Special Report

Diagnostic Proteomics in Disease Detection & Personalized Medicine


Emerging Trends of Diagnostic Proteomics in North America

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Global Diagnostic (DTx) Proteomics Market – An Overview

Diagnostic proteomics is rapidly advancing with innovative technologies and computational tools, with significant potential to revolutionize disease diagnosis, treatment, and patient care
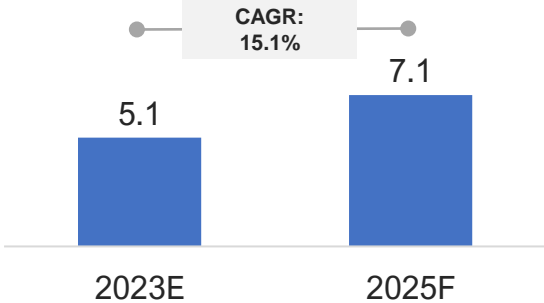
NA Diagnostic Proteomics Market Size | USD Bn

CAGR: 12.5%

6.2 — 2023E
7.9 — 2025F
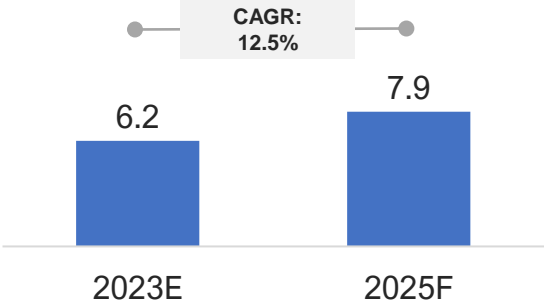
Europe Diagnostic Proteomics Market Size | USD Bn

CAGR: 14.5%

2.3 — 2023E
3.1 — 2025F
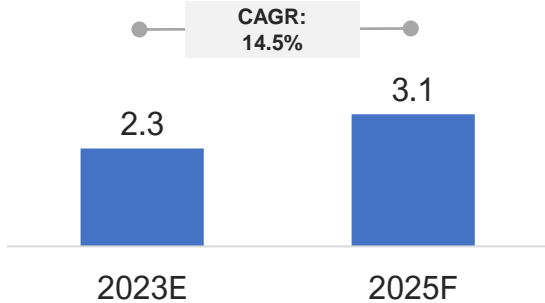
Asia Diagnostic Proteomics Market Size | USD Bn

CAGR: 15.1%

5.1 — 2023E
7.1 — 2025F

Diagnostic proteomics, which studies proteins and their interactions in biological systems, has emerged as a promising medical field, enabling the identification of biomarkers and disease mechanisms through advanced technology and data analysis. This would lead to more accurate disease detection and personalized treatment in precision medicine

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North America Proteomics DTx Market – A Deep Dive

North America holds majority share in the global proteomics market, with growth driven by increasing prevalence of chronic diseases, rise in geriatric population, and technological advancements that are seeing high uptake by diagnostic labs

Global Diagnostic Proteomics Market – % Share (By Geography)

Factors Driving North American Proteomics Dx Market

4.60%

6.10%

19.70%

43.70%

25.90%
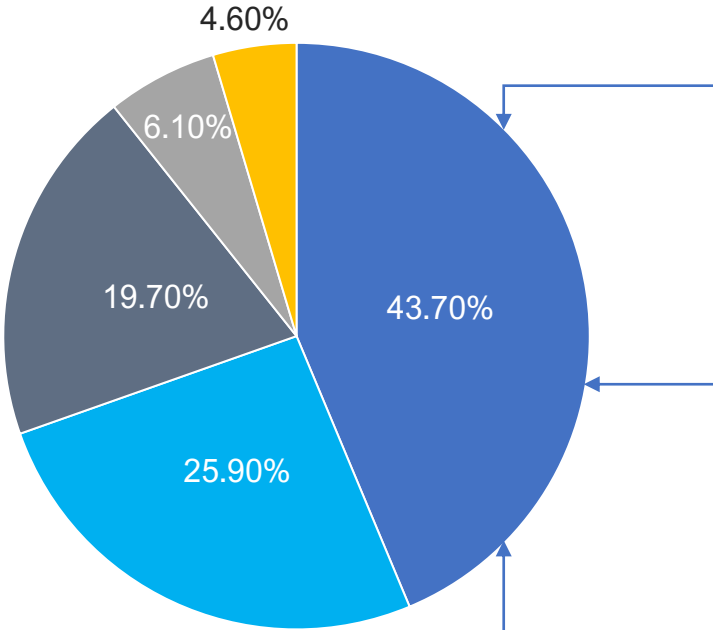
■ North America   ■ Europe

■ Asia Pacific   ■ South and Central America

■ Middle East and Africa

Increasing prevalence of chronic diseases

The region faces an increasing burden of chronic diseases that affects about 45% of the American population, such as cancer, cardiovascular issues, and neurodegenerative disorders. These conditions are associated with proteomic changes, detectable through proteomics

Growing geriatric population

The growing elderly population is fueling demand for point-of-care diagnostic testing, leading to increased opportunities for more frequent screenings

Development of new proteomics technologies and increased adoption by diagnostic laboratories

Advancements in proteomics technologies (including improved mass spectrometry) are driving development of new diagnostic tests for diseases, with labs increasingly leveraging these technologies to meet demand

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Proteogenomics – Integrating Genomics and Proteomics

Proteogenomics offers a comprehensive understanding of diseases, enabling identification of biomarkers, drug targets, and molecular pathways. This approach holds promise in cancer diagnostics, enhancing tumor profiling and treatment precision

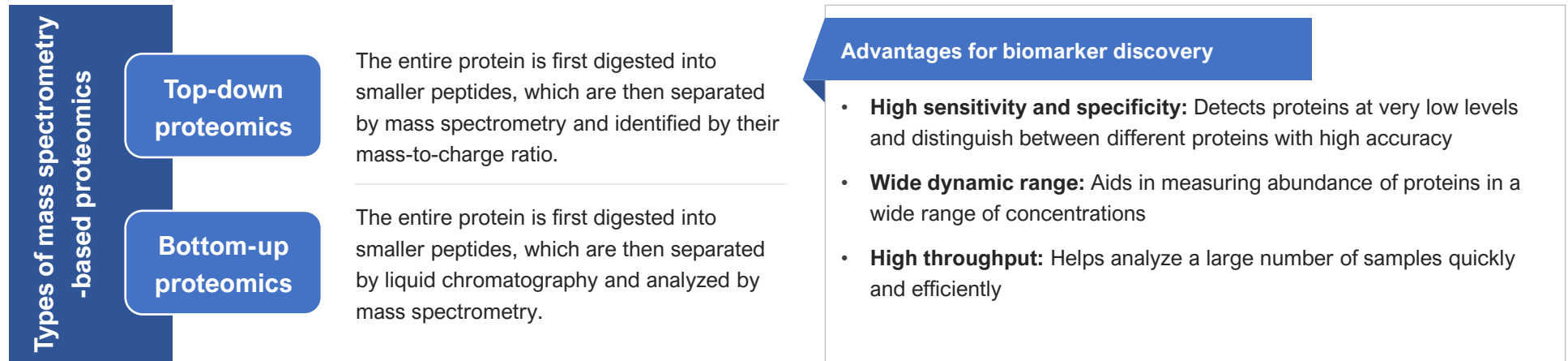| Application Area		Use Cases
Proteogenomics is being researched for its role in biomarker identification for early disease diagnosis, leading to specialized treatments and improved patient outcomes. This approach enables the discovery of novel biomarkers and monitoring treatment responses, deepening the understanding of disease processes through integrative systems biology	**Proteogenomics to identify biomarkers for early disease diagnosis**	• In January 2022, the University of Toronto researchers used proteogenomics to identify Alzheimer's biomarkers with 90% accuracy in distinguishing patients from healthy controls • In February 2022, the University of California researchers used proteogenomics for successful personalized cancer therapy by targeting altered proteins
Proteogenomics helps advance personalized medicine, enabling the identification of disease-specific biomarkers, targeted therapies, treatment response monitoring, personalized drug selection, disease subtyping, precision oncology, and personalized vaccine development	**Proteogenomics to develop personalized therapies**	• Genentech's T-DXd drug targets HER2-positive breast cancer cells using proteogenomics and is expected to gain FDA approval in 2023 after successful clinical trials • Quanterix's CardioMetRx test, utilizing proteogenomics, identifies altered proteins in a patient's blood for heart failure diagnosis and disease progression monitoring, with an expected launch in 2024
Proteogenomics enables comprehensive understanding of disease mechanisms including biomarker discovery, drug target identification, disease subtyping, and investigation of drug resistance. This approach sheds light on protein regulation and disease heterogeneity, offering valuable insights for targeted therapeutic strategies and improved patient care	**Proteogenomics to study disease mechanisms**	• In March 2023, researchers at the National Institutes of Health used proteogenomics to study HIV infection mechanisms and identified potential drug targets, paving the way for the development of new HIV treatments • In June 2023, researchers at the Broad Institute of MIT and Harvard published a study that used proteogenomics to study mechanisms of Alzheimer's disease

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Mass Spectrometry – Based Proteomics for Biomarker Discovery

Mass spectrometry-based proteomics is a potent technology for identifying and quantifying proteins in complex mixtures, making it ideal for biomarker discovery, aiding disease diagnosis, monitoring, and prediction

Types of mass spectrometry-based proteomics

Top-down proteomics

The entire protein is first digested into smaller peptides, which are then separated by mass spectrometry and identified by their mass-to-charge ratio.

Bottom-up proteomics

The entire protein is first digested into smaller peptides, which are then separated by liquid chromatography and analyzed by mass spectrometry.

Advantages for biomarker discovery

- **High sensitivity and specificity:** Detects proteins at very low levels and distinguish between different proteins with high accuracy
- **Wide dynamic range:** Aids in measuring abundance of proteins in a wide range of concentrations
- **High throughput:** Helps analyze a large number of samples quickly and efficiently

GE Healthcare's Proteomics Discovery Suite
GE Healthcare

GE Healthcare's Proteomics Discovery Suite was launched to identify and quantify proteins in complex mixtures, helping to develop biomarkers for several diseases such as cancer, diabetes, and Alzheimer's.

The technology consists of high-resolution mass spectrometers – Q Exactive Plus, Q Orbitrap Fusion, and Q Impact – supported by Proteome Discoverer and Progenesis QI software for proteomics data analysis.

Agilent Technology's Proteomics 2D Exploration Solution
Agilent Technologies

Agilent's Proteomics 2D Exploration Solution is designed to help researchers identify and quantify proteins in complex mixtures by using 2D gel electrophoresis (2DE). The technique can be used to separate proteins by their size and charge, thus effectively identifying biomarkers for several chronic diseases.
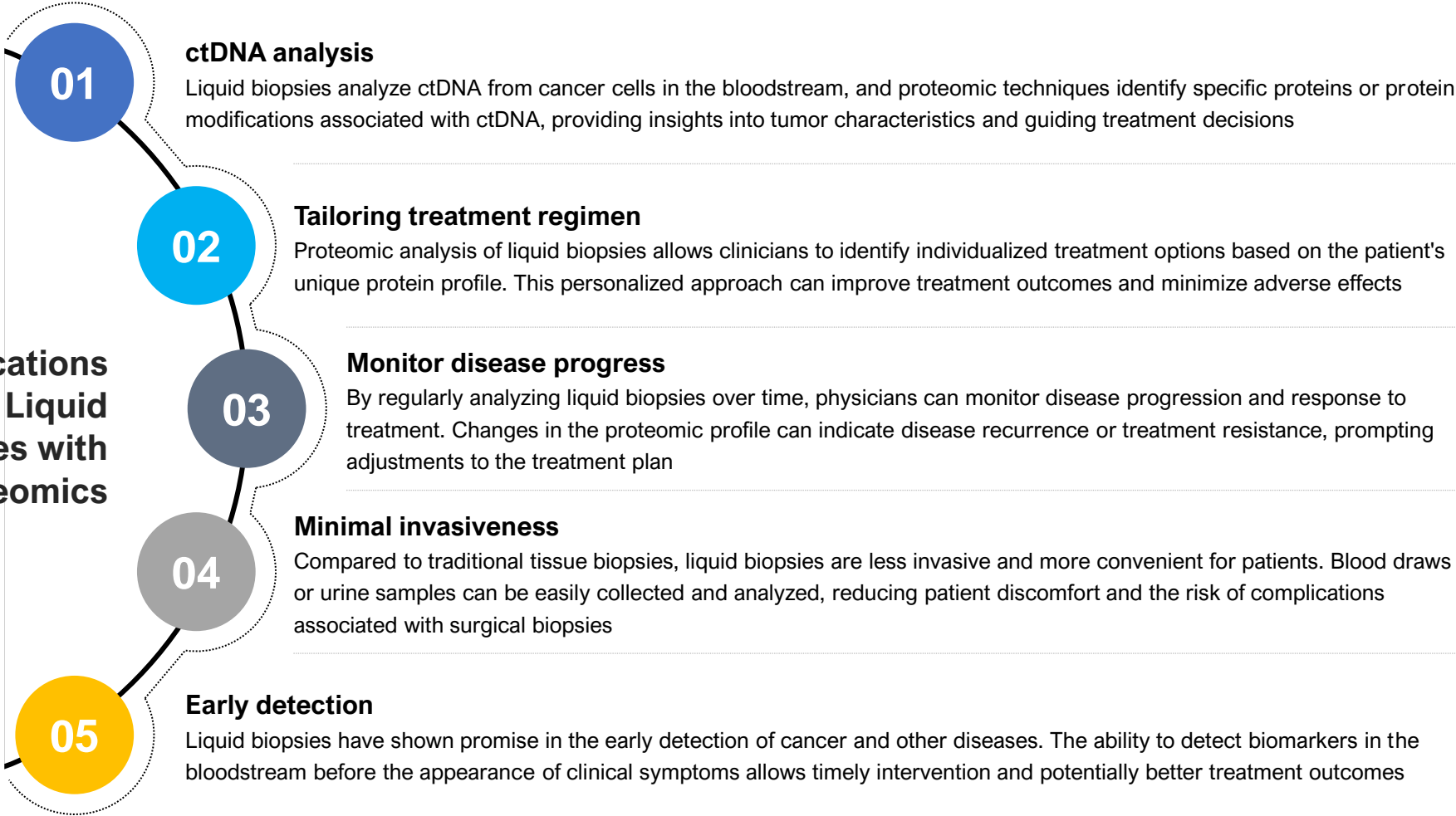
The solution includes a variety of 2DE gels, such as ProteomeLab 2D-PAGE Gels and ProteomeLab 2D-PAGE Minigels, combined with the company's proprietary ProteomeLab 2D Exploration software for data analysis.

Source: *Secondary Research, Industry Analysis*

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Liquid Biopsies: Non-Invasive Diagnostics with Proteomics

Liquid biopsies utilize proteomics and other techniques to analyze biomolecules in bodily fluids, enabling non-invasive disease monitoring, early cancer detection, treatment assessment, and personalized treatment target identification

Applications of Liquid Biopsies with Proteomics

01 — ctDNA analysis
Liquid biopsies analyze ctDNA from cancer cells in the bloodstream, and proteomic techniques identify specific proteins or protein modifications associated with ctDNA, providing insights into tumor characteristics and guiding treatment decisions

02 — Tailoring treatment regimen
Proteomic analysis of liquid biopsies allows clinicians to identify individualized treatment options based on the patient's unique protein profile. This personalized approach can improve treatment outcomes and minimize adverse effects

03 — Monitor disease progress
By regularly analyzing liquid biopsies over time, physicians can monitor disease progression and response to treatment. Changes in the proteomic profile can indicate disease recurrence or treatment resistance, prompting adjustments to the treatment plan

04 — Minimal invasiveness
Compared to traditional tissue biopsies, liquid biopsies are less invasive and more convenient for patients. Blood draws or urine samples can be easily collected and analyzed, reducing patient discomfort and the risk of complications associated with surgical biopsies

05 — Early detection
Liquid biopsies have shown promise in the early detection of cancer and other diseases. The ability to detect biomarkers in the bloodstream before the appearance of clinical symptoms allows timely intervention and potentially better treatment outcomes

Source: *Secondary Research, Industry Analysis*

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Companies Utilizing Liquid Biopsies in Proteomics – A North America Perspective

AI tools using the quantitative structure-property relationship can tackle formulation challenges in drug design by employing rule-based decision support systems to select appropriate excipients based on the drug's properties and adapt processes accordingly

FoundationOne Liquid CDx

FoundationOne Liquid CDx is an FDA-approved liquid biopsy test that analyzes DNA, RNA, and proteins in blood for cancer-related gene mutations and treatment response monitoring in advanced solid tumor patients. The technique combines next-generation sequencing for gene mutation identification and mass spectrometry for measuring cancer-associated proteins
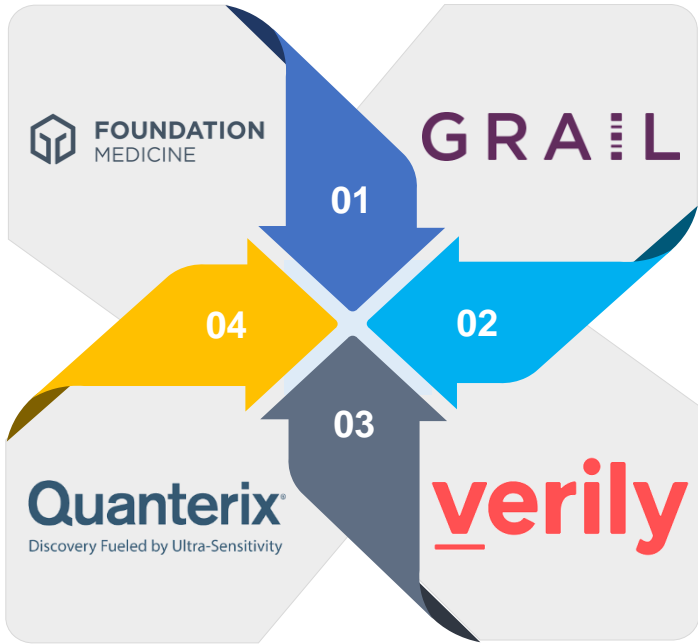
Galleri

Galleri is a liquid biopsy test that analyzes DNA, RNA, and proteins in blood to identify cancer-related gene mutations and measure cancer-associated proteins in asymptomatic patients. Its recent Breakthrough Device designation by the FDA expedites development and review, potentially leading to faster approval for patient use

CardioMet Rx

CardioMetRx is a liquid biopsy test developed by Quanterix that can be used to analyze proteins in a patient's blood. The test measures levels of proteins that are involved in heart failure, such as troponin and BNP, using mass spectrometry

The test has received Breakthrough Device designation by the FDA, which would essentially expedite its development and review, leading to expedited marketing authorization
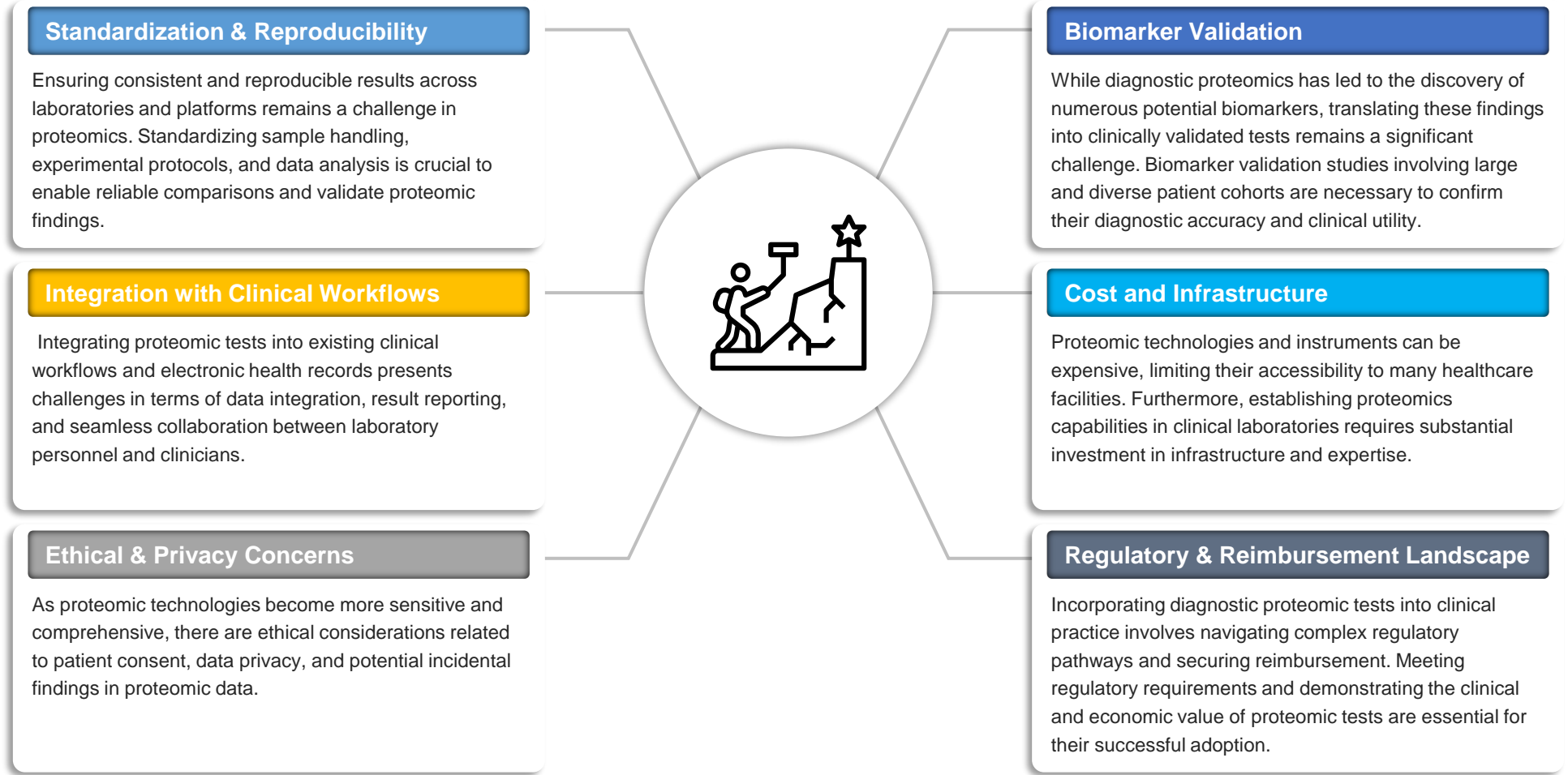
Veritas Cancer Assay

Verily Life Sciences has received Breakthrough Device designation from the FDA for its Veritas Cancer Assay, a test similar to Foundation Medicines' Liquid CDx, analyzing DNA, RNA, and proteins in blood samples to detect early signs of cancer in high-risk patients

01 FOUNDATION MEDICINE

02 GRAIL

03 verily

04 Quanterix — Discovery Fueled by Ultra-Sensitivity

Source: Secondary Research, Industry Analysis

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Key Challenges to Navigate in Proteomics Dtx Space

Challenges in diagnostic proteomics include complex data analysis, standardization, biomarker validation, obtaining representative samples, cost, regulatory considerations, integration with clinical workflows, and ethical and privacy concerns

Standardization & Reproducibility

Ensuring consistent and reproducible results across laboratories and platforms remains a challenge in proteomics. Standardizing sample handling, experimental protocols, and data analysis is crucial to enable reliable comparisons and validate proteomic findings.

Integration with Clinical Workflows

Integrating proteomic tests into existing clinical workflows and electronic health records presents challenges in terms of data integration, result reporting, and seamless collaboration between laboratory personnel and clinicians.

Ethical & Privacy Concerns

As proteomic technologies become more sensitive and comprehensive, there are ethical considerations related to patient consent, data privacy, and potential incidental findings in proteomic data.

Biomarker Validation

While diagnostic proteomics has led to the discovery of numerous potential biomarkers, translating these findings into clinically validated tests remains a significant challenge. Biomarker validation studies involving large and diverse patient cohorts are necessary to confirm their diagnostic accuracy and clinical utility.

Cost and Infrastructure

Proteomic technologies and instruments can be expensive, limiting their accessibility to many healthcare facilities. Furthermore, establishing proteomics capabilities in clinical laboratories requires substantial investment in infrastructure and expertise.

Regulatory & Reimbursement Landscape

Incorporating diagnostic proteomic tests into clinical practice involves navigating complex regulatory pathways and securing reimbursement. Meeting regulatory requirements and demonstrating the clinical and economic value of proteomic tests are essential for their successful adoption.

Source: *Secondary Research, Industry Analysis*

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Partnerships in Proteomics DX – Focus on North America

Companies are actively pursuing collaborations within the proteomic diagnostics space, to create vital healthcare tools for early disease diagnosis.

Agilent Technologies / Bio-Rad	Thermo Fisher Scientific / Guardant	GE Healthcare / Myriad genetics	Quanterix / Bristol Myers Squibb	Verily / 1Life Healthcare
Partnership to jointly develop and bring to the market a proteomics-based diagnostic test for Alzheimer's disease, utilizing Agilent's mass spectrometry and Bio-Rad's protein extraction and purification technology	Thermo Fisher Scientific and Guardant Health are collaborating to co-develop and launch a liquid biopsy test for early cancer detection, harnessing the former's mass spectrometry technology and the latter's expertise in cancer genomics	GE Healthcare and Myriad Genetics have collaborated to create and bring to market an innovative proteomics-based diagnostic test for breast cancer. This test would harness the former's cutting-edge mass spectrometry technology alongside the latter's exceptional proficiency in genomic testing	A novel proteomics-based diagnostic test for sepsis is currently under development for commercialization, leveraging Quanterix Corporation's advanced mass spectrometry technology, coupled with Bristol Myers Squibb's extensive drug development expertise	The companies have collaborated to develop and commercialize a proteomics-based diagnostic test for heart failure. The test will use Verily Life Sciences' proteomics technology and 1Life Healthcare's clinical expertise

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500+
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120+
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80+
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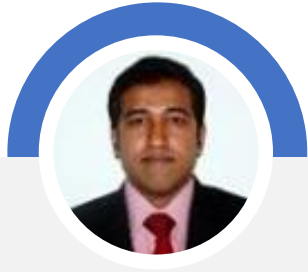
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