EXECUTIVE INSIGHTS

Looking Ahead in Diagnostics and Research Tools: Key Trends Impacting the Industry

The diagnostics and research tools industry has been thrust into the spotlight since the COVID-19 pandemic began. Almost all people reading this have likely purchased a COVID-19 molecular diagnostic test in the past two years, and terms like "PCR" and "antigen" are now part of our everyday vocabulary. Technological improvements and new business models in diagnostics and research tools are also supporting some of the timeliest innovations in healthcare — from personalized medicine to early detection of disease to home-based medicine.

This report discusses three trends that are expected to have the greatest impact on the industry:[1]

1. Rapid advancements in proteomics technology
2. Continued expansion of liquid biopsy to new applications
3. Accelerated consumerization of diagnostics

L.E.K. Consulting looks ahead at these trends, based on our expertise and analysis.

1. Rapid advancements in proteomics technology

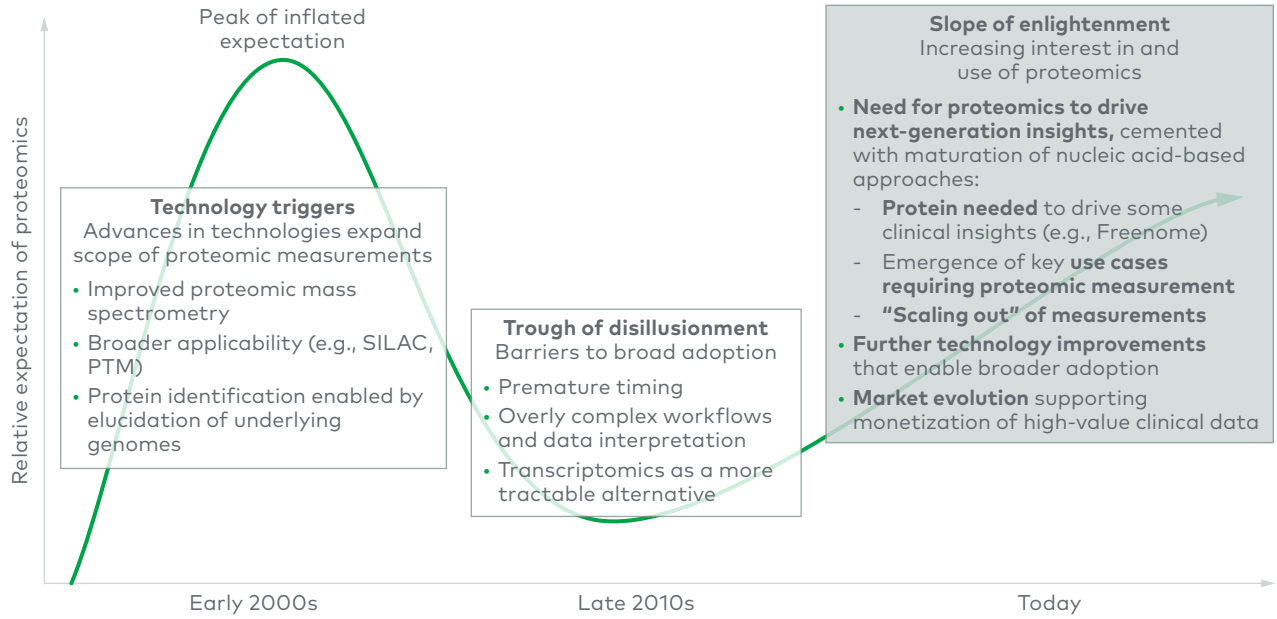
If the past two decades were the age of genomics, then the 2020s may be the age of proteomics (see Figure 1). Proteomics is more directly associated than genomics or transcriptomics (RNA) with human phenotypes, and therefore represents the most direct way to understand human diseases.

Proteomic tools like immunohistochemistry (IHC), mass spectrometry and enzyme-linked immunosorbent assay (ELISA) have existed for many decades. However, a mature market

for multiparametric proteomic tests has yet to emerge, as these legacy tools have lacked the necessary combination of sensitivity, plex and resolution to significantly advance understanding of disease states. But growing applications like advanced therapeutic modalities, immunology, liquid biopsy and precision medicine are driving demand for proteomics and spurring technological innovation.

New advancements including higher plex, higher sensitivity, single-cell resolution and spatial resolution have the potential to propel our understanding of disease etiology and our ability to identify targets and biomarkers and to develop and manufacture new therapeutic modalities and precision medicines.

Figure 1
Timeline of proteomics development



Low-complexity technologies (e.g., ELISA, IHC) have already reached maturity and will continue to have a role

Source: L.E.K. research and analysis; SILAC=stable isotope labeling by amino acids in cell culture, PTM=post-translational modification, ELISA=enzyme-linked immunosorbent assay, IHC=immunohistochemistry

Companies in the space are innovating to solve historical limitations of the two core proteomic technologies, mass spectrometry and protein array, which involve trade-offs on several performance characteristics. Mass spectrometry allows for hypothesis-free testing and could theoretically provide multiplexed coverage of the whole proteome, but it has relatively low sensitivity (1-1000 ng/mL) and throughput. Seer[2] and Biognosys[3] are developing pre-analytical and post-analytical solutions, respectively, to increase the throughput, sensitivity and plex of this technology.

Conversely, protein array approaches can have high sensitivity and throughput, but they have greater experimental bias and lower proteome coverage given the use of specific reagents for specific proteins. In this field, Olink is allowing for greater multiplexing using barcoded antibodies,[4] and SomaLogic has developed proprietary aptamers that can be screened at high throughput and 7,000-plex and growing.[5] Quanterix has developed an ultrasensitive biomarker digital detection technology that can detect proteins at very low levels in the blood,[6] an application well suited for screening, early detection and monitoring of disease. The science is exciting, but there are some key hurdles that must be overcome for these technologies to be used more broadly, including automation of sample preparation, standardization of analytical procedures and data sharing.[7]

Step changes in the past five years have also enabled scientists to characterize more than a thousand proteins from a **single cell**.[8,9] Scientists are increasingly interested in single-cell proteomics because many diseases are heterogeneous, and therefore bulk analysis — effectively a statistical average of an entire population of cells — is not necessarily representative of disease pathology. Single-cell proteomics enables identification of functional subpopulations of cells, providing a more granular understanding of disease pathology, mechanisms of therapy resistance, and relevant biomarkers and targets for new therapeutics. Some companies in the space include 10X Genomics, Mission Bio, Bio-Rad, Fluidigm, IsoPlexis and Berkeley Lights.

Proteomics represents a complementary approach to transcriptomics, a field also experiencing growth, and genomics. Therefore, innovators are also looking to **single-cell multiomics** as a next wave of single-cell technology. Companies like IsoPlexis, 10X Genomics, Becton Dickinson, Berkeley Lights and Mission Bio have developed platforms to measure different combinations of the genome, transcriptome and proteome (though not yet all three at once).

Spatial proteomics is another emerging market with high growth potential. This opportunity is largely in discovery and translational research today, but there is potential for spatial in the clinical setting, given immune-oncology pipeline activity and the shift toward precision medicine. Future clinical applications could include diagnosis, prognosis, treatment selection and monitoring. The current competitive landscape is defined by four to five key players using multiplex IHC (Akoya Biosciences, Ultivue), imaging mass cytometry (Fluidigm) and secondary ion mass spectrometry (Ionpath). NanoString Technologies, a key player in spatial transcriptomics, also offers spatial proteomics.[10] This combination of spatial and single-cell techniques would enable a more complete picture of disease states.

Proteomic technologies require data-intensive models and interpretation databases. As a result, numerous proteomics companies such as Seer,[11] Olink[12] and Biognosys[13] offer software

solutions for proteomic data analysis. Software and informatics offerings, including machine learning and artificial intelligence, represent an opportunity for innovators to differentiate and drive adoption and are increasingly a necessary part of the solution.

Many proteomics companies raised significant money over the past couple of years via initial public offering or venture capital and had high valuations based on the theoretical potential of their platforms. The financing market for proteomics tools in 2021 was white-hot, based on excitement in life sciences investing and on the promise of emerging proteomics companies becoming the Illumina of proteomics. Investor sentiment is shifting, however, toward expecting proteomics companies to demonstrate tangible business results, including revenue scaling through placements and pull through, and toward proteomics technologies gaining translational and clinical relevance. Multiple publicly traded companies experienced greater than 25% corrections in value in January 2022 alone.[14] This year and beyond, it will be critical for these companies to deliver on their promise and show real value for investors. Effectively segmenting and targeting customers — and forming partnerships with biopharmas, contract research organizations (CROs) and diagnostics companies — will be key to doing so.

2. Continued expansion of liquid biopsy to new applications

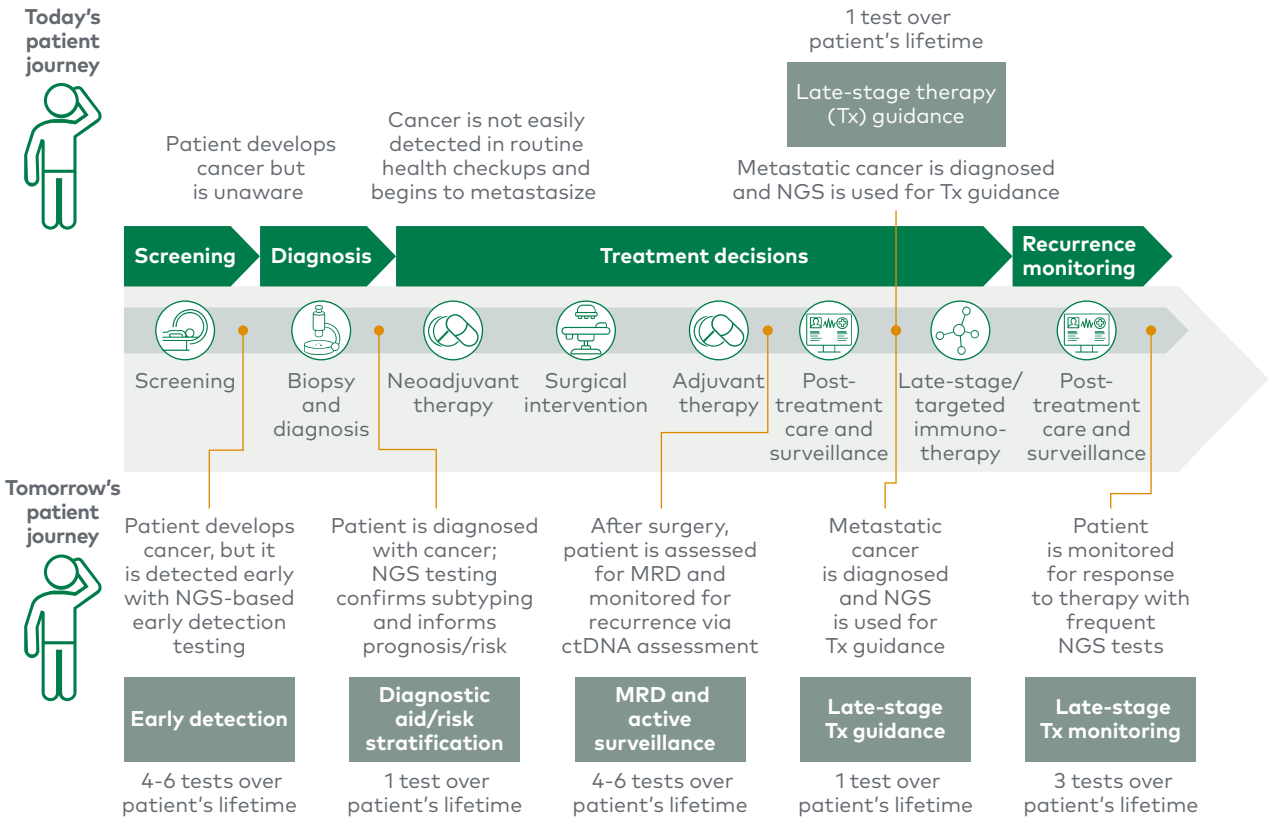
The liquid biopsy field is working to fulfill its potential to diagnose patients earlier and allow for more informed, precise patient management. There has been significant progress in the past couple of years, and the field is expected to continue to mature in existing applications while accelerating in nascent use cases and therapeutic areas.

Historically, the utility of molecular testing in oncology was limited to advanced disease-state patients" at first instance to provide guidance on treatment selection. Drivers for this include cost limitations, the focus of precision medicines on later-stage patients and the need for tissue biopsy. As a result, the first and most mature application for liquid biopsy today is **treatment selection for advanced oncology patients**. In 2020, the Food and Drug Administration (FDA) approved the first two next-generation sequencing (NGS), blood-based, oncology pan-solid tumor liquid biopsies that guide treatment decisions: Guardant Health's Guardant360 CDx[15] and Roche's FoundationOne Liquid CDx.[16] This field will continue to grow, given underlying growth in precision medicine targeted at a growing number of increasingly complex biomarkers. L.E.K. also expects the market to continue to mature as tests become more broadly reimbursed across geographies and in vitro diagnostic (IVD) kits allow for test decentralization.

Liquid biopsy applications are also catalyzing a paradigm shift from "one and done" NGS tests for late-stage patients toward longitudinal testing in broader populations across the entire patient journey (see Figure 2). They take advantage of established current procedural

terminology codes and coverage decisions, reduce sample collection challenges, and will increasingly use IVD content to enable testing outside of specialty reference labs.

Figure 2
Current and illustrative future oncology patient journey



Source: L.E.K. interviews and analysis; NGS=next-generation sequencing, MRD=minimum residual disease, ctDNA=circulating tumor DNA

One new application with significant progress in the past few years is **minimum residual disease (MRD) monitoring**, where ultrasensitive liquid biopsy tests can enable more effective surveillance and earlier detection of recurrence than can existing methods like carcinoembryonic antigen tests or imaging. Adaptive Biotechnologies is a leader in the space for hematological cancers.[17] Natera[18] and Guardant[19,20] are the most clinically advanced in the solid tumor space, having commercially launched laboratory-developed MRD liquid biopsy tests that measure circulating tumor DNA in 2019 and 2021, respectively. The initial focus for these tests is recurrence monitoring and risk stratification in colorectal cancers,[21] though Natera's liquid biopsy is now covered by the Centers for Medicare & Medicaid Services for pan-cancer immunotherapy monitoring, and Guardant is also planning to include additional tumor types.[22] Additionally, Invitae offers early access to its MRD liquid biopsy,[23] and NeoGenomics Laboratories is preparing to commercially launch an MRD assay this year.[24] This application

is valuable to biopharma companies developing treatments for the adjuvant setting. These technologies are still early in their adoption curve but are expected to see increased uptake, broader reimbursement and expansion into other tumor types.

Early detection is an even more nascent application of liquid biopsy that has long been considered the holy grail of cancer screening. Two FDA-approved liquid biopsy early detection tests are Exact Sciences Laboratories' stool-based Cologuard[25] and Epigenomics' blood-based Epi proColon,[26] both for colorectal cancer (CRC). In 2021, GRAIL launched Galleri,[27] the first multicancer early detection (MCED) test commercially available in the United States as a laboratory-developed test. The test sequences cell-free DNA in the blood to detect more than 50 cancer types.[28] The company is planning to pursue full FDA approval for the test in 2023.[29] Other companies developing early detection tests include Exact Sciences, which is developing a CRC blood screening test and a multiomic MCED test analyzing DNA and proteins;[30] Guardant, which is currently focusing on CRC but planning to expand to other tumor types;[31] Freenome;[32] Bluestar Genomics;[33] and Singlera Genomics.[34] Early detection tests are an incredible achievement, with the potential to have significant impact on patients, especially since the majority of cancer deaths occur in cancers without recommended screening tests.[35] Sufficient sensitivity for early-stage cancers and broad reimbursement are two key requirements for realizing the full potential of these tests.

Research in liquid biopsy **applications beyond oncology** is also increasing. Alzheimer's disease, for example, needs an inexpensive and scalable diagnostic to replace positron emission tomography (PET) scanning and allow for earlier identification of patients, even in pre-symptomatic stages. In 2020, C_2N Diagnostics launched a blood test for levels of amyloid beta that could enable this.[36] Nonalcoholic steatohepatitis (NASH) is another disease with a need for a less invasive, inexpensive test to replace liver biopsy and other less-specific blood test methods to screen for, triage, diagnose and/or monitor disease. Eighty million Americans are estimated to have nonalcoholic fatty liver disease, many of them undiagnosed, and of those, 10%-30% may have NASH.[37] Last year, Glympse Bio and DiscernDx both reported early proof-of-concept results for blood-based liquid biopsy tests for NASH.[38,39,40] These tests, if fully validated, could drastically increase the pool of diagnosed patients appropriate for disease-modifying treatments in development.

For liquid biopsy to move into early screening and detection in oncology and beyond at a wide scale, it will need to meet key requirements including test performance, pull through to confirmed diagnoses, and reimbursement. Minimizing false negatives and false positives will be important for driving widespread adoption. In oncology, physicians need to be able to reliably find the tumor, following a positive liquid biopsy screen, for the tests to be consistently

useful. Then, a key question will be whether the healthcare system will be able to afford the earlier and more frequent testing. For example, the total addressable market for pan-cancer screening in the U.S. could be ~$20 billion, assuming all ~120 million Americans aged 50 or older[41] receive a test at ~$500 per test every three years.[42] Cologuard is currently reimbursed by Medicare at ~$500,[43] but Galleri's list price is nearly twice as high at $949.[44] It is not yet clear what the screening frequency will be, what price the market would accept and whether NGS-based assays would be profitable at that price given the inherent costs. It will be important to monitor the market's progress on the above requirements.

3. Accelerated consumerization of diagnostics

Consumers are increasingly interested in taking their health into their own hands, and diagnostic tests are no exception. The COVID-19 pandemic has made diagnostics a more common part of everyday life and has popularized at-home testing as an alternative to less convenient in-lab testing. Now, consumers are "shopping" for diagnostic tests that are accurate, convenient, fast and affordable. At-home diagnostics may benefit the healthcare system as well, by reducing the number of in-person visits for routine tests and lowering the cost of care.

At-home sample collection is a common direct-to-consumer model outside of COVID-19 self-tests. In this model, consumers order tests, send samples to Clinical Laboratory Improvement Amendments-certified labs and then receive results, sometimes reviewed by physicians. Companies like LetsGetChecked,[45] Everlywell,[46] Verisana Laboratories[47] and myLAB Box[48] follow this model, offering menus of elective tests for (to various degrees) vitamin levels, thyroid levels, cholesterol levels, sexually transmitted diseases, fertility and more. Many of these companies were founded several years before the pandemic. However, investment in the space has been significant in the past two years — Everlywell raised a $175 million Series D round in 2020,[49] and LetsGetChecked raised a $150 million Series D round in 2021.[50]

Leading diagnostic companies and laboratories like Abbott Labs, Quidel, Quest Diagnostics and Becton Dickinson have also made significant investments in new channels for diagnostic tests. Abbott Labs and Quidel are looking to expand in direct-to-consumer diagnostics,[51] Quest Diagnostics is offering consumer-initiated lab testing in partnership with Walmart,[52] and Becton Dickinson acquired Scanwell Health, which has a smartphone app to analyze and interpret test results.[53] The market will likely experience the most growth in respiratory diseases, sexually transmitted diseases and colon cancer screening.

Several challenges with the at-home testing market will need to be addressed, as these tests shift some responsibility to the consumer for selecting the right test, conducting the test properly, paying for the test and, in some cases, interpreting the result correctly. It can

be difficult for consumers to assess or compare the reliability of different tests. Many of these tests are not covered by insurance, which will be a barrier to widespread adoption. Interpretation and counseling support will also be critical. As the market for more-complex at-home tests like cancer screening and organ function tests grows, patients will be discovering consequential health information at home and need support interpreting the results and determining next steps. These tests are often screening tests and not diagnostic tests, and patients need to understand the possibility of a false positive. Consumers, insurers, regulators, physicians and test providers will all need to confront these challenges as the market matures.

Conclusion

The diagnostics and research tools fields are expanding in new directions. New research tool technologies like proteomics are increasing scientists' understanding of human biology and disease. New diagnostic tools like liquid biopsy are making possible earlier detection and more targeted treatment of some of the most serious diseases. And new business models are bringing diagnostic tests to patients at home. These developments have the potential to transform the industry and have ramifications across the value chain, touching patients, providers, insurers, scientists, laboratorians and the biopharma industry. Diagnostics and research tools companies should consider their participation in these emerging fields as they build winning strategies.

For more information, please contact lifesciences@lek.com.

Endnotes

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