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LABORATORY INDUSTRY REPORT™

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DX Earnings Report: Q2 Revenues Slide but By Less than Wall Street Expected

As expected, the COVID-19 pandemic took a tremendous bite out of lab company earnings in the second quarter. However, the losses were largely below expectations, significantly below in many cases. And for the companies that were able to pivot and offer desperately needed coronavirus testing products and services, COVID-19 was actually a business windfall.

Losers Outnumber Gainers

In the past three years, year-over-year gainers have outnumbered decliners for quarterly revenue growth at a roughly 3-to-1 clip. And that's also the way 2020 began where,

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FDA Watch: Agency Stripped of Authority to Issue Premarket Approval of SARS-CoV-2 LDTs

The COVID-19 pandemic has exposed how the FDA's makeshift premarket control over laboratory developed tests (LDTs) stifles innovation and keeps desperately needed new tests from reaching the market. It has also accelerated the efforts to impose a modern, more transparent and workable system not only for the rest of the pandemic but the long-term future.

How FDA Regulates LDTs

Lab tests weren't included in the original legislation that created the FDA and current regulatory system of medical drug and device regulation. So, the agency has relied on its powers to regulate devices. Accordingly, LDTs must obtain

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in spite of the pandemic's onset, 29 companies of 39 surveyed companies reported higher 2020 Q1 revenues, as compared to the same period in 2019.

Expectedly, that pattern reversed itself in Q2 2020, with decliners leading gainers 29 to 12, including 6 of the 8 billion-dollar companies surveyed, towit, Abbott, Agilent, Becton Dickinson, LabCorp, Quest, Roche and Siemens Healthineers. The notable exceptions included Thermo Fisher Scientific, which posted an astounding 10% increase at $6.92 billion, which not only exceeded the average $6.13 billion Wall Street estimate but blew it to smithereens. Danaher was the other testing giant to post big revenue gains.

Losses Not as Big as Expected

But Thermo Fisher was hardly alone in beating Wall Street targets. Not counting European firms Roche and Siemens Healthineers, 34 companies reported better than expected earnings, and only 5 missed their top line revenue estimates. And these weren't close calls. The predominant pattern was a sizeable gap between expected and actual revenues, including among companies with notable year-over-year declines. Notable examples:

- Abbott: Revenues of $7.33 billion (-8%) vs. $6.75 billion estimated;
- Hologic: $822.9 million (-4%) vs. $616.7 million; and
- Waters: $520.0 million (-13%) vs. $496.9 million.

How Labs Were Able to Avert Expected Disaster

There were several reasons why so many companies were able to limit their losses. First and foremost was effectiveness in ramping up or, even in some cases, developing the capacity to produce COVID-19 testing products. Thus, firms like Roche, Thermo Fisher, LabCorp, Hologic, Quidel, Abbott, Quest, GenMark and PerkinElmer wasted little time after the public health emergency began to secure Emergency Use Authorization (EUA) for their SARS-CoV-2 laboratory developed tests. Others like Meridien, PerkinElmer and Thermo Fisher were quick to recognize and develop the capacity to respond to the need for reagents, test platforms and other supplies, including PPE.

The other major factor mitigating the extent of the losses was the gradual drop in new cases and resumption of routine doctor visits, elective surgeries and wellness services as the quarter progressed. By the end of June, companies were able to recoup at least some of the ground lost in April when the quarter began. Thus, for example, Abbott reported that non-COVID testing had rebounded to 90% of pre-pandemic levels by the end of the quarter. It was precisely the opposite of what happened in the first quarter when the outbreak of the pandemic in March wiped out the strong gains of January and February.

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Takeaway

The combination of a little luck and more resilience than the analysts on Wall Street expected has enabled lab companies to emerge from the second quarter of 2020 with just scratches and bumps. Companies that have made the strategic pivot to COVID-19 response will reap the rewards of their agility for as long as the pandemic lasts, as will the life science, molecular testing and other firms like Qiagen, Quidel, Meridien, who were perfectly positioned before the pandemic began. However, what is not likely to prove sustainable is the luck factor. Flu season and the expected surge in new cases could make the end of Q3 and all of Q4 a highly trying period for the vast majority of labs that rely on the testing products and services the pandemic disrupts.

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Diagnostics Earning Reports for Q2 (period ended June 30, 2020)
(At least $10 million in sales)

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories*	$7.33 billion ($6.75 billion)	-8% (-5% organic)	Adjusted +$0.57 (+$0.41)	DX up 5% to $1.99 billion, driven by 234% increase in molecular to $359 and 10% increase in rapid diagnostics to $530 million, which offset 16% decline in core diagnostics to $967 million; but non-COVID testing rebounds to 90% of pre-pandemic levels by end of quarter
Adaptive Biotech	$21.0 million ($18.8 million)	-5%	Net -$.26 (-$.28)	Sequencing down 33% to $8.0 million even though test volume increased 31% with 3,136 tests delivered; developmental revenues up 27% to $13.0 million
Agilent Technologies (FY 3Q)	$1.26 billion ($1.21 billion)	-1%	Adjusted +$0.78 (+$0.66)	Diagnostics and Genomic Group down 8% to $241 million, Life Sciences and Applied Markets up 2% to $544 million; CrossLab group down 1% to $463 million

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DX Earnings Report, *from page 3*

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Becton Dickinson (FY Q3)	$3.86 billion ($3.94 billion)	-11%	Adjusted +$2.20 (+$2.04)	Shipped more Veritor readers in first month after launch of SARS-CoV-2 antigen tests than it usually does for whole year; Life sciences down 10% to $951 on weakness in preanalytical systems and bioscience units; interventional down 20% to $782 million due to continuing deferral of elective procedures due to COVID
Bio-Rad Laboratories	$536.9 million ($517.1 million)	-6%	Adjusted +$1.61 (+$1.22)	Clinical DX down 21% to $283.2 million; but higher PCR, Drop Digital instruments sales drive 19% increase in life sciences to $252.1 million, $71 million of which attributable to COVID
Bio-Techne (FY Q4)	$175.8 million ($163.9 million)	-8%	Adjusted +$1.00 (+$0.75)	DX & Genomics flat at $48.7 million and Protein Sciences down 11% to $127.3 million due to COVID shutdowns of biopharma and academic sites; firm was on track for double-digit FY 2020 growth before pandemic
Bruker	$424.6 million ($390.9 million)	-13%	Adjusted +$0.21 (+$0.06)	Cost cutting + strength in life sciences mass spectrometry as microbiology and infectious disease consumables help offset 6% decline in CALID group ($132.7 million)
CareDx	$41.8 million ($35.6 million)	+33%	+$0.04 (-$0.04)	Testing services up 41% to $36.3 million driven by 44% increase in AlloSure and AlloMap sales; but COVID drives 28% decrease in products sales to $3.3 million

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Castle Biosciences	$12.7 million $8.8 million	+18%	-$0.08 (-$0.40)	$2.2 million positive revenue adjustment helps offset 43% decline in Decision Dx-Melanoma test reports due to COVID
Centogene (FY Q1)	$13.6 million ($14.7 million)	+13%	-$0.51 (-$0.44)	Whole-exome sequencing drives modest DX growth, offsetting significant declines in NIPT test orders
Danaher	$5.30 billion ($4.95 billion)	+19%	Adjusted +$1.44 (+$1.09)	DX up 2.5% to $1.66 billion, including 5% growth in core revenue; Life Sciences up 54% to $2.64 billion, including newly acquired Cytiva; Cepheid core revenues increase over 100% due to COVID testing with firm shipping over 6 million SARS-CoV-2 testing cartridges; but big dips in elective surgeries and wellness procedures hurt Beckman Coulter DX and Leica Biosystems revenues
Exact Sciences	$268.9 million ($228.4 million)	+35%	-$0.58 (-$0.63)	Precision oncology revenues from newly acquired Paradigm Diagnostics offset 34% decrease in screening products to $134 million with Cologuard hitting all-time low in April followed by rebound thru June
Fluidigm	$26.1 million ($19.1 million)	-8%	Adjusted -$0.07 (-$0.23)	Pandemic hurts sales of both mass cytometry (down 28% to $12.5 million) and microfluidics products (down 8% to $10 million)
Fulgent Genetics	$17.3 million ($10 million)	+100%	Adjusted +$0.17	COVID testing drives tenfold increase in billable tests at 180,513 tests
GenMark Diagnostics*	$40.1 million ($32.7 million)	+118%	Net -$0.07 (-$0.09)	Pandemic drives 195% increase in ePlex systems to $35.2 million (71 new systems placed during quarter)

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DX Earnings Report, *from page 5*

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Guardant Health	$66.3 million ($59.2 million)	+23%	Net -$0.57 (-$0.38)	Precision oncology up 21% to $51 million; development services up 29% to $15.3 million driven by new companion Dx products for biopharma
Hologic (FY Q3)	$822.9 million ($616.7 million)	-4% (+8% organic)	Adjusted +$0.75 (+$0.38)	Total DX up 75% to $305.4 million driven by 169% growth in molecular diagnostics to $460.3 million due to demand for COVID tests on Panther and Panther Fusion instruments; but decline in non-COVID tests, including 45% in blood screening (also reflecting sale of Grifols), 31% decline in breast health to $224 million, 54% decline GYN surgical to $51.5 million and 38% decline in skeletal to $24.4 million
Illumina	$633 million ($697.6 million)	-25%	+$0.62 (+$0.67)	COVID disruption to firm's research customers drives decline in sequencing services revenues from $129 million to $88 million; product revenue down 25% to $527 million
Invitae	$46.2 million ($39.6 million)	-14%	Non GAAP -$1.29 (-$0.70)	At-home saliva sample COVID tests at end of quarter help arrest sharp declines in April; average costs per sample increase 42% to $358
LabCorp	$2.77 billion ($2.50 billion)	-4% (-5% organic)	Adjusted +$2.57 (+$0.99)	Acquisitions contribute 1% but PAMA price cuts account for -1%; at start of Q, COVID testing doesn't offset decline in base testing, but that reverses in June with pattern of COVID more than offsetting base losses expected to continue

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Luminex	$109.5 million ($107.3 million)	+32%	Net +$0.11 (+$0.08)	COVID more than doubles molecular to $64.9 million, including 162 Aries and other sample-to-answer systems sold; Assays revenue up 95% to $31.4 million
Meridian Bioscience (FY Q3)*	$84.8 million ($66 million)	+75%	Adjusted +$0.64 (+$0.23)	Ramped up production of reagents for COVID tests drives 313% increase in life sciences to $63.2 million, including 605% growth in reagents for molecular tests to $38.8 million, and 149% growth in immunoassay reagents to $24.4 million; but DX declines 35%, including 46% for molecular assays, and 32% for blood chemistry assays and immunoassays
Myriad Genetics (FY Q4)	$93.2 million ($93.9 million)	-57%	Adjusted -$0.31 (-$0.41)	Overall testing volumes down 58% across all segments due to COVID-19, with molecular DX down 58% to $83.3 million, including 66% drop in hereditary cancer ($39.9 million), 34% decline in GeneSight ($16.6 million), 41% decline in Vectra ($7.2 million), 29% drop in Prolaris ($4.5 million); 27% drop in EndoPredict actually up 25% to $2.2 million
NanoString Technologies	$22.6 million ($16.2 million)	-25%	Net -$0.72 (-$0.52)	Product + service pro forma revenues up 2% due to acquisition of Prosigna breast cancer test; consumables down 42% to $8.4 million; instruments revenues double to $9.8 million, including $6.3 million from newly launched GeoMx system

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DX Earnings Report, *from page 7*

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Natera	$86.5 million ($73.1 million)	+16%	Net -$0.75 (-$0.58)	Follows huge Q1 with big Q2, despite COVID, with 24% increase in products to $80.4 million; 21% more tests processed than Q2 2019, at 234,100; lab has operated without disruption thanks to improvements to remote ordering capabilities
NeoGenomics	$87.0 million ($86.6 million))	-14%	Adjusted -$0.04 (-$0.01)	Clinical services down 14% to $73.9 million but pharma services up 3% to $13.1 million; test volume declines 18% and requisitions fall 21% due to COVID, but slight improvements made in May and June
Opko Health	$301.2 million ($245.6 million)	+33%	Pro forma +$0.05 (-$0.07)	40% increase in services revenues, $251 million, due to COVID testing which more than offset drops in genomic and clinical testing; product revenues up 2% to $29.3 million
OraSure Technologies	$29.3 million ($32.8 million)	-25%	Net -$0.16 (-$0.09)	Declines in genomic and infectious disease testing products, including 35% drop in OraQuick HIV and HCV assays, wipe out increases in specimen collection devices
Pacific Biosciences	$17.1 million ($13.7 million)	-14%	Net -$0.15 (-$0.18)	Pandemic causes lower utilization of Sequel instruments, although improvements made late in quarter
PerkinElmer	$811.7 million ($726.4 million)	+12%	+$1.57 (+$0.88)	After Q1 decline, DX rebounds with 46% growth to $420.7 million, driven by COVID PCR tests, RNA extraction solutions and serology kits; non-COVID X products down 20%; applied genomics up 150%

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Qiagen	$443.3 million ($425.8 million)	+16%	Adjusted +$0.55 (+$0.46)	12% growth in consumables to $375 million driven by unprecedent demand for COVID testing cartridges, reagents + RNA extraction kits; instruments up 45% to %68 million; QuantiFerron-TB tests fall 46% to $33.4 million
Quanterix	$13.1 million ($11.8 million)	-3%	Not reported	Products down 23% to $6.8 million but company expects 2H resurgence
Quest Diagnostics	$1.83 billion ($1.83 billion)	-6%	Adjusted +$1.42 (+$1.41)	Test volume down 18% but expanded COVID testing capacity + resumption of doctors' offices and elective surgeries rescue quarter + drive better than expected results
Quidel	$201.8 million ($189.8 million)	+86%	Adjusted +$1.86 (+$1.09)	Rapid immunoassays nearly triple to $109 million driven by $56.3 million in Sofia SARS antigen test; Cardiometabolic immunoassays down 20% to $54.2 million; Molecular DX up from $4 million to $55.2 million, mostly from Lyra SARS-CoV-2 test
Roche Diagnostics	$3.82 billion (Diagnostics sales)	-2%	Not reported	DX sales flat despite 51% growth in molecular flu and SARS-CoV-2 diagnostics; Roche has 7 different COVID products with 3 more expected before end of year
Siemens Healthineers (FY Q3)	$3.88 billion	-7%	Adjusted +$0.36	DX revenues decline 17% to $1.03 billion as COVID reduces utilization + reagent sales for routine tests
10x Genomics	$42.9 million ($29.6 million)	-23%	Net -$0.41 (-$0.55)	Consumables down 27% to $34.2 million; instruments down 12% to $7.3 million; service up 48% to $1.5 million

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DX Earnings Report, *from page 9*

COMPANY	FY 2020 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Thermo Fisher	$6.92 billion ($6.13 billion)	+10%	Adjusted +$3.89 (+$2.84)	19% of total revenues ($1.3 billion) come from COVID fueling massive quarter; Specialty DX up 5% to $988 million; Lab products + services up 6% (5% organic) to $2.79 billion driven by pharma services and research + safety, including PPE sales
Twist Biosciences (FY Q3)	$21.2 million ($14.2 million)	+56%	Net -$0.67 (-$0.73)	Despite COVID-19, synthetic biology, including gene pools, libraries and oligo pools increased 11% at $11.8 million
Veracyte	$20.7 million ($20.6 million)	-31%	Net -$0.22 (-$0.24)	Genomic testing revenues down 43% to $15.2 million due to COVID but finished quarter strong; biopharma up 153% to $3.8 million
Waters	$520.0 million ($496.9 million)	-13%	Non-GAAP +$2.10 (+1.54)	Strength in global pharma sales help weather COVID losses and lead to better than expected quarter

Bold face: Companies that met or exceeded average or consensus Q2 Wall Street revenue estimates

Italics: Companies that missed average or consensus Q2 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q2

Diagnostic Deals: New Study to Evaluate Clinical Effectiveness of CRISPR SARS-CoV-2 Testing

The FDA has granted emergency use authorization (EUA) for several different kinds of assays to detect the SARS-CoV-2 virus, including reverse transcription-polymerase chain reaction (PCR), blood-based serology antibody assays and rapid antigen tests. But while most of us are aware of those tests, there's also another form of EUA testing that has gotten little attention: tests based on Clustered Regularly Interspaced Short

Palindromic Repeats (CRISPR) technology. So far, only one CRISPR product has received EUA for coronavirus detection. But now the company that makes that kit has determined to expand its use and has secured the collaboration of an academic heavyweight to make that happen.

The Sherlock-Hitchcock Alliance

What may sound like the cast of a murder mystery, the Sherlock-Hitchcock alliance is actually a pairing of Cambridge, Mass-based Sherlock Biosciences with its New England neighbor, the Dartmouth-Hitchcock Health (D-HH) academic health system in New Hampshire. On Aug. 12, the parties announced plans to launch a clinical study of the Sherlock (short for Specific High-sensitivity Enzymatic Reporter unlocking) CRISPR SARS-CoV-2 kit which received EUA on May 7. The kit uses a CRISPR nuclease to detect the genetic signature for SARS-CoV-2 in a swab sample. When the signature is found, the CRISPR enzyme is activated and cuts reporter RNAs provided as part of the kit to release a detectable signal, yielding results in about an hour.

Does it work? Is it scalable? The plan calls for DH-H to find out by launching a clinical study to test samples from patients at its member hospitals. "We are excited to partner with Sherlock to understand how the company's novel CRISPR-based test may help circumvent some of the challenges with RT-PCR testing," noted **Gregory Tsongalis**, director of D-HH's Laboratory for Clinical Genomics and Advanced Testing.

Testing has begun at D-HH's member hospitals, Dartmouth-Hitchcock Medical Center, Alice Peck Day Memorial Hospital, Cheshire Medical Center, New London Hospital and Mt. Ascutney Hospital and Health Center. Results are expected in the coming weeks, according to Tsongalis.

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Here's a summary of other key strategic diagnostic deals announced in August 2020:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Foundation Medicine	OneOncology	• Objective: Use real-world clinical and genomics data to improve access to genomic profiling and personalized medicine in community oncology practices • Dynamic: Use clinico-genomic datasets to analyze patient data from OneOncology, a network of five independent, community oncology practices representing over 400 providers in US

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Diagnostics Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific	Hengrui Therapeutics	• Objective: Develop companion diagnostic for identifying lung cancer patients with HER2 mutations eligible for Jiangsu Hengrui Medicine's treatment pyrotinib • Dynamic: Thermo Fisher to retain global commercialization rights to companion diagnostic as part of its Oncomine Precision Assay, which runs on Ion Torrent Genexus System
Thermo Fisher Scientific	Labs from Emory University, Stanford University, University of Cincinnati, and University Health Network in Toronto	• Objective: Develop COVID-19 antibody assay for transplant donors and recipients • Dynamic: So-called LabScreen COVID Plus assay to be provided under Thermo Fisher's One Lambda brand and use Luminex xMAP technology to detect multiple antibodies and fragments
RenalytixAI	AstraZeneca + Mount Sinai Health System	• Objective: Pursue precision medicine strategies for cardiovascular, rental and metabolic diseases • Dynamic: Use RenalytixAI's KidneyIntelX platform to improve outcomes for patients with chronic kidney disease (CKD)
Amoy Diagnostics	Merck KGaA	• Objective: Develop a PCR-based companion diagnostic for Merck's cancer drug Tepmetko (tepotinib) • Dynamic: AmoyDx to develop and seek Japanese approval for its Pan Lung Cancer PCR Panel, which detects 167 hotspot variants in multiple oncogenes, for use as METex14-skipping companion diagnostic for Tepmetko
Genedrive	Beckman Coulter Life Sciences (owned by Danaher)	• Objective: Automate the entire laboratory PCR testing process for detecting SARS-CoV-2 • Dynamic: Validate Genedrive 96 Sars-CoV-2 kit on Biomek i7 automated workstation using saliva samples extracted with Beckman Coulter's RNAdvance viral extraction chemistry
IsoPlexis	Department of Medicine at Columbia University	• Objective: Study immune response in COVID-19 patients for therapeutics development • Dynamic: Use IsoPlexis' single-cell proteomics platform to identify drivers of durable and protective immune responses to the virus

Partner 1	Partner(s) 2+	Deal Summary
GeneCentric Therapeutics	Janssen Research & Development	• Objective: Discover RNA-based drug response biomarkers for non-muscle invasive bladder cancer (NMIBC) • Dynamic: Use GeneCentric's RNA-based molecular profiling platform to identify potential signatures of disease progression and drug response to standard-of-care therapy
GeneCentric Therapeutics	Erasmus University Medical Center	• Objective: Discover RNA-based drug response biomarkers and new therapies for NMIBC • Dynamic: GeneCentric to use its Bladder Cancer Subtype Profiler tool to characterize tumor, patient's immune biology and tumor microenviroment • Erasmus to perform retrospective longitudinal genomic analysis on bladder cancer tumor samples from patients who had surgery and received adjuvant treatment
HTG Molecular Diagnostics	Qiagen Manchester (Qiagen subsidiary)	• Objective: Provide pharmaceutical companies global development, distribution and commercialization capabilities for companion diagnostic assays based on HTG's EdgeSeq platform • Dynamic: 10-year commercialization and distribution agreement allowing HTG to work directly with biopharma customers to create CDx assays integrating an Illumina or Thermo Fisher Scientific NGS instrument
Biocept	Aegea Biotechnologies	• Objective: Develop superior PCR-based COVID-19 assay • Dynamic: Sides to leverage their co-owned Switch-Blocker technology • Biocept gets first option to negotiate a license agreement to commercialize the assay
Genuity Science (formerly known as WuXi NextCode)	Nashville Biosciences (subsidiary of Vanderbilt University)	• Objective: Apply analytics technology to a major clinicogenomic biobank for biomarker and drug discovery, as well as validation and drug development • Dynamic: Genuity to sequence, analyze and harmonize samples and deidentified clinical records in BioVU, Vanderbilt's bank of longitudinal medical records and DNA samples, through its lab in Ireland

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Diagnostics Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Todos Medical	Pathnova	• Objective: Advance and commercialize Todos' breast cancer and SARS-CoV-2 diagnostic kits • Dynamic: Pathnova to commercialize tests in Singapore • Todos to help Pathnova commercialize its own nasopharyngeal cancer tests in US and Singapore
Pacific Biosciences	Asuragen	• Objective: Develop assays based on PacBio's single-molecule, NGS technology • Dynamic: Asuragen researchers to use firm's AmplideX PCR technology to develop assays for PacBio's Sequel Systems
Akoya Biosciences	Hellen Diller Family Comprehensive Cancer Center, at University of California, San Francisco	• Objective: Develop predictive and prognostic cancer biomarkers for translational research studies • Dynamic: Use Akoya's Phenoptics multiplex immunofluorescence platform to develop biomarkers to help select the most effective neoadjuvant and adjuvant immunotherapies for early-stage breast cancer patients
Veracyte	MaviDx	• Objective: Develop ultra-high throughput genomic testing for SARS-CoV-2 on Veracyte's nCounter diagnostic platform • Dynamic: MaviDx to develop, validate, secure regulatory approvals for, and commercialize tests for SARS-CoV-2 and other infectious diseases, including influenza
Atomo Diagnostics	Access Bio	• Objective: Commercialize rapid COVID-19 antibody tests • Dynamic: Atomo to supply its rapid diagnostic test devices to Access Bio for use with latter's rapid test strip to detect COVID-19 antibodies to develop 2 co-branded tests—one for professional use and the other a self-test—for launch in US, Canada and Mexico • Access Bio must sell at least 2 million tests by Sept. 30, 2021, to maintain exclusive rights in North America
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Product Owner	Distributor	Deal Summary
IsoPlexis	Medquest	• Products: IsoPlexis' IsoLight System and other products for single-cell proteomics research • Territory: Singapore, Malaysia • Exclusive

Partner 1	Partner(s) 2+	Deal Summary
Cellex	Avalon GloboCare	• Products: Cellex's COVID-19 antibody-based rapid test kit • Territory: Global
Inspirata	Fujifilm	• Products: Inspirata's Dynamyx digital pathology workflow software • Territory: Global • Fujifilm gets exclusivity in UK, Italy, Spain, Portugal, Belgium, Netherlands, Luxembourg
Siemens Healthineers	Sysmex America	• Products: Distribution and servicing of Siemens' Clinitek Novus Automated Urine Analyzer • Territory: North America • Exclusive
Fluidigm	De Novo Software	• Products: Fluidigm's mass cytometer platforms to be sold alongside De Novo's FCS Express 7 Flow suspension data analysis software • Territory: Not specified • New purchases of Fluidigm's Helios cytometer and Hyperion imaging system to include one-year license for FCS Express 7 Flow
Maccura Biotechnology	Diazyme Laboratories	• Products: Maccura's SARS-CoV-2 PCR-based test • Territory: US
Hangzhou Laihe Biotech	QuestCap	• Products: Hangzhou Laihe Biotech's lateral flow IgM/IgG antibody test kit • Territory: US • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
Columbia University	Sorrento Therapeutics	Sorrento licenses Columbia's rapid point-of-care SARS-CoV-2 test which has received EUA from FDA

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
GeneDx	Pediatrix Medical Group	GeneDx to provide genomic services to physician services firm Pediatrix's neonatal intensive care units
BBI Solutions	Avacta	BBI to manufacture saliva-based rapid SARS-CoV-2 antigen test that Avacta is developing with Cytiva

M&A Report: One Blockbuster Dies and Another Arises as Sluggish Deal Making Continues

The decline in diagnostic M&A activity is reflective of what's been happening across the entire healthcare industry, with deals from down 20% during Q2, as compared to Q1 2020, according to consulting firm SOLIC Capital. The dip is even more pronounced on a year-over-year basis, with a decrease of 34%, only 322 M&A transactions in Q2 of this year, versus 486 in Q2 2019.

The obvious explanation for the trend is the COVID-19 pandemic, which is also the reason why eHealth was the most robust sector of the industry for M&A with 50 transactions, or 15% of total deal volume in the quarter. Meanwhile, deal making in the senior-care sector hit a seven-year low.

Lab Sector M&A Trends

After a relatively slow 2019, 2020 was expected to be a very active year for M&A in the labs sector with both major acquirers, Quest Diagnostics and LabCorp, preparing to scoop up smaller labs adversely affected by PAMA price cuts. But deals remain difficult to close and the pandemic has apparently deferred strategic deal making to at least some degree. But before it's all said and done, COVID-19 might actually accelerate M&A activity by putting more financially stressed hospital labs in play. The pandemic "could be an additional catalyst to help drive industry consolidation," Quest CEO Steve Rusckowski noted in a recent conference call with investors.

The Thermo Fisher Scientific-Qiagen Deal Dies. . .

Perhaps fittingly, the year's biggest M&A deal in the diagnostics space so far, Thermo Fisher Scientific's acquisition of Qiagen came to an end just months after it was announced. Back in March, the $11.5 billion, or roughly $46 per share price (representing a premium of 23% over the March 2 closing price of Qiagen's common stock), seemed like a fair price. But the pandemic caused a surge in demand for Qiagen's products and forced Thermo Fisher to sweeten the offer. Although the Qiagen board unanimously endorsed the new terms, the shareholders weren't convinced, with only 47.02% of the common shares tendered, far short of the necessary two-thirds. On August 13, Thermo Fisher announced that it was walking away, after pocketing the $95 million in expense reimbursement Qiagen was required to pay under the original acquisition contract if the deal didn't close.

. . . But a New Blockbuster Takes Its Place

Dibs for the biggest DX deal of 2020 now goes to the proposed $16.4 billion all-cash merger between Siemens Healthineers and Varian Medical Systems announced on August 2. Siemens Healthineers will acquire

100% of Varian's outstanding shares at a 42% premium rate of $177.50 per share. Adding Varian's artificial intelligence, machine learning and data analytics to Siemens Healthineers' cancer diagnostics portfolio will enable the merged firm to provide services across cancer-care continuum, including screening, diagnosis, care delivery and post-treatment.

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Here's a summary of the key M&A diagnostic deals announced in August 2020:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Siemens Healthineers	Varian Medical Systems	• Price: $16.4 billion all-cash merger deal for all of Varian's outstanding shares for $177.50 per share, a roughly 42% premium over Varian's 30-day volume-weighted average closing share price on July 31 • Status: No closing date announced • Acquisition of Varian's artificial intelligence, machine learning and data analytics to enable merged firm to provide services across cancer-care continuum, including screening, diagnosis, care delivery and post-treatment
Blackstone	Ancestry	• Price: $4.7 billion deal value • Status: No closing date announced • Acquisition of worldwide leader in consumer genomics with $1 billion in annual revenue via its AncestryDNA service business
Cancer Genetics	Stemonix	• Price: All-equity merger equity transaction in which Cancer Genetics obtains 100% of Stemonix's shares in exchange for 78% of Cancer Genetics' shares • Status: Expected to close in Q4 • Stemonix, which develops high-density, at-scale human induced pluripotent stem cell-derived neural and cardiac screening platforms for drug discovery to keep its name and become wholly-owned sub of Cancer Genetics

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Acquiring Company	Target(s)	Deal Summary
Bionano Genomics	Lineagen	• Price: Approximately $9.6 million, including 6.2 million shares of Bionano common stock and $1.7 million cash; Bionano to also take on $2.9 million in liabilities held by Lineagen • Status: Closed • Acquisition of diagnostics services provider with expertise in commercializing cytogenetic assays, genetic counseling, third party payor contracts and reimbursement
Cellink	Scienion	• Price: €80 million ($94.8 million), including €40 million in cash and €40 million in shares via 2,814,032 newly issued shares at price of SEK 146.6 per share • Status: No closing date announced • Scienion shareholders get 5% voting stake and roughly 7% of firm's share capital • Scienion, which provides microarray and ultra-low-volume handling technologies and controlled single-cell dispensing technologies, to retain its current management
Quest Diagnostics	Mid America Clinical Laboratories (MACL)	• Price: Undisclosed • Status: Closing of deal announced in June • Quest acquires all of MACL's lab in Indianapolis and about 50 patient service centers in Indiana • Quest to also provide lab management services for about 30 hospitals owned and operated by Community Health Network and Ascension St. Vincent (former joint venture partners in MACL) in Indiana via its AmeriPath business
Yourgene Health	Coastal Genomics	• Price: Up to $13.5 million, including $3 million cash, $2.5 million in equity and contingent cash and equity consideration of up to $8 million • Status: No closing date announced • Acquisition of Vancouver-based sample prep technology company and previous partner
MBio Diagnostics	Brava Diagnostics	• Price: Undisclosed • Status: Closed • Merger under which Brava will operate as MBio's human in vitro diagnostics division to develop point-of-care tests for time-critical conditions

FDA Watch: Agency Stripped of Authority to Issue Premarket Approval of SARS-CoV-2 LDTs, *from page 1*

premarket approval through the 510(k) pathway for medical devices. In addition to challenging the FDA's authority over LDTs, the lab industry has long objected to the agency's practice of skirting the regulatory process and relying on guidance, website statements and other informal issuances to make regulatory policy.

The HHS Decision

As the crisis has deepened, the agency has found itself in the position of backing away from its hands-on approach and has allowed laboratories and test makers greater discretion in launching LDTs detecting the SARS-CoV-2 virus. And now a new Administration pronouncement carries that policy to a new and significant level. On Aug. 19, HHS announced that the FDA will no longer be able to regulate by informal decrees but will have to go through the customary notice and comment rulemaking process required for new regulations to regulate LDTs.

One result of the HHS decision, which is part of the Administration's broader policy to cut government regulation over business, is that labs will now be able to offer LDTs for SARS-CoV-2 without going through the FDA's Emergency Use Authorization (EUA) process. "Those with an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement," HHS added.

The VALID Act

The unexpected HHS announcement is the most recent in a series of efforts to rein in FDA regulation over LDTs. After several aborted attempts, last March, legislators in the U.S. House of Representatives and Senate reintroduced the Verifying Accurate Leading-edge IVCT Development Act (VALID) creating a new system for FDA review of *in vitro* clinical tests (IVCTs). VALID would establish a risk-based framework, with high-risk tests, like novel assays, required to go through premarket review; lower-risk tests could go to market after passing through technological certification. Key features of VALID:

- Establishment of a technology certification program for lower-risk tests;
- Requirement that high-risk tests undergo premarket review to verify analytical and clinical validity;
- Authority of the FDA to require that any test undergo premarket review after providing the developer an opportunity to address issues identified by the agency; and
- Creation of a new system to allow hospitals and laboratories to submit their tests electronically to the FDA for approval.

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FDA Watch, *from page 19*

The law would also grandfather in existing LDTs being used clinically.

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Here are some of the key FDA EUAs and clearances announced in August:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Fluidigm	EUA for Advanta Dx SARS-CoV-2 RT-PCR assay, extraction-free saliva-based test
QDx Pathology Services	EUA for QDX SARS-CoV-2 Assay, home collection kit
DxTerity Diagnostics	EUA for DxTerity SARS-CoV-2 RT-PCR Test for use on saliva samples
Texas Department of State Health Services	EUA for DSHS SARS-CoV-2 Assay
Guardant Health	EUA for Guardant-19 RT-PCR, next-generation sequencing test
Streck	De novo clearance for use of Cell-Free DNA BCT blood collection tube with Guardant Health Guardant360 CDx liquid-biopsy companion-diagnostic assay
LumiraDx	EUA for LumiraDx SARS-CoV-2 Ag Test (third antigen test authorized for SARS-CoV-2)
LumiraDx	EUA for LumiraDx SARS-CoV-2 RNA STAR assay
Sinochips Bioscience	EUA for COVID-19 Nucleic Acid RT-PCR Test Kit
BioCheck	EUA for BioCheck SARS-CoV-2 IgM and IgG Combo Test (serology)
23andMe	510(k) clearance for CYP2C19 Drug Metabolism Report, informing customers if their genotypes may influence their ability to respond to clopidogrel and citalopram without need for confirmatory testing
Diazyme Laboratories	EUA for Diazyme DZ-Lite SARS-CoV-2 IgM test (serology)
Biomeme	EUA for SARS-CoV-2 Real-Time RT-PCR Test
Solaris Diagnostics	EUA for Solaris Multiplex SARS-CoV-2 Assay
Alpha Genomix Laboratories	EUA for TaqPath SARS-CoV-2 Combo Assay based on Thermo Fisher's Applied Biosystems TaqPath COVID-19 Combo Kit
George Washington University	EUA for GWU COVID-19 RT-PCR test
BioMérieux	EUA for Vidas SARS-CoV-2 IgM test used with firm's Vidas SARS-CoV-2 IgG test (serology)
Beijing Wantai Biological Pharmacy	EUA for Wantai SARS-CoV-2 Ab ELISA test (serology)
Helix	EUA for next-generation sequencing-based test to detect SARS-CoV-2 spike protein gene
Guardant Health	Clearance for Guardant360 CDx, targeted next-generation sequencing liquid biopsy assay, for tumor mutation profiling in advanced cancer patients with solid malignant neoplasm

Manufacturer(s)	Product
Adaptive Biotechnologies	Expanded clearance for its clonoSeq assay to assess minimal residual disease in patients with chronic lymphocytic leukemia
Roche	Clearance for Cobas Epstein-Barr Virus test
Quest Diagnostics	EUA for technique that speeds extraction of viral RNA from patient samples

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Natera	Signatera personalized circulating tumor DNA test
Curetis	SARS-CoV-2 Kit with PULB
Zymo Research	Quick SARS-CoV-2 rRT-PCR kit
Manufacturer(s)	**Product(s)**
Ender Diagnostics	ender Mass PCR SARS-CoV-2 test
DiaSorin	Liaison Testosterone xt test
NeuMoDx Molecular	Quantitative BK virus (BKV) viral load monitoring assay
Snibe Diagnostics	Maglumi SARS-CoV-2 S-RBD IgG serological assay
Yourgene Health	Clarigene SARS-CoV-2 diagnostic kit
Abingdon Health	AbC-19TM Rapid Test serological assay

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Yourgene Health	Australia	Therapeutics Goods Association approval of Iona Nx NIPT workflow as a Class 3 medical device