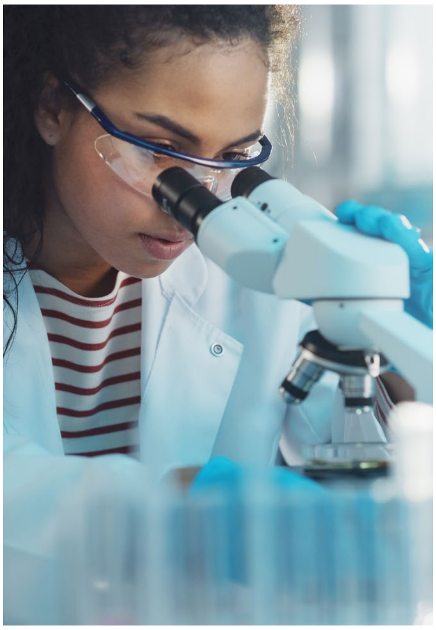
Dedalus

THE FUTURE OF In Vitro Diagnostics

In vitro diagnostics (IVD) has always been a cornerstone in healthcare, providing critical insights that guide clinical decisions. It is estimated that approximately 70% of clinical decisions rely on information derived from IVD tests[1] . These insights range from identifying infections and genetic disorders to monitoring chronic diseases and tailoring personalized treatment plans. For instance, IVD tests can detect the presence of specific pathogens, guiding the selection of appropriate antibiotics for bacterial infections. In oncology, biomarkers identified through IVD tests help determine the most effective targeted therapies for cancer patients. Additionally, in chronic disease management, IVD tests monitor glucose levels in diabetic patients, ensuring timely and precise adjustments to their treatment regimen.

The Future Role Of Clinical Labs[2]



The COVID-19 pandemic has revealed inadequacies in our current healthcare delivery models, underscoring the critical need for a more integrated approach between clinical diagnostics and public health. The pandemic's "test, trace, treat," approach has brought these two essential fields to the forefront of healthcare, significantly influencing policies and community actions.

There is now a compelling call for clinical laboratories to move beyond their traditional roles and actively engage in supporting community health by adopting population health principles. Population health focuses on improving health outcomes for groups by considering various social, economic, biological, and environmental factors. It aims to enhance chronic care management, quality and safety, public health, and health policy.

To effectively contribute, laboratories must collaborate with a wide range of stakeholders, including health systems, local health departments, and policymakers. This collaborative approach is encapsulated in the proposed model, the Future Role of Clinical Lab in Population Health. This model positions clinical laboratories as crucial players in managing population health, improving health outcomes, and ensuring public safety. It aligns with the Quadruple Aim: better outcomes, lower costs, improved patient experience, and enhanced provider experience.

The Clinical Lab 2.0[3] movement, initiated by the Project Santa Fe Foundation, advocates for transitioning laboratories from their traditional, transactional roles («Clinical Lab 1.0») to becoming a key component of value-based care, offering deeper clinical insights. This evolution enables laboratories to play a significant role in population health and chronic disease management through early disease identification and proactive interventions.

The principles of Clinical Lab 2.0 are particularly relevant for managing high-prevalence infectious diseases, including COVID-19. By leveraging predictive data analytics and clinical services, laboratories can manage disease spread, re-engage patients in post-pandemic healthcare, and reduce overall healthcare costs.

Key components of this forward-thinking model include engaging consumers with actionable health data and tools to improve access to care and self-management, maintaining high-quality and timely diagnostic services crucial for clinical decisions, and utilizing longitudinal lab data to provide actionable insights for healthcare stakeholders. Additionally, collaborating with stakeholders to align strategies and policies is essential for effective population health management. By connecting Clinical Lab 2.0 insights with community health, we can create a robust clinical action platform, supporting proactive care initiatives and improving both population-level and individual patient outcomes.

Clinical laboratories are urged to embrace this expanded role and form strategic partnerships with community health organizations to support value-based healthcare. Future efforts should focus on identifying high-impact areas for convergence between diagnostics and population health, optimizing healthcare policies, developing deliverables that support shared goals, enhancing IT for data analytics, and preparing the next generation of clinical laboratory professionals.

[1] Enhancing the Clinical Value of Medical Laboratory Testing

[2] Convergence of Diagnostics and Population Health

[3] https://cl2lab.org/

Digital Diagnostics: A New Frontier

The advent of digital diagnostics heralds a new era for IVD. This integration of data analytics with traditional testing methods is expected to generate new clinical insights and streamline workflows. Digital diagnostics is not just about improving the tests themselves but also about enhancing their interpretation and application in clinical settings.

Multiplex Testing and Digital Integration

The advent of multiplex disease testing is a game-changer, allowing for the detection of multiple pathogens or biomarkers from a single sample. This innovation is particularly crucial for complex diseases where various potential causes must be considered. Coupled with the rise of digital diagnostics, which merges data analytics with traditional testing, the IVD industry is moving towards a more interconnected and intelligent healthcare system.

Personalized Medicine

Recently, advancements in two key technologies have made personalized medicine more feasible:

> **Liquid Biopsies:** This involves using blood tests to detect small amounts of diseases like cancer. Unlike traditional tissue biopsies, which can be invasive, liquid biopsies offer a less invasive, more frequent, and genetically informative way to diagnose, monitor, and treat diseases.
> **Next-Generation Sequencing (NGS)**: This technology allows healthcare professionals to examine genetic material in more detail. It can identify
> specific genetic mutations and variations that are linked to diseases. This information helps doctors understand individual risks and responses to treatments better.

Healthcare professionals can thus adopt an increasingly personalised approach, tailoring care to patients' individual needs, while improving outcomes and reducing adverse outcomes. However, the convergence of digital technologies and of diagnostic tests also paves the way for rapid point-of-care testing and at-home diagnostic solutions.

Point-of-Care

The shift towards **point-of-care (POC) testing** is accelerating, driven by advancements in microfluidics that enable the miniaturization of assays. This trend is democratizing access to diagnostics, making tests more accessible and personalized, in line with the principles of **personalized medicine**.

In this field, various diagnostic devices are in development – ranging from wearable and “lab-on-a-chip” devices to biosensors[4] – providing immediate results at or near the patient’s location. Such devices offer patients timely, accurate results wherever they are, reducing reliance on traditional laboratory testing. Despite implementation and support-related constraints, such solutions reduce turnaround times and waiting times, increasing patient satisfaction and potentially reducing the burden on the healthcare system, as shown during the COVID-19 pandemic[5].

This could prove particularly useful in remote and developing regions. For instance, Flinders University (Australia) recently developed a new portable device to monitor patients with chronic kidney disease – a condition affecting 8% to 10% of the world’s population – and for screening high-risk populations. The results of this research demonstrated the device’s excellent performance and reliability.

Recent Outbreaks and the Shift to Real-Time Diagnostics

In recent years, and in particular following several outbreaks and pandemics, the healthcare landscape has been undergoing a major shift towards real-time diagnostics. Thanks to continuous patient data analysis and monitoring, professionals gain immediate insights into a patient’s health, and can identify potential issues as they arise, intervening much sooner. This helps prevent complications and increasingly tailor treatments. Despite constraints related to standardising protocols and guidelines, real-time tools can be vital during public health crises[6], improving healthcare systems’ reactivity. By avoiding future, costly interventions, such advancements can also alleviate the financial burden on healthcare systems.

The 4P’s of Healthcare

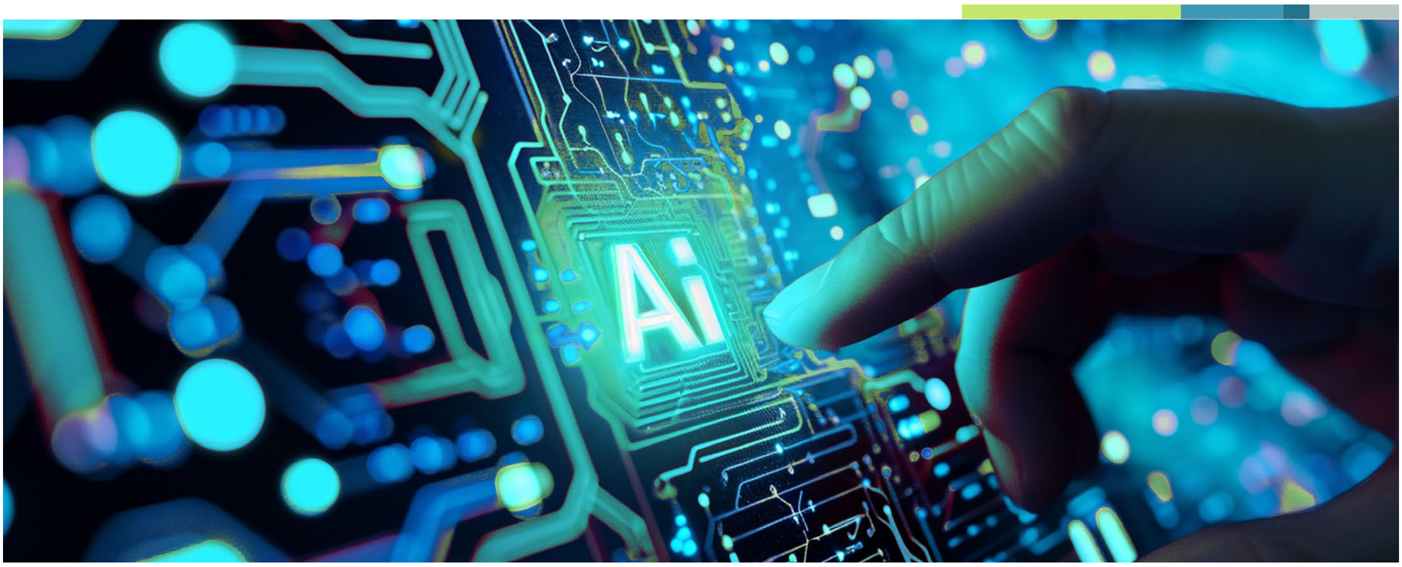
The future of IVD is closely aligned with the concept of **predictive, personalized, preventative, and participatory (4P) healthcare**. This approach emphasizes the importance of predicting diseases, personalizing treatments, preventing health issues before they arise, and encouraging patient participation in their own healthcare.

The IVD landscape has however not been spared by the impact of artificial intelligence, and several applications aiming to harness the power of AI and of machine learning in IVD have been developed over the last years, offering invaluable help both analytically and procedurally.

[4] Point-of-care diagnostics for infectious diseases: From methods to devices - ScienceDirect

[5] How to Realize the Benefits of Point-of-Care Testing at the General Practice: A Comparison of Four High-Income Countries (ijhpm.com)

[6] Diagnostics in Real-Time: An Innovative Approach to Improve Patient Outcomes (longdom.org)



The Rise of AI in Clinical Laboratories

AI tools are set to become ubiquitous in clinical laboratories this decade, offering potential enhancements in testing accuracy, operational quality, and efficiency. Clinical laboratorians are urged to lead this AI integration by understanding algorithm development, validation, and implementation to benefit patients and hospitals[7].

Currently, AI in medical labs is in its early stages. However, experts encourage laboratorians to start learning and developing AI models now.

AI's applications in clinical laboratories are extensive. These include automated spectroscopic data analysis, disease detection, test interpretation, digital image analysis for various medical fields, and data entry automation. AI also aids in creating standardized lab reports, minimizing inappropriate test orders, predicting test results, and reducing redundancy. Furthermore, AI can optimize laboratory operations planning, identify abnormal test results, and perform auto-verification for quality control.

A notable example of AI application is Mayo Clinic's AI model for automating the spectral analysis of kidney stones. Developed over six years, this model classifies 708 unique kidney stone types, significantly streamlining the workflow. Initially, stones were manually analysed, and the results entered into the Laboratory Information System (LIS). With AI, the process is automated, saving time and costs while improving efficiency. The AI system now classifies simple stones and uploads results to patients' electronic health records (EHRs) automatically, with complex cases flagged for manual review.

Similarly, AI tools in clinical microbiology, like Techcyte's AI-assisted screening tool, improve efficiency and accuracy in detecting faecal ova and parasites. This tool uses convolutional neural networks to identify and count various cells, significantly reducing the time and effort required for slide examination.

Moreover, AI algorithms and machine learning tools can use sets of patient data – be it images, results and patient histories – to identify patterns and anomalies. Such insights, which previously might have gone unnoticed, significantly enhance the diagnosis. Several applications have been assessed in pathology, including diagnosing breast and lung cancer, with promising results[8]. Regarding lung cancer, researchers trained a deep convolutional neural network to distinguish and classify whole-slide images from "The Cancer Genome Atlas" such as adenocarcinoma, squamous cell carcinoma, or normal lung tissue images[9]. While such images require visual inspection by experienced pathologists, in this study, the tested training method performed similarly to the method used by pathologists, with an average area under the curve (AUC) of 0.97. The same study demonstrated that such neural networks, when trained to predict the most commonly mutated genes in adenocarcinoma based on pathology images, successfully predicted six of them[10].

Work to apply AI and machine learning to diagnostics shows that such tools, overall, contribute to increasing diagnosis accuracy and decision quality, improving patient outcomes. They can also help reduce costs related to unnecessary testing and misdiagnoses.

In summary, AI-driven technologies are propelling the IVD industry towards personalized medicine and precise patient care. These innovations benefit healthcare providers and patients alike by improving outcomes and optimizing healthcare delivery.

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[7] Preparing for AI in clinical laboratories

[8] Artificial intelligence as the next step towards precision pathology - Acs - 2020 - Journal of Internal Medicine - Wiley Online Library

[9] Coudray, N., Ocampo, P.S., Sakellaropoulos, T. et al. Classification and mutation prediction from non–small cell lung cancer histopathology images using deep learning. Nat Med 24, 1559–1567 (2018). https://doi.org/10.1038/s41591-018-0177-5

[10] Ibid.

Conclusion

The future of IVD is being shaped by these advanced trends and the expanded role of Clinical Labs. Evolving beyond traditional transactional roles, Clinical Lab 2.0 exemplifies a transformative shift towards becoming integral to value-based care. By embracing digital diagnostics, personalized medicine, AI integration, and population health principles, clinical labs are poised to enhance diagnostic capabilities, optimize patient outcomes, and contribute significantly to a more responsive and equitable healthcare landscape.

Looking forward, Dedalus, leveraging over 30 years of expertise in laboratory solutions, stands as a pivotal partner in empowering clinical laboratories on this transformative journey. By leveraging Dedalus's innovative laboratory solutions, as well as advanced data analytics and interoperable systems, clinical labs can enhance their diagnostic capabilities, streamline operations, and contribute effectively to population health initiatives. Together with Dedalus, clinical laboratories can navigate the complexities of modern healthcare, driving towards a future where diagnostics are not just reactive but proactive, personalized, and seamlessly integrated into patient-centred care models.

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