The Growing Opportunities in the Lab Testing Market

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Most industries achieving an industrial level of scale and automation first must undergo a period of production that looks more like artisan craftsmanship than scaled modern manufacturing. This has been the pattern for industries such as rifle production in the late 18th and early 19th centuries, meat processing during the first half of the 19th century, and in more recent history the silicon chip industry. What the old and new economy industries that follow this pattern have in common prior to increasing economies of scale are an existing sizeable user base, growth in the face of the invention of new applications constrained by craftsman-like production methods, and high labor costs. Historically, these three traits are markers of industries ripe for innovation-driven advances in engineering principles and increased standardization.¹

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Rifle Production	Meat Processing	Silicon Chip Production	Lab Testing
 "An improvement is made here in the construction of the musket which it may be interesting to Congress to know. It consists in making every part of them so exactly alike that what belongs to any one may be used for every one musket in the magazineI put several together myself taking pieces at hazard as they came to hand, and they fitted in the most perfect manner. The advantages of this, when arms need repair, are evident." —Thomas Jefferson writing on Honoré Blanc's demonstration of interchangeable parts in 1785 	 "Chicago's livestock industry had begun nearly forty years earlier when Gurdon Hubbard drove about three hundred hogs from the Wabash Valley to Chicago in the winter of 1826-1827. Hubbard found ready customers among the army garrison at Fort Dearborn and the small surrounding unincorporated settlement." "The mechanical hog scraper first appeared in the 1870s. Before then, workers found the job grueling and very unpleasant as six men had to scrape the steaming carcassesLater in 1880, Amour and Company's Michael Cudahy and John Bouchard designed a superior scraper that adjusted itself to the size of the individual carcasses." —Dominic A. Pacyga, Slaughterhouse: Chicago's Union Stockyard and The World It Made 	 "Chipmakers produced marvelously complex patterns on each block of silicon, but their design methods were those of medieval artisans. Each company's fab (fabrication plant) had a long, complicated proprietary set of instructions for how chips must be designed if they were to be produced in that facility." -Chris Miller, <i>Chip War: The Fight for the World's Most Critical Technology</i> 	"Before, when we were handwriting or stickering the tubes ourselves, it would take four hours to do 1,000 tubes. Now it takes three minutes." -Life Sciences R&D Research Associate "Next Generation Sequencing ("NGS") is like a 20-step process, and that is where a molecular diagnostic specific LIMS comes in because there is a lot of equipment and transfers and all these different steps. Most LISs ("Lab Information Systems") are patient-focused, and they cannot add this level of granularity and step-by-step tracking. All of them [labs] will have a LIS, and some will be fine shoehorning into the existing LIS until they adopt NGS. To scale NGS, you must have a purpose-built solution." -LIMS Expert

i ii iii iv v vi vii viii

From our vantage point, we view several segments of the laboratory testing space to possess these markers. In many R&D labs, Ph.D.s are spending hours writing on test tubes. In genomics testing, the cost of sequencing has come down and the volume of associated data are rapidly rising. Purpose-made software is accelerating the process, replacing homegrown applications that failed to scale beyond a given

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academic or health system. As such, the industry is undergoing a period of investment and standardization that allows for new forms of scale and the development of new applications. From our work in the space, Splash 4 Partners identified five areas of opportunity driven by five macro factors.

Macro Drivers	Description	
Technical Debt Residing in Many Labs	Many labs, ranging from university programs to large health systems to contract resource organizations, invested in core IT applications—such as LMS and LIMS—five, ten, or fifteen years ago. Over time, the systems have been integrated with hardware and other software applications making changing out the system costly and disruptive.	
Rising Labor Expense in Staffing Labs	Labor rates for staffing labs continues to rise across the board. Most heads of labs have pathology degrees or advanced degrees in chemistry or biology. For tests that have not been commodified yet, expensive laborers are manually running tests with dozens of complex steps that must be done in a specific order. For commodified tests, automation in things like labeling, liquid handling, and reporting are primary focuses.	
The Genomics Revolution	The cost of sequencing the human genome continues to drop rapidly. This has resulted in blood tests for genomic disorders in mothers for early screening, early detection of cancer, the development of RNA-based vaccines, and the development of precision medical treatments. The volume of data being captured and analyzed is exploding within the field of genomics. To capitalize on this, Colossus-the startup taking aim at bringing a Wolly Mammoth back to life—has spun out a software offering—FormBio-that makes data analysis for CRISPER-related research easier.	
Advancements in Machine Learning and Al	ML and AI advancements are allowing for new patterns to be identified and for years of wet lab experiments to be simulated rapidly. One SME interviewed by S4P stated, "We're using more computationally assisted drug design and that is, we're using more computational modeling and simulation with our pre-clinical work, with our discovery work. We do virtual screening. Instead of high-throughput screening for molecules that hit your biological target, we use some of the structure-activity relationship computation with AI."	
Progress Towards Consumer Healthcare	Advances in drop shipping, sample accessioning, and electronic health records have helped usher in a direct-to-patient application that allows for the sale and kitting of tests processed through a centralized lab. Such centralized test processing of esoteric tests is able to aggregate large and potentially valuable datasets. This has been observed in the pending \$7.2 billion acquisition of the cancer screening company Grail by Illumina.	

These macro drivers are leading to changes in software adoption and key workflows that are changing the cost curve for a large volume of lab tests across a wide array of lab settings. We focus on five areas currently benefiting from a move toward standardization of processes in production.

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Areas of Standardization	Product Types	Product Descriptions	Example Companies
Automation of Wet Labs	 Labelling machines Automatic liquid handlers 	Machines that assist in the automation of handling and processing of the sample from the time the lab acquires it through testing, and disposal or storage.	 Brooks Life Sciences Illumina SPT Labs TubeWriter
Data Analysis	 Informatics programs 	Advanced statistical packages designed to help analyze terabytes of data for diagnosis or drug/therapeutic design.	 Grail Dotmatics Tetra Science
Data Management Systems	 Data lakes Electronic lab notebooks Lab information management systems Lab information systems 	Software systems that integrate with lab hardware used to track samples, manage inventory, and record notes from lab personnel.	 Benchling SapioScientific Tetra Science
Sample Tracking	 Newborn screening sample tracking Sexual assault kit tracking Marijuana supply chain tracking 	Samples for clinical and R&D labs are often collected at the bedside and shipped to a lab for testing. Samples are sometimes lost or contaminated in transit. End-to-end chain of custody helps improve the fidelity of the sample and prevent losses.	 JusticeTrax Kallaco TruLab STACSDNA
Testing Kits	 At-home test kits Employee drug testing kits In-office testing kits 	All-in-one kits to collect. Some kits, like a home COVID test or home pregnancy test, allow for test results to be provided within minutes at home. Other kits require the sample to be sent to a centralized lab for processing.	23&Me Everlywell Grail

The fragmented nature of the lab testing industry creates opportunities for hardware, software, and service providers to enter the market by tailoring offerings to use cases within and across labs, within a given market segment. For example, the STARLIMS offering is used in industrial manufacturers, chemical refineries, forensic labs, and clinical settings. Whereas companies like Benchling (an ELN, or an electronic lab notebook) and Tetra Sciences (a cloud-based data analytics and consulting services company) have found success among life sciences companies by building industry-specific applications used in drug discovery and development. More segment-specific go-to-market approaches appear to be more common due in part to the feature functionality catering to the demands of specific lab types.^{ix}

Each lab type and end market represent a different size total addressable market and different procurement processes tied to widely different funding sources. For example, in 2021, JusticeTrax, a LIS provider for government forensic labs, was acquired by Versaterm, a private equity-backed roll-up of public safety software providers.^x We believe the acquisition of JusticeTrax speaks to the large chasm between the forensic market and the broader lab information system and lab information management system market. Some subject matter experts report the rapid advances in genomics shakes up the breadth

The Growing Opportunities in the Lab Testing Market

January 2023 www.splash4partners.com

and depth of DNA testing done within forensic cases. Time will tell what the adoption rate of newer genetics applications will look like in government-focused labs.

Lab Types	Owners/Opera	ators	Description
Academics	 Universities 	Ø	Labs run by professors and staffed frequently by Ph.D. candidates and fellows. Funding often comes from large grants from private industry, governments, and non-profits.
Agricultural & Food Based Labs	Agriculture companiesFood producersMarijuana producers		Used commonly to test for quality, sources, and ingredients. Agriculture- based businesses may use genomic applications to breed more resilient crops.
Clinical	 Fertility practices/IVF labs Health systems Lab companies Urology practices Toxicology labs 		Processing lab tests for medical diagnoses. Multiple lab types in this setting, such as: anatomic pathology, clinical pathology, molecular, and genomics. Clinical labs' IT systems are built around tying sample and test results to a patient record and patient billing system.
Forensic Labs	 Law enforcement Military Lab testing companies 		Large volume of testing, driven mostly through a limited number of federal, state, and local labs. A smaller number of private forensic labs exist. The type of testing done at each forensic lab varies greatly, as do their budgets.
Industrial Labs	Oil producersChemical producersWater treatment facilities		Labs used to test quality and sources of inputs and finished materials.
Pharma: R&D, Manufacturing, QA, and Anti-Counterfeit Testing	Life science companiesCROs		Pharma labs often have multiple lab types, multiple buyers spread within and across divisions. R&D labs specialize based upon methods, materials, and application areas. Manufacturing labs focus on testing inputs to production and the quality of products coming out of their production facility. Anti-counterfeiting labs are also run to identify knockoffs and trace them back to a manufacturing source.
Public Health Labs	 State & local government officials 		Labs run by government agencies tasked with monitoring everything from water quality, the health of newborn infants, and the rate / speed of sexually transmitted diseases.

xi

Opportunities abound as the dollars and applications continue to expand for the lab testing industry. In addition to the rapid development of mRNA-based COVID vaccines, FormBio's spin-off from Colossal Scientific,^{xii} and numerous genomics-focused acquisitions by LabCorp in recent years,^{xiii} JPMorgan's healthcare venture group announced the formation of their own Life Sciences venture group^{xiv} to capitalize on the advances in precision medicine, vaccines, and software applications underfoot—all of which we see as part of this broader transformation being driven by the five macro factors laid out earlier.

We welcome a chance to connect with investors, advisors, and operators who are active or interested in the lab testing space. Reach out to the Splash 4 Partners principals at the email addresses on the next page.



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January 2023 www.splash4partners.com

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The Growing Opportunities in the Lab Testing Market

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End Notes

ⁱ https://www.bbc.com/news/business-49499444.

ⁱⁱ Honoré Balnc's demonstration in 1785 of interchangeable parts in weaponry reflected a multi-decade R&D effort by the French to have interchangeable parts produced across gunsmiths. This predated Eli Whitney's cotton gin. In fact, after Whitney lost control of his cotton gin patent, he turned his attention to producing rifles via the interchangeable parts method for the U.S. government. It would take the armory at Harper's Ferry decades to be able to replicate Whitney and Balnc's production methods reliably.

ⁱⁱⁱ Dominic A. Pacyga. Slaughterhouse: Chicago's Union Stock Yard and the World It Made, The University Chicago Press. 2015.

^{iv} Three hundred hogs were slaughtered by hand in 1826. By 1858, the daily processing capacity for hogs was 9,000, although the lack of refrigeration limited peak processing to fall and winter months. The rising volume of livestock pouring in via rail, drove innovation in the industry to create mechanized means of production.

^v Chris Miller. *Chip Wars: The Fight for the World's Most Critical Technology,* Scribner. 2022.

^{vi} Prior to the development of advanced machinery used to design and fabricate chips, engineers painstakingly used stencils, Exacto knives, tweezers, and other arts and crafts tools to design their chips. This craftsman-like approach led to idiosyncratic productions at scale and limited the variety and types of chips that could be produced. The ever-increasing variety and volume of information able to be stored on a given silicon chip are tied to the algorithmic approach that leverages exacting standards and methods of computer-aided lithography. More time was unlocked for chip design than production, leading to the abundance of silicon wafer applications that underwrite our world today.

^{vii} S4P interviews, research, and analysis.

viii Not only are there numerous steps to follow in most genomics-based tests, but the sequence can also vary from lab to lab for the same test. This is similar to the overly complicated set of production instructions in silicon wafers or the great variation across gunsmiths prior to the 19th century.

^{ix} S4P interviews, research, and analysis.

x https://www.govtech.com/biz/versaterm-buys-forensic-software-provider-justicetrax.

^{xi} S4P interviews, research, and analysis.

xii https://www.axios.com/pro/climate-deals/2022/09/27/woolly-mammoth-software-may-now-save-bees.

xiii <u>https://www.labcorp.com/about/history</u>.

xiv https://www.wsj.com/articles/jpmorgan-launches-life-sciences-venture-group-11667300402.