

TECHNOLOGICAL
ADVANCES IN
**MEDICAL
DIAGNOSTICS**

The background is a blue-tinted photograph of a laboratory. A scientist in a white lab coat, safety glasses, and a blue face mask is holding a red test tube. Overlaid on the image are various digital graphics: a DNA double helix, several circular progress indicators (one showing 90% and another 70%), and a network of blue dots connected by lines, suggesting data analysis or connectivity.

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INTRODUCTION

Technological advancements have been transforming the healthcare industry, and medical diagnostics is no exception. The integration of digital technologies has led to significant improvements in the accuracy, speed, and accessibility of diagnostic tools and procedures. From point-of-care testing to predictive and personalized diagnostics, the future of medical diagnostics is being shaped by technological trends that are revolutionizing the way healthcare is delivered. The use of artificial intelligence (AI), machine learning (ML), and big data analytics is enabling healthcare providers to make more informed decisions and provide better patient care.

Against the backdrop of a global healthcare landscape marked by challenges and opportunities, recent events, such as the COVID-19 pandemic, have underscored the pivotal role of diagnostics in public health. The ensuing urgency and demand for rapid, scalable, and accurate diagnostic solutions have accelerated the adoption of novel technologies, paving the way for a resilient and adaptable diagnostic ecosystem.

In this article, we will explore the latest technological trends in medical diagnostics and their potential impact on the future of healthcare. We will examine the use of digital technologies in medical diagnostics and the most recent diagnostic trends that are shaping the future of healthcare.

EVOLUTION OF MEDICAL DIAGNOSTICS

Imperative for accurate, timely, and personalized diagnostics has never been more pronounced. The integration of cutting-edge technologies are catalyzing a paradigm shift in how we approach healthcare. Following are the trends which led evolution of Medical diagnostics:



Technological Progress

Diagnostics industry has undergone substantial technological advancements in the past decade, with the introduction of innovative diagnostic products and services. Digital infrastructure integration and adoption of digital diagnostic technologies are crucial for the industry's future



Impact of Global Events

COVID-19 pandemic has influenced diagnostics industry, causing disruptions in business operations and unexpected shifts in product demand. It has underscored the industry's essential role, prompting heightened emphasis on safety measures and integration of new technologies



Rise in Health Awareness

Growing health awareness & wellbeing programs have fueled an increased demand for diagnostic services. General population's proactive approach to health management has resulted in a global rise in the number of labs and diagnostic facilities



Market Dynamics

Diagnostics industry has transformed with new players and competitive service rates, accompanied by surge in pathological labs, making diagnostic procedures more budget-friendly and accessible, marking a positive shift in affordability

CLASSIFICATION OF MEDICAL DIAGNOSTICS

Medical diagnostics can be classified in several ways, each providing a unique perspective on the process of identifying and differentiating diseases and health conditions.

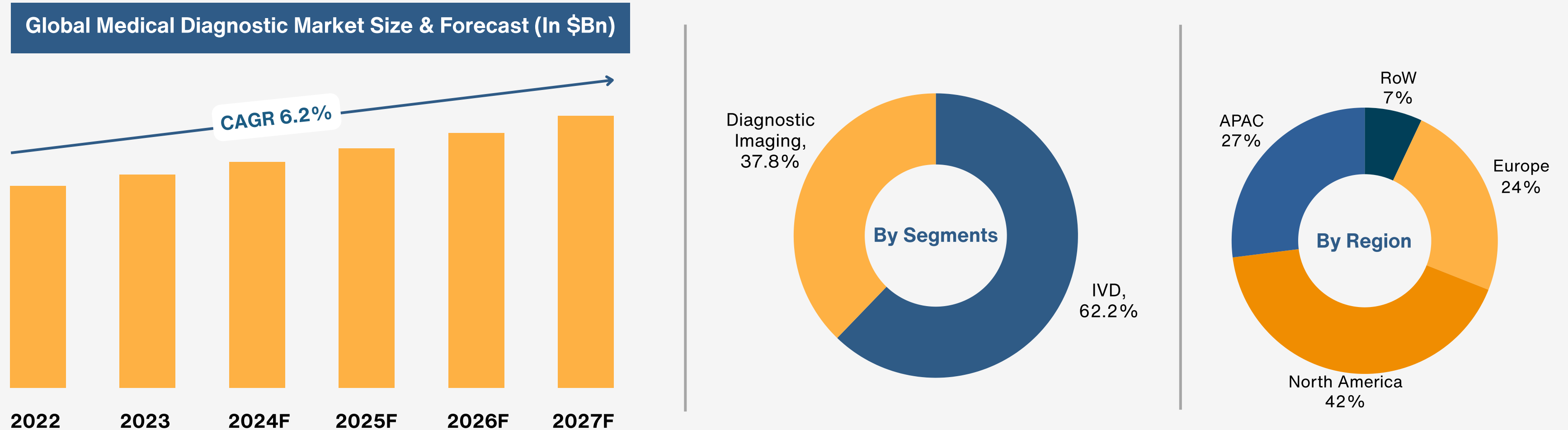
Category	Tests	Examples
Based on Invasiveness	Invasive Tests	Blood Tests, Imaging (X-rays, CT Scans, MRI), Endoscopies, Colonoscopies, Mammograms, Joint Aspirations
	In Vitro Tests (IVD)	Electrocardiograms, Blood Pressure Monitoring, Pulse Oximetry, Ultrasound, Electrophysiologic Activity Monitoring
Based on Type of Tests	Laboratory Tests	Blood Tests, Urine Tests, Stool Tests, Hormone Tests
	Imaging Tests	X-rays, CT Scans, MRI, Ultrasound, PET Scans
	Genetic Tests	Genetic Mutation Tests, Marker Tests, Predisposition Tests
	Diagnostic Procedures	Colonoscopies, Mammograms, Joint Aspirations, Endoscopies
	Laboratory Tests	Blood Tests, Urine Tests, Stool Tests, Hormone Tests
Based on Type of Device Used	Imaging Devices	X-Ray, MRI, Ultrasound, CT Scanners
	Laboratory Instruments	Blood Analyzers, Microscopes, Molecular Diagnostics tools
	Monitoring Devices	ECG, BP Monitors, Continuous Glucose Monitors

In recent years, advancements in digital technologies have led to the development of **new diagnostic tools and methods**, such as **point-of-care testing, predictive diagnostics, remote diagnostics and personalized medicine**. These technologies have the potential to improve the accuracy, speed, and accessibility of diagnostic tests and procedures, ultimately shaping the future of healthcare.

Current Market Scenario



MARKET SCENARIO OF MEDICAL DIAGNOSTICS



- Global medical diagnostics market is growing significantly due to an aging population and the rising prevalence of chronic diseases along with public awareness, technological innovations, regulatory approvals, and the launch of new IVD instruments
- Medical diagnostics play a crucial role in hospital and laboratory tests, with point-of-care testing (POCT) methods, particularly for blood glucose and pregnancy testing, being widely used
- Diagnostic imaging techniques like X-ray, MRI, and CT scans have witnessed increased global demand, driven by the surge in COVID-19 cases
- IVD procedures are contributing to the overall growth of the medical diagnostics market. Anticipated expansion is expected due to the growing demand for early diagnosis of infectious and chronic disease

DRIVING FORCES FOR TECHNOLOGICAL ADOPTION IN MEDICAL DIAGNOSTICS

Description	Recent Updates
<p>1. Miniaturization of Diagnostic Devices</p> <p>Miniaturization has potential to enhance portability, accessibility, and patient-centered design. It is driven by increasing demand for versatile and patient-friendly diagnostic solutions, the need for point-of-care testing and remote diagnostics, and the growing focus on home-based and personalized healthcare</p>	<p>Recently, Laura Health developed Miniaturized Diagnostic device that fit into patient's mouth to monitor biomarkers like pH levels of saliva and delivers real-time updates through mobile app to detect mouth and GI diseases</p>
<p>2. Conversion of Diagnostics into EMR</p> <p>EMR integration has potential to enhance patient care, outcome improvement and administrative burden reduction. It is driven by increasing adoption of digital health technologies, the need for seamless and integrated healthcare systems, and the growing focus on data-driven healthcare and use of predictive diagnostics</p>	<p>GE Healthcare is leveraging AI and data integration and connecting it with patient data for targeted therapies, disease specific focus and digital solutions to enhance patient care</p>
<p>3. AI assisted Medical Diagnostics</p> <p>AI systems, employing machine learning and advanced imaging, can enhance diagnostic precision by analyzing extensive medical data, reducing human errors. These systems swiftly and accurately identify various conditions, including cancer, cardiovascular diseases, and rare genetic disorders</p>	<p>Recently, Scientists of UK collaborated with NHS, GB Electronics and Vidiia to develop AI-assisted molecular diagnostic platform which identify variants of COVID-19 and other infectious diseases</p>
<p>4. Predictive & Personalized Diagnostics</p> <p>Predictive diagnostics has potential to revolutionize patient care, improve outcomes, and accelerate drug discovery. By leveraging data science and genetic information, predictive diagnostics enable early disease detection, personalized treatment plans, and more efficient drug discovery</p>	<p>Roche expanded its collaboration with Janssen Biotech to create personalized diagnostics for targeted therapies through multiple companion diagnostics technologies including immunochemistry, digital pathology, NGS, PCR etc.</p>

CHALLENGES FOR TECHNOLOGICAL ADVANCEMENT IN DIAGNOSTICS

Regulatory Challenges

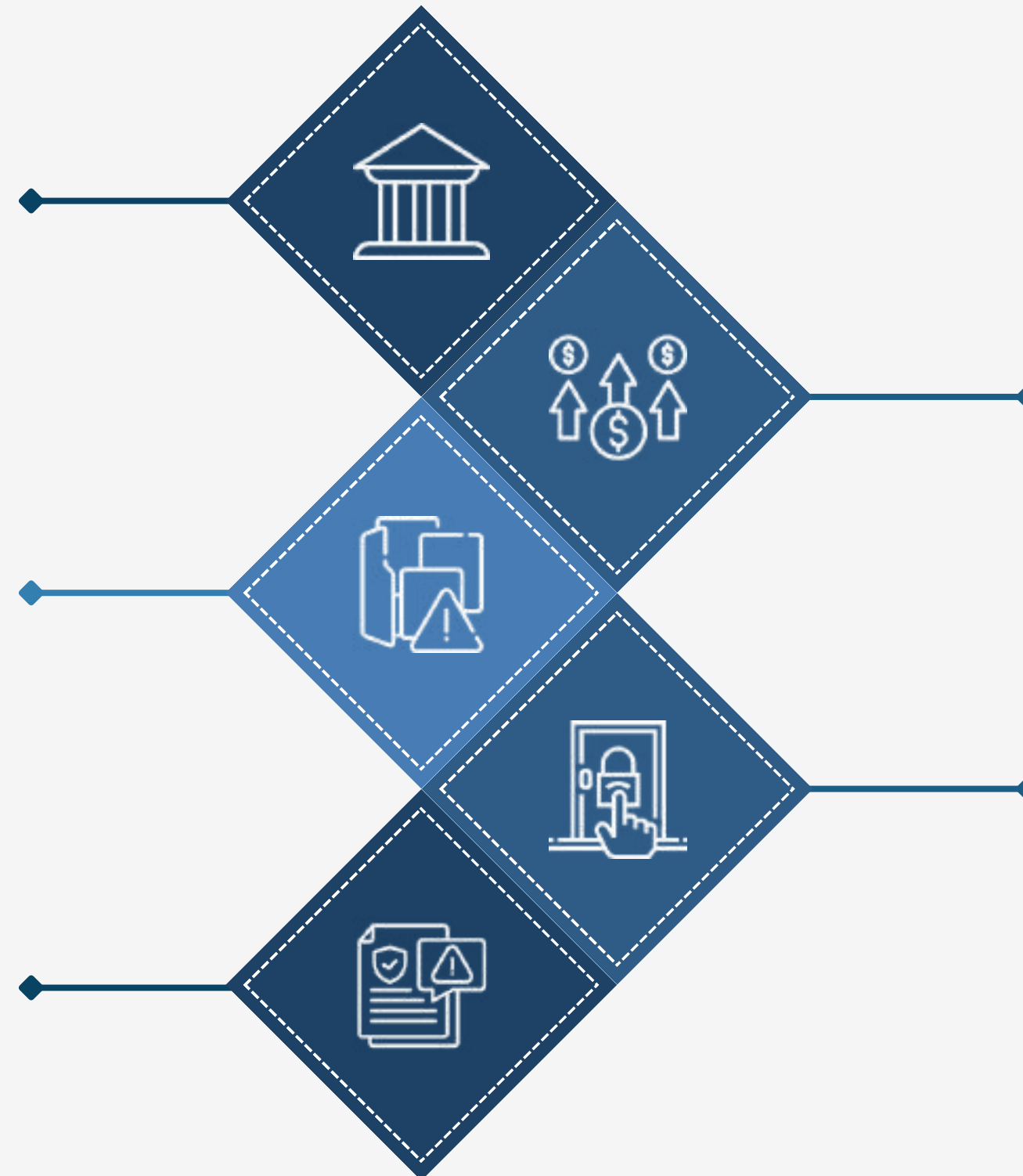
- Stringent regulatory processes and compliance requirements can impede rapid introduction of new diagnostic technologies to the market
- Lengthy approval timelines may hinder the timely availability of innovative diagnostic tools

Data Privacy & Security

- Increased reliance on digital technologies for diagnostics raises concerns about the privacy and security of patient data
- Ensuring robust cybersecurity measures is essential to prevent unauthorized access and data breaches

Interoperability Issues

- Lack of standardized protocols and interoperability between different diagnostic devices and information systems can hinder the seamless exchange of data
- This may lead to fragmented healthcare data and compromise the continuity of patient care



High Initial Costs









- Development and implementation of advanced diagnostic technologies often involve high initial costs
- This can be a barrier to adoption, particularly for smaller healthcare facilities with limited financial resources which may restrict the technological advances

Limited Accessibility

- While technology is advancing rapidly, ensuring equal access to diagnostic tools in remote or underserved areas remains a challenge
- Limited infrastructure and resources may hinder the widespread implementation of advanced diagnostic technologies

KEY PLAYERS IN MEDICAL DIAGNOSTICS SPACE

Diagnostic Industry is dominated by the top 5 players, accounting for ~40% of the market

Revenue (2022, in \$Bn)		Recent Developments
 Roche	19.2	Launched next gen. qPCR system to advance clinical needs in molecular diagnostics for cancer & infectious diseases (Nov'23)
 GE	18.5	Showcased 40+ innovation including AI enabled tech. within imaging, ultrasound and digital space at RSNA (Nov'23)
SIEMENS	17.0	Presented prototype chat system loads, links & prepares appropriate answers, reports & images with GenAI at RSNA (Nov'23)
 a	16.6	Launched new AI-enhanced vascular imaging technology in India which merges optical CT with AI (Oct'23)
 DANAHER	10.9	Partnered with Oxford University to develop new precision test for sepsis (Nov'23)
 labcorp	9.2	Completed acquisition of Legacy Health's lab business to expand its diagnostic capabilities and services (Nov'23)
 PHILIPS Healthcare	6.7	Unveiled next gen. ultrasound, mobile MRI & AI enabled cloud solutions to enhance radiology efficiency at RSNA (Nov'23)
 BD	5.6	Launched advanced ultrasound system designed to help clinician efficiency during catheters insertion (Nov'23)
 ThermoFisher Scientific	4.8	Signed companion diagnostic partnership with BI to develop test for small cell lung cancer with specific gene mutation (Nov'23)
FUJIFILM	4.6	Launched MRI system ECHELON Synergy with DLR technology powered by AI, to enhance the sharpness of images (Aug'23)

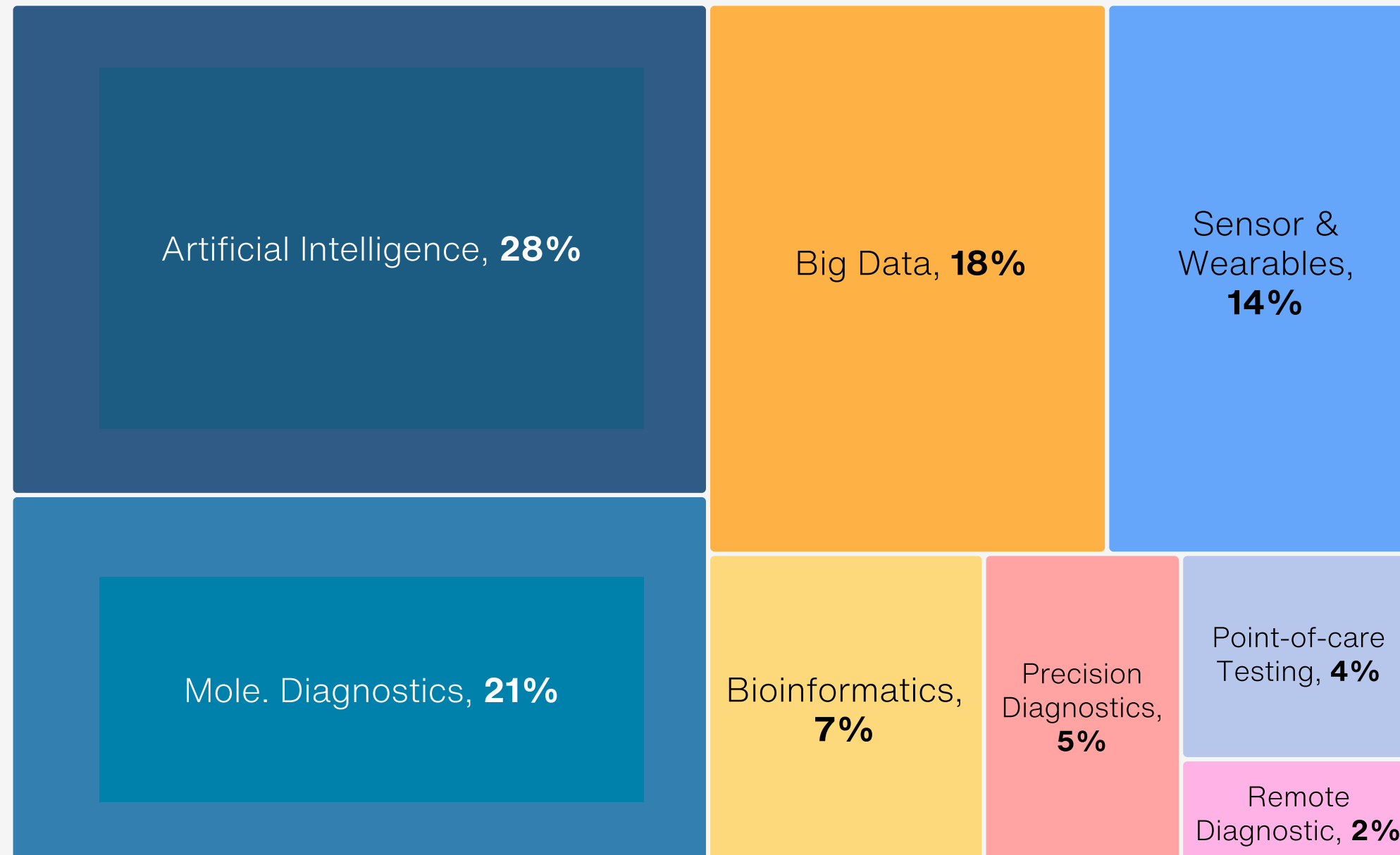
Technological Trends in Medical Diagnostics



TECHNOLOGICAL TRENDS IN MEDICAL DIAGNOSTICS

Advancement of medical technology has witnessed remarkable progress in recent years. Innovations revolutionized the way we diagnose, monitor, and treat diseases. The possibilities are endless, from cutting-edge technology and medical advances like mRNA and CRISPR to data integration and artificial intelligence. Such advanced medical systems technology improves the accuracy and efficiency of diagnostics and enhances patient experiences and outcomes.

Current Adoption of Technologies in Medical Diagnostics











AI and Molecular Diagnostics are driving technological advances in Medical Diagnostics followed by other technologies.

- Impact of **Artificial Intelligence** on Medical Diagnostics is quite high, as AI enables diagnostics capability through analysis of complex images and data algorithms providing early detection and actionable insights for chronic and aggressive diseases
- **Molecular diagnostics** have significantly impacted medical diagnostics by leveraging the analysis of genetic and molecular information. Advanced techniques are employed to examine genetic material, proteins, and other molecular markers within the body










Recent Launches & Approvals











RECENT TECH BASED LAUNCHES IN MEDICAL DIAGNOSTICS (1/4)

Tech	Company	Year	Description
 Artificial Intelligence		2023	Launched Paige Breast Suite, an AI-powered radiology tool to help early diagnosis of breast cancer metastases (It expanded its technology to reduce subjectivity, and manual tasks for pathologists)
		2023	Launched adjunctive AI software combined with CT that can produce 3D CT breast images through integration with the company's existing breast CT devices for early detection of breast cancer
		2022	Launched Omni Legend system, combining the PET and CT scanner with the aim to make the device compatible with upcoming advancements in digital detectors, AI software and injectable tracers
 Molecular Diagnostics		2023	Launched LightCycler PRO System which allow users to develop their own tests and enable portfolio of more than 200 LightMix Modular research assays and over 60 LightMix CE-IVD assays for cancer, infectious diseases etc.
		2023	Launched scalable Diomni Enterprise Software for molecular diagnostics labs for streamlining routine diagnostics testing for standardization and rapid time-to-results
		2023	Launched QIAstat-Dx syndromic testing solution in Japan with a SARS-CoV-2 Respiratory Panel that can detect more than 20 pathogens from a single patient sample





RECENT TECH BASED LAUNCHES IN MEDICAL DIAGNOSTICS (2/4)

Tech	Company	Year	Description
 Big Data & Analytics		2022	Introduced Medical Imaging Suite for digital imaging , designed to make diagnostic data more accessible and interoperable (It serves as gateway for the development and implementation of AI programs)
		2022	Launched LIMS v8.8 that uses analytics for integrated electronic laboratory notebook, laboratory execution system, scientific data management system and advanced analytics for laboratory diagnostic informatics solutions
 Precision Diagnostics		2023	Launched Precision Health unit to close gap between monitoring, awareness and diagnosis with digital health tools on one end and education, treatment and prevention on the other
		2023	Launched Well Longevity+ Program , a preventive health division that will utilize state-of-the-art technologies and precision diagnostic testing to identify potential conditions for cancer, heart, and neurodegenerative diseases
 Remote Diagnostics		2023	Launched at-home kidney health test to expand access to prevention, diagnosis & treatment of chronic kidney disease
		2022	Launched portable heart diagnostic device for better assessment of cardiovascular and heart failure risk and affordable access to basic imaging of the heart







RECENT TECH BASED LAUNCHES IN MEDICAL DIAGNOSTICS (3/4)

Tech	Company	Year	Description
 <p>Sensors & Wearables</p>	 <p>Neuramics</p>	2023	Announced to launch Magnetic Sensor Development Kit for monitoring the magnetic activities of the heart and transfer recordings via Bluetooth
		2023	Launched 24/7 in-ear wearable general wellness product that measures blood flow to the head to allow better understanding of conditions of body that occurs upon standing
		2022	Launched new company Radius XR , providing diagnostic capability to the proprietary VR/AR assistive device for multimodal diagnostics, practice management & patient engagement
 <p>Bio-informatics</p>		2023	Announced release of GeneSpect Somatic Reporter , the state-of-the-art variant interpretation and reporting with NGS panels and bioinformatics solutions
		2023	Launched EsoGuard 2.0 for the detection of esophageal pre-cancer that incorporate advanced molecular techniques, more efficient bioinformatics, and higher-throughput testing
		2023	Launched TruSight Oncology 500 ctDNA v2 , enables noninvasive comprehensive genomic profiling of circulating tumor DNA from blood when tissue testing is not available



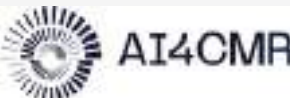
RECENT TECH BASED LAUNCHES IN MEDICAL DIAGNOSTICS (4/4)

Tech	Company	Year	Description
 Point of Care Testing		2023	Launched Nova Max Pro , a new point-of-care tool to improve kidney function screening and early detection of kidney disease outside the hospital in CE countries
		2023	Launched world's first Point-of-Care Testing system in Europe for rapid detection of Antimicrobial susceptibility in 30 minutes specifically for Urinary Tract Infection
		2022	Launched Cippoint, its first point-of-care testing device, detecting cardiac markers, diabetes, infectious diseases, fertility, thyroid function, inflammation, metabolic markers, & coagulation markers, approved by European IVD Device Directive

RECENT FDA APPROVALS FOR ADVANCED DIAGNOSTICS (1/2)

Tech	Company	Year	Description
Point of Care Diagnostic		2023	Announced de novo FDA regular-use clearance for an at-home COVID test, becoming first company to get the nod
Remote Diagnostic		2023	Received FDA clearance of DermoSight for tele-dermatology screening of suspected skin cancer lesions in early stages
Artificial Intelligence		2022	Received FDA clearance for QmTriage AI platform that uses 2D mammograms to analyze the images for potential signs of cancer and was built in partnership with University of Texas Southwestern (UTSW) Medical Center
		2022	Received EU approval for its two AI models: RlapsRisk BC (Analyzes risk of relapses with primary invasive breast cancer) and MSIntuit CRC (Identifies cases of colorectal cancer with microsatellite instability)
		2022	Achieved CE-IVD mark for Histotype Px Colorectal, an AI algorithm that predicts patient outcomes in colorectal cancer patients by analyzing standard histology images
Sensors & Wearable		2022	Announced FDA clearance for Zio Watch and ZEUS System, a new precision health solution integrated into clinical care delivery & designed to assist health care providers in identifying & monitoring Atrial Fibrillation

RECENT FDA APPROVALS FOR ADVANCED DIAGNOSTICS (2/2)

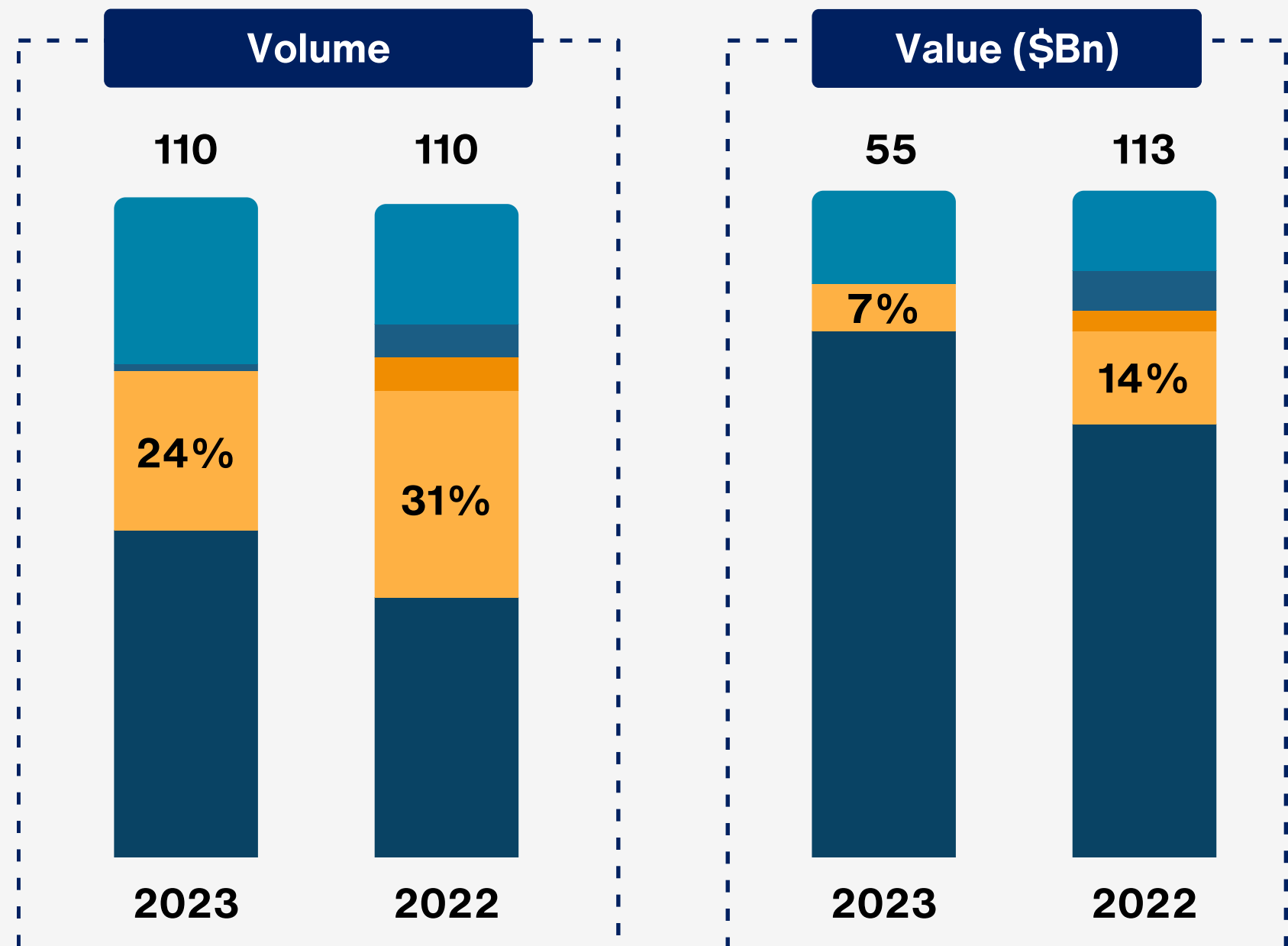
Tech	Company	Year	Description
Sensor & Wearables		2022	Announced FDA approval of wearable Atusa technology, a portable ultrasound system using ML to generate whole-breast images to detect breast cancer
		2022	Received FDA clearance to launch at-home epilepsy monitoring system which uses Seer Sense device (series of electrodes attached to the chest and forehead) to capture EEG and ECG to monitor epilepsy and episodic events
		2022	Received FDA 510K clearance for its AI4CMR solution, to automate the interpretation of cardiac magnetic resonance imaging (CMRI) using AI

M&A and Collaborations



M&A ACTIVITIES IN MEDICAL DIAGNOSTICS

M&A in life sciences by subsector (H1'22-23)



1 Overall M&A activities in Diagnostics sector **decline** in **H1'23** as compared to H1'22

2 Diagnostics accounted for **24%** (**26 M&A deals**) of M&A activity across life sciences in H1'23

3 Out of all M&A deal activities, **Small Cap M&A** accounted for **major deals (~73%)**

■ Pharmaceuticals ■ **Diagnostics** ■ Digital Health ■ Health Tech ■ CRO/CDMO/Suppliers

RECENT TECH BASED M&A DEALS

Tech	Company	Year	Description
Artificial Intelligence	SpectralMD <small>Solving the Challenge</small>	2023	Spectral MD, an AI based medical diagnostic company merged with Rosecliff Acquisition Corp with the deal value of \$170 Mn for improved capital access and commercialization for AI wound diagnostics in US, EU & UK
Bio-informatics	Renovaro Biosciences	2023	Announced to acquire multimodal, multi-omics AI based Bioinformatics start up Gedi Cube and rebrand as Renovaro.AI
Point of Care Testing	Nuclein	2023	Merged with Minute Molecular Diagnostics to advance commercialization of rapid & low-cost qPCR system
Remote Diagnostic	imaware™	2023	Acquired binx health's at-home consumer testing business to expand its presence in home-health testing specifically for Sexually Transmitted Diseases
Sensors & Wearable	908devices	2023	Acquired Trace Analytics for ~\$17 Mn to utilize its biosensors and mass spec devices as on-line bioprocess monitors

RECENT COLLABORATIONS IN MEDICAL DIAGNOSTICS FOR TECH ADVANCEMENTS

Tech	Company	Year	Description
Artificial Intelligence	Medtronic	2023	Partnered with Nvidia to build out an entire ecosystem of AI tools to spot colorectal polyps and adenomas on the lining of the colon in real-time during a colonoscopy
Mole. Diagnostic	XtalPi	2023	Extended its partnership with CK Lifesciences to develop miRNA based postoperative molecular diagnostic models for prognostic risk prediction for cancer patients
Big Data & Analytics	Redcliffe labs	2023	Partnered with Abbott India to launch clinical decision support AiniQ powered by Big Data Engines & AI, providing insights and recommendations to improve patient care
Sensors & Wearable	medidata	2023	Partnered with Sibel Health to integrate Sibel's discovery platform into its offering to gather insights from Sibel's wearable sensor technology
Precision Diagnostic	genomill	2023	Partnered with iCAN, to improve its Geno1 platform, to detect trace tumor DNA from thousands of biobank samples and lower barrier for adoption of liquid biopsy in precision medicine
Point of Care Testing	csem	2023	Collaborated with MOMM Diagnostics to develop a cutting-edge point-of-care solution for preeclampsia that detects two crucial biomarkers associated with this prevalent disease simultaneously
Bio-informatics	G42	2022	Partnered with Saphetor SA, for its VarSome Bioinformatics Platform to provide insights and facilitate early diagnosis of cancer, rare and metabolic diseases, and other genetic conditions
Remote Diagnostic	MedArrive	2022	Partnered with Spect to use its AI enabled telemedicine platform to perform critical eye screening for diabetic retinopathy, glaucoma and age-related molecular degeneration

RECENT INVESTMENTS IN MEDICAL DIAGNOSTICS

Funding (2023)



Raised \$30 Mn Series B funding to develop comprehensive AI imaging model which help radiologists to find and triage injuries and health conditions based on imaging results



Secured **€7.5 Mn Series A investment** for its **wearable biosensor of lung** to provide remote diagnosis as well as expand its facility in US



Debuted with **\$35 Mn in Series A** funding led by PXV Fund II to **commercialize company's mNGS & precision diagnostics** based infectious disease test

Grants (2023)



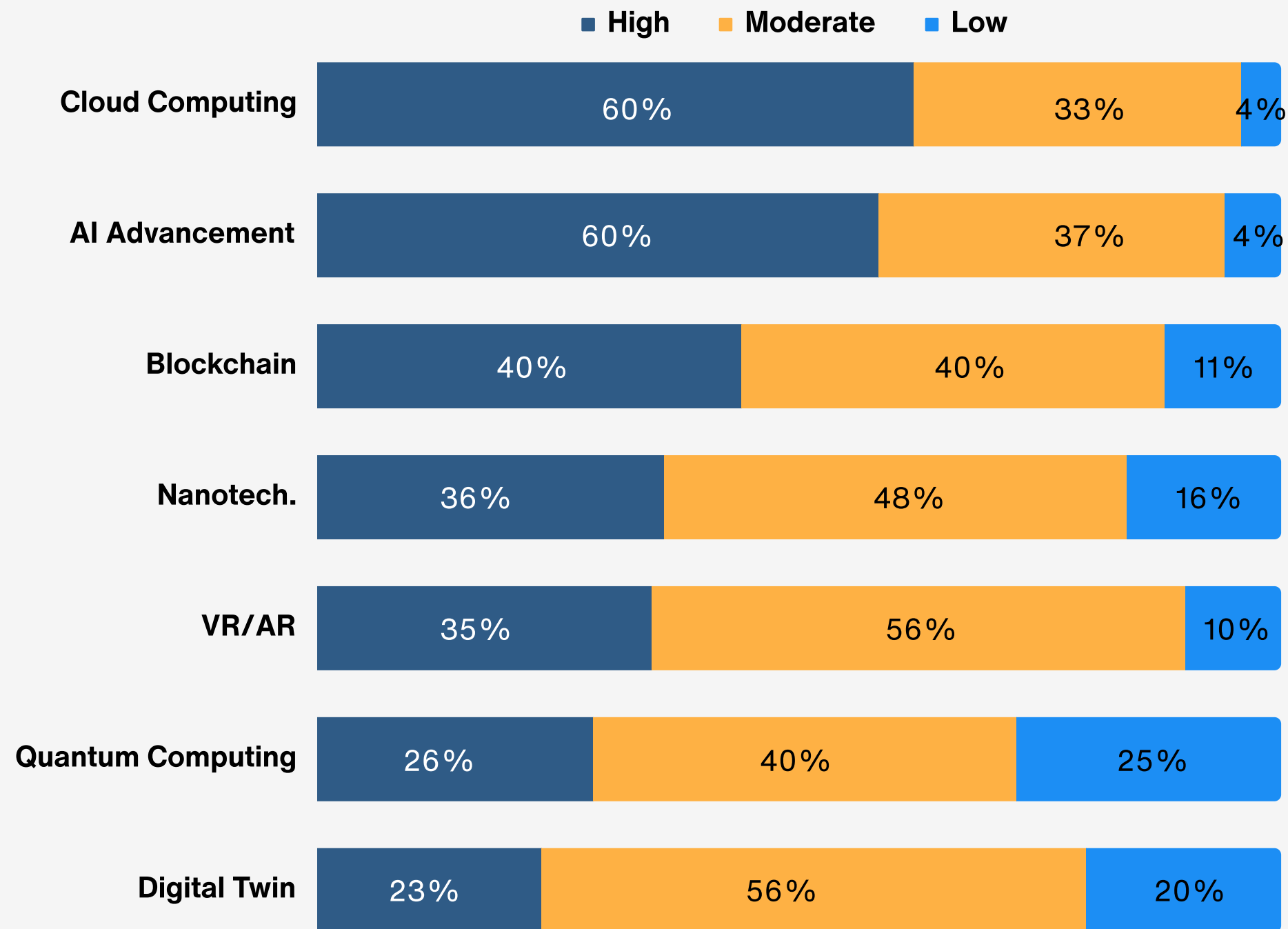
Received **~\$9 Mn grant from Bill & Melinda Gates Foundation** to develop **molecular diagnostic test for TB** on its upcoming Co-Dx PCR platform



NIH's division NIGMS **awarded two Phase 2 SBIR grant of \$4.8 Mn** to develop **Prenosis's Immunix AI based precision diagnostic platform** for acute immune states and sepsis

Future Outlook

CLOUD COMPUTING AND AI WILL LEAD DIAGNOSTICS LAUNCHES IN NEXT 5 YEARS



Based on Deloitte analysis of Research survey of 250 MedTech companies about technologies to be introduced in organization over the next five years to better understand, protect, and use the data generated from your medical devices

Emerging diagnostic paradigm involves digitalization, robotization, and automation, giving rise to smart laboratories and imaging systems. Diagnostic companies are strategizing to advance in AI and cloud computing, capitalizing on the increasing adoption of advanced diagnostic devices disrupting the market. These innovations enhance diagnostic capabilities, with current technologies already making an impact and future advancements expected to further transform the diagnostic landscape.

Along with that, there will be renewed focus on partnerships between traditional and non-traditional players, fostering collaboration for continued innovation which will help in accurate and advanced care. Industry is moving towards 4P medicine, emphasizing Predictive, Preventive, Personalized, and Participatory care, leveraging the potential of technological advancements in diagnostics for a more holistic and individualized approach to healthcare.



CONCLUSION

Diagnostic industry is witnessing significant trends shaped by consumer demands for personalized, value-added, and precise tests, with robust support from extensive data collection and intelligent integration. These trends often intersect with real-time diagnostics and at-home testing generating valuable datasets for training AI models in classification and prediction. The growing interest in personal genomics prompts consumers to contribute more DNA samples for testing and research, enhancing our understanding of epigenetics. These samples also serve as crucial data for Deep Learning algorithms, offering deeper insights into the intricacies of the human body.

Since the 2020 pandemic, scientific breakthroughs in diagnostics have been remarkable. However, in 2023, consumers expect these innovations to be the norm, sparking a transformative shift in the diagnostic industry's approach to drug therapy development.

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Authors



Parth Upadhyay
Senior Consultant
Healthark Insights



Pruthvi B.
Consultant
Healthark Insights



CONTACT US

821, Sun Avenue One
Manekbag, Ambawadi,
Amdedabad, India

contact@healtharkinsights.com

healtharkinsights.com