



# Capitalizing on Changes in the Molecular Diagnostics Market

## Industry Dynamic

The traditional MDx landscape is rapidly changing. Next generation sequencing has led to a deeper understanding of the meaning of genetic markers, increasing the need to test for them. New regulations have led hospitals and ACO's to push labs to provide more sophisticated assays predicting disease, so they can be treated earlier. In addition, there has been increasing pressure for companies to provide less invasive sampling techniques.

For the companies bringing these innovations to market, success will be determined by the ability to identify and capitalize on these changes.

Kaiser Associates specializes in supporting strategy and commercial teams at molecular diagnostic companies to answer some of their most pressing questions as they bring innovations to market:

- What unmet diagnostic needs can be addressed with our platform?
- What assay menu for our platform will best suit the labs for which it was designed?
- What is the optimal product profile and regulatory pathway for a specific assay?
- What is the right business model to gain commercial momentum domestically? Internationally?
- Which emerging technologies would fit well in our portfolio?

Kaiser's Healthcare Practice works with specialty pharmaceutical, biotechnology, and medical device companies. We work with these clients to help manage products throughout their lifecycle, from portfolio strategy and product development to commercialization and lifecycle management.

## How Kaiser Can Help

Kaiser Associates understands the challenges companies face in bringing new MDx technologies to market. Our team brings a unique balance of commercial and clinical expertise. We specialize in fact-based strategy—identifying unknowns, collecting external data and insights, creating quantitative models, and making informed strategic choices. And we do this all with our proven approach, tailored for each company's goals, whether they include commercialization, acquisition, licensing, or portfolio planning.

## Case Studies in Brief

	The Challenge	Our Solution	The Results
<b>Platform Menu Planning</b>	Large Diagnostics company with a PCR platform was looking to expand into new testing areas	Assessed market demand for tests for infectious disease, oncology, and genetics and primary research with lab directors in US and EU5 countries	Client launched commercially in US, and is launching the platform in additional countries
<b>Market Opportunity Assessment</b>	Large MDx company looking at market opportunity for their accurate and cost-effective immunoassay for a highly infectious disease	Kaiser performed an adjacent market opportunity assessment and created a go to market strategy for a specific segment of medical institutions	Client's test is now used in nationwide network of government institutions
<b>Acquisition Strategy</b>	Large global MDx company was working to identify an entry point to sequencing space	Performed M&A due diligence for a next generation sequencing platform	Client went through with a successful \$100MM+ acquisition
<b>Portfolio Strategic Planning</b>	Large global company with a growing MDx division needed a strategic plan for their Point of Care portfolio	Kaiser developed a long-term portfolio strategy and plan around 5 target markets, based on a comprehensive analysis of the entire medical landscape	The client is executing on their long-term strategy for building market leadership in their 5 target markets