The Future of Laboratory Tests from an Economic Perspective

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Clinical Biochemistry

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- The economics of laboratory medicine
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- The Future of Laboratory Medicine
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4. Artificial intelligence &Cloud computing
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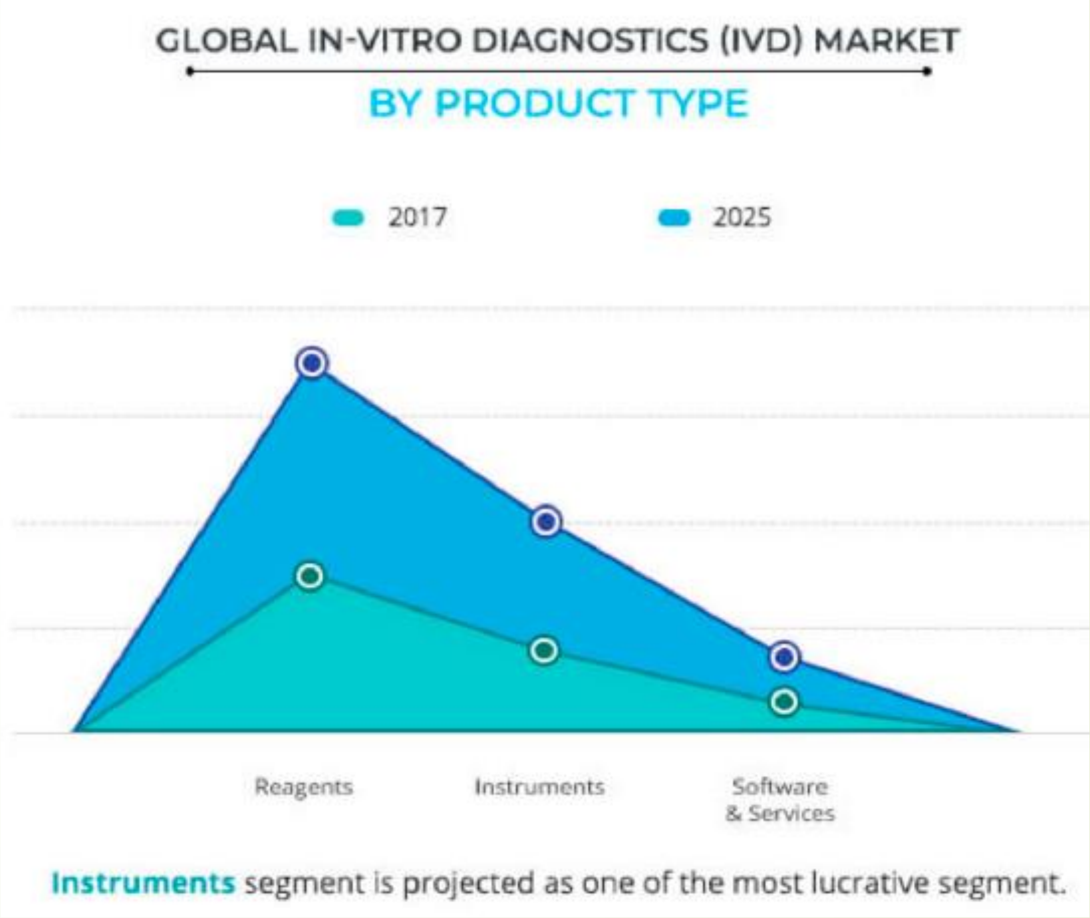
Industry overview of IVD

- **In the United States** gross domestic product in healthcare increased from 5.1% **($27 billion)** in **1960** to 17.9% **($3.5 trillion** or $10,739 per person) in **2017**
- **3 percent on laboratories** (Public Health Foundation, 1984)
- Three types of strategies in IVD:
- • Screening
- • Diagnosing
- • Monitoring
- **3 to 5 percent** of all healthcare resources in **IRAN** are allocated to laboratories**.**

Industry overview of IVD

- The **global** in vitro diagnostics (IVD) market was valued at **$64,479 million in 2017**, and is estimated to reach at **$93,614 million** by **2025**,
- More **accurate** and **faster test results** are expected to boost the growth of the global IVD market



The economics of laboratory medicine

- Every organization accounting of its monetary resources.
- The laboratory is no exception

Director/manager:

- Identify and categorize costs
- Relationships between revenue and reimbursement
- Familiar with the budget process
- Use financial ratios and information to make sound decisions.

Defining and identifying costs

- It is important to **understand costs** to accurately price tests and other services, to determine when and how to **offer new tests**

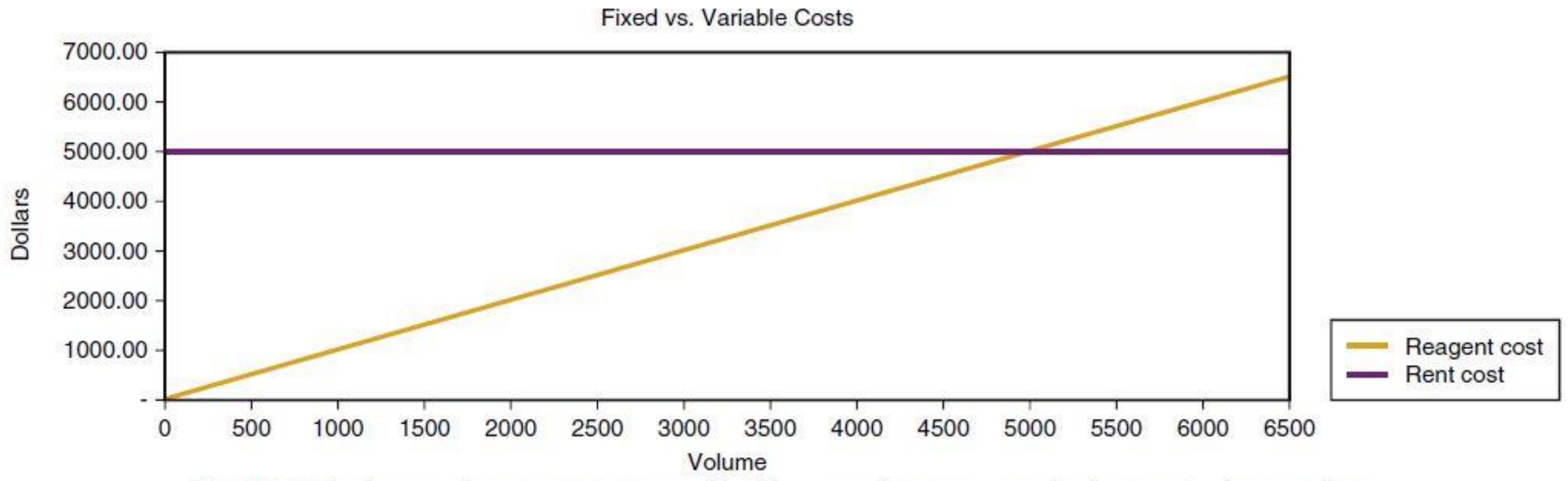


Figure 13.1 Fixed costs, such as rent, remain constant. Variable costs, such as reagents, are directly proportional to test volume.

same if the laboratory produces 1000 or 20,000 tests per month

Defining and identifying costs

- ***Salary costs*** expenses account for approximately **50% to 70%** of the laboratory budget.
- ***Operating costs*** are the expenses **incurred** to produce a product or service. Many items have **only a one-time use**
- ***Micro costing*** determines **the total direct labor and supply costs** of producing a test, and it is the starting point for **determining the fully loaded cost** and **ultimately the price for a test**.
- A run can be a group of tests that are performed once or many times during a shift or an **entire 24-hour period**.
- A run includes all quality **control** and **calibration** costs needed to produce patient results

Test Cost Analysis*

Test: Prostate-Specific Antigen

A. Microcosting: Instrument Run of One Reportable Test

Direct Labor

Determine the total "hands-on" time in minutes required to perform an instrument "run" of one patient test. Assume labor cost is $20 per hour.

	Minutes	Expense
Prepare specimen	5	
Prepare reagents	10	
Prepare instrument	10	
Computer and/or worksheet setup	5	
Documentation of results/quality control/maintenance	10	
Cleanup	10	
Total direct labor	50	$16.67

Direct Supplies

List all consumables needed to perform the test. Note that four tests (one sample and three controls) are needed to produce one patient reportable result. Calibration costs should be added if they are required with each run.

	Unit cost	Units	Expense
Reagent ($700 kit/100 tests)	$7	4	$28.00
Disposable pipettes ($10/100 pipettes)	$0.10	4	$0.40
Disposable reagent cups ($10/200 cups)	$0.05	4	$0.20
Low-, medium-, and high-control material (0.05 mL/test @ $20/mL)	$1	3	$3.00
Total direct supplies			$31.60
Total direct costs			$48.27
Cost per reportable (total direct cost/reportable results)	$48.27/1		$48.27
Testing efficiency (reportable patient results/tests)	1 result/4 tests		25%

Timing is important

The Future of Laboratory Medicine

Major changes because of **technological advances** and **external economic pressures.**

- In clinical laboratories, **cost savings** have frequently been realized by consolidation of laboratory sections with the creation **of central core** laboratories.
- Cost-pressure will most probably lead to more consolidation and a **trend to larger laboratories.**
- In some situations, supposed savings have also been achieved by the **addition of automated pre-analytical specimen** handling using robotic systems.

Reasons for a change

- **Real-time results**:

Physicians, particularly those working in **Emergency** Departments/ want their therapeutic decisions to be supported by as much information as possible

Now rapid laboratory response is feasible through **point-of-care testing (POCT)** and **centralized** laboratory facilities

- **Availability of more effective tests:**

Allow physicians to achieve a **better diagnosis**, **treatment** and **management** of patients/ Introduction of **new biochemical markers**

- **Involvement in therapeutic decisions**:

Assist physicians with patient therapy

Monitoring transplant patients

Measurement of immunosuppressive drugs

New Developments In Vitro Diagnostics

- Automation and robotics
- Artificial intelligence/Cloud computing
- New Generation of POCT Devices
- Apps for Medical Data Management
- Mass Spectrometry/ NMR
- Omics
- Microtechnology (Lab On a chip)

Humanoid robot ASIMO (Honda)

Automation

- In the **past half-century**, routine central laboratory testing has become **increasingly automated** and **efficient**.
- clinical chemistry/ immunochemistry/ hematology testing
- Originally **introduced** by the Auto Analyzer which performed continuous flow analysis, and the Robot Chemist
- Recent advancements in the digitization of **culture plate images** and the ability **to electronically read** incubated plates

Reduced **costs** /freeing **technicians** for more skilled responsibilities /improved **efficiency** /reduced **turnaround time** /improved **performance** /consolidation of **laboratory space**

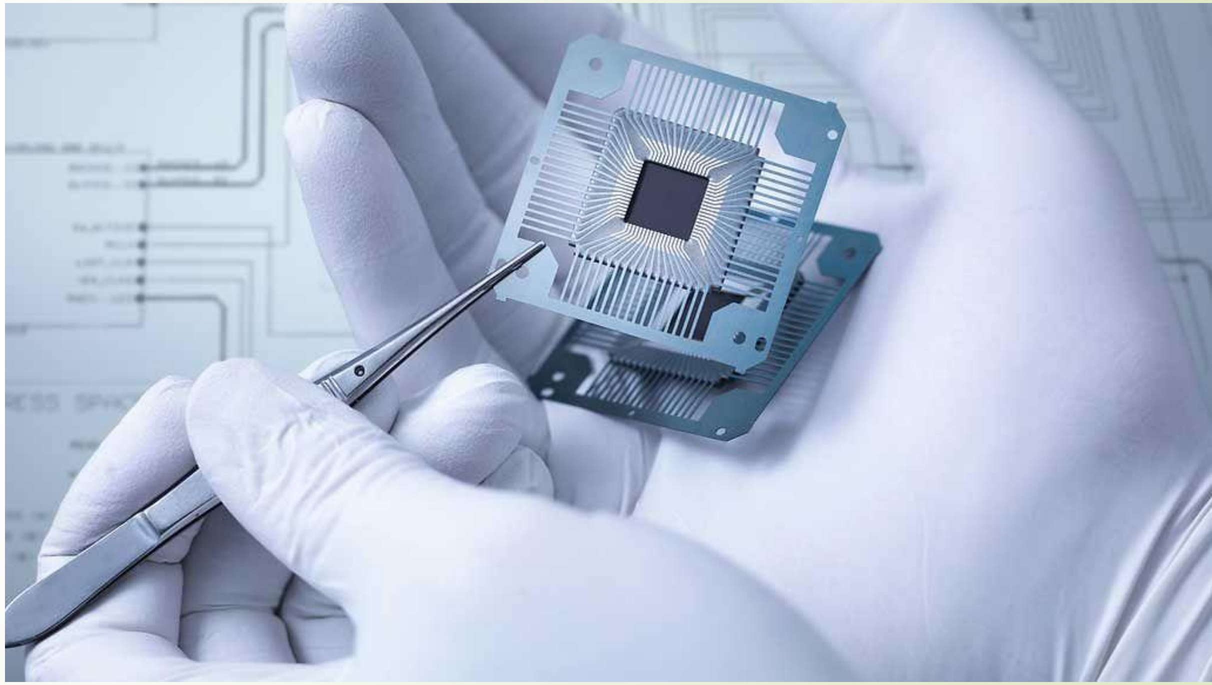
Cobots

- Recent development has been the use of a **cobot** (collaborative robot) in a shared workspace
- They are designed to **automate repetitive tasks**

- **Further** automation was introduced to **tackle time-consuming** and **laborious steps** within the **pre**-analytical phase and **post**-analytical phase
- sample identification, sorting, centrifugation, /specimen storage and archiving.
- **Two** Universal Robot **UR5 cobots** have been deployed in **a Danish hospital** to automate **sorting of blood specimens**. The first cobot **picks up samples**, places them in a **bar code scanner**, **identifies cap color** (via a camera), and **places tubes in racks according to cap color**. A second cobot picks **up the racks and places the racks in a feeder for centrifugation** and subsequent analysis.
- These technological advancements ultimately culminated in the generation of **total laboratory automation (TLA)**

Microtechnology (lab on a chip)

- Prominent examples of this are microfluidic devices such as the 'lab-on-a-chip' or micro total analysis system
- These **miniature** devices are composed of a **network** of **microchannel** or **Nano channels** that allow for the integration of multiple laboratory processes



Point-of-care testing(POCT)

- **Fast**

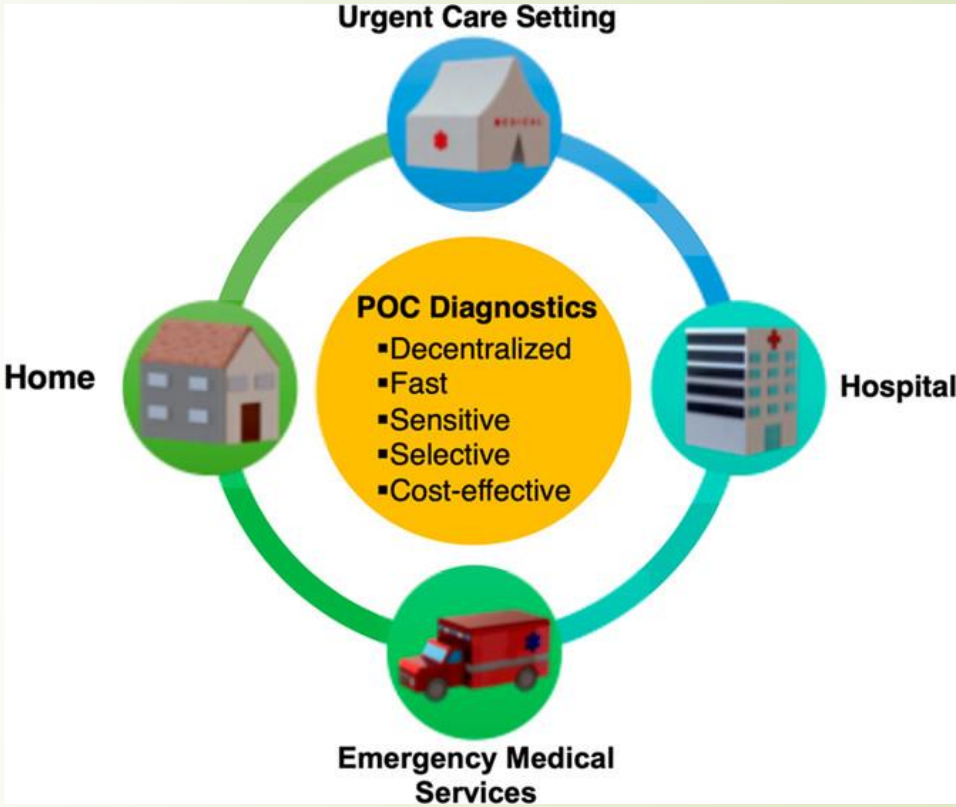
POCT delivers short turnaround time of **approximately 5–15 min**

- Simple **specimen handling**,
- Simpler **sample requirement**
- No **transportation**

Four main types of laboratories:

- 1.Hospital-based laboratories
- 2. Independent laboratories
- **3. Physician office laboratories**
- 4. Other laboratories

- **cost** of a hemoglobin A1c assay by high performance liquid chromatography (HPLC) in the central laboratory is **less than US$2**, whereas the point-of-care (POC) **immunoassay version of the test costs about US$10.**



POCT from an Economic Perspective

Developing of POCT:

The **global POC** diagnostics market reached **US$13.4 billion** in **2010**, and **US$16.5 billion** in **2016**

In Germany and Belgium, **as much as 25% of the total laboratory** tests are performed in the POC setting.

Another interesting development in **Japan** is the government's decision to **allow pharmacies to perform HbA1c POCT**

- POC tests are **not designed to replace the core laboratory**,

will help narrow the clinical-laboratory interface and **improve timely** clinical decision-making.

New Generation of POCT Devices

Smartphone-based devices

- Advancements in **molecular analysis**, **biosensors**,, **3D printing**, and **microfluidics , lab on a chip** Enabled smartphones to serve as read-out platforms for diagnostic tests,
- Recently, there has been an emergence of **smartphone-based devices** for **quantitative nucleic acid detection** using **paper-based sensors**, microfluidic chips, and digital droplet assays, particularly for **viral** detection

Wearable devices

- The **GlucoWatch** is an early example of a watch-like device designed to measure glucose.
- Recently, Samsung announced a **smart watch** that will **monitor vital signs** Smartphones
- They facilitate the measurement of biomarkers in various fluids, including **sweat**, **tears**, **saliva**
- These wearable devices are becoming more accurate, reliable, and efficient, thereby substantially improving their **clinical utility and opportunity for commercialization**
- Continuing innovations in **telecommunications**
- **1.3 million lives** saved by wearables by 2020.
- **$200 billion** saved — Estimated global health cost savings from wearable tech over the **next 25 years** .
- **50% reduction in hospital visits** — Projected reduction in hospitalizations through use of home monitoring devices of chronic diseases
- **$56.8 billion market** value market projection for wearable tech by **2025**

Drones

- The potential prime applications of drones in laboratory medicine are for **collection** and **delivery of blood specimens**.
- In **Lugano, Switzerland**, is developing a medical transport network based on quadcopter drones
- Recently in **Naples** (Italy) the transport of samples through drones with visual navigation has been implemented with success between two neighboring hospitals
- **Economic benefits:**
- **20–50%** saving over on-demand ground transportation
- **speed** of delivery

Artificial intelligence & Cloud computing

- **Machine learning** and **artificial intelligence** (AI) suitable for **data mining** and deep learning
- Data Mining: the practice of **examining large pre-existing databases** in order to generate new information.

Discovering patterns in large data sets involving methods at the intersection of machine learning, statistics, and database systems

- Indirect **reference intervals**
- Shortened **turnaround time**
- Availability of more **effective tests**
- **Biomarkers** for an early diagnosis and risk factors for disease prevention

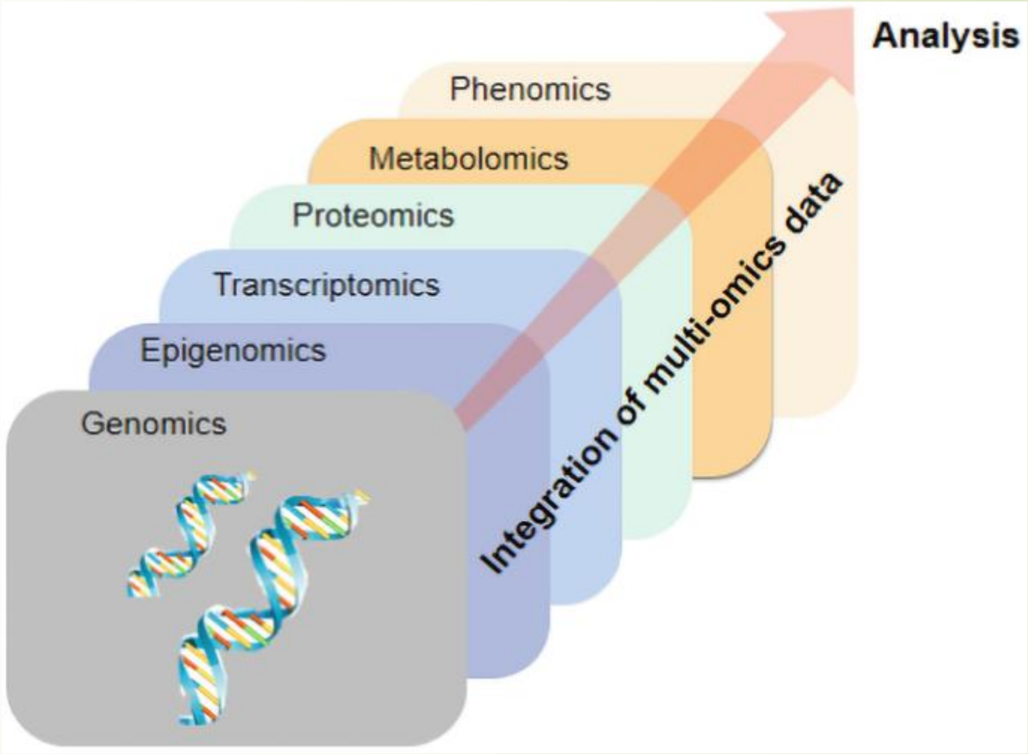
- The **AI** healthcare market will grow from **$600 million in 2014** to **$6 billion by 2021**

Laboratory **applications** and recent advancements

- In recent years, an increasing number of **web-based** and mobile applications has been developed to improve access **to laboratory test information and test result interpretation** and **help to cloud computing**
- Range from **simple apps** that provide reference lab value information to complex **medical diagnostics data management**
- The **global laboratory informatics market** size was valued at **USD 3.3 billion** in **2022** and is expected to expand at a compound annual growth rate of **4.9% from 2023 to 2030**.

Omics

- Refers to the sum of constituents within a cell
- In this context, the "Omics" revolution, including mainly **genomics**, **proteomics** and **metabolomics**
- The growing application of these technologies, as well as their integration with **micro technology** and **point-of-care testing**, has contributed to improved patient outcomes and **narrowing of the clinical-laboratory interface to facilitate a patient-centered approach (personalized medicine) to healthcare**.



Omics

- **Genomics:**

Most readily to the field of **oncology** and **circulating tumor DNA**.

Cancer Personalized Profiling by deep Sequencing which detects ctDNA, or cell-free methylated DNA immunoprecipitation-sequencing which identifies regions of the genome with DNA methylation

- **Transcriptomics:**

Performed *via* **microarrays** or **RNA sequencing**

Single-cell sequencing has revolutionized the field of genomics and transcriptomic to allow whole-genome DNA and RNA sequencing with high-throughput and lower cost

- **Metabolomics** and **Proteomics:**

Advances in **NMR** and **MS** technologies have largely defined the current fields of **proteomics** and **metabolomics**.

These omics fields are predominantly focused on identifying **novel biomarkers** and **therapeutic targets** for various disease pathologies.

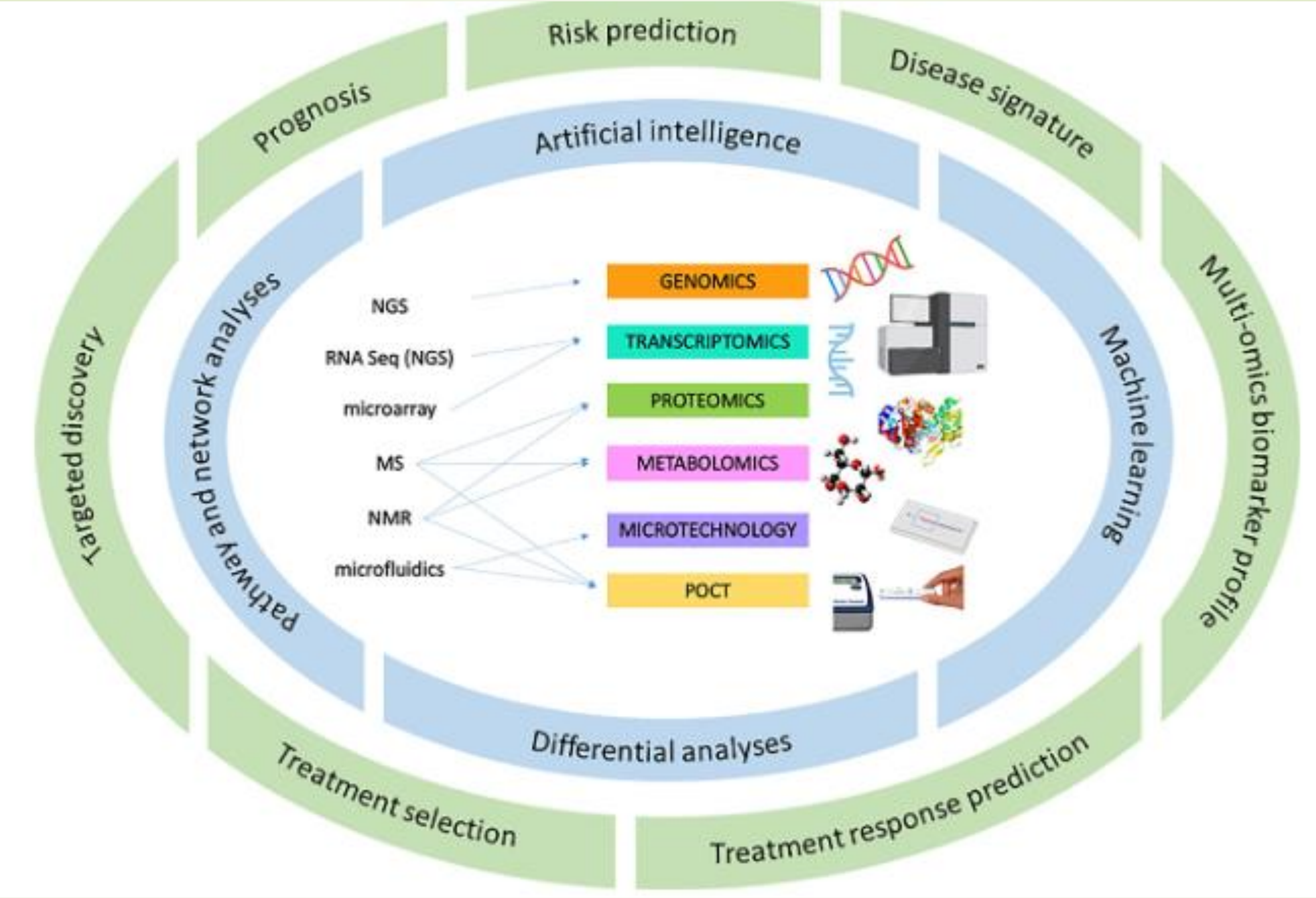
The global **omics-based clinical trials market size** was estimated at **USD 26.2 billion in 2021** and is reach **USD 28.1 billion in 2022** and It is expected to reach **USD 49.5 billion in 2030**

Mass spectrometry

Changes to mass spectrometry testing in the **next decade span** the total testing process and include:

- 1) Increase in the **number of clinical laboratories** providing MS-based testing applications
- 2) Increase in the **type of testing**, expanding across all disciplines of laboratory medicine
- 3) **Miniaturization** of mass spectrometry instruments;
- 4) **Automation**, including placing on routine laboratory track systems;
- 5) Sensitivity and the use of **smaller sample volumes** to allow for testing and monitoring patients;
- 6) **Moving away from immunoassay for most endocrine** (peptide and non-peptide hormones) and **drug testing**;
- 7) Location of instruments outside of **traditional laboratory** settings for **near patient testing**;
- 8) Improvements in **connectivity**
- 9) Improved **big data management** bring omics applications into the diagnostic laboratory.

The **global market** for **Mass Spectrometry** estimated **at US$4.2 Billion** in the year **2022**, is projected to reach a revised size of **US$5.8 Billion by 2030**


Risk prediction
Prognosis
Disease signature
Artificial intelligence
Targeted discovery
Pathway and network analyses
Machine learning
Multi-omics biomarker profile
NGS
RNA Seq (NGS)
microarray
MS
NMR
microfluidics
GENOMICS
TRANSCRIPTOMICS
PROTEOMICS
METABOLOMICS
MICROTECHNOLOGY
POCT
Differential analyses
Treatment selection
Treatment response prediction

Thank you for your attention