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Lab-on-a chip: nanobiosensors for point-of-care diagnostics - from technology to diagnostics

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ABSTRACT

Introduction: The pressing need for rapid and sensitive diagnostic tools has driven innovation in nanobiosensors and smart microfluidic systems for Point-of-Care applications. Integrating advanced nanomaterials (such as graphene and nanoparticles) with microscale detection technologies enables highly specific in situ biomarker analysis for cancer and infectious diseases. Although Lab-on-a-Chip platforms represent a major advance in this new diagnostic landscape, the transition from laboratory proof-of-concept to commercial deployment still faces significant hurdles.
Objectives: The main objective of this literature review is to identify Lab-on-a-Chip platforms already implemented in clinical practice, compare their efficacy with current reference methods, and critically analyse the main obstacles limiting their commercialization and widespread adoption.
Methodology: A comprehensive search of the scientific literature was conducted for articles published between 2010 and 2026. A total of 49 articles were identified. Of these, 27 were excluded based on relevance criteria and 22 were included in this review.
Results: Lab-on-a-Chip platforms and microfluidic devices offer significant advantages in various clinical areas, such as early cancer detection, infectious disease diagnosis, and fertility treatments, surpassing traditional methods in terms of speed and efficiency. However, their large-scale clinical adoption is still hindered by major challenges. Chief among these obstacles are the technological difficulties in integrating the chips with existing equipment and workflows, the economic and regulatory barriers linked to high production and commercialization costs, and the negative environmental impact caused by the plastic waste from disposable devices. In summary, although this technology presents clear technical benefits, its global implementation depends on the ability to overcome these technological, economic, and environmental barriers.
Conclusion: The true clinical impact of Lab-on-a-Chip technologies will depend on overcoming current manufacturing and interface barriers. The development of sustainable, low-cost alternatives, such as paper-based electrochemical biosensors, is a promising strategy not only to reduce environmental waste but also to democratize access to diagnostics in resource-limited settings and developing countries.

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RESUMO

Introdução: A busca por métodos de diagnóstico rápidos e sensíveis acelerou o desenvolvimento de novas tecnologias, como nanobiossensores e sistemas microfluídicos para testes Point-of-Care. A incorporação de novos materiais (como grafeno e nanopartículas) em métodos de deteção em microescala permitiu o desenvolvimento de métodos in situ muito específicos para detetar biomarcadores associados a cancros e doenças infeciosas. Apesar de as plataformas Lab-on-a-Chip se terem tornado o centro desta revolução diagnóstica, ainda é um grande desafio transformar essas tecnologias promissoras em produtos comerciais.
Objetivos: O principal objetivo desta revisão da literatura é identificar plataformas Lab-on-a-Chip já implementadas na prática clínica, comparar a sua eficácia com os métodos de referência atuais e analisar criticamente os principais obstáculos que limitam a sua comercialização e adoção generalizada.
Metodologia: Foi realizada uma busca na literatura científica por artigos entre 2010 e 2026. Foram identificados 49 artigos, dos quais 27 foram excluídos com base em relevância e, 22 foram incluídos nesta revisão.
Resultados: As plataformas Lab-on-a-chip e os dispositivos microfluídicos oferecem vantagens significativas em diversas áreas clínicas, como a deteção precoce de cancro, diagnóstico de doenças infeciosas e tratamentos de fertilidade, superando os métodos tradicionais em rapidez e eficiência. No entanto, a sua adoção clínica em larga escala ainda é travada por desafios importantes. Entre estes obstáculos destacam-se as dificuldades tecnológicas na integração dos chips com os equipamentos e fluxos de trabalho existentes, as barreiras económicas e regulatórias ligadas aos altos custos de produção e comercialização, e o impacto ambiental negativo associado ao uso de dispositivos descartáveis de plástico. Em suma, apesar dos claros benefícios técnicos, a implementação global depende da capacidade de superar estas barreiras tecnológicas, económicas e ambientais.
Conclusões: O impacto clínico das tecnologias Lab-on-a-Chip dependerá da superação dos desafios de fabricação e interface. O desenvolvimento de soluções alternativas sustentáveis e de baixo custo como biossensores eletroquímicos de papel é uma estratégia particularmente promissora, não apenas para a redução dos danos ambientais mas também para democratizar o acesso ao diagnóstico em países com poucos recursos ou em desenvolvimento.

Introduction

The global rise of infectious diseases and chronic conditions has accelerated the development of faster and more sensitive diagnostic methods through point-of-care testing (PoCT), reducing dependency on centralized laboratory infrastructures.[1,2,3,4] Standard diagnostic approaches require specialized personnel, complex workflows, and central laboratories, which often result in long turnaround times.[4,5,6] In resource-limited settings, and especially during disease outbreaks, this delay represents one of the major challenges for the diagnosis and evaluation of chronic or infectious diseases, as well as for clinical decision-making.[3,4,5] For this reason, PoCT has emerged as a transformative clinical strategy that brings the diagnosis directly to the patient at the point of care.[4,5,7,8] This strategy is based on the pioneering use of lab-on-a-chip (LoC) tools and microfluidics.[2,4,5,6] LoC systems enable the integration and automation of complex, multi-step laboratory processes, such as sample preparation, reagent mixing, and micro-target detection, within a single miniaturized device.[2,5,6] These systems offer unparalleled advantages over conventional macroscale methods, including significantly reduced reagent consumption, faster analysis, and enhanced diagnostic sensitivity and specificity.[2,4,5,6] Despite these capabilities and advanced technology, moving LoC devices from laboratory prototypes to clinical environments remains a challenging process.[1,5,9]

The path from the laboratory to clinical practice is constrained by technical and economic obstacles that must be overcome to achieve widespread clinical implementation.[1,5,9]

To scale up production from a laboratory prototyping to mass manufacturing, scientists need to overcome micro- and nanoscale manufacturing challenges.[5,6,10] Although polydimethylsiloxane (PDMS) is a common material that meets many prototyping requirements, it lacks the robustness and clinical acceptance for commercial deployment. As a result, it is necessary to use materials with greater clinical acceptance and compatibility with industrial manufacturing, such as polymethyl methacrylate (PMMA).[1]

In addition to material selection, the physical integration of these devices into clinical practice is highly important, and the design of "chip-to-world" interfaces is a crucial aspect[9]. Most laboratory connectors are unsuitable or too delicate for non-specialists, making the development of a simple and user-friendly physical interface essential to ensure reliable point-of-care diagnostics[9]. Even when a technology has been clinically validated, many LoC technologies face restricted market

access due to high costs and monopolistic commercial models.[11] For this reason, developing countries with high epidemiological burdens that require more urgent molecular testing find it difficult to access these Technologies, as pricing remains prohibitive.[11]This creates a clear disparity between public health funding and equitable global access.[11]

Beyond engineering and economic barriers, real-world clinical integration requires LoC devices to offer genuine operational improvements rather than simply replicating conventional multistep laboratory protocols on a miniaturized scale.[1,4]

Furthermore, the rapid expansion of PoCT has led to increased use of disposable plastic cartridges, triggering significant public health and environmental concerns regarding the massive accumulation of medical waste.[12] To mitigate these ecological drawbacks, the scientific community is seeking affordable and sustainable alternatives.[12]

Thus, the primary objective of this review is to examine the current progress of LoC and PoCT technologies,[4,5,6] identify systems that have successfully reached clinical implementation, and compare their diagnostic efficacy with standard reference methods. While highlighting the main manufacturing, commercial, and operational obstacles to the global adoption of these devices and providing recommendations for future research and clinical applications.

Methodology

The review was conducted to assess recent developments in the application of advanced laboratory diagnostic technologies in clinical practice.

The study followed a comprehensive review methodology. A search was performed in electronic databases and publishing platforms, including PubMed, ScienceDirect, MDPI, Springer Nature Link, IOPscience, Journal of Science and Medicine in Sport (JSAMS), Royal Society of Chemistry, Wiley, Hahn-Schickard, ThaiScience, and the World Journal of Clinical Cases (WJCC). The search terms used were: 1) "Lab-on-a-chip" OR "microfluidics") AND ("chip-to-world" OR "manufacturing" OR "commercialization" OR "PMMA"; 2) (organ on a chip) AND (practice); 3) ((lab on a chip) AND (fertility)) AND (clinical impact); 4) (circulating tumour cells) AND (lab on a chip); 5) (lab on a chip) AND (infectious diseases) AND point of care. Beyond the initial database screening, cross-referencing bibliographies led to the inclusion of an additional 11 articles. The search included publications from 2010 to 2026, with emphasis on studies from 2020 to 2026 due to significant progress in nanobiosensors, microfluidics, and LoC platforms. Paper

Inclusion criteria included publication between 2010 and 2026, addressing the development, implementation, or evaluation of LoC, PoCT, or MPS systems including commercialization obstacles, technical manufacturing issues in micro- and nanoscopic contexts, and the clinical integration problems of the examined technologies. Only studies providing a complete evaluation of the diagnostic performance were considered.

Exclusion criteria included not comparing the analytical performance of the new devices with standard laboratory reference methods. Patents, editorials, non-peer-reviewed communications, and studies lacking direct clinical relevance were also excluded. Papers focused on excessively restricted subpopulations, whose specificity would prevent the extrapolation of results to the general population, were also excluded.

Based on the initial analysis, 49 articles were found. Of these, 27 were excluded, and 22 included in the present review.

Results

Platforms already commercially available and implemented in clinical practice

The transition of LoC and microfluidic technologies from laboratory to clinical practice resulted in commercial platforms at the vanguard of PoCT diagnostics.[1,7,13] Systems have evolved from prototypes to robust integrated equipment, encompassing rapid LoC diagnostics in diverse applications.[1,13,14]

In automated molecular diagnostics, the GeneXpert system (Cepheid) is one of the most prominent successes. It has been deployed worldwide and was endorsed by the World Health Organization in 2010. This system can prepare samples, extract, amplify, and detect nucleic acids in a single hermetically sealed cartridge[11,13]. Its automated molecular test Xpert MTB/RIF detects Mycobacterium tuberculosis and rifampicin resistance in under two hours.[15] Adoption of this technology by the public sector in developing countries was massive (>10,500 instruments; 45.9 million cartridges), despite its cost ($17,000 for basic equipment and $9.98 for cartridges).[15]

Within the same area, the BioFire FilmArray (bioMérieux) has been widely used in the diagnosis of severe bloodstream infections, especially in patients with febrile neutropenia.[14] This system incorporates a blood culture identification panel capable of identifying 43 targets (including Gram-negative and Gram-positive bacteria, fungal agents and antimicrobial resistance genes) in a single hour when applied to positive blood cultures.[14]

The Truelab Uno (Bigtec Labs) is a battery-powered microPCR device that weighs only 900 grams and can bring molecular diagnostics to low-resource settings or areas without laboratory infrastructure.[16] It was built to rapidly identify malaria parasites (Plasmodium falciparum and Plasmodium vivax) and can process up to 16 samples per day, at approximately one fifth the cost of an equivalent commercial PCR test.[16,17]

Another technological aspect that has been successful in clinical practice is centrifugal microfluidics (lab-on-a-disc). The LabDisk platform is a small 2 kg system (28 x

18 x 15 cm). It is capable of performing, in a disc format, chemical lysis, RNA extraction, and RT-PCR.[18] This system has been able to operate in sample-to-answer mode, allowing the detection of 22 respiratory pathogens (18 viruses and 4 bacteria) in 3.5 hours.[18]

In addition to infectious disease diagnostics, LoC technology also provides portable biochemical analyzers widely used in emergency and intensive care settings. The i-STAT Alinity analyzer (Abbott) is a portable device that does not need to be connected to a central laboratory and uses single-use cartridges that combine microfluidic biosensors[7]. This allows rapid organic monitoring with the assistance of different panels: the CG4+ cartridge is capable of evaluating pH and partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), and lactate in two minutes; the CHEM8+ cartridge measures electrolytes (sodium and potassium), ionized calcium, urea, creatinine, glucose, haematocrit, and haemoglobin in two minutes; and the PT/INR cartridge evaluates prothrombin time in five minutes.[7]

Commercial lab-on-a-chip technology for diabetes management primarily consists of Point-of-Care Testing (PoCT) analyzers to measure glycated haemoglobin (HbA1c). Examples of such devices are the Roche cobas b 101, Abbott Afinion 2, and Siemens Atellica DCA. By providing rapid data on glycemic control, they facilitate immediate therapeutic decisions and offer greater patient convenience than central laboratory testing. All these analysers have demonstrated acceptable accuracy around the treatment target for diabetic patients (HbA1c of 53 mmol/mol or 7.0%). They also exhibit adequate precision for disease monitoring, meeting the recommended imprecision criterion with a coefficient of variation (CV) less than 3%. The Abbott Afinion 2 is the fastest, delivering results in approximately 3.5 minutes, followed by the Siemens Atellica DCA at around 4 minutes, and the Roche cobas b 101, which requires about 5 minutes. Although they have proved to be suitable and reliable for regular clinical monitoring, it is important to note that these PoCT analyzers may exhibit significant biases at extreme HbA1c concentrations.[19] Specifically, the Abbott Afinion 2 and the Roche cobas b 101 may exhibit a positive bias at lower HbA1c values, which could influence accuracy in screening populations. The Roche cobas b 101 and the Siemens Atellica DCA may present a negative bias in samples with very high concentrations. Therefore, it is recommended that borderline results that may prompt changes in diagnosis or treatment be analytically confirmed using standardized central laboratory methods.[19]

Finally, LoC is transforming various clinical areas (for example, reproductive medicine). The ZyMot is a microchip for male infertility that obtained FDA approval in the USA as a class II medical device in 2018.[1] It is based on biocompatible and conventional materials (PMMA and polycarbonate membranes). It allows the selection of spermatozoa with a high level of DNA integrity, eliminating the centrifugation steps that are time-consuming and mechanically damaging step of traditional methods.[1]

LoC diagnostic efficacy versus reference methods

The clinical implementation of LoC and PoCT has been continuously assessed by comparing its results to the sensitivity and specificity provided by centralized laboratories (used as gold standard), revealing that diagnosis of infectious diseases by LoC has high diagnostic sensitivity and short turnaround times, but at the cost of significant variation of sensitivity across LoC methods.[8,13,20,21]

GeneXpert MTB/RIF is currently one of the most precise diagnostic systems for infectious disease detection. It provides substantially higher accuracy than smear microscopy and achieves very high specificity (91.7%, 100%).[16] However, its efficacy depends heavily on the sample matrix.[20,21]. The sensitivity of pleural biopsies was 85.5%, and the specificity was 97.2%[15]. However, if the same method is applied to a single pleural fluid sample with low bacterial load, the sensitivity falls to 43.6% and 51.4%, but the specificity remains very good (98.6%).[19,20] Sensitivity and specificity are 72.2% and 100%, respectively, when the test is performed on pericardial fluid.

Malaria is another major application area for decentralized PoCT diagnostics. The Truelab Uno (MTCR) portable micro-PCR system shows an excellent performance. With 100% sensitivity and specificity; it meets the WHO reference method standards.[19] Compared to microscopy, the device obtained 99.3% sensitivity and stood out significantly in identifying mixed infections. The platform managed to detect 32 complex cases of parasitic co-infection, against only 4 identified by the traditional microscopy method.[19,16]

Transitioning from molecular biology to biochemical and haematological evaluation, the portable i-STAT Alinity analyzer illustrates well the compromise between convenience at the point of care and laboratory precision. This system demonstrated a strong analytical correlation with large central laboratory instruments, presenting correlation coefficients (R^2) of 90% to 95% for most critical parameters (pH, lactate, and electrolytes).[8] Despite the favourable results, there may be significant clinical differences that need to be carefully interpreted (the device overestimated the partial pressure of oxygen by +7.9% and creatinine by +5.4%, and the Prothrombin Time calculation by -6.6%).[8]

Manufacturing, commercial, and operational bottlenecks

Although the diagnostic efficacy of LoC platforms and PoCT tests has been validated, the transition from an already well-established laboratory concept to international clinical acceptance constitutes a challenge, with numerous barriers.[1,5,6,9,11,12]

The first and most important obstacle is manufacturing at the micro- and nanoscale. Besides being very complex, it becomes expensive, which hinders scaling for mass production.[5, 6]

In the production and construction phase, researchers and developers frequently resort to polydimethylsiloxane (PDMS) due to its high flexibility and ease of manipulation.[1] However, for commercial purposes, these techniques must be replaced. Polymers that allow large-scale manufacturing and possess broad clinical acceptance, such as PMMA or polycarbonate, are the most sought after.[1] Technological translation is extremely crucial for this material shift, as demonstrated by the ZyMot device in the fertility area, which obtained FDA approval by adopting a scalable and robust structure based on PMMA and commercial membranes[1].

The physical and operational integration of these devices into the clinical workflow, in addition to the choice of materials, represents one of the major technological hurdles, referred to as the "chip-to-world" interface[9]. Standard laboratory fluidic and optical connections are too complex and delicate to be reliably handled by non-specialist staff at the point of care.[9] Without standardized and intuitive interfaces, diagnostic reliability is significantly affected. Therefore, the development of simple coupling solutions (for example, "plug and measure") that use standardized optical fiber connectors (SMA) and avoid the user having to perform major alignment procedures is paramount so that the equipment can be used immediately and safely by any professional.[9]

Even if engineering and design challenges are overcome, the commercialization of technologies is frequently hindered by high costs and monopolizing markets. This prevents access to a wide range of significant diagnostics, especially relevant for developing countries where infectious diseases are much more common.[11]

GeneXpert illustrates this problem[11]. Despite receiving over 252 million dollars in public funding, the system remains expensive with equipment and cartridges far exceeding that of traditional sputum smear testing. In this regard, this commercialization model systematically excludes countries with a high epidemiological burden, highlighting the dissonance between global public health investment and fair access to medical innovation.[11].

Additionally, with the rapid increase and widespread use of PoCT devices, we are now facing a new operational challenge for hospital culture: environmental sustainability. The. proliferation of test cartridges manufactured in disposable plastics has raised concerns. Serious ecological and public health issues occur, resulting in environmental destruction associated with the enormous amount of highly contaminated medical waste accumulated in plastic cartridges.[11,12] This problem has led the scientific community to investigate and develop more sustainable and low-cost operational alternatives. Electrochemical paper-based analytical devices emerge as a particularly promising solution.[12] These biosensors can be destroyed through incineration, which significantly reduces the ecological footprint of diagnostics. They also exploit the inherent capillary forces of paper fibers, which facilitate fully autonomous operation without the need for external pumps or devices with complex electronic components.[12]

Discussion

Consolidated solutions for infectious disease diagnostics, biochemical testing, and fertility assessment—such as GeneXpert, i-STAT Alinity, and ZyMot—have already begun to make decentralized analytical testing a clinical reality.

In various scenarios, especially in emergencies or in mixed infections, these technologies already match and sometimes exceed conventional methods. However, the incorporation of analytical excellence into clinical practice remains a slow and uneven process, especially in regions with scarce resources.

During the literature research underlying this study, a marked scarcity of independent and long-term clinical validation that rigorously evaluates the operational impact of these technologies in the 'real world' became evident.

Most scientific publications remain heavily focused on proof-of-concept studies and oriented towards the design and optimization of microfluidic devices. Furthermore, they are essentially developed in highly controlled laboratory environments.

Significant gaps persist in longitudinal studies that assess not only diagnostic performance, but also interface reliability under real clinical conditions. The ergonomics of use by non-specialists and the true cost-effectiveness for national health systems are aspects that must also be considered.

The lack of solid studies prevents a rigorous assessment of the true level of technological readiness of these platforms for universal adoption. Most proof-of-concept articles are done in highly controlled laboratories, so it is not feasible to use them to assess the technological readiness of these tools for the general population.

The lack of translational evidence is the source of the bottleneck identified in the review. This technological bottlenek, which prevents the launch of many biosensors results from reaching the market, stems largely from manufacturing challenges. These are associated with the transition from rapid prototyping materials to clinically accepted and scalable polymers, as well as the need for minimally invasive "chip to world" interfaces that are advantageous for healthcare professionals.

While one of the main obstacles to adoption remains the gap between microfluidic engineering and clinical application, the economic structures and business models that impact global access to diagnostics are much broader. One of the paradigmatic examples continues to be the commercial monopoly that formed around GeneXpert. Despite being one of the most publicly financed systems in the world, (about 252 million dollars in public resources), it still charges the highest prices in the world, which excludes countries with the greatest epidemiological burden. This case illustrates well that the

biggest obstacles for PoCT are not only technological, but rather economic and political: if the devices are not available to the populations that need them most, their impact on health remains limited.

Environmental sustainability adds another layer of complexity that can hardly be postponed. Plastic cartridges, increasingly common in PoCT, generate hazardous and non-degradable waste. This demands a systematic transition to sustainable alternatives. Paper-based electrochemical biosensors are a simultaneously analytical and environmental solution. The safe disposal of these components by incineration and autonomous paper operation, which are naturally controlled by capillarity, allows for an effective reduction in costs and simplifies production. These devices contribute efficiently to diagnostic practices aligned with global sustainability goals.

Material, ergonomic, industrial, economic, and environmental issues will be the basis for many more advanced developments in the future. Microfluidics is already transforming the field of organ-on-a-chip (OOC) systems and will have a central impact on personalized medicine and pre-clinical drug testing in the future.[22]

As highlighted by Shuler, the success of OOC will depend on the same level of industrial maturity, standardization, and scalability observed in the diagnostics industry. For this to be possible, future microfluidic technologies and the current lack of real data must be readily addressed.

Future research must go beyond technology and be a holistic process. It should integrate from the start the feasibility of manufacturing, health economics, clinical ergonomics, and environmental sustainability. Only then will innovation not be limited to the laboratory, but will have a real, equitable, global and measurable impact in clinical practice.

Conclusion

The development of LoC and PoCT from laboratory proof-of-concept to clinical practice has become one of the most significant advances in contemporary diagnostic medicine. Published results make it evident that commercialized microfluidic technologies already match, and sometimes exceed, the speed and sensitivity of centralized reference methods. However, the international success of these microscale technologies does not translate into a universal democratization of healthcare access. Multiple translational barriers persist that hinder their worldwide adoption.

Material production, the need to create truly intuitive interfaces for non-specialists, and the growing environmental impact of disposable medical plastics remain major challenges. Development cannot remain focused solely on analytical innovation.

The future of the sector must integrate practical utility, industrial scalability, and ecological sustainability—dimensions increasingly addressed by electrochemical paper-based biosensors, which stand out as viable alternatives.

Even more critically, economic barriers and rigid pricing structures must be addressed to prevent diagnostic exclusion in developing countries. Public funding policies must be aligned with commercialization models that benefit both the common person and the global population.

The scientific and medical communities must conduct longitudinal studies to overcome the scarcity of literature on real-world applications and the clinical impacts of these tools in medical practice.

To face and overcome these challenges, a truly integrated approach is necessary. We must align precision engineering with health economics and public policies. Only in this way can we expect to overcome the commercial, operational, and structural barriers that still limit the large-scale adoption of PoCT.

This convergence will allow for the consolidation of decentralized diagnostics, while simultaneously advancing technologies that sit at the heart of translational and personalized medicine.

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