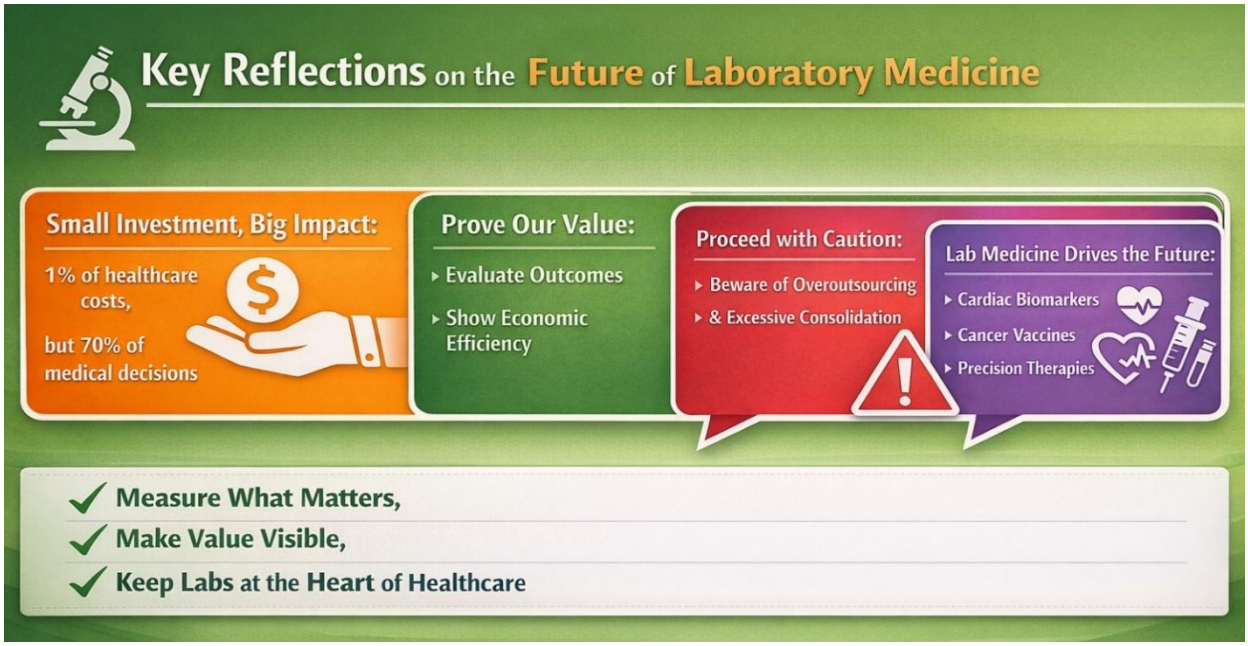

Figure 5. Laboratory medicine: maximizing impact and value in healthcare.

By doing so, we can safeguard the critical role of diagnostics as both a driver of clinical excellence and a cornerstone of modern medicine.

Research Funding. None declared.

Conflict of Interest. The author declares no conflict of interest.

REFERENCES

1. Wolf HF 3rd. Global Healthcare Enters a Transformative Era of Accelerating Technology. Front Health Serv Manage. 2025 Summer 01;41(4):34-39. doi: 10.1097/HAP.0000000000000219.
2. Lippi G, Cadamuro J, Danese E, Favaloro EJ, Favresse J, Henry BM, Jovičić S, Ozben T, Plebani M, Thachil J. Results of the first survey of the EFLM Task Force Preparation of Labs for Emergencies (TF-PLE). Clin Chem Lab Med. 2023 Jun 29;61(12):e235-e238. doi: 10.1515/cclm-2023-0622.
3. Lippi G, Henry BM, Mattiuzzi C. The Crucial Role of Laboratory Medicine in Addressing Future Public Health Infectious Threats: Insights Gained from the COVID-19 Pandemic. Diagnostics (Basel). 2025 Jan 30;15(3):323. doi: 10.3390/diagnostics15030323.
4. Olver P, Bohn MK, Adeli K. Central role of laboratory medicine in public health and patient care. Clin Chem Lab Med. 2022 Nov 28;61(4):666-673. doi: 10.1515/cclm-2022-1075.
5. Arshoff L, Hoag G, Ivany C, Kinniburgh D. Laboratory medicine: The exemplar for value-based healthcare. Healthc Manage Forum. 2021 May;34(3):175-180. doi: 10.1177/0840470421990041.
6. Forsman RW. Why is the laboratory an afterthought for managed care organizations? Clin Chem. 1996 May;42(5):813-6.
7. Hallworth MJ. The '70% claim': what is the evidence base? Ann Clin Biochem. 2011 Nov;48(Pt 6):487-8. doi: 10.1258/acb.2011.011177.

8. Lord SJ, Horvath AR, Sandberg S, Monaghan PJ, M Cobbaert C, Reim M, Tolios A, Mueller R, Bossuyt PM. Is this test fit-for-purpose? Principles and a checklist for evaluating the clinical performance of a test in the new era of in vitro diagnostic (IVD) regulation. Crit Rev Clin Lab Sci. 2025 May;62(3):182-197. doi: 10.1080/10408363.2025.2453148.
9. Magiorkinis E, Diamantis A. The fascinating story of urine examination: From uroscopy to the era of microscopy and beyond. Diagn Cytopathol. 2015 Dec;43(12):1020-36. doi: 10.1002/dc.23370.
10. Eknoyan G, Nagy J. A history of diabetes mellitus or how a disease of the kidneys evolved into a kidney disease. Adv Chronic Kidney Dis. 2005 Apr;12(2):223-9. doi: 10.1053/j.ackd.2005.01.002.
11. Lippi G, Lavie CJ, Sanchis-Gomar F. Detecting cardiac injury: the next generation of high-sensitivity cardiac troponins improving diagnostic outcomes. Clin Chem Lab Med. 2025 May 5;63(10):1941-1951. doi: 10.1515/cclm-2025-0418.
12. Chairaj T, Mongkhon P, Leewongsakorn P, Saensongkwae K, Nangola S, Saoin S, Prompunt E, Chantharit P, Kloypan C. Diagnostic performance of procalcitonin and presepsin in sepsis: a systematic review and meta-analysis. BMC Emerg Med. 2025 Dec 4;26(1):9. doi: 10.1186/s12873-025-01433-3.
13. Miranda D, Holznienkemper L. 10 Most Profitable Businesses Today. Available at: https://www.forbes.com/advisor/business/most-profitable-businesses/. Last accessed, March 7, 2026.
14. Lippi G, Plebani M. Cost, profitability and value of laboratory diagnostics: in God we trust, all others bring data. J Lab Med 2019;43(1):1-3. doi: 10.1515/labmed-2018-0321.
15. Lippi G, Da Rin G. Advantages and limitations of total laboratory automation: a personal overview. Clin Chem Lab Med. 2019 May 27;57(6):802-811. doi: 10.1515/cclm-2018-1323.
16. Rohr UP, Binder C, Dieterle T, Giusti F, Messina CG, Toerien E, Moch H, Schäfer HH. The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. PLoS One. 2016 Mar 4;11(3):e0149856. doi: 10.1371/journal.pone.0149856.
17. Lippi G, Plebani M. The add value of laboratory diagnostics: the many reasons why decision-makers should actually care. J Lab Precis Med 2017;2:100. doi: 10.21037/jlpm.2017.12.07.
18. Pennestrì F, Banfi G. Value-based healthcare: the role of laboratory medicine. Clin Chem Lab Med. 2019 May 27;57(6):798-801. doi: 10.1515/cclm-2018-1245.
19. Plebani M, Coskun A. Promoting value-based laboratory medicine: Moving towards an innovative model of clinical laboratory. Clin Chim Acta. 2025 May 15;572:120269. doi: 10.1016/j.cca.2025.120269. Epub 2025 Mar 27.
20. Plebani M, Cadamuro J, Vermeersch P, Jovičić S, Ozben T, Trenti T, McMillan B, Lowe CR, Lennerz J, Macintyre E, Gabelli C, Sandberg S, Padoan A, Wiencek JR, Banfi G, Lubin IM, Orth M, Carobene A, Zima T, Cobbaert CM, van Schaik RHN, Lippi G. A vision to the future: value-based laboratory medicine. Clin Chem Lab Med. 2024 Sep 13;62(12):2373-2387. doi: 10.1515/cclm-2024-1022.
21. World Health Organization. Laboratory test costing tool (LTCT). Available at: https://www.who.int/europe/tools-and-toolkits/laboratory-test-costing-tool-(ltct). Last accessed, March 7, 2026.
22. Jordan B, Mitchell C, Anderson A, Farkas N, Batrla R. The Clinical and Health Economic Value of Clinical Laboratory Diagnostics. EJIFCC. 2015 Jan 27;26(1):47-62.
23. Olver P, Bohn MK, Adeli K. Central role of laboratory medicine in public health and patient care. Clin Chem Lab Med. 2022 Nov 28;61(4):666-673. doi: 10.1515/cclm-2022-1075.
24. Porter ME. What is value in health care? N Engl J Med. 2010 Dec 23;363(26):2477-81. doi: 10.1056/NEJMp1011024.
25. Plebani M, Langlois M, von Meyer A, Vermeersch P, Zaninotto M, Smeets RL, Padoan A, Cubukcu HC, Monaghan PJ, Coşkun A, Orth M, Thelen M. Science, Quality and Value of Laboratory Medicine. Clin Chem Lab Med. 2026 Jan 22;64(4):797-805. doi: 10.1515/cclm-2026-0041.
26. St John A. The Pursuit of Value in Laboratory Medicine - Progress and Challenges. Clin Biochem Rev. 2020 Feb;41(1):3-11. doi: 10.33176/AACB-19-00035.
27. Tomaiuolo R, Banfi G. Value is equal to outcome/costs: how to apply to laboratory medicine. Clin Chem Lab Med. 2025 Sep 10;64(2):284-289. doi: 10.1515/cclm-2025-0691.
28. Mrak RE, Parslow TG, Tomaszewski JE. Outsourcing of Academic Clinical Laboratories: Experiences and Lessons From the Association of Pathology Chairs Laboratory Outsourcing Survey. Acad Pathol. 2018 Apr 2;5:2374289518765435. doi: 10.1177/2374289518765435.
29. Chasin BS, Elliott SP, Klotz SA. Medical errors arising from outsourcing laboratory and radiology services. Am J Med. 2007 Sep;120(9):819.e9-11. doi: 10.1016/j.amjmed.2006.07.024.
30. Barletta G, Zaninotto M, Faggian D, Plebani M. Shop for quality or quantity? Volumes and costs in clinical laboratories. Clin Chem Lab Med. 2013 Feb;51(2):295-301. doi: 10.1515/cclm-2012-0415.
31. Lippi G, Mattiuzzi C. Testing volume is not synonymous of cost, value and efficacy in laboratory diagnostics. Clin Chem Lab Med. 2013 Feb;51(2):243-5. doi: 10.1515/cclm-2012-0502.
32. Scott KW, Scott JW, Sabbatini AK, Chen C, Liu A, Dieleman JL, Duber HC. Assessing Catastrophic Health Expenditures Among Uninsured People Who Seek Care in US Hospital-Based Emergency Departments. JAMA Health Forum. 2021 Dec 30;2(12):e214359. doi: 10.1001/jamahealthforum.2021.4359.

33. Zafar SY, Abernethy AP. Financial toxicity, Part I: a new name for a growing problem. Oncology (Williston Park). 2013 Feb;27(2):80-1, 149.
34. Lackner KJ, Gillery P, Lippi G, Melichar B, Schlattmann P, Tate JR, Plebani M. The Theranos phenomenon, scientific transparency and freedom of speech. Clin Chem Lab Med. 2016 Sep 1;54(9):1403-5. doi: 10.1515/cclm-2016-0520.
35. Diamandis EP. Theranos phenomenon: promises and fallacies. Clin Chem Lab Med. 2015 Jun;53(7):989-93. doi: 10.1515/cclm-2015-0356.
36. Diamandis EP, Lackner KJ, Plebani M. Theranos revisited: the trial and lessons learned. Clin Chem Lab Med. 2021 Sep 17;60(1):4-6. doi: 10.1515/cclm-2021-0994.
37. Mrak RE, Parslow TG, Tomaszewski JE. Outsourcing of Academic Clinical Laboratories: Experiences and Lessons From the Association of Pathology Chairs Laboratory Outsourcing Survey. Acad Pathol. 2018 Apr 2;5:2374289518765435. doi: 10.1177/2374289518765435.
38. Lippi G, Bassi A, Bovo C. The future of laboratory medicine in the era of precision medicine. J Lab Precis Med 2016;1:7. 10.21037/jlpm.2016.12.01.
39. Riedl JM, Moik F, Esterl T, Kostmann SM, Gerger A, Jost PJ. Molecular diagnostics tailoring personalized cancer therapy-an oncologist's view. Virchows Arch. 2024 Feb;484(2):169-179. doi: 10.1007/s00428-023-03702-7.
40. Lippi G, Mattiuzzi C, Beffagna G. Cancer vaccines and immune monitoring: shaping the future of cancer treatment. J Lab Precis Med 2025;10:17. 10.21037/jlpm-25-44.
41. Lubin IM, Astles JR, Shahangian S, Madison B, Parry R, Schmidt RL, Rubinstein ML. Bringing the clinical laboratory into the strategy to advance diagnostic excellence. Diagnosis (Berl). 2021 Jan 6;8(3):281-294. doi: 10.1515/dx-2020-0119.
42. Lippi G, Plebani M. Integrated diagnostics: the future of laboratory medicine? Biochem Med (Zagreb). 2020 Feb 15;30(1):010501. doi: 10.11613/BM.2020.010501.

УДК: 616-074:614.2
DOI: 10.62151/2786-9288.4.1-2.2026.03

Giuseppe Lippi
Секція клінічної біохімії, Університет Верони, Верона, Італія

ЛАБОРАТОРНА МЕДИЦИНА НА РОЗДОРІЖЖІ: ЦІННІСТЬ, ПРИВАТИЗАЦІЯ ТА МАЙБУТНЄ ДІАГНОСТИЧНОГО УПРАВЛІННЯ

Резюме

Лабораторна медицина займає особливе місце в сучасній системі охорони здоров'я. Попри відносно невелику частку у структурі медичних витрат, лабораторні дослідження *in vitro* є невід'ємною складовою скринінгу, діагностики, вибору лікувальної тактики та моніторингу перебігу захворювань. Зростання фінансового навантаження на системи охорони здоров'я в усьому світі посилює дискусії щодо аутсорсингу, приватизації та консолідації лабораторних послуг як можливих шляхів підвищення ефективності їхнього функціонування.

Водночас перехід до ціннісно-орієнтованої моделі охорони здоров'я вимагає від усіх медичних спеціальностей чітких доказів їхнього клінічного та економічного внеску. У цій дискусійній статті розглянуто економічний парадокс лабораторної медицини, проаналізовано потенційні наслідки приватизації та аутсорсингу діагностичних послуг, а також обґрунтовано зростаюче стратегічне значення лабораторної діагностики в епоху прецизійної медицини.

Підвищення цінності лабораторної медицини в межах концепції ціннісно-орієнтованої системи охорони здоров'я не повинно зводитися до механічного скорочення витрат. Натомість воно передбачає систематичне оцінювання результатів, прозору демонстрацію клінічної цінності лабораторних досліджень та впровадження ефективних моделей управління, здатних забезпечити належну якість і доступність лабораторних послуг. Лабораторна медицина має залишатися одним із ключових елементів сталої та справедливої системи охорони здоров'я.

Ключові слова: *лабораторна медицина, якість, цінність, витрати.*

Email for correspondence: giuseppe.lippi@univr.it
ORCID IDs: Giuseppe Lippi https://orcid.org/0000-0001-9523-9054