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## Inside the Lab Industry: COVID-19 Continues Driving Growth but in a New Way as Core Revenues Rebound

The earnings narrative for Q1 is essentially the combination of growing COVID-19 revenues, albeit at a slightly slower pace than the previous quarter, and the continued recovery of non-coronavirus core segments. Essentially, the DX industry is getting the best of both worlds. And while the long-term sustainability of COVID revenues remain in doubt, the boost from resumption and catch up in medical care and surgery engendered by the pandemic should be more than enough to take up the slack.

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## Increasing Revenue: New Colorectal Cancer Screening Guidelines Are a Windfall for Exact Sciences, Cologuard

If you held stock in Exact Sciences on May 17, chances are you went to bed happy on May 18. It was on May 18 that a U.S. government taskforce officially announced a change in its guidelines for colorectal cancer testing by recommending that screening begin at age 45, rather than 50. In addition to saving thousands of lives by promoting earlier detection, the announcement lifted the stock price of Exact Sciences, maker of Cologuard, the top selling molecular colorectal cancer screening tests that the task force recommends. The prospect of more users at an earlier age is certainly exciting news, especially since those late 40-somethings with commercial insurance won't have to lay out any of their own money for Cologuard.

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## Revenues Continue to Surge but Growth Patterns Change

Of the 39 diagnostics firms that had reported their 2021 Q1 earnings as of press time, Abbott and Quidel were the only two to fall short of their Wall Street top line revenue targets. But Abbott just narrowly missed and both firms generated robust growth levels. In fact, every single company experienced positive year-over-year growth, the vast majority growth in the double digits. No fewer than seven companies increased their revenue guidance for the full year, with only two trimming down their projections, Fluidigm and Meridian Biosciences.

Continuing pandemic patterns, the demand for COVID-19 tests, collection kits and instruments fuelled unprecedented growth in diagnostic revenues at a time when routine testing volumes have fallen off a cliff. However, the pattern is changing. The previous engine of growth, SARS-CoV-2 molecular testing, is now in sharp decline thanks to the COVID-19 and falling case rates. Exhibit A: LabCorp reported that it delivered an average 112,000 molecular COVID-19 tests per day during Q1 but that the daily average had dropped to 80,000 by the end of the quarter. During the company's Q1 earnings call, LabCorp CEO Adam Schechter projected that molecular testing revenues would decline between 35 percent and 50 percent for the full year.

The pattern was much the same with Quest Diagnostics, which reported that it expected to be average around 50,000 SARS-CoV-2 molecular tests per day throughout Q2, as opposed to the 73,000 daily tests it was averaging at the end of Q1. Similarly, Opko Health subsidiary BioReference Laboratories reported that daily averages fell from between 50,000 and 60,000 molecular tests in Q4 2020 to between 40,000 and 50,000 tests in Q1. Neither company projected an overall rate of decline for all of 2021.

## From PCR to POC Testing

The flipside to the decline in molecular testing is the surge for rapid point-of-care (POC) and antigen COVID-19 testing. As society reopens, the center of gravity in the coronavirus testing market is shifting to relatively lower cost, fast and scalable tests that can be provided at the point of care for screening the asymptomatic, including at schools, workplaces and major sports leagues like Major League Baseball and the NBA.

"If you look at PCR testing throughout the United States and you look at the estimates that are coming from the antigen and point-of-care providers, you see that the actual level of testing is almost at the same level as we were [last] summer, but in different forms," noted Quest CEO and chairman Steve Rusckowski. "There is a transition from PCR exclusively ... to more capabilities around point-of-care and antigen testing."

Many of the leading companies have done a good job of anticipating the shift and pivoting by delivering the products to meet it, including POC and antigen tests as well as tests and self-collection kits for home use. The Q1 earnings reports demonstrate that this strategy is paying off, with many companies, including Abbott, Danaher, Opko Health, Quest and Siemens Healthineers reporting significant spikes in rapid COVID-19 POC and antigen tests.

### The At-Home and DTC Opportunity

Direct to consumer (DTC) and at-home testing represent a parallel path for COVID-related growth. Abbott has staked out an early claim by focusing on its BinaxNOW COVID-19 Antigen Self Test, which customers can now buy over the counter from CVS, Walmart and Walgreens. The strategy looks to develop a template that can be used to deliver DTC, at-home test products for other ailments if and when the COVID-19 crisis ever ends.

Quest estimates consumer testing to represent a \$2 billion opportunity by 2025, growing at a 10 percent compound annual growth rate and is expanding its DTC operation with hopes of capturing a \$250 million share of the market.

### The Recovery of Core Testing Markets

The other positive development to emerge from the 2021 Q1 earnings reports is the continued rebound of other segments devastated by the pandemic, with many firms reporting positive growth in cancer screening, blood testing, non-COVID genetic molecular testing and other divisions that experienced steady declines in 2020. Although the pandemic losses haven't yet been made up, things are clearly trending in that direction as surgeries, clinical trials and doctor visits resume, often at a stepped-up pace to make up for lost time.

Still another indicator of financial strength lies in the bottom lines, with only eight companies missing their Wall Street earnings per share targets during the quarter: Fluidigm, Guardant Health, Hologic, Invitae, NeoGenomics, Quidel, Twist Bioscience and Veracyte.

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### Diagnosics Earning Reports for 2021 Q1 (period ended March 31, 2021)

(Companies with at least \$10 million in sales)

COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	\$10.46 billion (\$10.69 billion)	+35% (+33% organic)	Adjusted +\$1.32 (+\$1.27)	DX up 120% to \$4.01 billion. Core DX up 20% at \$1.18 billion as base business continues to recover; DX growth driven by massive demand for COVID tests, including 221% increase in molecular to \$447 million; rapid diagnostics up 303% to \$2.26 billion; point of care drops 7% to \$129 million; significant increase in instrument sales
Adaptive Biotech	\$38.4 million (\$27.8 million)	+84%	Net -\$0.29 (-\$0.41)	After declines of Q4, sequencing revenues grew 60% to \$15.2 million due to COVID, test volume for ClonoSeq also turned last quarter's decline around with increase of 35% (4,757 tests); Development revenues up 111% to \$23.3 million driven by higher demand for biopharma services
Becton Dickinson (FY 2021 Q2)	\$4.91 billion (\$4.89 billion)	+15%	Adjusted +\$3.19 (+\$3.04)	Growth driven by COVID-19 testing, which brings in \$480 million, including \$239 million from newly launched Veritor Plus; all core non-COVID segments also came in ahead of expectations but still remain below pre-pandemic levels
Biodesix	\$28.9 million (\$26.3 million)	+550%	Net -\$0.26 (-\$0.17)	COVID testing revenue goes from \$0 to \$23.2 million; Core businesses also up, including lung cancer DX by 11% to \$4.0 million and biopharma by 13% to \$1.7 million
BioMérieux	\$1.02 billion	+10%		Clinical applications up 10% to \$803.86 million; BioFire Film Array products up 19%; Immunoassays reverse decline by increasing 22% at \$133.87 million; Molecular biology also goes from down to up 11% to \$361.39 million; Microbiology down again by 2% to \$275.53 million
Bio-Rad Laboratories	\$726.8 million (\$661.0 million)	+27%	Adjusted +\$5.21 (+\$3.00)	Life Sciences up 61% to \$366.5 million driven by PCR and Droplet Digital PCR products in response to COVID-19, which also drove Clinical DX down 2% to \$358.5 million

COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
<b>Bio-Techne (2021 FY Q3)</b>	\$243.6 million (\$228.2 million)	+25%	Adjusted +\$1.79 (+\$1.55)	DX & Genomics up 18% to \$58.1 million; Protein Sciences up 28% to \$185.6 million; Growth driven by Exosome DX business (up over 100%), including rebound in ExoDx Prostate orders
<b>Bruker</b>	\$554.7 million (\$513.1 million)	+31%	Adjusted +\$0.44 (+\$0.32)	Significant recovery in businesses hurt by pandemic, especially mass spectrometry; COVID also continued to drive growth in molecular DX testing (\$7 million contributed) and microbiology
<b>*CareDx</b>	\$67.4 million (\$61.1 million)	+76%	+\$0.14 (break-even)	Testing services up 89% to \$59.3 million driven by increase in AlloSure Kidney and AlloMap Heart sales; Products sales up 23% to \$5.8 million; Digital and other revenues up 5% to \$2.3 million
<b>Castle Biosciences</b>	\$22.8 million \$16.7 million	+31%	Net -\$0.17 -\$0.23	Gene expression tests up 4% with 5,142 delivered; DecisionDx-Melanoma test volume down 11% with 4,060 reports delivered
<b>Centogene</b>	\$84.1 million (\$50.8 million)	+500%	Net -\$1.25 (-\$1.56)	\$73.05 million in COVID revenues more than offsets 19% decline in core testing revenues at \$7.09 million and 41% decline in pharmaceutical revenues \$5.74 million
<b>Danaher</b>	\$6.86 billion (\$6.26 billion)	+58%	Adjusted +\$2.52 (+\$1.75)	Core revenues up 30%, including newly acquired Cytiva; DX up 34% to \$2.18 billion, including 90% growth of Cepheid driven by continuing unprecedented demand for COVID testing; Life sciences up 115% to \$3.55 billion; Biopharma up in low 20% range, excluding COVID revenues
<b>Exact Sciences</b>	\$402.1 million (\$388.6 million)	+16%	Net -\$0.18 (-\$1.03)	Screening revenues up 10% to \$240.3 million, including Cologuard which over 8,000 providers ordered; Precision oncology, including Oncotype products, up just 1% to \$129.4 million; COVID testing \$32.3 million, vs. \$99.1 million in Q4
<b>Fluidigm**</b>	\$32.8 million (\$32.0 million)	+19%	Adjusted -\$0.15 (-\$0.14)	Product revenues up 30% to \$24.7 million; Service revenues up 21% decline to \$6.3 million; Instruments down 19% to \$7.7 million; COVID revenues of \$6.5 million
<b>Fulgent Genetics*</b>	\$359.4 million (\$321.5 million)	From \$7.8 million to \$359.4 million	Net +\$6.52 (+\$5.86)	Massive growth driven by COVID with 3.8 million billable tests delivered; Next generation sequencing also up 115% to \$16.7 million

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COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
<b>Guardant Health</b>	\$78.7 million (\$73.8 million)	+17%	Net -\$1.09 (-\$0.89)	Precision oncology up 6% to \$63.7 million; Development services more than double at \$14.9 million driven by new companion Dx products for biopharma
<b>Hologic (FY 2021 Q2)</b>	\$1.54 billion (\$1.54 billion)	+104%	Adjusted +\$2.59 (+\$2.62)	COVID surge continues with total DX up 233% to \$1.05 billion, including 391% growth in molecular diagnostics to \$935.3 million driven by demand for COVID tests on Panther Fusion systems; Cytology and perinatal revenues up 3% to \$117.2 million; Non-COVID segments recover, including Breast Health (up 9% to \$336.3 million) and Gyn surgical (up 8% to \$114.2 million)
<b>Illumina</b>	\$1.09 billion (\$1.00 billion)	+27%	Net +\$1.89 +\$1.38	First ever billion dollar quarter driven by 36% growth in products to \$953 million, which more than offset 11% decline in services and other revenues; Sequencing up 29% to \$979 million; Instruments more than double to \$176 million
<b>Invitae</b>	\$103.6 million (\$101.5 million)	+61%	Non GAAP -\$0.63 (-\$0.59)	\$99.3 million in testing revenues (up 57%) (259,000 tests billed) with test volumes bouncing back due to easing of COVID conditions; Other revenues triple to \$4.3 million
<b>*LabCorp</b>	\$4.16 billion (\$3.91 billion)	+47%	Adjusted +\$8.79 (+\$7.43)	Slightly slower growth from Q4 with total DX up 62% to \$2.76 billion driven by COVID; Test volume up 27% but COVID testing declines and base volume down 1%; But non-COVID, core segments recovering faster than expected, which will have to drive future growth with COVID testing expected to continue tailing off
<b>**Meridien Biosciences (FY 2021, Q2)</b>	\$85.3 million (\$84.5 million)	+49%	Adjusted +\$0.56 (+\$0.48)	Life sciences more than doubles to \$53.3 million, including \$31 million from COVID products; But DX continues to decline 9% (vs 13% in Q1) to \$31.9, with molecular assays down 39% to \$4.4 million and non-molecular assays flat at \$27.6 million

COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
<b>Myriad Genetics (FY 2021, Q3)</b>	\$173.1 million (\$156.2 million)	+6% (vs. -21% in Q2)	Adjusted -\$0.06 (-\$0.14)	Testing volumes continue to recover under new corporate leadership; Molecular DX goes from 21% decline to 6% growth (to \$150.5 million); Hereditary cancer down again but by less, 11% vs. 33%, to \$76.1 million; By product, Vectra rheumatoid arthritis up 2% to \$10.7 million and Prolaris prostate more than doubles to \$18.5 million
<b>*Natera</b>	\$152.3 million (\$114.4 million)	+62%	Net -\$0.74 (-\$1.02)	Growth driven by 48% increase in test volume and one-time payment from Qiagen related to terminated NGS test distribution partnership; Product revenues up 36% to \$118.4 million
<b>NeoGenomics</b>	\$115.5 million (\$112.4 million)	+9%	Adjusted -\$0.04 (-\$0.01)	Core divisions continue recovery, including clinical services up 4% to \$96.5 million, driven by COVID testing revenues; Pharma services up 46% to \$19.0 million
<b>Opko Health</b>	\$545.2 million (\$495.1 million)	+200%	Pro forma +\$0.05 (+\$0.05)	Services revenues nearly triple to \$507 million, due to COVID testing by BioReference Lab; Product revenues reverse Q4 decline with 9% growth to \$33.9 million; Intellectual property revenues down 55% to \$4.3 million due to decrease in amortization of payments from Pfizer for somatrogon growth hormone
<b>OraSure Technologies</b>	\$58.6 million (\$57.0 million)	+85%	Net +\$0.05 (+\$0.04)	Molecular DX revenues more than triple to \$43.2 million, driven by COVID collection device sales, including DNA Genotek kits and ORAcollect RNA saliva collection device; HIV up 26% to \$5.3 million in US but down 50% to \$3.5 million abroad
<b>Pacific Biosciences</b>	\$29.0 million (\$25.6 million)	+86% (reversing 3% decline of Q4)	Net -\$0.01 (-\$0.46)	Instrument revenues more than triple to \$14.9 million driven by multi-instrument sales; Consumables up 20% to \$10.4 million; Service and other revenues slightly up from \$3.3 to \$3.7 million
<b>PerkinElmer</b>	\$1.31 billion (\$1.21 billion)	+100%	Adjusted +\$3.72 (+\$3.07)	COVID PCR tests and RNA extraction solutions drive third massive quarter in a row, including 236% growth in DX to \$853.1 million; Applied genomics up 330% and immunodiagnosics up 420%; Reproductive health up in high single digits

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COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
Personalis	\$20.9 million (\$20.4 million)	+9%	Net -\$0.29 (-\$0.36)	VA Millions Veterans Program revenues down 11% to \$13.2 million but other customer revenues up 74% to \$7.7 million, with firm projecting high growth in oncology
Qiagen	\$567.2 million (\$557.5 million)	+52%	Adjusted +\$0.66 (+\$0.63)	186% growth in COVID products to \$203 million coupled with return of non-COVID products to near pre-pandemic levels; Molecular DX up 59% to \$279 million; Life sciences up 47% to \$288 million; NGS returns to growth with 17% increase to \$50 million driven by oncology applications for bioinformatic products
*Quest Diagnostics	\$2.72 billion (\$2.64 billion)	+49%	Adjusted +\$3.76 (+\$3.71)	Continued demand for COVID testing drives 26% increase in overall test volume and 21% growth in revenue per requisition; Base testing recovers to near pre-pandemic levels, despite 10% to 15% hit of PAMA Medicare price cuts
Quidel	\$375.3 million (\$400.8 million)	+115%	Adjusted +\$4.09 (+\$4.71)	Massive COVID growth continues but at slower rate; Molecular DX up more than 7-fold to \$60.3 million driven Lyra PCR and Solana assays for COVID; Rapid immunoassays up 148% to \$237.7 million, including \$212.1 million from Sofia SARS Antigen; Cardio immunoassays up 24% to \$66.6 million; Specialized DX continue slide at faster rate, 34% (vs. 20% in Q4), to \$16.5 million as demand for respiratory products remains weak
Roche Diagnostics	\$16.26 billion	+50%	Not provided	Total DX up 55% to \$4.82 billion, including \$1.2 billion COVID sales; Molecular DX up 86% to \$1.24 billion driven by high-throughput PCR COVID testing; Core lab up 28% to \$1.97 billion driven by immunoDX; Point of Care nearly quadruples to \$797 million
*Siemens Healthineers (FY 2021, Q2)	\$4.78 billion	+8%	Adjusted +\$0.54	DX up 23% to \$1.51 billion, including \$231.9 million in rapid SARS-CoV-2 antigen and molecular tests; Recovery in core non-COVID businesses, including nearly \$400 million in rapid antigen tests for the first half of FY

COMPANY	FY 2021 Q1			DX Segment Performance
	Total Revenue (vs. Wall St)	YOY Revenues	EPS (vs. Wall Street)	
<b>10x Genomics</b>	\$105.8 million (\$102.5 million)	+47%	Net -\$0.22 (-\$0.27)	Continues rebound with 52% increase in consumables to \$93.1 million and 23% increase in Instruments to \$11.1 million and 21% jump in Service revenues to \$1.6 million
<b>*Thermo Fisher Scientific</b>	\$9.91 billion (\$9.72 billion)	+59%	Adjusted +\$7.21 (+\$6.65)	Life sciences up 137% to \$4.20 billion; Specialty DX up 69% (about half of Q1 rate) to \$1.62 billion; Analytical instruments up 26% to \$1.39 billion; Laboratory products and services revenues up 32% to \$3.60 billion
<b>*Twist Bioscience (FY 2021, Q2)</b>	\$31.2 million (\$28.3 million)	+62%	Net -\$0.78 (-\$0.77)	Next-generation sequencing revenues, including SNP microarray conversions and liquid biopsy panels more than double to \$17.7 million, topping Synthetic biology revenues (\$12.9 million) for second quarter in a row
<b>Veracyte</b>	\$36.7 million (\$32.7 million)	+18%	Net -\$0.66 (-\$0.12)	Overall testing up 23% to \$32.7 million; Product revenues slightly down at \$3.1 million, including 14% decline in Prosigna (2,144 tests); Genomic test volume up 11% to 14,437 tests, including 1,560 Decipher tests
<b>Waters</b>	\$608.5 million (\$525.3 million)	+31%	Non-GAAP +\$2.37 (+\$1.57)	All sectors achieve higher growth, with Pharma up 28%, Industrial up 24%, Academic and government sales up 29% after declining 15% in previous quarter

**Bold face:** Companies that met or exceeded average or consensus Q1 Wall Street revenue estimates

\* Companies that raised their revenue or EPS guidance during Q1

\*\* Companies that lowered their revenue or EPS guidance during Q1



## DX Deals: Labs Cutting Deals to Provide Pooled COVID-19 Testing for Schools

As schools return to in-person learning environments, communities across the country are turning to COVID-19 testing programs to monitor and contain the virus. Although, more and more teachers, parents and guardians become vaccinated against the virus clinical vaccine trials for individuals under 16 are just beginning, so testing to track and mitigate viral spread is critical.

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**■ DX Deals: Labs Cutting Deals to Provide Pooled COVID-19 Testing for Schools, from page 9****Who's Paying for School Testing**

Funded by the \$10 billion provided by the Biden administration for COVID-19 testing in K-12 schools and a new Rockefeller Foundation initiative to guide schools on providing COVID-19 testing, labs are partnering with Ginkgo Bioworks to ramp up testing. Quest Diagnostics, Dascena Labs, Helix, COuentia and Olive labs have all announced collaborations to provide COVID-19 testing services for K-12 students in the U.S. The labs are partnering with Ginkgo to provide free COVID-19 pooled testing services for every K–12 student each week.

“We are very excited to partner with Ginkgo on this highly important initiative as our country continues to work to recover from the ongoing COVID-19 crisis,” said James Wingrove, Ph.D., Chief Scientific Officer of Dascena, Inc., who oversees Dascena Labs in a [statement](#). “Enabling the safe return of children and teachers back to in-person learning is a crucial step in that recovery. By providing accessible and accurate testing to teachers and students, we hope, that together with Ginkgo, we can help to provide safe learning environments.”

**Testing Services to Be Provided**

Many of the deals call for testing on pooled samples, a testing protocol that the FDA is temporarily allowing to meet the unprecedented demand for COVID-19 testing. Ginkgo’s platform offers pooled testing, where 5 to 25 samples are pooled into one sample, to reduce the cost of testing without sacrificing accuracy. Children as young as kindergarten age swab their own noses. Ginkgo’s website notes that they currently provide their pooled testing service to 946 schools.

Concentric by Ginkgo is Ginkgo Bioworks, Inc.’s biosecurity and public health effort and a national testing provider for K-12 schools. Its goal is to provide easy, affordable pooled testing to every school in America. Ginkgo Concentric is currently running testing in more than 15 states in 800 schools.

Pooled classroom testing, which combines swabs from all consenting individuals in a classroom and runs them as a single test, is an effective way to significantly increase testing capacity and lower the cost of testing programs. For example, Ferndale, Michigan-based Olive Labs will perform the PCR testing and currently has a turnaround time of 24 hours, it said. The lab has scaled its testing equipment and has the capacity to “potentially test all the schools” in Michigan, it added.

The services are based on recommendations provided by the Rockefeller Foundation in its [K–12 National Testing Action Program: Connecting Schools with the Nation’s Leading Testing Companies to Safely Reopen \(NTAP\)](#), which provides a testing roadmap for schools and cites both Quest and Ginkgo for their COVID-19 testing expertise.



Here's a summary of other key strategic diagnostic deals announced in May 2021:

### STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Qiagen	Mirati Therapeutics	<ul style="list-style-type: none"> <li>Objective: Develop tissue-based companion diagnostic test to identify cancer patients for adagrasib, Mirati's investigational oral small molecule inhibitor of KRAS G12C</li> <li>Dynamic: Test to become part of Qiagen's Therascreen KRAS testing portfolio</li> <li>Initial focus on CDx test for non-small cell lung cancer with possibility of expansion to other Mirati oncology programs</li> </ul>
Fujifilm Medical Systems USA	Helio Health	<ul style="list-style-type: none"> <li>Objective: Develop blood-based test for earlier detection of liver cancer</li> <li>Dynamic: Use Helio Health's HelioLiver DNA methylation and biomarker-based blood test for detecting hepatocellular carcinoma — with Fujifilm's µTASWako i30 immunoanalyzer</li> </ul>
Siemens Healthineers	Genetron Health	<ul style="list-style-type: none"> <li>Objective: Expand hospital use of Genetron's S5 sequencing platform and 8-gene lung cancer IVD assay in China</li> <li>Dynamic: Partners to also work together to help standardize cancer molecular testing practices in hospitals in China</li> </ul>
Sciex	Waters	<ul style="list-style-type: none"> <li>Objective: Offer Sciex's mass spectrometry systems fully configured and interoperable with Waters' liquid chromatography instruments</li> <li>Dynamic: Collaboration will make it easier for Sciex mass spec customers to configure their systems with Waters' UPLC instruments</li> </ul>
Quest Diagnostics	Paige	<ul style="list-style-type: none"> <li>Objective: Discover biomarkers for cancer and other diseases</li> <li>Dynamic: Leverage Paige's AI and machine learning expertise of pathology diagnostic data for biomarker discovery and develop new tests and software products</li> </ul>
Quest Diagnostics	CIC Health	<ul style="list-style-type: none"> <li>Objective: Provide SARS-CoV-2 testing for K-12 schools, summer camps and other programs</li> <li>Dynamic: Quest to augment CIC Health's lab network, which currently facilitates pooled COVID-19 testing for over 80 school districts and 600 schools across 20 states</li> </ul>

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■ DX Deals: Labs Cutting Deals to Provide Pooled COVID-19 Testing for Schools, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Quest Diagnostics	Ginkgo Bioworks	<ul style="list-style-type: none"> <li>Objective: Provide COVID-19 screening testing for grades K-12 to support in-class learning across U.S.</li> <li>Dynamic: Patterned after Ginkgo's existing collaborations with other COVID-19 testing labs, including Dascena Labs, Olive Labs and CQentia</li> </ul>
Watchmaker Genomics	Molecular Loop have	<ul style="list-style-type: none"> <li>Objective: Commercialize genetic tests for pathogen surveillance</li> <li>Dynamic: Combine Watchmaker's expertise in computational biology, high-throughput enzyme engineering, and large-scale enzyme production with Molecular Loop's molecular inversion probe (MIP)-based assays</li> </ul>
Exagen	Allegheny Health Network Research Institute + AHN Autoimmunity Institute	<ul style="list-style-type: none"> <li>Objective: Develop develop new patented biomarkers for diagnosis, prognosis and monitoring of autoimmune diseases</li> <li>Dynamic: Exagen to acquire a worldwide exclusive license to four families of inventions and access to Autoimmunity Institute's clinical biobank</li> </ul>
Alzheon	Institute of Organic Chemistry and Biochemistry of Czech Academy of Sciences (IOCB)	<ul style="list-style-type: none"> <li>Objective: Develop test for Alzheimer's disease</li> <li>Dynamic: IOCB to use Alzheon's analytical chemistry technology to develop the test and Alzheon to commercialize it</li> </ul>
Bio-Techne	908 Devices	<ul style="list-style-type: none"> <li>Objective: Develop extended workflow for protein characterization</li> <li>Dynamic: Combine Bio-Techne's Maurice icIEF protein separation instrument with 908 Devices' ZipChip platform to enable in-depth characterization of intact and near-native biotherapeutics</li> </ul>
Echelon Diagnostics	Cradle Genomics	<ul style="list-style-type: none"> <li>Objective: Accelerate development of Cradle's cell-based noninvasive prenatal diagnostic products</li> <li>Dynamic: EchelonDx to use its PrenatalDx technology to enhance data analysis and reporting capabilities of Cradle's fetal genetic analysis and health screening solutions</li> </ul>

Partner 1	Partner(s) 2+	Deal Summary
Inivata	Agendia	<ul style="list-style-type: none"> <li>Objective: Commercialize Inivata's liquid biopsy assay for minimal residual disease detection in breast cancer</li> <li>Dynamic: Agendia to get co-exclusive rights to distribute Inivata's RaDaR liquid biopsy assay for breast cancer detection in North America and Europe</li> <li>Agendia also gets option to extend the deal to additional territories later</li> </ul>
NuProbe	AcornMed Biotechnology	<ul style="list-style-type: none"> <li>Objective: Develop tests for minimal residual disease detection in genitourinary tract cancer and hematological cancer</li> <li>Dynamic: Leverage NuProbe's blocker displacement amplification, or BDA, technology to create assays</li> </ul>
BostonGene	Medical College of Wisconsin	<ul style="list-style-type: none"> <li>Objective: Identify predictive biomarkers for pancreatic cancer</li> <li>Dynamic: Analyze whether patients' pancreatic ductal adenocarcinoma unique tumor microenvironments affect their treatment responses</li> </ul>
Illumina	Kartos Therapeutics	<ul style="list-style-type: none"> <li>Objective: Develop NGS-based TP53 companion diagnostic</li> <li>Dynamic: Base test on Illumina's pan-cancer comprehensive genomic profiling assay, TruSight Oncology 500 (TSO 500) for use to detect TP53 mutations in multiple hematologic indications</li> </ul>

### DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Yourgene	Alliance Global	<ul style="list-style-type: none"> <li>Products: Yourgene's noninvasive prenatal testing products, reproductive health tests and QS250 and LightBench enrichment technologies</li> <li>Territory: Middle East and Africa</li> </ul>
IsoPlexis	Bucher Biotec	<ul style="list-style-type: none"> <li>Products: IsoPlexis' IsoLight and IsoSpark proteomics platforms</li> <li>Territory: Switzerland</li> <li>Exclusive</li> </ul>
Namocell	SingLab Technologies	<ul style="list-style-type: none"> <li>Products: Namocell's single-cell isolation systems</li> <li>Territory: Singapore</li> </ul>
Euformatics	Al-Jeel Medical and Trading Co.	<ul style="list-style-type: none"> <li>Products: Euformatics' Omnomics interpretation and validation software for next-generation sequencing</li> <li>Territory: Saudi Arabia</li> </ul>

*Continued on page 14*

■ DX Deals: Labs Cutting Deals to Provide Pooled COVID-19 Testing for Schools, *from page 13*

Product Owner	Distributor	Deal Summary
Quidel	McKesson	<ul style="list-style-type: none"> <li>• Products: Quidel's QuickVue at-home COVID-19 test</li> <li>• Territory: US</li> </ul>

### LICENSES

Licensor	Licensee	Deal Summary
Guardant Health	Foundation Medicine	Roche subsidiary pays \$25 million plus royalties on future sales of Foundation's liquid biopsy products for nonexclusive license to Guardant's digital sequencing technology patents in agreement to settle Guardant's patent lawsuits against Foundation
221b Foundation (nonprofit organization established by Sherlock Biosciences)	Rokline Health Concepts	Rokline gets non-exclusive license to SHERLOCK (Specific High Sensitivity Enzymatic Reporter unLOCKing technology), which uses CRISPR for amplicon detection for single-molecule detection of nucleic acid targets to develop COVID-19 tests
221b Foundation	LogicInk	LogicInk gets non-exclusive license to use SHERLOCK to develop instrument-free diagnostic biosensor for SARS-CoV-2
ERS Genomics	GenScript Biotech	GenScript gets non-exclusive license to use ERS' CRISPR-Cas9 patent portfolio to strengthen its own CRISPR-based services
Mayo Clinic	Phenomix Sciences said on Tuesday that it has signed an	Exclusive license to multiomics MyPhenome test blood test to predict obesity phenotypes
Harvard University	Rhinostics	Rhinostics licenses nasal swab collection technology developed at Harvard's Wyss Institute

### SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Becton Dickinson	USA Track & Field	Becton Dickinson to provide rapid COVID-19 testing for USATF athletes with BD Veritor Plus system during Olympics qualifying events and trials

### GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Hologic	US Dept. of Defense	\$178.5 million firm-fixed-price Army contract for Hologic's Panther Fusion SARS-CoV-2 assays, Aptima SARS-CoV-2 assays, multiplex test kits, and associated reagents and consumables 

## M&A Report: PerkinElmer Turns COVID Cash into Acquisitions While Myriad Genetics Keeps Divesting

After a frantic month marked by an unusually high number of blockbusters, M&A deal making was relatively slow in May in terms of both deal volume and value. Still, the pace of strategic M&A transactions has just about returned to where it was before the pandemic as massive COVID-19 cash windfalls burn a hole in test makers' pockets. Here's a quick rundown of the two biggest deal makers and the diametrically opposite strategies they're pursuing.

### PerkinElmer Continues Its Buying Spree

No diagnostics firm has made more M&A deals in 2021 than PerkinElmer. With 146% net operating cash flow growth in the first quarter of 2021, PerkinElmer's cash flow exceeded its total for all of 2019, or in any other year for that matter. The firm is now parlaying that COVID-generated cash into strategic acquisitions. It began in January when PerkinElmer plunked down \$591 million to acquire Oxford Immunotec in an apparent bid to challenge Qiagen for the tuberculosis testing market. This month, the company made two more big M&A moves.

On May 13, PerkinElmer announced that it had reached an agreement to buy Nexcelom Bioscience for \$260 million in cash. Founded in 2003, Nexcelom produces tools and instruments for cell counting and analysis, as well as fit-for-purpose cell counting method selection and development instruments that follow ISO cell counting standards for use in development of cell, gene, and immune-oncology therapies, virology drugs, and vaccines. PerkinElmer CEO Prahlad Singh said the acquisition would expand the company's "efforts to help academic, government, and biopharmaceutical organizations streamline their complete workflows and support efforts to accelerate time to target and time to market for novel therapies."

Four days after the Nexcelom buy, PerkinElmer struck again by agreeing to shell out \$155 million in cash for Immunodiagnostic Systems (IDS) to bolster its immunodiagnostics business. PerkinElmer plans to fold the UK-based firm's chemiluminescence products for endocrinology, autoimmunology and infectious diseases into its Euroimmun business. "This proposed transaction is highly valuable for both parties as the respective product lines are to a large extent complementary," noted Euroimmun CEO Wolfgang Schlumberger in a statement.

### Myriad Genetics Continues Its Selling Spree

Myriad Genetics, which is under new management, has been pursuing the precisely opposite strategy by divesting assets as part of a strategic corporate restructuring. Over a span between April 27 and May 26, Myriad announced three sell-off deals, including in reverse chronological order:

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■ M&A Report: PerkinElmer Turns COVID Cash into Acquisitions While Myriad Genetics Keeps Divesting, *from page 15*

- ▶ Sale of its Myriad RBM contract research services for the pharmaceutical industry to IQVIA subsidiary Q<sup>2</sup> for an undisclosed price with the deal scheduled to close in the third quarter;
- ▶ Sale of its Vectra blood-based proteomic rheumatoid arthritis test and related intellectual property and assets to LabCorp for \$150 million in cash; and
- ▶ Sale of its Myriad myPath Melanoma Utah lab and test to Castle Biosciences for \$32.5 million in cash.

The divestitures, which are likely to continue, enable Myriad Genetics to focus on its core women's health, oncology and mental health while freeing up growth capital for future investment.



Here's a summary of the key new M&A diagnostic deals announced in late April and May 2021:

#### MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
PerkinElmer	Immunodiagnostic Systems (IDS)	<ul style="list-style-type: none"> <li>• Price: \$155 million all-cash deal</li> <li>• Status: Expected to close in Q3</li> <li>• PerkinElmer bolsters its immunodiagnostics segment by acquiring maker of immunoassays and automated immunoanalyzer technologies, with IDS to be integrated into Euroimmun</li> </ul>
PerkinElmer	Nexcelom Bioscience	<ul style="list-style-type: none"> <li>• Price: \$260 million in cash</li> <li>• Status: Expected to close in Q2</li> <li>• Acquisition of Massachusetts-based provider of tools and instruments for cell counting and analysis with expected annual revenues of \$40 million</li> </ul>
Ginkgo Bioworks	Dutch DNA Biotech	<ul style="list-style-type: none"> <li>• Price: Undisclosed amount consisting of cash, equity and earn-out payments to shareholders upon achievement of technical and commercialization milestones</li> <li>• Status: Expected to close in July</li> <li>• Acquisition of Netherlands-based producer of fungal biotechnology processes for industrial production of enzymes, proteins and organic acids</li> </ul>

Acquiring Company	Target(s)	Deal Summary
Discovery Life Sciences	Targos Molecular Pathology	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• Acquisition of German-based provider of standardized clinical biomarker development services to pharma and diagnostic customers builds on Discovery's 2019 purchase of immunohistochemistry services provider QualTek Molecular Laboratories</li> </ul>
NeoGenomics	Inivata	<ul style="list-style-type: none"> <li>• Price: \$390 million</li> <li>• Status: No closing date announced</li> <li>• NeoGenomics exercises option to acquire remaining equity stake in liquid biopsy startup which is developing assays for cancer diagnosis and treatment and which will become a new division of the company</li> </ul>
CellCarta (previously called Caprion-HistoGeneX)	Reveal Biosciences	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• Acquisition of artificial intelligence-based pathology firm bolsters CellCarta's AI-enabled multiomic data analysis services and applications</li> </ul>
Exact Sciences	PFS Genomics	<ul style="list-style-type: none"> <li>• Price: \$30.6 million in cash</li> <li>• Status: Closed</li> <li>• Exact acquires 90% equity stake in firm that has developed a screening test for early-stage invasive breast cancer patients to identify who may benefit from radiotherapy treatment</li> </ul>
New England Biolabs	Fluorogenics	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: No closing date announced</li> <li>• UK-based lyophilization R&amp;D service company to become wholly-owned subsidiary and part of NEB's OEM and Customized Solutions business</li> </ul>
Soulbrain Holdings	PixCell Medical	<ul style="list-style-type: none"> <li>• Price: Approximately \$40 million,</li> <li>• Status: Closed</li> <li>• South Korean semiconductor firm, which had recently acquired PixCell, acquires all controlling shares of point-of-care blood analyzer company as part of its strategy to enter point-of-care testing market</li> </ul>
Q2 Solutions	Myriad Genetics	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Expected to close in Q3</li> <li>• Myriad continues restructuring by selling off Myriad RBM unit which provides contract research services for pharmaceutical industry after selling Vectra to LabCorp (see below)</li> </ul>

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■ M&A Report: PerkinElmer Turns COVID Cash into Acquisitions While Myriad Genetics Keeps Divesting, from page 17

Acquiring Company	Target(s)	Deal Summary
LabCorp	Myriad Genetics	<ul style="list-style-type: none"> <li>• Price: \$150 million in cash</li> <li>• Status: Expected to close in Q3</li> <li>• LabCorp to purchase assets and intellectual property related to the Vectra rheumatoid arthritis test that Myriad acquired via its 2014 acquisition of Crescendo Bioscience</li> </ul>
Castle Biosciences	Myriad Genetics	<ul style="list-style-type: none"> <li>• Price: \$32.5 million in cash</li> <li>• Status: Expected to close in Q2</li> <li>• Castle expands dermatologic cancers tests pipeline via acquisition of Myriad myPath Melanoma test and Utah CLIA lab that performs it</li> </ul>
Oncocyte	Chronix Biomedical	<ul style="list-style-type: none"> <li>• Price: Price: \$2.675 million in cash + \$1.5 million of Oncocyte common stock; Oncocyte also assumes \$5.5 million in Chronix liabilities and will pay share on net collected revenues for certain tests, as well as up to \$14 million in cash or stock if certain milestones are achieved</li> <li>• Status: Closed</li> <li>• Merger enabling Oncocyte to acquire Chronix’s cancer immunotherapy monitoring test, TheraSure-CNI Monitor, and organ transplant monitoring technology patents</li> </ul>
Todos Medical	Provista Diagnostics	<ul style="list-style-type: none"> <li>• Price: \$1.25 million in cash upfront + \$1.25 million cash payment before July 1 + \$1.5 million in Todos common stock priced at \$.0512 per share + \$3.5 million convertible promissory note</li> <li>• Status: Closed</li> <li>• Israel-based Todos bolsters presence in U.S. market via acquisition of Provista’s Videssa proteomic breast cancer test and a PCR- and ELISA-capable lab currently performing SARS-CoV-2 testing</li> </ul>



# Master Guide to Clinical Lab Compliance 2021

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■ Increasing Revenue: New Colorectal Cancer Screening Guidelines Are a Windfall for Exact Sciences, Cologuard, *from page 1*

## The Diagnostic Challenge

### The New Colorectal Screening Recommendations

The U.S. Preventive Services Task Force (USPSTF) reviews its screening recommendations every four years. The new recommendations, which were published in the [Journal of the American Medical Association](#) on May 18, are an update to its previous 2016 guidelines and a final version of draft recommendations published in October 2020.

Colorectal cancer is the third leading cause of cancer death among adults in the U.S., with more than 52,000 people projected to die from the disease in 2021, the task force notes. Most colorectal cancer cases are diagnosed in people ages 65 to 74. Only 10.5 percent of new cases occur in those below age 50. However, the case incident rate among this group has steadily increased—at a nearly 15 percent clip between 2000 and 2016.

Unfortunately, there’s been no commensurate increase in colorectal cancer screening over this period. Accordingly, the new guidelines recommend that asymptomatic adults at average risk start colorectal cancer screening at age 45, rather than waiting until age 50 as the 2016 guidelines recommended. The new recommendation is in line with the American Cancer Society, which also recommended starting routine colorectal cancer screening at age 45 in 2018.

Significantly for Exact Sciences and other test makers, the task force assigns members of the 45 to 49 age group a “B” grade, as opposed to the “A” grade given to the age 50 to 75 members of the cohort. Even so, a B grade is enough to ensure members who have commercial insurance won’t have to pay out-of-pocket costs to receive their screenings under Affordable Care Act rules. First-dollar health insurance coverage for adults starting at age 45 could impact up to 15 million adults, according to the patient advocacy organization Colorectal Cancer Alliance.

#### USPSTF Colorectal Cancer Screening Recommendations

Ages	Recommendations	Grade
50 to 75	Screening for all members	A
45 to 49	Screening for all members	B
76 to 85	Screening for selective cases determined by clinician based on patient’s health, screening history and preferences	C

### Takeaway: Impact on the Lab Industry

Reducing the starting age for colorectal cancer screening to age 45 with a “B” classification will significantly boost sales of molecular screening tests. The real breakthrough came in 2016, when the USPSTF first added molecular colorectal cancer screening to its guidelines. In addition to multitargeted stool DNA (mtDNA) tests like

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■ Increasing Revenue: New Colorectal Cancer Screening Guidelines Are a Windfall for Exact Sciences, Cologuard, from page 19

Cologuard, the task force recommends two other stool-based tests, namely high-sensitivity Guaiac-based fecal occult blood tests (gFOBT) and Fecal immunochemical tests (FIT), as well as direct visualization approaches like colonoscopy.

Stool-Based Tests

Test Type	Recommended Frequency
High-sensitivity gFOBT	Every year
FIT	Every year
mtDNA	Every 1 to 3 years based on manufacturer's recommendations

Direct Visualization Tests

Test Type	Recommended Frequency
Colonoscopy	Every 10 years
CT colonography	Every 5 years
Flexible sigmoidoscopy	Every 5 years
Flexible sigmoidoscopy with FIT	Every 10 years + FIT every year

Exact Sciences is the clear market leader in mtDNA at-home colorectal testing with the greatest visibility among the late 40-somethings who will now be able to get screened for free each year, especially if it means avoiding colonoscopy. **G2**



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**OCTOBER 2020**  
**Emerging Tests: COVID-19 Antigen Tests Are Ready for Mass Utilization but Antigen Test Reporting Is Not**

It will take something on the order of 200 million COVID-19 screening tests per month, as opposed to the 25 million being performed currently, to safely reopen the U.S., estimates a new report from Duke University. Because of their low costs, scalability and speed, antigen tests may play a crucial role in meeting this unprecedented level of demand, particularly in nursing home, educational and workplace settings. However, if antigen testing is to be the answer, there is one significant problem that will need to be addressed: lack of reliable and consistent test data reporting.

**The Promise of Antigen Testing**  
What the country and world need right now are point-of-care tests that can deliver accurate results at cost-effective prices that can be

*Continued on page 2*

Testing Strategy: New Study Shows Saliva-Based

**G2 LAB COMPLIANCE ADVISOR**  
For Clinical and AP Laboratories and Pathology Practices

November 2020

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**Enforcement Trends: Labs Caught Up in Massive National Telemedicine Takedown**  
So much for the pandemic's dulling the momentum of federal fraud enforcement. Dubbed "Operation Rubber Stamp," the new nationwide enforcement arbiter revealed by the Department of Justice (DOJ) on Sept. 29 is the largest "take-down" in Department history involving 45 federal districts, 343 defendants, including over 400 doctors, nurses and other licensed medical professionals, and \$6 billion in false claims. And, while not necessarily the primary target, medical labs have been pulled in to the "Rubber Stamp" dragnet.

**The Takedown Target**  
Of the \$6 billion in false and federal claims submitted to federal health care programs and private insurers involved

*Continued on page 2*

**Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy**

**Bottom Line on Top:**  
Make it all about fitness for duty, not just drug testing

**G2 NATIONAL LAB REPORTER**  
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**Special Report: The 5 Things Labs Need to Know about the Biden COVID-19 Testing Plan**  
Testing labs on the front lines of the COVID-19 battlefield are getting federal reinforcements. And it's not just money. The new administration is taking an entirely new line of attack that differs from the approach of its predecessor in almost every conceivable way. Perhaps the starkest contrast is with regard to urgency, with the new president unveiling his COVID-19 testing strategy on his very first day in office. Here's a quick overview of the five key elements of the Biden plan, aka, National Strategy for COVID-19 Response and Pandemic Preparedness.

- 1. Provide More Money**  
Let's start with money. The administration's proposed \$1.0 trillion American Rescue Plan includes \$50 billion to expand COVID-19 testing by providing funding to purchase rapid tests, expand lab capacity and support regular testing efforts of schools and local governments.

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**Focus On: How the Transition from Trump**

Contact Andrea for details on this special offer  
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