



INTESA SANPAOLO
INNOVATION CENTER

INDUSTRY TRENDS REPORT **HEALTHCARE**

*DIAGNOSTIC TECHNOLOGIES AND
SURGICAL ROBOTS*





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EXECUTIVE SUMMARY

With the arrival of Point-of-Care Testing (POCT) for COVID-19, decentralized workflows have driven the global **in vitro diagnostics** markets. Frost & Sullivan believes that the segment represents a continued motor for growth with forecasted revenues of \$18.7b in 2022 built on rapid innovation while, more generally, the positive outlook for the IVD space is underpinned by the presence of a rapidly ageing population in developed economies.

This is notably to the advantage of both molecular and tissue diagnostics.

The **molecular diagnostics** segment is fragmented with new entrants focusing on niche areas and established participants pursuing chronic diseases. In the latter, liquid biopsies are notably increasingly being used as a biomarker-driven tool for oncology and accelerating the growth of next-generation sequencing.

Here and elsewhere, Artificial Intelligence (AI) is changing the game by, for example, deciphering unseen patterns in very complex molecular data with Machine Learning (ML) enabling cancer discovery. In the longer term, AI-powered molecular diagnostics is expected to pave the way to the development and provision of precision medicine by leveraging algorithms for the pre-symptomatic detection of infections.

Overall, in six years, funding for AI-based molecular diagnostics has exceeded \$3b while, in the future, assay-agnostic flexible AI analytics platforms are set to unleash further potential by democratizing and decentralizing molecular testing.

The **tissue diagnostics** (TDx) segment is similarly being shaped by innovation with analysis of samples in laboratories now more precise and automated.

Preanalytical staining techniques remain a cornerstone of the market with global sales of \$2.6b in 2020 but lack reliability and upgradability. However, advanced staining techniques which offer personalized diagnoses are continuing to gain ground and now represent 58% of revenues. Anatomical Pathology Lab Information Management Systems manage both of these processes and are growing rapidly at 10.6%.

From a supplier perspective, Roche (Switzerland) leads the way and is well positioned with solutions which address the market hotspots. The company is working with GSK (UK) to develop new Companion Diagnostic tests while partnerships with biopharma are now considered to be best practice. Moving forwards, opportunities include extending beyond oncology to enable TDx adoption and embracing Whole Slide Imaging technology to support with caseload management.

As with in vitro solutions, conventional **wound diagnostics** and monitoring methods have their limitations and market participants are seeking alternatives. This is particularly true in the context of the growing burden of chronic wounds.

The application of new advanced technologies brings the promise of greater accuracy, standardization and affordability and reduced patient discomfort. In particular, innovative computing, imaging and sensing is being applied notably in the domains of digital wound assessment and hand-held scanners. In the former, AI, ML and computer vision are minimizing clinic visits and accelerating wound documentation while, in the latter, hyperspectral, fluorescence and biocapacitance technology are enabling early pathogen detection and helping healing.

In the long-term, theranostic products represent the next frontier in wound care.

In addition to AI, **Digital Twins** (DTs) represent a key emerging technology that will shape the diagnostics and broader healthcare space. DTs initially found their use in the production and engineering sectors but can now be applied to humans, devices and hospitals. A human digital twin supports with the delivery of personalized healthcare while, for medical devices, DTs enable improved design and performance and, for hospitals, they provide for ever more dynamic operations and processes.

Overall, the market for DTs in healthcare remains nascent and sizing it can be challenging but Frost & Sullivan expects global revenues to reach \$2.4b by 2025. Growth will be aided by the fact that – unlike many other digital solutions – the impact of DTs can quite easily be quantified and assessed while healthcare executives and clinicians are increasingly recognizing the benefits of simulating physical assets which is translating into fresh investment.

This is to the benefit of an emerging vendor ecosystem which includes large equipment manufacturers and smaller firms focused on niche applications and where ultimately success will rest on suppliers' ability to increase quality and cut costs through interoperability and data integration. Clinical trials represent a growth opportunity with DTs being deployed to accelerate drug discovery and development via digital modelling while, in the future, a focus on femtech will facilitate the use of digital twins in addressing women's health.

The ageing population is causing challenges and creating opportunities not only on the demand side but also in terms of supply with retirements expected to provoke a shortfall of between 55,000 and 150,000 physicians globally by 2030.

Surgical robots are one of several emerging solutions which, in addition to Digital Twins, can help to bridge this gap. Robot-assisted Surgical Devices' (RASD) uptake is being driven by their ability to support with Minimally Invasive Surgeries (MIS) with Frost & Sullivan expecting the RASD market to be valued at \$14.3b globally by 2026.

Growth will stem largely from instruments and accessories to the advantage of dominant leader Intuitive Surgical (US) which boasts an 81% share globally. The rising demand for portability will however broaden the ecosystem and encourage new entrants.

The advent of AI is improving performance in the RASD space, notably in the areas of human to robot interaction and system modelling and control. This, combined with the transition from multi-port to single site surgery and a shift to address multiple specialties will mean that robotics will gradually become the gold standard of care.

Slowly, market participants are in parallel moving towards a leasing model, which offers mutual benefits to both “sellers” and “buyers”, and are also sharpening their focus on enabling microsurgery procedures. In the long run, this and other areas will enable them to untap the ~90% of the market in volume terms which lies beyond MIS.

This paper examines each of these areas in turn with a focus on the way in which innovation is shaping the diagnosis, monitoring and treatment of conditions and diseases. More broadly, it examines how technological advances and new business models are benefiting the patient and provider by providing better healthcare more efficiently.



IN VITRO DIAGNOSTICS

With the arrival of Point-of-Care Testing (POCT) for COVID-19, decentralized workflows have driven the global *in vitro diagnostics* markets

In vitro diagnostics (IVD) pertain to the reagents, instruments and systems that are intended for the collection, preparation and examination of samples, such as blood, urine and tissue, that have been taken from the human body.

The purpose of such testing is to detect diseases or other conditions and monitor the overall health of a patient to help cure, treat and prevent illness.

The market can be segmented by technology (e.g., POCT) application (e.g., molecular diagnostics) and by workflow. While there is some correlation between each area, there is also overlap which depends on the testing requirements and context.

Centralized, referral and peripheral and decentralized testing constitute the three major workflows or avenues across the clinical and laboratory facilities that employ IVD reagents, instruments and systems for analytical testing.

Centralized testing is *high throughput* and suitable for *expert users*.

For this type of testing, samples are procured at collection sites and then delivered to an equipped laboratory where multiple samples are processed and a variety of tests are run by trained laboratory staff. Centralized testing is

typically conducted within a hospital or offsite reference lab. Complex platforms that offer high throughput processing along with automated workflows are used to process hundreds and thousands of samples.

Referral and peripheral testing is *medium throughput* and suitable for *semi-expert users*.

Here, samples are obtained at a collection site and then delivered to a clinical pathology laboratory. The volume of patient samples is relatively low when compared with centralized testing. This type of testing is typically conducted in a hospital or offsite reference lab. Platforms might be complex, catering for medium throughput, as multiple steps are required during analysis and are usually performed by trained pathology staff.

Decentralized testing is *low throughput* and suitable for *non-expert users*.

This segment involves single sample or low volume testing that occurs near the patient at the point of care (POC). Tests are often conducted by a wide variety of clinicians and lab professionals or by the patients themselves. Typically, the instruments used offer portability and rapid turnaround times. Decentralized tests can be performed at a patient's bedside or even at a clinician's office. Other places of deployment include but are not limited to urgent care settings, emergency departments and community pharmacies.

Decentralized POCT and the kit-based segment will witness steady growth and account for 28% of global IVD revenue in 2025. The need for widely available, rapid turnaround testing became more evident during the pandemic. Abbott entered the decentralized lab market with its ID NOW test. Several other participants, such as Thermo Fisher and Hologic, have adopted an acquisitive approach while players such as Bosch, Sense Bio and Nuclein, have also shown an interest in the space. The direct-to-patient approach has intensified since the Covid-19 outbreak with the launch of new at-home collection kits by a wide range of companies including Everlywell, Ambry Genetics, Color Health, Quest and LabCorp.





PRINCIPAL ABBREVIATIONS

AI	<i>Artificial Intelligence</i>	KPI	<i>Key Performance Indicator</i>
APLIS	<i>Anatomical Pathology Lab Information Management System</i>	LDT	<i>Lab-developed Test</i>
AR	<i>Augmented Reality</i>	LIS	<i>Laboratory Information System</i>
ASC	<i>Ambulatory Surgery Center</i>	M	<i>Million</i>
B	<i>Billion</i>	M&A	<i>Mergers & Acquisitions</i>
B2B	<i>Business-to-Business</i>	MDx	<i>Molecular Diagnostics</i>
CAGR	<i>Compound Annual Growth Rate</i>	MINIR	<i>Minimally Invasive Neurosurgical Intracranial Robots</i>
CDx	<i>Companion Diagnostic</i>	MIS	<i>Minimally Invasive Surgeries</i>
CTC	<i>Circulating Tumor Cell</i>	ML	<i>Machine Learning</i>
ctDNA	<i>Circulating Tumor DNA</i>	MRD	<i>Molecular Residual Disease</i>
DL	<i>Deep Learning</i>	OEM	<i>Original Equipment Manufacturer</i>
DNA	<i>Deoxyribonucleic Acid</i>	OR	<i>Operating Room</i>
DRL	<i>Deep Reinforcement Learning</i>	PCR	<i>Polymerase Chain Reaction</i>
DT	<i>Digital Twin</i>	POC	<i>Point-of-Care</i>
ELISA	<i>Enzyme-linked Immunosorbent Assay</i>	POCT	<i>Point-of-Care Testing</i>
EMR	<i>Electronic Medical Record</i>	R&D	<i>Research & Development</i>
H&E	<i>Hematoxylin and Eosin</i>	RASD	<i>Robot-assisted Surgical Device</i>
HRI	<i>Human to Robot Interaction</i>	RNA	<i>Ribonucleic Acid</i>
ICU	<i>Intensive Care Unit</i>	TDx	<i>Tissue Diagnostics</i>
IDE	<i>Investigational Device Exemption</i>	UK	<i>United Kingdom</i>
IHC	<i>Immunohistochemistry</i>	US	<i>United States</i>
IoT	<i>Internet of Things</i>	VC	<i>Venture Capital</i>
ISH	<i>In Situ Hybridization</i>	VR	<i>Virtual Reality</i>
IVD	<i>In Vitro Diagnostics</i>	WSI	<i>Whole Slide Imaging</i>

ABOUT INTESA SANPAOLO INNOVATION CENTER:

Intesa Sanpaolo Innovation Center is the company of Intesa Sanpaolo Group dedicated to innovation: it explores and learns new business and research models and acts as a stimulus and engine for the new economy in Italy. The company invests in applied research projects and high potential start-ups, to foster the competitiveness of the Group and its customers and accelerate the development of the circular economy in Italy.

Based in the Turin skyscraper designed by Renzo Piano, with its national and international network of hubs and laboratories, the Innovation Center is an enabler of relations with other stakeholders of the innovation ecosystem - such as tech companies, start-ups, incubators, research centres and universities - and a promoter of new forms of entrepreneurship in accessing venture capital. Intesa Sanpaolo Innovation Center focuses mainly on circular economy, development of the most promising start-ups, venture capital investments of the management company Neva SGR and applied research

For further detail on Intesa Sanpaolo Innovation Center products and services, please contact

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