Opinion Paper

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Improving diagnosis in health care: laboratory medicine

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Abstract: Accurate and timely diagnosis remains one of the most complex and challenging processes in medicine. Diagnostic errors pose a significant burden on patients and healthcare systems, with laboratory-related errors playing a substantial role, especially in the pre- and post-analytical phases of the testing process. However, recent innovations have mitigated some key challenges by optimizing workflows and reducing human errors. Notable advancements include automated systems for specimen check-in, preparation, aliquoting and storage for downstream analysis. Technologies such as automated interference detection, alongside sensors monitoring specimen volume and integrity, have enhanced standardization and reliability. Automated sample storage and retrieval systems have improved traceability and retrospective analyses while preserving specimen integrity. In the analytical phase, automation has facilitated real-time anomaly detection, enabling reflex or repeat testing to ensure result accuracy. The multiple integration of different analytical platforms, coupled with automated quality control features, has reduced inter-system variability, minimized manual errors and enhanced efficiency. Advancements in molecular and genetic diagnostics have enabled more precise and personalized treatments, reducing ineffective therapies and side effects. The ongoing deployment of lab-on-a-chip technology, integration of artificial intelligence, and reinforced patient safety culture highlight the vital role of continuous innovation in laboratory medicine to enhance patient safety. However, several challenges remain, including diagnostic errors from test result misinterpretation, poor sample quality, regulatory and compliance constraints, limited data sharing among laboratories, high cost of advanced diagnostic tools and shortage of trained laboratory professionals and pathologists. Addressing these barriers is essential for further safeguarding patient safety.

Keywords: diagnostic errors; patient safety; innovation; laboratory medicine

Introduction

Laboratory diagnostics is an essential branch of science and medicine, as diagnostics tests are fundamental to both scientific research and clinical decision-making. Like all other fields of modern medicine, diagnostic testing is not exempted from the risk of errors that may compromise the quality of results as well as patient safety. Clinical laboratory professionals have unique expertise regarding the availability, uses and limitations of tests, expertise that can help clinicians with test selection and interpretation of results to optimize patient management [1]. “Improving Diagnosis in Health Care” [2], the 2015 publication that followed the milestone report “To Err Is Human” published by the Institute of Medicine in 2000 [3], established that diagnostic errors have been underappreciated as threats to quality and safety in health care. It also established that most diagnostic errors are preventable. Ten years after the publication of that report, this manuscript provides an update from the laboratory medicine perspective, describing progress, remaining problems, future priorities, and key actors.

Progress over the past 10 years

Advancements in laboratory medicine have improved diagnostic accuracy and patient outcomes over the past decade. This includes advances in automation, genomic medicine and molecular diagnostics, artificial intelligence (AI) and machine learning, and digitalization, as well as improved culture of patient safety, e.g., through acknowledgment of the importance of reporting, learning

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Table 1: Recent advancements in laboratory medicine.

Advancement area	Impact on laboratory medicine
Automation	Improved efficiency, reduced human error, and increased throughput of laboratory testing.
Genomic medicine and molecular diagnostics	More precise diagnostics, personalized treatment, and better understanding of diseases at a genetic level.
Artificial intelligence and machine learning and digitalization	Enhanced diagnostic accuracy, e.g. through real-time data verification, validation, and interpretation. AI-based image analysis can improve detection and classification of cells and other elements in body fluids. AI can also support predictive analytics, early disease detection, and personalized treatment.
Patient safety culture	Broader appreciation for the importance of diagnostic quality in patient safety has led to better error reporting, learning systems that improve healthcare outcomes, and improving the integration of clinical laboratory professionals into the patient care team.

Table 2: Advancements in laboratory automation and their impact on patient safety.

Feature	Examples	Benefits
Pre-analytical automation	Automated specimen check-in, centrifugation, aliquoting, and HIL detection sensors	Reduction of clerical errors, increased standardization
Analytical process automation	Reflex/repeat testing algorithms, automated QC management, reagent cassettes with embedded QC	Enhanced accuracy, minimized human intervention, and real-time error detection.
Sample storage & retrieval	Automated biorepositories with real-time tracking and retrieval capabilities	Efficient long-term sample management, reduced loss or misplacement
Integrated analytical platforms	Direct connection of clinical chemistry, immunochemistry, genetic testing, and LC-MS analyzers	Improved workflow efficiency and reduced inter-system variability.
Patient safety	Standardized processes for data management and quality management,	Rapid result turnaround, enhanced traceability, faster clinical decisions, improved patient outcomes

from errors, and improving the integration of clinical laboratory professionals into the patient care team (Table 1).

Advancements in laboratory automation and their impact on diagnostics

Laboratory automation has made significant advancements in recent years (Table 2), which have improved the reliability of preanalytical processes [4]. It is now widely acknowledged that a substantial proportion of testing errors – estimated to be as high as 70% – originate from the preanalytical phase [5]. This phase encompasses all processes and activities preceding sample analysis, such as specimen collection, handling and preparation. Errors in this phase often stem from manually intensive tasks, including sample labeling, transport and processing [6]. Preanalytical errors, including errors in specimen collection, preparation, labelling and transport, are particularly common in patient care areas that are not under the direct management of clinical laboratories.

Modern laboratories now routinely integrate multiple levels of automation that address specimen check-in, preparation for testing (e.g., automated centrifugation for serum or plasma separation), and aliquoting for subsequent offline analysis or storage for future re-testing or storage in biobanks [7]. Automated sample verification can include hemolysis, icterus and lipemia (HIL) detection, as well as sensors to measure specimen volume and detect bubbles or clots [8]. Implementing these tools reduces the risk of human (mainly clerical) errors and enhances the standardization of preanalytical workflows, improving diagnostic accuracy and efficiency.

Laboratory automation has also been applied to analytical phase processes. For instance, modern laboratory analyzers incorporate sophisticated algorithms to identify anomalous analytical reactions in real-time, which can then trigger reflex or repeat testing based on predefined criteria, thereby ensuring result reliability and reducing the need for manual interventions [9]. Additionally, automated quality control (QC) management has emerged as a transformative feature, wherein analyzers can now schedule and perform QC assessments at fixed intervals, automatically flagging deviations and mitigating errors. Some recent analyzers also use reagent cassettes, including pre-configured internal QCs, eliminating the need for human intervention and enhancing reproducibility [10].

An important breakthrough in laboratory automation has been the development of automated sample storage and retrieval systems, which enable laboratories to efficiently manage vast repositories of biological specimens while providing real-time tracking and retrieval capabilities. This facilitates seamless sample re-evaluation, retrospective

analysis and research, without compromising integrity or traceability [11]. Another advance in laboratory automation is the integration of multiple analytical platforms encompassing very different analytical techniques. While clinical chemistry and immunochemistry platforms have traditionally been consolidated, new technological frameworks allow the direct integration of genetic testing and liquid chromatography-mass spectrometry (LC-MS) analyzers within a total laboratory automation (TLA) model [12]. This integration enhances patient safety by reducing inter-system variability, minimizing manual handling errors, saving patient blood, reducing turnaround times and improving overall laboratory throughput, thus redefining modern laboratory operations and making them more efficient, accurate and scalable.

Advancements in molecular and genetic testing and their impact on patient safety

Molecular and genetic testing is revolutionizing healthcare by enabling earlier and more accurate diagnoses, personalized treatments, and improved disease prevention strategies (Table 3). Next-generation sequencing (NGS) allows for comprehensive genetic analysis, facilitating better characterization of various types of cancers and screening for rare diseases and hereditary conditions [13]. However, the implementation of NGS varies among clinical laboratories, and guidance and standards are evolving. For example, laboratories vary in their identification and reporting of potential disease-associated variants, requiring the need for clinicians who use these tests to have a clear understanding of limitations. Innovative technologies like Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), especially CRISPR-Cas9 and Cas12/Cas13 systems, can be engineered for identifying specific genetic sequences and detecting pathogens or mutations in genetic material [14]. The test format can be easily adapted to fit portable diagnostic platforms (i.e., point-of-care instrumentation), reducing the need for specialized lab equipment [15]. Single-cell sequencing provides detailed insights into individual cell genetic makeup, enabling a better understanding of disease progression and accurate personalization of therapies [16].

Table 3: Advancements in molecular and genetic testing and their impact on patient safety.

Advancement	Impact on patient safety
Next-generation sequencing (NGS)	Improved detection of hereditary conditions and cancer
Liquid biopsies	Non-invasive cancer monitoring and diagnosis
Pharmacogenomics	Reduced adverse drug reactions, optimized drug selection
Targeted therapies	Personalized treatment with fewer side effects; avoidance of less-effective treatments
Carrier screening	Identification of hereditary risks for informed family planning
Prenatal/Newborn screening	Early intervention for genetic and other conditions
Rapid pathogen detection	Faster and more targeted therapy for infections
Genetic risk assessment tools	Proactive management of patients at high risk for cancers or other diseases

Microfluidics technology is the foundation of Lab-on-a-Chip (LoC) systems, enabling the deployment of fast and highly accurate assays [17]. Miniaturized systems require less sample volume and can reduce errors, contamination and reagent waste [18]. These platforms can also support the simultaneous detection of multiple biomarkers, enabling more comprehensive and “green” diagnoses. This technology is also particularly suited for expanding access to diagnostics accessibility in underserved areas such as rural areas and low-income countries [19].

Liquid biopsy represents a promising and non-invasive method for detecting and monitoring cancer biomarkers, offering several practical and clinical advantages over traditional tissue biopsies [20]. Unlike tissue biopsies, which often require invasive procedures to collect specimens, liquid biopsies only need a simple blood draw, making the diagnostic process safer, faster, and more comfortable for patients while significantly lowering the risk of infection or complications. Liquid biopsies also play a crucial role in identifying minimal residual disease, detecting traces of cancer that may persist after treatment, and aiding in early relapse prediction [21]. As research and technological advancements continue, liquid biopsy is expected to become an essential tool in routine management of cancer patients, improving patient outcomes and advancing the era of personalized medicine. Another key advantage of liquid biopsies is their potential for real-time, continuous monitoring of disease progression. By providing dynamic insights into how a cancer evolves or responds to treatment, liquid biopsies may enable personalized and adaptive treatment strategies, detecting genetic mutations associated with resistance to targeted therapies, allowing oncologists to adjust treatment plans before resistance fully develops [22].

Pharmacogenomics, traditionally defined as the study of how an individual genetic makeup may influence response to certain drugs, can enable the tailoring of therapies based on genetic variations that influence drug metabolism,

efficacy, and potential side effects [23]. In simple terms, pharmacogenomics refers to identifying genetic markers that can guide the selection of the most appropriate therapeutic agents and dosing regimens, thus minimizing the risk of side effects and optimizing treatment outcomes [24]. Clopidogrel, a widely prescribed antiplatelet medication for patients at risk of thrombotic events, is one of the many examples of the potential usefulness of pharmacogenomics in clinical practice [25]. The efficacy of clopidogrel is highly influenced by genetic polymorphisms in the *CYP2C19* gene, which encodes the enzyme responsible for converting the drug into its active metabolite. Patients with genetic variations that impair *CYP2C19* activity (i.e., "poor metabolizers") may not achieve the expected therapeutic benefit from the standard dose of the drug [26].

Prevention of genetic disorders has also improved with carrier screening, which allows the identification of individuals at higher risk of transmitting severe hereditary conditions, aiding in informed reproductive choices [27]. Prenatal and newborn screening also allows early detection of genetic abnormalities, enabling the use of timely interventions and management to reduce the risk of developing more severe complications [28]. For example, with early diagnosis of Spinal Muscular Atrophy (SMA) and Severe Combined Immunodeficiency (SCID), early interventions can dramatically improve outcomes [29, 30]. For SMA, newborn screening is now part of routine practices worldwide, where a single capillary blood test can detect deletions or mutations in the *SMN1* gene. When SMA is suspected, genetic testing can confirm the diagnosis and determine type and severity, enabling timely treatments (e.g., gene therapy, which provides functional copies of the *SMN1* gene and prevents further motor neuron degeneration) [31]. In SCID, newborn screening involves testing for low T-cell receptor excision circles (TRECs), which reflects impaired T-cell production. Positive screening results prompt genetic testing to identify the specific mutation responsible for SCID, which can guide treatment, including bone marrow transplantation or gene therapy [32]. Early diagnosis of both conditions, made possible through newborn screening and genetic testing, significantly enhances the likelihood of successful treatment and better long-term health outcomes.

Infection control has been enhanced by rapid pathogen detection technologies [33] that aid in managing outbreaks, inside and outside the hospital environment, as early and accurate detection can significantly influence the outcome of containment measures and overall patient safety. For example, the global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) highlighted the importance of rapid diagnostic testing. Real-time polymerase chain reaction (RT-PCR) tests, rapid antigen tests, and other diagnostic innovations allowed healthcare providers to quickly identify infected individuals, even before symptoms appeared [34]. This allows healthcare workers to isolate infected patients promptly, reducing transmission (including within healthcare facilities). Identifying pathogens responsible for hospital-acquired infections enables healthcare facilities to implement specific infection control practices, such as isolating infected patients and thoroughly disinfecting affected areas, preventing further spread within the hospital setting [35].

Rapid pathogen detection is critical in controlling multidrug-resistant organisms (MDROs) [36]. The World Health Organization (WHO) has long warned about the consequences of antimicrobial resistance (AMR), calling for immediate global action [37]. AMR makes infections more challenging to treat and leads to longer hospital stays, more intensive care and increased mortality [38]. Thus, it is essential to identify bacterial and fungal strains and determine whether they are resistant to specific antibiotics and antifungals [39].

Nonetheless, genetic testing requires robust ethical standards and regulatory frameworks to prevent commercializing tests with uncertain diagnostic utility, such as multi-cancer detection assays that claim to detect a broad spectrum of cancers. Both false-positive and false-negative results could lead to patient harm [40].

Advancements in artificial intelligence and machine learning and their impact on patient safety

AI, machine learning (ML), and digital pathology have the potential to profoundly transform various aspects of healthcare, including contributing to improved patient safety [41]. AI-driven tools, particularly deep learning models (DLMs), have been used to analyze medical images, pathology slides, clinical data, and laboratory results. In laboratory hematology, the adoption of AI-driven digitalized systems for blood cell classification has surged, making them an integral component of modern diagnostic instrumentation [42]. Automated blood smear production has standardized the process, minimizing inter-human variability and improving reproducibility [43]. AI-powered classification tools improve accuracy by detecting subtle morphological abnormalities that may be overlooked by human observers, facilitating the early detection of hematological disorders such as anemia, leukemia and infections. These systems also streamline laboratory workflows, reducing turnaround times and optimizing resource utilization [42].

AI may also improve laboratory data verification, validation and interpretation [44]. In data verification, AI-driven systems can be instructed to cross-check laboratory results in real time, identifying preanalytical errors (e.g., sample mislabeling, contamination, or inadequate volume) and flagging potential instrument malfunctions. For data validation, AI can compare longitudinal test results against patient history, identifying discrepancies between new results and prior patient records. AI-powered decision support systems can suggest repeat testing when results are incongruent with clinical expectations, ensuring that test outcomes align with disease patterns and reducing inaccuracies [45].

In laboratory medicine, AI has the potential to expand algorithmic test ordering. [46]. Laboratory diagnostics has long relied on standardized protocols and manual interpretation of results, and the integration of automated diagnostic algorithms within laboratory instrumentation or the laboratory information system (LIS) introduces a dynamic approach. Especially in high-throughput laboratories, AI-driven diagnostic algorithms can help optimize test scheduling and resource allocation, enabling faster turnaround time and improved operational efficiency. For example, consider the long-standing "TSH-reflex". In traditional thyroid function testing, thyroid-stimulating hormone (TSH) is often used as the first-line screening test. According to the "TSH-reflex", when TSH levels fall outside a predefined reference range, additional tests – such as free T4 and sometimes free T3 – are automatically performed to assess whether the abnormality underlines conditions like hypothyroidism or hyperthyroidism. This reflex testing approach reduces unnecessary assays, conserves time and biological samples, and enhances patient convenience by minimizing the need for additional blood draws if further testing is warranted based on initial results [47].

In terms of data interpretation, AI may enhance clinical insights by identifying early disease markers for faster and more efficient diagnoses, and correlating multiple biomarkers to refine differential diagnoses and supporting personalized medicine by integrating laboratory data with genetic, imaging and clinical information [48].

Challenges remain in the use and implementation of AI in clinical laboratory settings [49]. First, not all clinical laboratories are positioned to integrate AI into their workflow. Second, for those applications in which population-level data is required to inform result interpretation or application of a diagnostic algorithm, the dataset may be incomplete. Patient and family-level data may not be readily available, and population-level data is incomplete for persons of many ancestries. This does not preclude the use of AI, but rather argues for developing workflows that identify these limitations and alert users in a way that supports informed decisions.

Advancements in patient safety culture

Laboratory medicine has witnessed significant advancements in patient safety culture over the past decade, facilitated by developing and implementing robust reporting and learning systems.

Laboratory medicine has historically operated within a framework that often isolated its processes from other clinical practices. This siloed approach has sometimes led to communication gaps and errors that adversely affect patient care. After acknowledging these challenges, a concerted effort has been fostered to better integrate patient safety concepts and competencies into clinical laboratory science. Clinical laboratories have developed and implemented sophisticated reporting systems designed to capture, analyze and learn from errors [50]. These systems encourage healthcare professionals to report near misses and patient safety events, fostering a culture of transparency and continuous improvement. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Model of Quality Indicators (MQI) in laboratory medicine, originally designed to monitor performance across different phases of laboratory testing [51], has been increasingly applied to more laboratories, standardizing error detection and recording, helping laboratories to identify the most important areas of improvement opportunities, and enabling benchmarking between institutions [52]. The Agency for Healthcare Research and Quality (AHRQ) has promoted Patient Safety Learning Laboratories (PSLLs). These laboratories adopt a multidisciplinary approach, using systems engineering to identify and address safety vulnerabilities. By fostering collaboration among healthcare providers, educators and policymakers, PSLLs aim to develop innovative solutions that enhance patient safety [53]. The Centers for Disease Control and Prevention (CDC) has introduced the "Core Elements of Hospital Diagnostic Excellence" to improve hospital diagnoses [54]. These elements include leadership commitment, multidisciplinary expertise, and continuous monitoring [55].

Another innovation that has gained momentum over the past several years is the concept of the diagnostic management team. The concept is based on the recognition that clinical laboratory expertise can provide invaluable insights to clinicians in diagnosis and patient management and, in particular, may reduce diagnostic errors attributable to laboratory testing [56]. These insights are most effectively incorporated into patient care when laboratory

professionals are recognized as important members of the healthcare team and actively contribute to the care of the patient beyond providing a written or electronic copy of test results. This can include test selection, specimen collection, preparation, transport and result interpretation, all of which have been documented to be important sources of errors that affect patient safety [57]. Tumor boards and antimicrobial/antibiotic stewardship teams illustrate the diagnostic management team concept in that clinical laboratory professionals collaborate with clinicians on patient care decisions.

Remaining challenges

Despite these advancements, a number of residual challenges persist, and diagnostic errors due to misinterpretation of test results, poor sample quality and cognitive (interpretation) errors continue to be a tangible concern. Many rural and underserved populations lack access to advanced laboratory testing and specialized diagnostic services, creating disparities in healthcare. Regulatory and compliance challenges hinder innovation and implementation of new technologies, while interoperability issues continue to affect data sharing among laboratories, healthcare providers, and electronic health record systems. The high cost of advanced diagnostic tools and testing methodologies limits their widespread adoption, particularly in low-resource settings. Furthermore, a shortage of trained laboratory professionals and pathologists strains healthcare systems globally. While automation and AI have improved standardization, variability still exists in preanalytical practices, especially in smaller or resource-limited laboratories. Despite improvements, fostering a universally strong patient safety culture, with transparent reporting of errors and near misses, remains a challenge, as does interprofessional collaboration. As laboratory medicine continues to evolve, it is important to ensure that healthcare professionals stay updated with new technologies (e.g., enhanced automation, miniaturization, AI, etc.), regulatory changes and best practices. Addressing these challenges will require ongoing investment in technology, education and regulatory frameworks, alongside a commitment to fostering a culture of continuous improvement and patient-centered care.

Future priorities

Moving forward, several priorities should be emphasized further to improve laboratory medicine and its role in diagnostics. Continued investment in AI-driven diagnostics, miniaturization and robotic automation can reduce errors and improve efficiency. Establishing global standards for laboratory preanalytical procedures will ensure consistency and reliability. Advancing highly efficient molecular testing techniques will accelerate the progress of personalized medicine and strengthen the fight against AMR. Training and recruiting more laboratory professionals will be crucial in addressing workforce shortages. Laboratory professionals need to build a business case for investing in clinical laboratory expertise and capabilities based on improving patient management and outcomes while reducing downstream healthcare costs.

Key groups and agencies and their roles

National and international organizations play a critical role in shaping the future of laboratory medicine and diagnostics. The WHO and the Clinical and Laboratory Standards Institute (CLSI) are responsible for setting international standards, developing guidance, and promoting global health initiatives in laboratory medicine. The Food and Drug Administration (FDA), the European Community (EC), and other national regulatory agencies ensure the safety and efficacy of new diagnostic devices. Organizations like the Community Improving Diagnosis in Medicine (CIDM), the IFCC (together with its regional federations and the national societies of laboratory medicine), can promote education, research, and professional development through guidelines, recommendations and scientific meetings. Healthcare providers and hospitals will also be crucial in integrating laboratory advancements into clinical practice. Lastly, diagnostic companies drive innovation through technological development (e.g., new diagnostic tests, total laboratory automation, miniaturization, robotic sample collection, etc.).

Conclusions

Accurate and timely diagnosis is one of the most difficult and complex processes in medicine. Diagnostic errors impose a significant burden on patients and healthcare systems. Laboratory mistakes contribute to diagnostic errors, particularly in the pre- and post-analytical phases of the testing process. Further developments, including the use of AI tools, have the potential to improve diagnostic accuracy and patient safety further. However, a patient safety culture is a prerequisite to achieving all of these benefits.

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References

1. Lubin IM, Astles JR, Shahangian S, Madison B, Parry R, Schmidt RL, et al. Bringing the clinical laboratory into the strategy to advance diagnostic excellence. Diagnosis 2021;8:281–94.
2. Committee on Diagnostic Error in Health Care; Board on Health Care Services. Institute of medicine; the national academies of sciences, engineering, and medicine. Balogh EP, Miller BT, Ball JR, editors. Improving diagnosis in health care. Washington (DC): National Academies Press (US); 2015. Available from: https://www.ncbi.nlm.nih.gov/books/NBK338596/.
3. Institute of Medicine (US) Committee on quality of health care in America. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): National Academies Press (US); 2000.
4. Rupp N, Ries R, Wienbruch R, Zuchner T. Can I benefit from laboratory automation? A decision aid for the successful introduction of laboratory automation. Anal Bioanal Chem 2024;416:5–19.
5. Lippi G, Mattiuzzi C, Bovo C. Are we getting better at the preanalytical phase or just better at measuring it? J Lab Precis Med 2018;3:11.
6. Lippi G, Baird GS, Banfi G, Bölenius K, Cadamuro J, Church S, et al. Improving quality in the preanalytical phase through innovation, on behalf of the european Federation for clinical chemistry and laboratory medicine (EFLM) working group for preanalytical phase (WG-PRE). Clin Chem Lab Med 2017;55:489–500.
7. Yu HE, Lanzoni H, Steffen T, Derr W, Cannon K, Contreras J, et al. Improving laboratory processes with total laboratory automation. Lab Med 2019;50:96–102.
8. Lippi G, Plebani M, Favaloro EJ. Technological advances in the hemostasis laboratory. Semin Thromb Hemost 2014;40:178–85.
9. Spies NC, Farnsworth CW, Jackups R. Data-driven anomaly detection in laboratory medicine: past, present, and future. J Appl Lab Med 2023;8:162–79.
10. Tzortzopoulos A, Raftopoulos V, Talias MA. Performance characteristics of automated clinical chemistry analyzers using commercial assay reagents contributing to quality assurance and clinical decision in a hospital laboratory. Scand J Clin Lab Invest 2020;80:46–54.
11. Linsen L, Van Landuyt K, Ectors N. Automated sample storage in biobanking to enhance translational research: the bumpy road to implementation. Front Med 2020;6:309.
12. Vogeser M, Habler K, Reuter A, Schneider-Thauern C. Research letter: pilot study of a prototype fully automated mass spectrometry system for routine clinical laboratory use. J Mass Spectrom Adv Clin Lab 2024;34:44–5.
13. Yadav D, Patil-Takbhate B, Khandagale A, Bhawalkar J, Tripathy S, Khopkar-Kale P. Next-generation sequencing transforming clinical practice and precision medicine. Clin Chim Acta 2023;551:117568.
14. Huang YY, Zhang XY, Zhu P, Ji L. Development of clustered regularly interspaced short palindromic repeats/CRISPR-associated technology for potential clinical applications. World J Clin Cases 2022;10:5934–45.
15. Ahmed MZ, Badani P, Reddy R, Mishra G. Clustered regularly interspaced short palindromic repeats (CRISPR)/cas advancement in molecular diagnostics and signal readout approaches. J Mol Diagn 2021;23:1433–42.
16. Wang S, Sun ST, Zhang XY, Ding HR, Yuan Y, He JJ, et al. The evolution of single-cell RNA sequencing technology and application: progress and perspectives. Int J Mol Sci 2023;24:2943.
17. Arshavsky-Graham S, Segal E. Lab-on-a-Chip devices for point-of-care medical diagnostics. Adv Biochem Eng Biotechnol 2022;179:247–65.
18. Wang X, Hong XZ, Li YW, Li Y, Wang J, Chen P, et al. Microfluidics-based strategies for molecular diagnostics of infectious diseases. Mil Med Res 2022;9:11.
19. Yang SM, Lv S, Zhang W, Cui Y. Microfluidic point-of-care (POC) devices in early diagnosis: a review of opportunities and challenges. Sensors 2022;22:1620.
20. Bao Y, Zhang D, Guo H, Ma W. Beyond blood: advancing the frontiers of liquid biopsy in oncology and personalized medicine. Cancer Sci 2024;115:1060–72.
21. Frullanti E, Serrano MJ. Editorial: current trends and future perspectives about liquid biopsy. Front Genet 2023;14:1345876.
22. Wang H, Zhang Y, Zhang H, Cao H, Mao J, Chen X, et al. Liquid biopsy for human cancer: cancer screening, monitoring, and treatment. MedComm 2020)2024;5:e564.
23. Weinshilboum RM, Wang L. Pharmacogenomics: precision medicine and drug response. Mayo Clin Proc 2017;92:1711–22.
24. Aneesh TP, Sonal Sekhar M, Asha J, Chandran L, Zachariah SM. Pharmacogenomics: the right drug to the right person. J Clin Med Res 2009;1:191–4.
25. Pereira NL, Rihal CS, So DYF, Rosenberg Y, Lennon RJ, Mathew V, et al. Clopidogrel pharmacogenetics. Circ Cardiovasc Interv 2019;12:e007811.
26. Lopez J, Mark J, Duarte GJ, Shaban M, Sosa F, Mishra R, et al. Role of genetic polymorphisms in clopidogrel response variability: a systematic review. Open Heart 2023;10:e002436.
27. Andermann A, Blancquaert I. Genetic screening: a primer for primary care. Can Fam Physician 2010;56:333–9.
28. Sagaser KG, Malinowski J, Westerfield L, Proffitt J, Hicks MA, Toler TL, et al. Expanded carrier screening for reproductive risk assessment: an evidence-based practice guideline from the national society of genetic counselors. J Genet Counsel 2023;32:540–57.
29. Schwartz O, Vill K, Pfaffenlehner M, Behrens M, Weiß C, Johannsen J, et al. Clinical effectiveness of newborn screening for spinal muscular atrophy: a nonrandomized controlled trial. JAMA Pediatr 2024;178:540–7.
30. Lev A, Somech R, Somekh I. Newborn screening for severe combined immunodeficiency and inborn errors of immunity. Curr Opin Pediatr 2023;35:692–702.
31. Ghetti G, Mennini FS, Marcellusi A, Bischof M, Pistillo GM, Pane M. Cost-effectiveness analysis of newborn screening for spinal muscular atrophy in Italy. Clin Drug Invest 2024;44:687–701.
32. Puck JM. Newborn screening for severe combined immunodeficiency and T-cell lymphopenia. Immunol Rev 2019;287:241–52.

33. Lippi G, Plebani M. The critical role of laboratory medicine during coronavirus disease 2019 (COVID-19) and other viral outbreaks. Clin Chem Lab Med 2020;58:1063–9.
34. Favresse J, Douxfils J, Henry B, Lippi G, Plebani M. Clinical chemistry and laboratory medicine celebrates 60 years - narrative review devoted to the contribution of the journal to the diagnosis of SARS-CoV-2. Clin Chem Lab Med 2022;61:811–21.
35. Mehta Y, Gupta A, Todi S, Myatra S, Samaddar DP, Patil V, et al. Guidelines for prevention of hospital acquired infections. Indian J Crit Care Med 2014;18:149–63.
36. Guo C, Wu JY. Pathogen discovery in the Post-COVID era. Pathogens 2024;13:51.
37. World Health Organization. Antimicrobial resistance. https://www.who.int/health-topics/antimicrobial-resistance [Accessed 1 April 2025].
38. Tang KWK, Millar BC, Moore JE. Antimicrobial resistance (AMR). Br J Biomed Sci 2023;80:11387.
39. Yamin D, Uskoković V, Wakil AM, Goni MD, Shamsuddin SH, Mustafa FH, et al. Current and future technologies for the detection of antibiotic-resistant bacteria. Diagnostics 2023;13:3246.
40. Lippi G, Lackner KJ, Melichar B, Schlattmann P, Greaves R, Gillery P, et al. Multi-cancer early detection: searching for evidence. Clin Chem Lab Med 2024;63:459–61.
41. Choudhury A, Asan O. Role of artificial intelligence in patient safety outcomes: systematic literature review. JMIR Med Inform 2020;8:e18599.
42. Fan BE, Yong BSJ, Li R, Wang SSY, Aw MYN, Chia MF, et al. From microscope to micropixels: a rapid review of artificial intelligence for the peripheral blood film. Blood Rev 2024;64:101144.
43. Simson E, Gascon-Lema MG, Brown DL. Performance of automated slidemakers and stainers in a working laboratory environment - routine operation and quality control. Int J Lab Hematol 2010;32:e64–76.
44. Al-Antari MA. Advancements in artificial intelligence for medical computer-aided diagnosis. Diagnostics 2024;14:1265.
45. Zou X, He W, Huang Y, Ouyang Y, Zhang Z, Wu Y, et al. AI-Driven diagnostic assistance in medical inquiry: reinforcement learning algorithm development and validation. J Med Internet Res 2024;26:e54616.
46. Dodig S, Čepelak I, Dodig M. Are we ready to integrate advanced artificial intelligence models in clinical laboratory? Biochem Med 2025;35:010501.
47. Lewis CW, Raizman JE, Higgins V, Gifford JL, Symonds C, Kline G, et al. Multidisciplinary approach to redefining thyroid hormone reference intervals with big data analysis. Clin Biochem 2024;133–134:110835.
48. Chi EA, Chi G, Tsui CT, Jiang Y, Jarr K, Kulkarni CV, et al. Development and validation of an artificial intelligence system to optimize clinician review of patient records. JAMA Netw Open 2021;4:e2117391.
49. Xie H, Jia Y, Liu S. Integration of artificial intelligence in clinical laboratory medicine: advancements and challenges. Interdiscip Med 2024;2:e20230056.
50. Lippi G, Sciacovelli L, Simundic AM, Plebani M. Innovative software for recording preanalytical errors in accord with the IFCC quality indicators. Clin Chem Lab Med 2017;55:e51–3.
51. Plebani M, Sciacovelli L, Marinova M, Marcuccitti J, Chiozza ML. Quality indicators in laboratory medicine: a fundamental tool for quality and patient safety. Clin Biochem 2013;46:1170–4.
52. Sciacovelli L, Lippi G, Sumarac Z, Del Pino Castro IG, Ivanov A, De Guire V, et al. Pre-analytical quality indicators in laboratory medicine: performance of laboratories participating in the IFCC working group “Laboratory Errors and Patient Safety” project. Clin Chim Acta 2019;497:35–40.
53. Businger AC, Fuller TE, Schnipper JL, Rossetti SC, Schnock KO, Rozenblum R, et al. Lessons learned implementing a complex and innovative patient safety learning laboratory project in a large academic medical center. J Am Med Inf Assoc 2020;27:301–7.
54. Centers for Disease Control and Prevention. Core elements of hospital diagnostic excellence (DxEx). https://www.cdc.gov/patient-safety/hcp/hospital-dx-excellence/index.html [Accessed 1 April 2025].
55. Morgan DJ, Singh H, Srinivasan A, Bradford A, McDonald LC, Kutty PK. CDC’s core elements to promote diagnostic excellence. Diagnosis 2025;12:197–200.
56. Verna R, Velazquez AB, Laposata M. Reducing diagnostic errors worldwide through diagnostic management teams. Ann Lab Med 2019;39:121–4.
57. Mrazek C, Lippi G, Keppel MH, Felder TK, Oberkofler H, Haschke-Becher E, et al. Errors within the total laboratory testing process, from test selection to medical decision-making - a review of causes, consequences, surveillance and solutions. Biochem Med 2020;30:020502.